Screening Assessment

Aromatic Azo and Benzidine-based Substance Grouping

Certain Azo Disperse Dyes

Environment Canada
Health Canada

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Synopsis

Pursuant to section 68 and 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment on 74 Azo Disperse Dyes. These substances constitute a subgroup of the Aromatic Azo and Benzidine-based Substance Grouping being assessed as part of the Substance Groupings Initiative of the Government of Canada's Chemicals Management Plan (CMP) based on structural similarity and applications. Substances in this Grouping were identified as priorities for assessment as they met the categorization criteria under subsection 73(1) of CEPA 1999 and/or were considered as a priority based on other human health concerns. The Chemical Abstracts Service Registry Number[1] (CAS RN), *Domestic Substances List* (DSL) name, and Colour Index (C.I) generic name, or acronym of the Azo Disperse Dyes in this subgroup, are presented in the following table.

Identity of substances assessed in the Azo Disperse Dyes Screening Assessment

CAS RN	DSL name	Colour Index name or acronym
2537-62-4	Acetamide, *N*-[2-[(2-bromo-6-cyano-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-	N/A
2832-40-8[a]	Acetamide, N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]-	Disperse Yellow 3 (Solvent Yellow 77)
3618-72-2[b]	Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	Disperse Blue 79:1
5261-31-4[c]	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2,6-dichloro-4-nitrophenyl)azo] phenyl]amino]-	Disperse Orange 30
6232-56-0[c]	Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl] methylamino]-	Disperse Orange 5
6250-23-3[c]	Phenol, 4-[[4-(phenylazo)phenyl]azo]-	Disperse Yellow 23
6253-10-7[c]	Phenol, 4-[[4-(phenylazo)-1-naphthalenyl]azo]-	Disperse Orange 13
6300-37-4[c]	Phenol, 2-methyl-4-[[4-(phenylazo)phenyl]azo]-	Disperse Yellow 7

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CAS RN	DSL name	Colour Index name or acronym
6465-02-7	Carbamic acid, [4-[[4-[(4-hydroxyphenyl)azo]-2-methylphenyl]azo]phenyl]-, methyl ester	N/A
6657-00-7	Phenol, 4-[[2-methoxy-5-methyl-4-(phenylazo) phenyl]azo]-	N/A
12239-34-8[c]	Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-	Disperse Blue 79
15958-27-7	Propanenitrile, 3-[[4-[(4-nitrophenyl)azo]phenyl][2-[[(phenylamino)carbonyl]oxy]ethyl]amino]-	N/A
16421-40-2[c]	Acetamide, *N*-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	ANAM[d]
16421-41-3[c]	Acetamide, *N*-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]-	N/A
16586-42-8[c]	Propanenitrile, 3-[ethyl[3-methyl-4-[(6-nitro-2-benzothiazolyl)azo]phenyl]amino]-	Disperse Red 179[d]
17464-91-4[c]	Ethanol, 2,2′-[[4-[(2-bromo-6-chloro-4-nitrophenyl)azo]-3-chlorophenyl]imino]bis-	Disperse Brown 1:1
19745-44-9	Propanenitrile, 3-[4-[(5-nitro-2-thiazolyl)azo](2-phenylethyl)amino]-	N/A
19800-42-1[c]	Phenol, 4-[[2-methoxy-4-[(4-nitrophenyl)azo]phenyl]azo]-	Disperse Orange 29
21811-64-3[c]	Phenol, 4,4′-[1,4-phenylenebis(azo)]bis-	Disperse Yellow 68
23355-64-8[c]	Ethanol, 2,2′-[[3-chloro-4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bis-	Disperse Brown 1
24610-00-2	Benzonitrile, 2-[[4-[(2-cyanoethyl)(2-phenylethyl)amino]phenyl]azo]-5-nitro-	N/A
25150-28-1	Propanenitrile, 3-[[4-[(6,7-dichloro-2-benzothiazolyl)azo]phenyl]ethylamino]-	N/A
25176-89-0[c]	Propanenitrile, 3-[[4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]ethylamino]-	DAPEP[d]
26021-20-5	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-cyanoethyl)(2-hydroxyethyl)amino]-4-methoxyphenyl]-	Disperse Blue 94
26850-12-4[c]	Propanamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-chloro-4-nitrophenyl)azo]phenyl]-	Disperse Red 167
27184-69-6	Phenol, 4,4′-[1,4-phenylenebis(azo)]bis[3-methyl-	N/A
28824-41-1	Propanenitrile, 3-[[4-[(4,6-dibromo-2-benzothiazolyl)azo]phenyl]ethylamino]-	N/A
29765-00-2[c]	Benzamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(4-nitrophenyl)azo]phenyl]-	BANAP[d]
31030-27-0	Benzenamine, 4-[(2-chloro-4-nitrophenyl)azo]-*N*-	N/A

CAS RN	DSL name	Colour Index name or acronym
	ethyl-*N*-(2-phenoxyethyl)-	
33979-43-0	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]amino]-	N/A
41362-82-7	Propanenitrile, 3-[[4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]methylamino]-	N/A
42357-98-2	1H-Benz[de]isoquinoline-1,3(2H)-dione, 6-hydroxy-5-[(2-methoxy-4-nitrophenyl)azo]-2-methyl-	N/A
42358-36-1	1H-Benz[de]isoquinoline-1,3(2H)-dione, 2-ethyl-6-hydroxy-5-[(2-methoxy-4-nitrophenyl)azo]-	N/A
42852-92-6	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxy-5-[(phenylmethyl)-2-propenylamino]phenyl]-	N/A
51249-07-1	3-Pyridinecarbonitrile, 1-(2-ethylhexyl)-1,2-dihydro-6-hydroxy-4-methyl-5-[(2-nitrophenyl)azo]-2-oxo-	N/A
52697-38-8[b]	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]-	N/A
53950-33-7[b]	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-cyanoethyl)amino]-4-methoxyphenyl]-	N/A
55252-53-4	Acetamide, *N*-[2-[(2-cyano-6-iodo-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-	N/A
55281-26-0[c]	Propanenitrile, 3-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl]ethylamino]-	Disperse Orange 61
55290-62-5	Benzenesulfonamide, 4-[(1-butyl-5-cyano-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl)azo]-*N*-(2-ethylhexyl)-	N/A
55619-18-6[c]	Ethanol, 2,2′-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl]imino]bis-, diacetate (ester)	N/A
56532-53-7	Acetamide, *N*-[2-[(2,6-dicyano-4-nitrophenyl)azo]-5-(dipropylamino)phenyl]-	N/A
58104-55-5	2-Naphthalenesulfonamide, 6-hydroxy-*N*-(2-hydroxyethyl)-*N*-methyl-5-[[4-(phenylazo)phenyl]azo]-	N/A
59709-38-5	β-Alanine, *N*-[4-[(2-bromo-6-chloro-4-nitrophenyl)azo]phenyl]-*N*-(3-methoxy-3-oxopropyl)-, methyl ester	ANMOM[d,e]
61799-13-1	3-Pyridinecarbonitrile, 5-[(2-cyano-4-nitrophenyl)azo]-2-[(2-hydroxyethyl)amino]-4-methyl-6-[[3-(2-phenoxyethoxy)propyl]amino]-	N/A
63133-84-6	1(2H)-Quinolineethanol, 6-[(2-chloro-4,6-dinitrophenyl)azo]-3,4-dihydro-2,2,4,7-tetramethyl-	N/A
63134-15-6	Acetamide, *N*-[5-(dipropylamino)-2-[[5-(ethylthio)-1,3,4-thiadiazol-2-yl]azo]phenyl]-	Disperse Red 338
63833-78-3	3-Pyridinecarbonitrile, 5-[(2-cyano-4-nitrophenyl)azo]-6-[(2-hydroxyethyl)amino]-4-methyl-2-[[3-(2-phenoxyethoxy)propyl]amino]-	N/A

CAS RN	DSL name	Colour Index name or acronym
65122-05-6	Diazene, [(1,3-dihydro-1,1,3-trimethyl-2H-inden-2-ylidene)methyl](2-methoxyphenyl)-	N/A
66693-26-3	Propanamide, *N*-[5-[bis[2-(2-cyanoethoxy)ethyl]amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	Disperse Blue 125
67905-67-3	Propanenitrile, 3-[butyl[4-[(6-nitro-2-benzothiazolyl)azo]phenyl]amino]-	N/A
68214-63-1	3-Pyridinecarbonitrile, 5-[(3,4-dichlorophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-1-(phenylamino)-	N/A
68214-66-4	Carbamic acid, [2-[(2-chloro-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-, 2-ethoxyethyl ester	N/A
68516-64-3	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2-chloro-4-nitrophenyl)azo]-3-methylphenyl]amino]-	N/A
68877-63-4	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-cyanoethyl)-2-propenylamino]-4-methoxyphenyl]-	N/A
68992-01-8	3-Pyridinecarbonitrile, 1-(2-ethylhexyl)-1,2-dihydro-6-hydroxy-5-[(4-methoxy-2-nitrophenyl)azo]-4-methyl-2-oxo-	N/A
69472-19-1	Propanenitrile, 3-[butyl[4-[(4-nitrophenyl)azo]phenyl]amino]-	N/A
70210-08-1	2-Naphthalenesulfonamide, *N*-[2-(acetyloxy)ethyl]-6-hydroxy-*N*-methyl-5-[[4-(phenylazo)phenyl]azo]-	Disperse Red 151
70660-55-8	1-Naphthalenamine, 4-[(2-bromo-4,6-dinitrophenyl)azo]-*N*-(3-methoxypropyl)-	N/A
72828-63-8	Benzonitrile, 2-[[4-[[2-(acetyloxy)ethyl]butylamino]-2-methylphenyl]azo]-3-bromo-5-nitro-	N/A
72828-64-9	1,3-Benzenedicarbonitrile, 2-[[4-[[2-(acetyloxy)ethyl]butylamino]-2-methylphenyl]azo]-5-nitro-	Disperse Blue 287
72927-94-7[c]	Benzenamine, 4-[(2,6-dichloro-4-nitrophenyl)azo]-*N*-(4-nitrophenyl)-	N/A
72968-82-2[c]	Methanesulfonamide, *N*-[2-[(2,6-dicyano-4-methylphenyl)azo]-5-(dipropylamino)phenyl]-	DADM[d]
73003-64-2	2,4,10-Trioxa-7-azaundecan-11-oic acid, 7-[4-[(2,6-dichloro-4-nitrophenyl)azo]-3-methylphenyl]-3-oxo-, methyl ester	N/A
73398-96-6	3-Pyridinecarbonitrile, 5-[(9,10-dihydro-9,10-dioxo-1-anthracenyl)azo]-2,6-bis[(2-methoxyethyl)amino]-4-methyl-	Disperse Brown 21
79542-46-4	Acetamide, *N*-[4-chloro-2-[2-(2-chloro-4-nitrophenyl)azo]-5-[(2-hydroxy-3-phenoxypropyl)amino]phenyl]-	Disperse Red 349

CAS RN	DSL name	Colour Index name or acronym
83249-47-2	Acetamide, *N*-[2-[(2-bromo-6-cyano-4-nitrophenyl)azo]-5-(dipropylamino)phenyl]-	N/A
83249-49-4	Benzonitrile, 3-bromo-2-[[4-(diethylamino)-2-methylphenyl]azo]-5-methyl-	N/A
83249-53-0	Methanesulfonamide, *N*-[2-[(2-bromo-6-cyano-4-methylphenyl)azo]-5-(diethylamino)phenyl]-	N/A
83249-54-1	Methanesulfonamide, *N*-[2-[(2-bromo-6-cyano-4-methylphenyl)azo]-5-(dipropylamino)phenyl]-	N/A
90729-40-1	3-Pyridinecarbonitrile, 1-butyl-5-[[4-(4-chlorobenzoyl)-2-nitrophenyl]azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-	N/A
93805-00-6[c]	Phenol, 4-[[2-methoxy-4-[(2-methoxyphenyl)azo]-5-methylphenyl]azo]-	N/A
106276-78-2[c]	Benzoic acid, 2,3,4,5-tetrachloro-6-cyano-, methyl ester, reaction products with 4-[(4-aminophenyl)azo]-3-methylbenzenamine and sodium methoxide	MATCB[d]
127126-02-7	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(6,7-dichloro-2-benzothiazolyl)azo]phenyl]amino]-	N/A

Abbreviation: NA, not available

[a]CAS RN 2832-40-8 (Disperse Yellow 3) is included in the current assessment to assess ecological concerns. The substance was a part of the Azo Solvent Dyes assessment as Solvent Yellow 77.

[b]This substance was not identified under subsection 73(1) of CEPA 1999 but was included in this assessment as it was considered a priority based on other human health concerns.

[c]Previously assessed and concluded in the Challenge Initiative of the CMP.

[d]The acronym that the substance was previously referred to under the Challenge initiative.

[e]The substance ANMOM (CAS RN 59709-38-5) was included in the Challenge initiative, however no conclusion under section 64 of CEPA 1999 was published for this substance.

Among the 74 substances in this assessment is Disperse Yellow 3 (CAS RN 2832-40-8 also known as Solvent Yellow 77) which has expected uses as both a solvent and disperse dye. As such, Disperse Yellow 3 was not originally part of the 73 substances in the draft assessment of Azo Disperse Dyes but was instead evaluated in the draft assessment of Azo Solvent Dyes under the name Solvent Yellow 77.

Azo Disperse Dyes are not expected to occur naturally in the environment. No manufacture of any substance above the 100 kg/year reporting threshold has been reported in response to any recent surveys under section 71 of CEPA 1999. Thirteen substances in this subgroup have been reported as having an import quantity above the 100 kg/year survey reporting threshold, with total quantities between 10 000 and 100 000 kg/year. Disperse Yellow 3 had an import quantity between 100 and 1 000 kg/year. Three additional substances were identified as being used in Canada in 2010, based on information submitted by the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD). No measured concentrations in the Canadian environment have been identified for any of these substances since 1987.

Environment

The ecological portion of this Screening Assessment addresses the 74 Azo Disperse Dyes: the 73 azo disperse dyes identified in this subgroup and the use of Disperse Yellow 3 in textile dye formulation and textile dyeing.

Due to structural similarities and the expectation that Azo Disperse Dyes will act in similar ways in the environment, substances were grouped together with respect to their environmental fate.

Based on the available experimental data, Azo Disperse Dyes have low solubility in water (< 1 mg/L) and moderate to high solubility in *n*-octanol (10–1000 mg/L). They also possess low vapour pressures (< 4.53×10^{-7} Pa), densities higher than that of water (1.19 – 1.55 g/cm^3) and moderate to high octanol–water partition coefficients (log K_{ow} ranging from 3.4 to 5.7).

Empirical data indicate that under aerobic conditions, Azo Disperse Dyes are not expected to degrade rapidly in water, soil and sediment. If released to wastewater, these dyes are expected to be either caught by sludge filters or adsorbed during wastewater treatment, rather than staying in the water compartment. If released to water, it is anticipated that a greater percentage of these substances will find their way into sediment and undergo reductive degradation in anaerobic sediments. The bioavailability of these substances is expected to be low based on their low solubilities in water and slow uptake due to their large cross-sectional diameters. Results from experimental studies suggest that the potential for these substances to bioaccumulate in pelagic organisms is low. Azo Disperse Dyes are expected to have a common mode of action with respect to ecotoxicity, based on their similar structural components. Due to the potential cleavage of the azo bonds, degradation products can be released containing the amine, aniline or phenolic functional groups resulting from biotransformation of the parent structure.

The available aquatic toxicity data for Azo Disperse Dyes indicated highly variable effects on different taxa and between acute and chronic tests. Acute toxicity tests using fish, crustaceans, and bacteria reported no effects near the known water solubility limits; however, available chronic studies showed that fish and aquatic invertebrates were sensitive to Azo Disperse Dyes, in particular those substances having a smaller molecular weight and cross sectional diameter, indicating that the smaller sized Azo Disperse Dyes are likely more bioavailable than the larger Azo Disperse Dyes.

A predicted no-effect concentration (PNEC) in the aquatic environment was calculated to be 0.0025 mg/L, based on the lowest toxicity value from a chronic study on fish (fathead minnow) exposed to Disperse Yellow 7 (CAS RN 6300-37-4). The PNEC was used to represent a subset of azo disperse dyes with a with a molecular weight less than 360 g/mol. Considering the potential major environmental releases due to industrial activities (textile formulation and dyeing), the Predicted Environmental Concentrations (PECs) for this subset of dyes are likely to exceed their PNEC. There

are eight Azo Disperse Dyes in the current subgroup having a molecular weight less than 360 g/mol that have not been identified to be in commerce in Canada. As a result, these eight Azo Disperse Dyes currently do not pose a risk to the environment. However, the future use of an azo disperse dye in textiles with a molecular weight less than 360 g/mol would likely have effects of concern based on their aquatic toxicity.

For substances with a molecular weight greater than or equal to 360 g/mol (including the 13 Azo Disperse Dyes in this subgroup which are in commerce in Canada), the PNEC, if calculated, would exceed the water solubility for most of these substances, suggesting no long term effect even at their water solubility limits.

For Disperse Yellow 3, the PNEC was calculated as 0.0023 mg/L based on the read-cross of an acute toxicity data for Solvent Yellow 1 (CAS RN 60-09-3, 96-hour LC50). The aquatic PEC from a site specific textile formulation scenario was estimated as 0.011 mg/L. The outcome of the risk quotient analysis was 4.7, suggesting a concern to aquatic organisms. Furthermore, Disperse Yellow 3 has a molecular weight of 269 g/mol, therefore it is also a concern to aquatic organisms if used in textile dyeing.

In preliminary soil and sediment toxicity studies on other azo substances, no effects were found at the concentration of 1000 mg/kg soil (dry weight); the analogue demonstrated moderate toxicity in sediment organisms. Applying these data across the substances in this grouping, it is expected that Azo Disperse Dyes are not harmful to soil or sediment-dwelling organisms.

Considering all available lines of evidence presented in this Screening Assessment, there is a low risk of harm to organisms and the broader integrity of the environment from 73 of the 74 Azo Disperse Dyes evaluated in the Azo Disperse Dye subgroup. It is concluded that 73 Azo Disperse Dyes do not meet section 64*(a)* or 64*(b)* of CEPA 1999, as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

CAS RN 2832-40-8 (Disperse Yellow 3), was assessed for its use in dye formulation and textile dyeing for ecological concerns. Considering lines of evidence presented in this Screening Assessment and in the Screening Assessment for Azo Solvent Dyes, it is concluded that CAS RN 2832-40-8, Disperse Yellow 3 (also known as Solvent Yellow 77) meets the criteria under paragraph 64*(a)* of CEPA 1999 as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, this substance does not meet the criteria under paragraph 64(*b*) of CEPA 1999 as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

Human Health

With respect to human health risk assessment, this Screening Assessment addresses 64 of the 74 substances, which includes Disperse Yellow 3, 13 substances previously assessed in the Challenge Initiative of the CMP for which significant new information relevant to human health has become available, and one additional substance (ANMOM, CAS RN 59709-38-5) which was part of the Challenge Initiative but not previously concluded on. For 10 of the 74 substances in this assessment previously concluded under the Challenge Initiative, no significant information relevant to human health were identified, therefore the human health conclusions for these 10 substances have not been updated.

Carcinogenicity and genotoxicity are considered critical health effects of potential concern for Aromatic Azo and Benzidine-based Substances, due to potential azo bond cleavage and release of aromatic amines. Therefore, the health effects of the Azo Disperse Dyes were evaluated by examining their hazard potential (including their ability to undergo reductive cleavage and the hazard potential of the released aromatic amines), and the direct and prolonged exposure potential for the general population.

Direct and prolonged general population exposure potential from textiles was expected for 13 of the 64 Azo Disperse Dyes being assessed for human health in this assessment: Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3, ANMOM, and Disperse Yellow 3. Aside from Disperse Yellow 3, limited health effects data were available for these 13 substances. Therefore critical effect levels were selected based on Disperse Yellow 3 as well as on read-across to other azo disperse dyes not formally part of this assessment, specifically Disperse Yellow 97 (Sudan I/Solvent Yellow 14) and Disperse Red 17.

The critical effect levels for the available hazard data were used to characterize risk to the 13 substances for which exposure of the general population of Canada is expected. Margins between estimates of exposure from direct and prolonged contact to textiles containing these dyes and the critical effect level were considered to be adequate to address uncertainties in the health effects and exposure databases.

For the remaining 51 of 64 Azo Disperse Dyes being assessed for human health in this assessment, no information was identified to support current sources of exposure to these substances for the general population of Canada therefore exposure to these substances is not expected. As a result, risk for the general population of Canada from exposure to these 51 substances is not expected.

Some of the Azo Disperse Dyes in this assessment have effects of concern based on potential carcinogenicity. While available information does not indicate a risk to human health for Canadians at current levels of exposure, there may be a concern if exposures were to increase.

Based on the information presented in this Screening Assessment, and based on information for Disperse Yellow 3 (Solvent Yellow 77) presented in the Azo Solvent Dyes Screening Assessment, it is concluded that 64 of the 74 substances in this assessment, including the 13 substances previously assessed for which significant new information was available, as well as ANMOM (CAS RN 59709-38-5), do not meet the criteria under paragraph 64*(c)* of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

In addition, there are no updates to the conclusions made with respect to paragraph 64*(c)* for 10 substances previously considered by the Government of Canada under the Challenge Initiative of the CMP.

Overall Conclusion

It is concluded that 73 of the 74 Azo Disperse Dyes identified above do not meet any the criteria set out in section 64 of CEPA 1999.

It is concluded that CAS RN 2832-40-8 (Disperse Yellow 3) meets one or more of the criteria set out in section 64 in CEPA 1999. The information supporting the human health assessment for this substance under the name Solvent Yellow 77 appears in the Screening Assessment of Azo Solvent Dyes.

It has been determined that CAS RN 2832-40-8 (Disperse Yellow 3) meets the persistence criteria but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA 1999.

Table of Contents

List of Tables

1. Introduction

Pursuant to sections 68 or 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999), the Minister of the Environment and the Minister of Health conduct screening assessments of substances to determine whether these substances present or may present a risk to the environment or to human health.

The Substance Grouping Initiative is a key element of the Government of Canada's Chemicals Management Plan (CMP). The Aromatic Azo and Benzidine-based Substance Grouping consists of 358 substances that were identified as priorities for assessment, as they met the categorization criteria under section 73 of CEPA 1999 and/or were considered as a priority based on human health concerns (Environment Canada and Health Canada 2007). Some substances within this Substance Grouping have been identified by other jurisdictions as a concern due to the potential cleavage of the azo bonds, which can lead to the release of aromatic amines that are known or likely to be carcinogenic.

While many of these substances have common structural features and similar functional uses as dyes or pigments in multiple sectors, diversity within the substance group has been taken into account through the establishment of subgroups. Subgrouping based on structural similarities, physical and chemical properties, and common functional uses and applications accounts for variability within this Substance Grouping and allows for subgroup-specific approaches in the conduct of screening assessments. This Screening Assessment considers 74 substances, including:

- 73 Azo Disperse Dyes originally identified in the Azo Disperse Dye subgroup, and
- CAS RN 2832-40-8 (hereinafter referred to as Disperse Yellow 3). Ecological concerns associated with the environmental exposure and effects of Disperse Yellow 3 are evaluated in this assessment with respect to textile dye formulation and textile dyeing; while other information (i.e., physical chemical properties, persistence and bioaccumulation potentials, etc.) are presented in the screening assessment for Azo Solvent Dyes. Other uses for this substance, as well as human health concerns are considered in the Azo Solvent Dyes assessment (Environment Canada, Health Canada 2015). The section 64 conclusions of CEPA 1999 for this substance appear in this assessment.

Consideration of potential azo bond cleavage products (aromatic amines) is a key element of human health assessment in each subgroup. Some aromatic amines, commonly referred to as EU22 aromatic amines[2], as well as associated azo dyes are restricted in other countries (EU 2006). Information on the subgrouping approach for the Aromatic Azo and Benzidine-based Substance Grouping under Canada's CMP, as well as additional background information and regulatory context, is provided in a separate document prepared by the Government of Canada (Environment Canada, Health Canada 2013).

Among the 74 substances in this assessment, 24 of the substances(Table 1-1) were previously assessed during the Challenge Initiative, and submissions pertaining to the properties, persistence, hazard and uses of these substances were received at that time (Canada 2006, 2008a, 2008b, and 2008c). As new ecotoxicity information has been identified, these 24 substances are assessed as part of the subgroup Azo Disperse Dyes for ecological risk, and consequently ecological conclusions are updated as appropriate. Similarly, 14 of these 24 Challenge substances will also be concluded on for human health in the current assessment of Azo Disperse Dyes, of which 13 had significant new information relevant to human health identified (Disperse Orange 30, Disperse Orange 5, Disperse Blue 79, ANAM, CAS RN 16421-41-3, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 55619-18-6, CAS RN 72927-94-7), and one additional substance ANMOM (CAS RN 59709-38-5) which was assessed but not concluded on in the Challenge Initiative, will also be concluded on in this assessment. For 10 of the 24 Challenge substances (Disperse Yellow 23, Disperse Yellow 13, Disperse Yellow 7, Disperse Red 179, Disperse Orange 29, Disperse Yellow 68, DAPEP, DADM, 93805-00-6, MATCB), no significant new information related to the health assessment were identified therefore the previous conclusions on human health for these 10 substances have not been updated. Therefore excluding these 10 Challenge substances, human health conclusions are being made on 64 of the 74 total substances in this assessment.

Table 1-1. List of 24 Azo Disperse Dyes in the subgroup that were assessed under the Challenge Initiative

CAS RN	C.I. generic name or acronym[a]

[2]Twenty-two aromatic amines listed in Appendix 8 of Regulation (EC) No. 1907/2006 (EU 22).

CAS RN	C.I. generic name or acronym[a]
5261-31-4	Disperse Orange 30[b]
6232-56-0	Disperse Orange 5[b]
6250-23-3	Disperse Yellow 23[c]
6253-10-7	Disperse Orange 13[c]
6300-37-4	Disperse Yellow 7[c]
12239-34-8	Disperse Blue 79[b]
16421-40-2	ANAM[b]
16421-41-3	NA[b]
16586-42-8	Disperse Red 179[c]
17464-91-4	Disperse Brown 1:1[b]
19800-42-1	Disperse Orange 29[c]
21811-64-3	Disperse Yellow 68[c]
23355-64-8	Disperse Brown 1[b]
25176-89-0	DAPEP[c]
26850-12-4	Disperse Red 167[b]
29765-00-2	BANAP[b]
52697-38-8	NA[b]
55281-26-0	Disperse Orange 61[b]
55619-18-6	NA[b]
59709-38-5	ANMOM[d]
72927-94-7	NA[b]
72968-82-2	DADM[c]
93805-00-6	NA[c]
106276-78-2	MATCB[c]

Abbreviation: NA, not available
[a]Acronym that the substance was previously referred to under the Challenge Initiative
[b]Updated ecological and health effects assessments
[c]Updated ecological effects assessment only
[d]ANMOM was assessed but not concluded on in Batch 12 of the Challenge Initiative.

In addition, 33 Azo Disperse Dyes (Table 1-2) were previously included as part of a screening assessment, in April 2008, of 145 persistent, bioaccumulative, and inherently ecotoxic (PBiT) substances that were considered not to be in commerce. Certain information on these substances, including submissions pertaining to their uses received at that time, is used here to inform the subgroup assessment of Certain Azo Disperse Dyes (Environment Canada and Health Canada 2009, 2010, 2011). Based on significant new information relevant to the ecological assessment of the Azo Disperse Dyes, all 33 substances are re-assessed to determine risk to the environment. Similarly, for the human health risk assessment, all 33 substances are being assessed and concluded on in this assessment.

Table 1-2. List of 33 Azo Disperse Dyes that were part of the Screening Assessment of 145 PBiT Substances

Substance Name	C.I. generic name
2537-62-4	NA

6465-02-7	NA
15958-27-7	NA
19745-44-9	NA
24610-00-2	NA
25150-28-1	NA
28824-41-1	NA
31030-27-0	NA
33979-43-0	NA
41362-82-7	NA
42852-92-6	NA
55252-53-4	NA
56532-53-7	NA
61799-13-1	NA
63133-84-6	NA
63134-15-6	Disperse Red 338
63833-78-3	NA
68214-66-4	NA
68516-64-3	NA
68877-63-4	NA
70210-08-1	Disperse Red 151
70660-55-8	NA
72828-63-8	NA
72828-64-9	Disperse Blue 287
73003-64-2	NA
73398-96-6	Disperse Brown 21
79542-46-4	Disperse Red 349
83249-47-2	NA
83249-49-4	NA
83249-53-0	NA
83249-54-1	NA
90729-40-1	NA
127126-02-7	NA

Abbreviation: NA, not available

Screening assessments focus on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA 1999, by examining scientific

information to develop conclusions by incorporating a weight of evidence approach and precaution.[3]

This Screening Assessment includes consideration of information on chemical properties, environmental fate, hazards, uses and exposure, including additional information submitted by stakeholders. Relevant data were identified up to August 2014. Empirical data from key studies as well as some results from models were used to reach conclusions. When available and relevant, information presented in assessments from other jurisdictions was considered.

The Screening Assessment represents a critical review of key available data. It presents the critical studies and lines of evidence pertinent to the conclusion.

The Screening Assessment was prepared by staff in the Existing Substances Programs at Health Canada and Environment Canada and incorporates input from other programs within these departments. The ecological and human health portions of this assessment have undergone external written peer review and/or consultation. Comments on the technical portions relevant to the environment were received from Dr. Harold Freeman (North Carolina State University, USA) and Dr. Gisela Umbuzeiro (University of Campinas, Brazil). Comments on the technical portions relevant to human health were received from Dr. Harold Freeman (North Carolina State University, USA), Dr. David Josephy (University of Guelph, Canada), Dr. Michael Bird (University of Ottawa, Canada) and Dr. Kannan Krishnan (University of Montreal, Canada). Additionally, the draft of this Screening Assessment was subject to a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the Screening Assessment remain the responsibility of Health Canada and Environment Canada.

The critical information and considerations upon which the Screening Assessment is based are given below.

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[3]A determination of whether one or more of the criteria of section 64 are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and the use of consumer products. A conclusion under CEPA 1999 is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations* and the *Controlled Products Regulations*, which is part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA or other Acts.

2. Identity of Substances

This Screening Assessment focuses on 73 substances that belong to the subgroup of Azo Disperse Dyes that is part of the Aromatic Azo and Benzidine-based Substance Grouping. The 73 Azo Disperse Dyes in this subgroup are all discrete chemicals with molecular weights ranging from 302 to 639 g/mol. Of the 73 substances, 62 are monoazo dyes and 11 are disazo dyes.

The ecological portion of this Screening Assessment addresses 74 substances; the 73 in the Azo Disperse Dye subgroup, in addition to the uses of Disperse Yellow 3 in textile dye formulation and textile dyeing.

In this Screening Assessment, the Azo Disperse Dyes are referred to by their Colour Index name, where available, or acronyms, as they were referred to under the Challenge initiative; otherwise, the substance is referred to by its CAS RN.

For the purpose of this assessment, Azo Disperse Dyes are divided into six structurally related groups to facilitate the characterization of their physical and chemical properties. These structurally related groups are based on 1) the number of azo bonds, 2) the number of aromatic rings and other heterocyclic rings and 3) a variety of structural fragments contained in the chemical structures. The identities of the substances in the six structurally related groups, including the maximum cross sectional diameters (D_{max}) and the effective cross sectional diameters (D_{eff}), are presented in Tables 2-1 to 2-6; three other substances that possess unique chemical structures are listed separately in Table 2-7. Chemical structures of these 73 Azo Disperse Dyes are presented in Appendix A, sorted according to each structurally related group. The identity of Disperse Yellow 3 is presented in Table 2-8.

Table 2-1. Identity of eight Azo Disperse Dyes in Structurally Related Group 1 that have two azo bonds and three aromatic rings with no naphthalene or halogenated structure

CAS RN	DSL name	C.I. generic name	Molecular weight (g/mol)	Min-max D_{max} (nm)[a]	D_{eff} (nm)
6250-23-3	Phenol, 4-[[4-(phenylazo)phenyl]azo]-	Disperse Yellow 23	302	1.53-2.07	0.77
6300-37-4	Phenol, 2-methyl-4-[[4-(phenylazo)phenyl]azo]-	Disperse Yellow 7	316	1.34-2.07	0.86
6465-02-7	Carbamic acid, [4-[[4-[(4-hydroxyphenyl)azo]-2-methylphenyl]azo]phenyl]-, methyl ester	NA	389	1.40-2.50	1.02
6657-00-7	Phenol, 4-[[2-methoxy-5-methyl-4-(phenylazo) phenyl]azo]-	NA	346	1.24-2.06	0.99

19800-42-1	Phenol, 4-[[2-methoxy-4-[(4-nitrophenyl)azo]phenyl]azo]-	Disperse Orange 29	377	1.26-2.19	0.99
21811-64-3	Phenol, 4,4′-[1,4-phenylenebis(azo)]bis-	Disperse Yellow 68	318	1.64-2.13	0.81
27184-69-6	Phenol, 4,4′-[1,4-phenylenebis(azo)]bis[3-methyl-	NA	346	1.21-2.14	0.86
93805-00-6	Phenol, 4-[[2-methoxy-4-[(2-methoxyphenyl)azo]-5-methylphenyl]azo]-	NA	376	1.29-2.06	1.01

Abbreviation: NA, not available
[a]Based on range of maximum diameters (D_{max}) for conformers calculated using CPOPs (2008)

Table 2-2. Identity of three Azo Disperse Dyes in Structurally Related Group 2 that have two azo bonds, two aromatic rings and one naphthalene structure

CAS RN	DSL name	C.I. generic name	Molecular weight (g/mol)	Min-max D_{max} (nm)	D_{eff} (nm)
6253-10-7	Phenol, 4-[[4-(phenylazo)-1-naphthalenyl]azo]-	Disperse Orange 13	352	1.22-2.07	1.02
58104-55-5	2-Naphthalenesulfonamide, 6-hydroxy-*N*-(2-hydroxyethyl)-*N*-methyl-5-[[4-(phenylazo)phenyl]azo]-	NA	490	1.39-2.50	1.13
70210-08-1	2-Naphthalenesulfonamide, *N*-[2-(acetyloxy)ethyl]-6-hydroxy-*N*-methyl-5-[[4-(phenylazo)phenyl]azo]-	Disperse Red 151	532	1.55-2.76	1.20

Abbreviation: NA, not available

Table 2-3. Identity of ten Azo Disperse Dyes in Structurally Related Group 3 that have one azo bond, one aromatic ring and one heteroaromatic structure (either a benzotriazole or a thiazole ring)

CAS RN	DSL name	C.I. generic name or acronym	Molecular weight (g/mol)	Min-max D_{max} (nm)	D_{eff} (nm)
16586-42-8	Propanenitrile, 3-[ethyl[3-methyl-4-[(6-nitro-2-benzothiazolyl)azo]phenyl]amino]-	Disperse Red 179	394	1.58-2.13	1.01
19745-	Propanenitrile, 3-[4-[(5-nitro-2-	NA	406	1.46	1.06

44-9	thiazolyl)azo](2-phenylethyl)amino]-			- 2.14	
25150-28-1	Propanenitrile, 3-[[4-[(6,7-dichloro-2-benzothiazolyl)azo]phenyl]ethylamino]-	NA	404	1.52 - 2.06	0.93
25176-89-0	Propanenitrile, 3-[[4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]ethylamino]-	DAPEP	404	1.52 - 2.13	0.93
28824-41-1	Propanenitrile, 3-[[4-[(4,6-dibromo-2-benzothiazolyl)azo]phenyl]ethylamino]-	NA	493	1.47 - 2.52	0.97
33979-43-0	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]amino]-	NA	462	1.60 - 2.25	1.11
41362-82-7	Propanenitrile, 3-[[4-[(5,6-dichloro-2-benzothiazolyl)azo]phenyl]methylamino] -	NA	390	1.58 - 2.13	1.11
63134-15-6	Acetamide, *N*-[5-(dipropylamino)-2-[[5-(ethylthio)-1,3,4-thiadiazol-2-yl]azo]phenyl]-	Disperse Red 338	407	1.37 - 2.09	1.11
67905-67-3	Propanenitrile, 3-[butyl[4-[(6-nitro-2-benzothiazolyl)azo]phenyl]amino]-	NA	408	1.58 - 2.23	1.03
127126-02-7	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(6,7-dichloro-2-benzothiazolyl)azo]phenyl]amino]-	NA	462	1.65 - 2.30	1.04

Abbreviation: NA, not available

Table 2-4. Identity of 40 Azo Disperse Dyes in Structurally Related Group 4 that have one azo bond and two aromatic rings with a variety of substituent groups

CAS RN	**DSL name**	**C.I. generic name or acronym**	**Molecular weight (g/mol)**	**Min-max D_{max} (nm)**	**D_{eff} (nm)**
2537-62-4	Acetamide, *N*-[2-[(2-bromo-6-cyano-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-	NA	459	1.36 - 1.81	1.11
3618-72-2	Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	Disperse Blue 79:1	625	1.43 - 2.03	1.23
5261-31-4	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2,6-dichloro-4-nitrophenyl)azo] phenyl]amino]-	Disperse Orange 30	450	1.43 - 2.12	1.04
6232-56-0	Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl] methylamino]-	Disperse Orange	369	1.33 -	0.88

		5		1.85	
12239-34-8	Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-	Disperse Blue 79	639	1.57 - 2.08	1.29
15958-27-7	Propanenitrile, 3-[[4-[(4-nitrophenyl)azo]phenyl][2-[[(phenylamino)carbonyl]oxy]ethyl]amino]-	NA	458	1.57 - 2.54	1.21
16421-40-2	Acetamide, *N*-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	ANAM	585	1.55 - 2.14	1.27
16421-41-3	Acetamide, *N*-[5-[[2-(acetyloxy)ethyl](phenylmethyl)amino]-2-[(2,4-dinitrophenyl)azo]-4-methoxyphenyl]-	NA	551	1.55 - 2.13	1.22
17464-91-4	Ethanol, 2,2′-[[4-[(2-bromo-6-chloro-4-nitrophenyl)azo]-3-chlorophenyl]imino]bis-	Disperse Brown 1:1	478	1.41 - 1.84	0.95
23355-64-8	Ethanol, 2,2′-[[3-chloro-4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bis-	Disperse Brown 1	434	1.39 - 1.85	0.81
24610-00-2	Benzonitrile, 2-[[4-[(2-cyanoethyl)(2-phenylethyl)amino]phenyl]azo]-5-nitro-	NA	424	1.38 - 2.16	1.11
26021-20-5	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-cyanoethyl)(2-hydroxyethyl)amino]-4-methoxyphenyl]-	Disperse Blue 94	550	1.45 - 1.95	1.17
26850-12-4	Propanamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-chloro-4-nitrophenyl)azo]phenyl]-	Disperse Red 167	520	1.49 - 2.11	1.21
29765-00-2	Benzamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(4-nitrophenyl)azo]phenyl]-	BANAP	534	1.57 - 2.13	1.30
31030-27-0	Benzenamine, 4-[(2-chloro-4-nitrophenyl)azo]-*N*-ethyl-*N*-(2-phenoxyethyl)-	NA	425	1.53 - 2.31	1.08
42852-92-6	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxy-5-[(phenylmethyl)-2-propenylamino]phenyl]-	NA	583	1.39 - 2.13	1.19
52697-38-8	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]-	NA	479	1.33 - 1.81	1.08
53950-33-7	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-	NA	506	1.43 -	1.14

	cyanoethyl)amino]-4-methoxyphenyl]-			1.98	
55252-53-4	Acetamide, *N*-[2-[(2-cyano-6-iodo-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-	NA	506	1.41 - 1.81	1.13
55281-26-0	Propanenitrile, 3-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl]ethylamino]-	Disperse Orange 61	481	1.42 - 1.91	0.94
55619-18-6	Ethanol, 2,2′-[[4-[(2,6-dibromo-4-nitrophenyl)azo]phenyl]imino]bis-, diacetate (ester)	NA	572	1.50 - 2.10	1.16
56532-53-7	Acetamide, *N*-[2-[(2,6-dicyano-4-nitrophenyl)azo]-5-(dipropylamino)phenyl]-	NA	433	1.48 - 1.92	1.15
59709-38-5	β-Alanine, *N*-[4-[(2-bromo-6-chloro-4-nitrophenyl)azo]phenyl]-*N*-(3-methoxy-3-oxopropyl)-, methyl ester	ANMOM	528	1.37 - 2.15	1.14
63133-84-6	1(2H)-Quinolineethanol, 6-[(2-chloro-4,6-dinitrophenyl)azo]-3,4-dihydro-2,2,4,7-tetramethyl-	NA	462	1.39 - 1.89	1.01
66693-26-3	Propanamide, *N*-[5-[bis[2-(2-cyanoethoxy)ethyl]amino]-2-[(2-chloro-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-	Disperse Blue 125	617	1.74 - 2.34	1.34
68214-66-4	Carbamic acid, [2-[(2-chloro-4-nitrophenyl)azo]-5-(diethylamino)phenyl]-, 2-ethoxyethyl ester	NA	464	1.33 - 2.05	1.23
68516-64-3	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2-chloro-4-nitrophenyl)azo]-3-methylphenyl]amino]-	NA	430	1.43 - 2.15	1.10
68877-63-4	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-[(2-cyanoethyl)-2-propenylamino]-4-methoxyphenyl]-	NA	546	1.46 - 1.94	1.18
69472-19-1	Propanenitrile, 3-[butyl[4-[(4-nitrophenyl)azo]phenyl]amino]-	NA	351	1.78 - 2.05	0.97
72828-63-8	Benzonitrile, 2-[[4-[[2-(acetyloxy)ethyl]butylamino]-2-methylphenyl]azo]-3-bromo-5-nitro-	NA	502	1.41 - 2.07	1.16
72828-64-9	1,3-Benzenedicarbonitrile, 2-[[4-[[2-(acetyloxy)ethyl]butylamino]-2-methylphenyl]azo]-5-nitro-	Disperse Blue 287	448	1.77 - 2.12	1.13
72927-94-7	Benzenamine, 4-[(2,6-dichloro-4-nitrophenyl)azo]-*N*-(4-nitrophenyl)-	NA	432	1.43 - 2.10	0.94
72968-	Methanesulfonamide, *N*-[2-[(2,6-	DADM	439	1.51	1.17

82-2	dicyano-4-methylphenyl)azo]-5-(dipropylamino)phenyl]-			-1.90	
73003-64-2	2,4,10-Trioxa-7-azaundecan-11-oic acid, 7-[4-[(2,6-dichloro-4-nitrophenyl)azo]-3-methylphenyl]-3-oxo-, methyl ester	NA	529	1.34-2.21	1.19
79542-46-4	Acetamide, *N*-[4-chloro-2-[2-(2-chloro-4-nitrophenyl)azo]-5-[(2-hydroxy-3-phenoxypropyl)amino]phenyl]-	Disperse Red 349	518	1.47-2.43	1.22
83249-47-2	Acetamide, *N*-[2-[(2-bromo-6-cyano-4-nitrophenyl)azo]-5-(dipropylamino)phenyl]-	NA	487	1.42-1.93	1.13
83249-49-4	Benzonitrile, 3-bromo-2-[[4-(diethylamino)-2-methylphenyl]azo]-5-methyl-	NA	385	1.39-1.77	0.96
83249-53-0	Methanesulfonamide, *N*-[2-[(2-bromo-6-cyano-4-methylphenyl)azo]-5-(diethylamino)phenyl]-	NA	464	1.41-1.76	1.09
83249-54-1	Methanesulfonamide, *N*-[2-[(2-bromo-6-cyano-4-methylphenyl)azo]-5-(dipropylamino)phenyl]-	NA	492	1.40-1.90	1.13
106276-78-2	Benzoic acid, 2,3,4,5-tetrachloro-6-cyano-, methyl ester, reaction products with 4-[(4-aminophenyl)azo]-3-methylbenzenamine and sodium methoxide	MATCB	493	1.24-2.20	1.03

Abbreviation: NA, not available

Table 2-5. Identity of seven Azo Disperse Dyes in Structurally Related Group 5 that have one azo bond, one aromatic ring and one 3-pyridinecarbonitrile structure with a variety of substituents

CAS RN	DSL name	C.I. generic name	Molecular weight (g/mol)	Min-max D_{max} (nm)	D_{eff} (nm)
51249-07-1	3-Pyridinecarbonitrile, 1-(2-ethylhexyl)-1,2-dihydro-6-hydroxy-4-methyl-5-[(2-nitrophenyl)azo]-2-oxo-	NA	411	1.34-1.92	1.14
55290-62-5	Benzenesulfonamide, 4-[(1-butyl-5-cyano-1,6-dihydro-2-hydroxy-4-methyl-6-oxo-3-pyridinyl)azo]-*N*-(2-ethylhexyl)-	NA	502	1.45-2.43	1.18
61799-13-1	3-Pyridinecarbonitrile, 5-[(2-cyano-4-nitrophenyl)azo]-2-	NA	545	1.64-2.41	1.37

	[(2-hydroxyethyl)amino]-4-methyl-6-[[3-(2-phenoxyethoxy)propyl]amino]-				
63833-78-3	3-Pyridinecarbonitrile, 5-[(2-cyano-4-nitrophenyl)azo]-6-[(2-hydroxyethyl)amino]-4-methyl-2-[[3-(2-phenoxyethoxy)propyl]amino]-	NA	545	1.77-2.81	1.25
68214-63-1	3-Pyridinecarbonitrile, 5-[(3,4-dichlorophenyl)azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-1-(phenylamino)-	NA	414	1.28-1.81	1.14
68992-01-8	3-Pyridinecarbonitrile, 1-(2-ethylhexyl)-1,2-dihydro-6-hydroxy-5-[(4-methoxy-2-nitrophenyl)azo]-4-methyl-2-oxo-	NA	441	1.31-1.93	1.16
90729-40-1	3-Pyridinecarbonitrile, 1-butyl-5-[[4-(4-chlorobenzoyl)-2-nitrophenyl]azo]-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-	NA	494	1.43-2.26	1.15

Abbreviation: NA, not available

Table 2-6. Identity of two Azo Disperse Dyes in Structurally Related Group 6 that have one azo bond, one aromatic ring and one 1H-benz[de]isoquinoline-1,3(2H)-dione structure

CAS RN	DSL name	C.I. generic name	Molecular weight (g/mol)	Min-max D_{max} (nm)	D_{eff} (nm)
42357-98-2	1H-Benz[de]isoquinoline-1,3(2H)-dione, 6-hydroxy-5-[(2-methoxy-4-nitrophenyl)azo]-2-methyl-	NA	406	1.46-1.78	1.01
42358-36-1	1H-Benz[de]isoquinoline-1,3(2H)-dione, 2-ethyl-6-hydroxy-5-[(2-methoxy-4-nitrophenyl)azo]-	NA	420	1.41-1.84	1.04

Abbreviation: NA, not available

Table 2-7. Identity of three Azo Disperse Dyes that have unique chemical structures

CAS RN	DSL name	C.I. generic name	Molecular weight	Min-max D_{max}	D_{eff} (nm)

			(g/mol)	(nm)	
65122-05-6	Diazene, [(1,3-dihydro-1,1,3-trimethyl- 2H-inden-2-ylidene)methyl](2-methoxyphenyl)-	NA	306	1.34-1.61	0.88
70660-55-8	1-Naphthalenamine, 4-[(2-bromo-4,6-dinitrophenyl) azo]-*N*-(3-methoxypropyl)-	NA	488	1.33-2.15	1.09
73398-96-6	3-Pyridinecarbonitrile, 5-[(9,10-dihydro-9,10-dioxo- 1-anthracenyl)azo]-2,6-bis[(2-methoxyethyl)amino]-4-methyl-	Disperse Brown 21	499	1.59-2.02	1.25

Abbreviation: NA, not available

Table 2-8. Identity of CAS RN 2832-40-8[a]

CAS RN	DSL name	C.I. generic name	Molecular weight (g/mol)	Min-max D_{max} (nm)	D_{eff} (nm)
2832-40-8	Acetamide, N-[4-[(2-hydroxy-5-methylphenyl)azo]phenyl]-	Disperse Yellow 3 (Solvent Yellow 77)	269.3	1.27-1.71	0.84

Abbreviation: NA, not available
[a] Assessed for ecological concerns in textile dye formulation and textile dyeing only

2.1 Selection of Analogues and Use of (Q)SAR Models

Guidance on the use of read-across approaches has been prepared by various organizations such as the Organisation for Economic Co-operation and Development (OECD 2014). It has been applied in various regulatory programs including the European Union's (EU) Existing Substances Programme. The general method for analogue selection and the use of (quantitative) structure–activity relationship ((Q)SAR) models is provided in Environment Canada and Health Canada (2013). For characterization of human health effects, the basis for the use of analogues and/or (Q)SAR modelling data is documented in the Health Effects Assessment section of this report.

Analogues used to inform the ecological assessment were selected based on the availability of relevant empirical data pertaining to physical-chemical properties, persistence, bioaccumulation and ecotoxicity. Such data were used as read-across data for those Azo Disperse Dyes that lacked empirical data, where appropriate, or to support the weight of evidence of existing empirical information. Although analogue data

are used preferentially to fill data gaps for the substances in this assessment, the applicability of (Q)SAR models to the Azo Disperse Dyes is determined on a case-by-case basis.

The selected analogues for this subgroup are listed in Table 2-8 and are distinguished with an asterisk (*) added at the end of either the C.I. generic name or the CAS RN when they are referred to in the assessment. For estimating physical and chemical properties, analogues with experimental data are listed with Azo Disperse Dyes in structurally related groups (see Appendix A). For assessing potential for persistence and bioaccumulation and characterizing the ecological effects of Azo Disperse Dyes, the analogues with experimental data are presented in the relevant sections.

Table 2-9. Identities of selected analogues with experimental data considered to inform the physical and chemical properties and environmental fate of Azo Disperse Dyes and their potential to cause ecological harm

CAS RN[a]	Chemical name	C.I. generic name[a]	Experimental data to be considered in report
85-83-6*	2-Naphthalenol, 1-[[2-methyl-4-[(2-methylphenyl)azo] phenyl]azo]-	Solvent Red 24*	Ecotoxicity
842-07-9*	2-Naphthalenol, 1-(phenylazo)-	Disperse Yellow 97 (Sudan I/Solvent Yellow 14)	Human health hazard
1533-74-0*	2,2′-[[3-acetamido-4-[(4-nitrophenyl)azo] phenyl]imino]diethyl diacetate	Disperse Red 74:1*	Bioconcentration
12222-69-4 (20721-50-0)*	Ethanol, 2,2ó-[[4-[(4-aminophenyl)azo]phenyl]imino]bis-	Disperse Black 9*	Human health hazard
2581-69-3*	Benzenamine, 4-[(4-nitrophenyl)azo]-*N*-phenyl-	Disperse Orange 1*	Physical-chemical properties and ecotoxicity (with impurity)
2872-52-8*	Ethanol, 2-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]-	Disperse Red 1*	Physical-chemical properties, half-life in sediment and ecotoxicity
3025-52-3*	*N*,*N*-Diethyl-4-[(4-nitrophenyl)azo]aniline	NA	Physical-chemical properties
3179-89-3*	Ethanol, 2,2′-[[3-methyl-4-[(4-nitrophenyl) azo]phenyl]imino]bis-	Disperse Red 17*	Ecotoxicity & Human health hazard
3180-81-	Ethanol, 2-[[4-[(2-chloro-4-nitrophenyl)	Disperse	Physical-chemical

CAS RN[a]	Chemical name	C.I. generic name[a]	Experimental data to be considered in report
2*	azo]phenyl]ethylamino]-	Red 13*	properties and ecotoxicity (with impurity)
3769-57-1*	Ethanol, 2,2′-[[4-[(2-chloro-4-nitrophenyl) azo]-3-methylphenyl]imino]bis-	Disperse Red 5*	Physical-chemical properties and half-life in sediment
6657-33-6*	Propanenitrile, 3-[[4-[(2-chloro-4-nitrophenyl) azo]phenyl](2-hydroxyethyl)amino]-	NA	Physical-chemical properties and bioconcentration
13301-61-6*	Propanenitrile, 3-[[4-[(2,6-dichloro-4-nitrophenyl) azo]phenyl]ethylamino]-	Disperse Orange 37*	Ecotoxicity
16889-10-4*	Benzonitrile, 2-[[4-[(2-cyanoethyl)ethylamino] phenyl]azo]-5-nitro	Disperse Red 73*	Ecotoxicity
26630-87-5*	Benzamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[2-(6-chloro-2-benzothiazolyl)diazenyl]phenyl]-	NA	Biodegradation, bioconcentration and ecotoxicity
30449-81-1*	Benzamide, 4-[(5-cyano-1,6-dihydro-2-hydroxy-1,4-dimethyl-6-oxo-3-pyridinyl)azo]-*N*-(2-ethylhexyl)-	NA	Physical-chemical properties and bioconcentration
31482-56-1*	Propanenitrile, 3-[ethyl[4-[(4-nitrophenyl)azo]phenyl]amino]-	Disperse Orange 25*	Ecotoxicity
40690-89-9*	Propanenitrile, 3-[[2-(benzoyloxy)ethyl][4-[(4-nitrophenyl)azo]phenyl]amino]-	Disperse Orange 73*	Physical-chemical properties, biodegradation and ecotoxicity
41642-51-7*	Acetamide, *N*-[2-[(2,6-dicyano-4-nitrophenyl) azo]-5-(diethylamino)phenyl]-	Disperse Blue 165*	Physical-chemical properties
51248-73-8*	β-Alanine, *N*-[3-(acetylamino)-4-[(2-chloro-4-nitrophenyl) azo]phenyl]-*N*-(2-cyanoethyl)-, 2-methoxyethyl ester	NA	Physical-chemical properties (calculated) and bioconcentration
51249-07-1*	3-Pyridinecarbonitrile, 1-(2-ethylhexyl)-1,2-dihydro- 6-hydroxy-4-methyl-5-[(2-nitrophenyl)azo]-2-oxo -	NA	Bioaccumulation
56548-64-2*	Acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl) azo]-5-(diethylamino)-4-methoxyphenyl]-	Disperse Blue 291*	Ecotoxicity
58528-60-2*	2,2′-[[4-[(2,6-Dichloro-4-nitrophenyl)azo]-3-methylphenyl]imino]bisethanol	NA	Physical-chemical properties

CAS RN[a]	Chemical name	C.I. generic name[a]	Experimental data to be considered in report
58979-46-7*	Acetamide, *N*-[5-(diethylamino)-2-[(3,5-dinitro-2-thienyl)azo]phenyl]-	Disperse Green 9*	Bioconcentration
61038-97-9*	Benzoic acid, 4-[[2-(acetylamino)-4-[bis(3-methoxy-3-oxopropyl)amino]phenyl]azo]-, methyl ester	NA	Bioconcentration
62072-81-5*	β-Alanine, *N*-[5-(acetylamino)-4-[(2,4-dinitrophenyl)azo]-2-methoxyphenyl]-*N*-(3-methoxy-3-oxopropyl)-, methyl ester	NA	Bioconcentration
63134-15-6*	Acetamide, *N*-[5-(dipropylamino)-2-[[5-(ethylthio)-1,3,4-thiadiazol-2-yl]azo]phenyl]-	Disperse Red 338*	Human health hazard
63439-92-9*	This CAS RN is not recognized in DSL, NDSL, or ChemID. No chemical name was provided in NCI.	Disperse Yellow 198*	Bioaccumulation
65125-87-3*	The CAS RN is not recognized in DSL, NDSL, NCI or ChemID.	NA	Physical-chemical properties
67923-43-7*	Propanenitrile, 3,3′-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]imino]bis-	Disperse Yellow 163*	Physical-chemical properties, biodegradation, bioconcentration and ecotoxicity
68110-29-2*	Ethanol, 2,2′-[[4-[2-(3,5-dinitro-2-thienyl)diazenyl]-3-methylphenyl]imino]bis-, 1,1′-diacetate	NA	Bioconcentration
68133-69-7*	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4- [(6-nitro-2-benzothiazolyl)azo]phenyl]amino]-	Disperse Red 177*	Physical-chemical properties and bioconcentration
70198-17-3*	Ethanol, 2-[[4-[(6-chloro-2-benzothiazolyl)azo]phenyl]ethylamino]-, acetate (NDSL)	NA	Ecotoxicity
70528-90-4*	3-Pyridinecarbonitrile, 5-[(4-chloro-2-nitrophenyl) azo]-1-ethyl-1,2-dihydro-6-hydroxy-4-methyl-2-oxo-	Disperse Yellow 211*	Physical-chemical properties
71617-28-2*	Acetamide, *N*-[4-chloro-2-[(2-chloro-4-nitrophenyl)azo]-5-[(2-hydroxypropyl)amino]phenyl]-	NA	Physical-chemical properties and bioconcentration
73384-66-4*	Ethyl, 5-[3-chloro-4-[(2-cyano-4-nitrophenyl)azo]phenyl]-9-oxo-2,8,10-trioxa-5-azadodecanoate	NA	Bioconcentration
129710-76-5*	The CAS RN is not recognized in DSL, NDSL, NCI or ChemID.	Disperse Red 206*	Human health hazard

CAS RN[a]	Chemical name	C.I. generic name[a]	Experimental data to be considered in report
NA	The analogue for Disperse Brown 21. The chemical name has not been identified based on the structure search in ChemID; hence, the substance is referred to as “the analogue of Disperse Brown 21” in the assessment. The chemical structure is provided in Table A-7 in Appendix A.	NA	Physical-chemical properties

Abbreviation: NA, not available.
[a]An asterisk (*) after the C.I. generic name or the CAS RN indicates that the subject chemical is an analogue.

3. Physical and Chemical Properties

Physical and chemical properties determine the overall characteristics of a substance and are used to determine the suitability of different substances for different applications. Such properties also play a critical role in determining the environmental fate of substances (including their potential for long-range transport), as well as their toxicity to humans and non-human organisms.

A subset of physical and chemical properties of 73 Azo Disperse Dyes—namely, melting point, water solubility and log octanol–water partition coefficient (log K_{ow})—is important in terms of ecological and human health assessment. A summary of the experimental physical and chemical properties of substances in the Azo Disperse Dyes subgroup that are relevant to their environmental fate and ecotoxicity is presented in Table 3-1 and Appendix A. A subset of information on the physical and chemical properties for Disperse Yellow 3 is also presented in Table 3-1, more detailed information is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015).

Table 3-1. Summary of key physical and chemical properties of the 73 Azo Disperse Dyes

Physical-chemical property	Experimental value range for 73 Azo Disperse Dyes	Experimental value range for Disperse Yellow 3
Molecular weight (g/mol)	302–639	182-269
Melting point (°C)	132–152	67–195
Density (g/cm^3)	1.19–1.55	1.2
Vapour pressure (Pa at 25°C)	3.40×10^{-9} – 4.53×10^{-7}	1.87×10^{-4}–0.048
Log K_{ow} (at 25°C)	3.4–5.7	1.5–4.6
Water solubility (mg/L at 25°C)	1×10^{-6} – 0.45	< 1–34
n-Octanol solubility (mg/L)	14.1–5056	
$D_{max\text{-}min}$ (nm)	1.21–1.78	
$D_{max\text{-}max}$ (nm)	1.61–2.81	
$D_{eff\text{-}min}$ (nm)	0.67–1.14	0.65–0.79
$D_{eff\text{-}max}$ (nm)	0.96–1.70	0.71–0.88

Solubility in Water and *n*-Octanol

As indicated in Table 3-1, 73 Azo Disperse Dyes in this subgroup have demonstrated low solubility in water at room temperature, with solubilities ranging from 1×10^{-6} mg/L (Disperse Brown 21) to 0.45 mg/L (Disperse Brown 1:1 and Disperse Brown 1). The majority of 16 water solubility values are less or much less than 0.1 mg/L (Appendix A). Using more precise analytical techniques, new studies also show water solubilities of Azo Disperse Dyes to be well below 0.1 mg/L, with reported values of 2.2×10^{-4} mg/L for Disperse Orange 13 and 0.027 mg/L for Disperse Yellow 7 (Balakrishnan 2013).

At temperatures of 60°C or above, the water solubility can increase significantly, reaching 10 mg/L or higher (Bird 1954; Patterson and Sheldon 1960; Datyner 1978a,b).

There is no clear trend suggesting that substances in any one structurally related group possess water solubilities that are higher or lower than those in other structurally related groups. Due to their low water solubility, these dyes, which in their raw form are finely ground solid particles (Bardi and Marzona 2010), are usually mixed with a combination of auxiliary agents in commercial products (Koh 2011). Such auxiliary agents (e.g., carriers, surfactants, dispersing agents) may affect the environmental fate of these substances by increasing their solubility and potentially their bioavailability in the aquatic compartment (water and sediment). This assessment focuses on the specific chemicals referred to by their CAS RNs rather than dye formulations, which may vary and contain auxiliary agents and impurities. However, the effect of auxiliary agents is discussed throughout the assessment, as available data often relate to particular formulations.

The solubility of these substances is much higher in *n*-octanol than in water at room temperature (Sijm et al. 1999; ETAD 2005). Fourteen Azo Disperse Dyes and analogues have been identified with data on *n*-octanol solubility: 4 with *n*-octanol solubility between 10 and 100 mg/L, 6 between 100 and 1,000 mg/L and 4 above 1,000 mg/L.

Disperse Yellow 3 is more soluble than the other 73 Azo Disperse Dyes in this assessment.

Octanol–Water Partition Coefficient

According to the identified experimental data, these 73 substances possess moderate to high octanol–water partition coefficients (log K_{ow} values), ranging from 3.4 (Disperse Yellow 211*) to 5.7 (CAS RN 55290-62-5). For Azo Disperse Dyes, most reported values for this parameter were obtained from laboratory experiments; however, a few were calculated values, as specified in Appendix A. Log K_{ow} values are relevant to the bioaccumulation of these substances and are discussed further in the section on Potential for Bioaccumulation.

No organic carbon–water partition coefficient (log K_{oc}) data have been identified for any substance in this subgroup or their analogues.

Melting Point and Vapour Pressure

Melting points for these 73 Azo Disperse Dyes are 132°C and above. These may also be described as decomposition points, as disperse dyes are expected to char at high temperatures before completely reaching a melted state. For example, Disperse Yellow 23 was found with no significant decomposition from a stability test in water after 2 hours at 127°C by evaporating to dryness (Datyner 1978a). Based on their very low vapour pressures, Azo Disperse Dyes are not expected to be volatile under environmental conditions.

Molecular Weight and Density

These 73 Azo Disperse Dyes possess moderate to high molecular weights, ranging from 302 to 639 g/mol. The density of these substances varies within a relatively narrow range, from 1.19 to 1.55 g/cm^3, which is higher than the density of water.

Calculated Cross-sectional Diameter

For characterizing their molecular size, cross-sectional diameters for Azo Disperse Dyes are calculated by CPOPs (2012). These substances have maximum diameters (D_{max}) ranging from 1.21 to 2.81 nm; the effective diameters (D_{eff}) range from 0.67 to 1.70 nm. Molecular sizes are important to the permeation of substances through biological membranes, and cross-sectional diameters of these substances are further discussed in the sections of Potential for Bioaccumulation and Potential to Cause Ecological Harm.

4. Sources and Uses

4.1 Sources

Azo Disperse Dyes are anthropogenically produced and are not expected to occur naturally in the environment.

Since 2005, all 74 substances in this assessment including Disperse Yellow 3 have been included in at least one survey pursuant to section 71 of CEPA 1999. These surveys aimed to collect information on manufacturing and importing activities in Canada based on a 100 kg/year reporting threshold. Fifty-five of these substances were included in a survey for the 2005 calendar year (Canada 2006). Surveys were also conducted on 24 of these substances relating to the 2006 calendar year under the Challenge Initiative (Canada 2008a, 2008b, 2008c, 2009b); of the 24 substances surveyed in 2006, 22 were also included in the survey for the 2005 calendar year, and 2 had not been previously surveyed. Disperse Yellow 3 was included in Phase One of the DSL Inventory Update survey (Canada 2009a). Finally, 16 substances in the subgroup that had not been previously surveyed were included in a survey conducted for the 2010 calendar year that focused on the Aromatic Azo and Benzidine-based Substance Grouping (Canada 2011). The results of the surveys showed that none of the 74 substances in this assessment including Disperse Yellow 3 were identified with a manufacturing quantity above the 100 kg/year reporting threshold. However, 14 substances in this assessment including Disperse Yellow 3 were identified in one or more surveys with import quantities above the threshold, as summarized in Table 4-1.

Table 4-1. Fourteen substances in this assessment including Disperse Yellow 3 that have been identified with an import quantity above the 100 kg/year reporting threshold in Canada in a section 71 survey since 2005

C.I. generic name, acronym, or CAS RN	Annual import quantity (kg) identified in section 71 survey year 2005[a]	Annual import quantity (kg) identified in section 71 survey year 2006[b]	Annual import quantity (kg) identified in section 71 survey year 2008[c]	Annual import quantity (kg) identified in section 71 survey year 2010[d]
Disperse Blue 79:1	N/A	N/A	N/A	100–1 000
Disperse Orange 30[e]	1 001–100 000	1 000–10 000	N/A	N/A
Disperse Blue 79[e]	N/A	1 000–10 000	N/A	N/A
ANAM[e]	Not reported	100–1 000	N/A	N/A
Disperse Red 179[f]	100–1 000	100–1 000	N/A	N/A
Disperse Orange 29[f]	1 001–100 000	1 000–10 000	N/A	N/A
DAPEP[f]	Not reported	100–1 000	N/A	N/A
Disperse Red	100–1 000	1 000–10 000	N/A	N/A

167[e]				
BANAP[e]	1 001–100 000	100–1 000	N/A	N/A
52697-38-8[e]	100–1 000	10 000–100 000	N/A	N/A
Disperse Orange 61[e]	1 001–100 000	1 000–10 000	N/A	N/A
ANMOM[g]	1 001–100 000	Not reported	N/A	N/A
MATCB[f]	Not reported	100–1 000	N/A	N/A
Disperse Yellow 3	Not reported	N/A	100-1 000	N/A

[a]Canada (2006).
[b]Canada (2008a, 2008b, 2008c, 2009b).
[c]Canada (2009a).
[d]Canada (2011).
[e]Substance assessed in the Challenge Initiative for which ecological and health conclusions are being updated
[f]Substance assessed in the Challenge Initiative for which only ecological conclusion is being updated
[g]Substance assessed in the Challenge Initiative but was not previously concluded onAbbreviations: N/A, substance not included in survey.

Three additional substances—Disperse Brown 1:1, Disperse Brown 1 and CAS RN 63833-78-3—were identified as being used in Canada in 2010, based on information submitted by Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) (2010 email from ETAD to Environment Canada; unreferenced).

4.2 Uses

Disperse dyes are used primarily for the dyeing of polyester, polyester blends, nylon and acrylics (ETAD 1995b; Bardi and Marzona 2010). Historically, disperse dyes were first used to dye cellulose acetate. The common properties of disperse dyes, including their moderate to high molecular weight, neutral character and low water solubility, make them suitable dyes for synthetic fibres (Ullmann's Encyclopedia 2010).

Based on recent section 71 surveys (Canada 2006, 2008a, 2008b, 2008c, 2009a, 2009b, 2011), 14 substances in this assessment including Disperse Yellow 3 (see Table 4-1) were reported as having import activities with uses identified in the Canadian textile sector as a "colourant – pigment, stain, dye, or ink" as summarized under the alternative name Solvent Yellow 77 in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015).

In Canada, food colouring agents are regulated as food additives under the *Food and Drug Regulations*. Colours that are permitted for use in foods are listed in the *List of Permitted Colouring Agents* incorporated by reference in the *Marketing Authorization for Food Additives that May be Used As Colouring Agents,* issued under the authority of the *Food and Drugs Act.* None of the 73 Azo Disperse Dyes in this assessment is listed on the *List of Permitted Colouring Agents* as permitted food colouring agents. In addition, none of these substances was identified as being used in food packaging applications in Canada (2011 emails from the Food Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced).

Colourants that are permitted to be used in drugs in Canada are regulated under Part C, Division 1, of the *Food and Drug Regulations* (Canada [1978]). None of the substances in this subgroup are listed as a permitted drug colourant, nor have any been identified to be present in human pharmaceuticals (2011 email from the Therapeutic Products Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced), veterinary drugs (2011 email from the Veterinary Drugs Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced) or biologics in Canada (2011 email from the Biologics and Genetic Therapies Directorate, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced).

None of the Azo Disperse Dyes are listed in the Natural Health Products Ingredients Database (NHPID 2015) as ingredients for use in natural health products or in the Licensed Natural Health Products Database (LNHPD 2015) as being present in currently licensed natural health products.

Based on notifications submitted under the *Cosmetic Regulations* to Health Canada, none of the Azo Disperse Dyes are expected to be used in Canada (2011 and 2013 emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, unreferenced). In addition, these substances are not included on the List of Prohibited and Restricted Cosmetic Ingredients (more commonly referred to as the Cosmetic Ingredient Hotlist or simply the Hotlist), an administrative tool that Health Canada uses to communicate to manufacturers and others that products containing certain substances are unlikely to be classified as a cosmetic under the *Food and Drugs Act* (FDA), and in addition, that certain substances, when present in a cosmetic at certain concentrations, may contravene the general prohibition found in section 16 of the *Food and Drugs Act* or a provision of the *Cosmetic Regulations* (Health Canada, 2011).

None of the Azo Disperse Dyes were identified for use as a formulant in pest control products registered in Canada (2011 email from the Pest Management Regulatory Agency, Health Canada, to the Risk Management Bureau, Health Canada; unreferenced).

In addition, no uses of Azo Disperse Dyes were identified for military applications in Canada (2011 email from the Department of National Defence to the Risk Management Bureau, Health Canada; unreferenced).

Three substances—Disperse Brown 1:1, Disperse Brown 1 and CAS RN 63833-78-3—were identified as being used in Canada in 2010, based on information submitted by ETAD (2010 email from ETAD to Environment Canada; unreferenced). Specific uses for these substances were not identified; however, since the reported uses for all Azo Disperse Dyes (including Disperse Yellow 3) in this Screening Assessment were for textile dyeing and as disperse dyes were specifically designed for this use, it is assumed that the activities reported by ETAD were for textile dyeing.

5. Releases to the Environment

The environmental fate of chemicals describes the processes by which chemicals move and are transformed in the environment. In this section, some general characteristics of the substances considered in this Screening Assessment will be discussed with respect to their environmental fate in different compartments in an effort to understand how organisms come into contact with the substances in a particular medium, the persistence of the substances in environmental compartments, and their degradation, distribution among media, migration in groundwater, removal from effluents by standard wastewater treatment methods and bioaccumulation in organisms.

Information on the releases to the environment for Disperse Yellow 3 is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015).

5.1 Water and Sediment

If released to natural waters or wastewater in an untransformed state, the substances are expected to remain in the neutral form, due to a lack of ionizable groups, and are not expected to significantly dissociate under environmental conditions (pH 6–9). Evaporation from the surface of water is not expected, and hydrolysis is expected to be negligible. Rapid degradation is also not expected under aerobic conditions.

If released to wastewater, due to their low water solubilities, densities higher than that of water and associations with organic matter, these dyes are expected to be either caught by sludge filters or adsorbed during wastewater treatment, rather than staying in the water compartment. The remaining disperse dye particles, due to the recalcitrant nature of azo dyes under aerobic conditions, are expected to eventually end up in anaerobic sediments upon release to the environment, due to gravity (Razo-Flores et al. 1997). After partitioning to sediment or wastewater sludge, some azo dyes may bind reversibly and become resuspended, while others will bind irreversibly and remain buried. As mentioned in the Subgrouping Approach and Background Information document (Environment Canada and Health Canada 2013), sorption is an important fate process for dyes in aquatic and sediment systems.

In a recent environmental monitoring project, four Azo Disperse Dyes (Disperse Orange 5, Disperse Orange 13, Disperse Yellow 7 and Disperse Blue 79) were included in the analysis of samples collected in effluents from a total of 26 publically-owned wastewater treatment plants across Canada between 2009 and 2012 (2012 email from Aquatic Ecosystem Research Protection Division, Water Science and Technology Directorate, Environment Canada, to Environmental Assessment Division, Science and Risk Assessment Directorate, Environment Canada; unreferenced). However, none of them were detected in any sample. It should be noted that only one of the above substances (Disperse Blue 79) was reported to be in commerce from recent surveys. Furthermore, various treatment processes were used (including primary, secondary and lagoon treatment), depending on the wastewater treatment plant sampled, and it was not

confirmed whether industrial activities related to these Azo Disperse Dyes were releasing effluents to any of these systems.

If Azo Disperse Dyes are released to water, it is anticipated that some may stay in the water column (up to their water solubility limit). Over time, a greater percentage of these substances will deposit into sediment. Azo Disperse Dyes are expected to undergo reductive degradation under anaerobic conditions, upon the cleavage of the azo bond (-N=N-), and produce aromatic amines.

5.2 Soil

Azo Disperse Dyes may be released to soil indirectly via the application of wastewater biosolids to agricultural land or deposition in landfills. Since Azo Disperse Dyes have low water solubilities and are unlikely to dissociate, it is expected that they will demonstrate low mobility and remain in soil upon release to this environmental medium.

5.3 Air

Due to their very low vapour pressures (at or below 10^{-7} Pa), Azo Disperse Dyes are not expected to be released to air or significantly partition to this compartment (HSDB 1983– ; Øllgaard et al. 1998). While pre-mixed dyes in their solid states may have some limited capacity for dispersal into the air as large particles, air is not considered to be a carrying medium for dyes, as these substances exhibit low or negligible volatilities (Brown and Hamburger 1987; ETAD 1995b; Øllgaard et al. 1998).

If released to the atmosphere, Azo Disperse Dyes are expected to exist primarily in the particulate phase and be removed from this environmental medium by wet and dry deposition close to the source.

Given these characteristics, Azo Disperse Dyes are not expected to be subject to long-range atmospheric transport.

5.4 Environmental Persistence

In order to characterize the environmental persistence of the Azo Disperse Dyes, available empirical and modelled data on abiotic and biotic degradation were considered. Experimental and modelled biodegradation data for the Azo Disperse Dyes were considered for both aerobic and anaerobic conditions. Atmospheric oxidation is predicted to be an important fate process for these substances if they are released to the atmosphere. However, hydrolysis is not expected to be an important factor in the aquatic environment, as these substances do not contain any hydrolyzable groups. In addition, the process of ecological biotransformation is considered with respect to the potential for the Azo Disperse Dyes to degrade to aromatic amines as a result of cleavage of the azo bond under anaerobic or reducing conditions.

Additional information on the environmental persistence of Disperse Yellow 3 is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015).

5.4.1 Empirical Data for Persistence

As presented in Environment Canada and Health Canada (2013), colourants are designed to be chemically and photolytically stable in order to achieve their expected performance in dyeing applications and to maintain their colour in finished products (Pagga and Brown 1986; Øllgaard et al. 1998; CPMA 2003; Bafana et al. 2011). Hydrolysis of certain classes of dyes (reactive dyes) has been observed; however, this is considered to be an insignificant pathway of degradation for Azo Disperse Dyes.

No experimental data on the atmospheric degradation of Azo Disperse Dyes have been identified. Given their very low vapour pressures, their partitioning to air is negligible. Therefore, air is not a medium of concern for the persistence for these substances.

Experimental data identified in the OECD QSAR Toolbox (OECD 2012) as well as submissions from stakeholders demonstrate consistently that biodegradation rates of the test substances were all less than 20% in the 28-day studies, below the cut-off for rapid degradation. Such findings suggest that Azo Disperse Dyes are persistent in water under aerobic conditions. These data are summarized in Table 5-1. Most of them are considered as being of high quality; however, details of some studies are not available.

For example, experimental biodegradation studies on Disperse Red 179 and DAPEP (BMG 2001, 2003a) evaluated the inherent biodegradability of these two Azo Disperse Dyes under aerobic conditions in an aqueous medium of activated sludge. The degree of biodegradation was calculated as a percentage of the theoretical carbon dioxide evolution, which is the total quantity of carbon dioxide calculated to be released from the known or measured carbon content of the test substances when fully mineralized. The 28-day biodegradation rates for both Disperse Red 179 and DAPEP were reported to be less than 20%, indicating no rapid biodegradation under the experimental conditions.

Table 5-1. Summary of experimental data on biodegradation of Azo Disperse Dyes and analogues in the aquatic environment

C.I. generic name, acronym, or CAS RN	Test medium or inoculum	Degradation endpoint and value	Reference
Disperse Blue 79:1	Activated sludge	28 DOC < 20%	Environment Canada 2012
Disperse Blue 79	Activated sludge	No significant degradation	US EPA 1990
Disperse Red 179	Activated sludge	28-day ThCO_2 < 20%	BMG 2001
DAPEP	Activated sludge	28-day ThCO_2 < 20%	BMG 2003a

Disperse Red 167	Microorganisms	28-day BOD = 0%	OECD 2012 (originally reported by JETOC 1992)
Disperse Red 167	N/A	Non-biodegradable[a]	CHRIP ©2008
26630-87-5*[b]	Microorganisms	28-day BOD = 0%	OECD 2012 (originally reported by JETOC 1992)
Disperse Orange 73*	Microorganisms	28-day BOD = 7%	OECD 2012 (originally reported by JETOC 1992)
Disperse Orange 73*	N/A	Non-biodegradable	CHRIP ©2008
Disperse Yellow 163*	Microorganisms	28-day BOD = 0%	OECD 2012 (originally reported by JETOC 1992)

Abbreviations: BOD; biochemical oxygen demand; DOC, dissolved organic carbon; $ThCO_2$, theoretical carbon dioxide
[a]There is no value reported in CHRIP (©2008); however, the conclusion was made based on the criteria as set in the Chemical Substances Control Law in Japan.
[b]An asterisk (*) after the C.I. generic name or the CAS RN indicates that the subject chemical is an analogue.

Due to their low water solubilities and very low vapour pressures, Azo Disperse Dyes are expected to enter the aquatic system mostly as a dispersion of fine suspended particles, eventually settling to the aerobic layers of surface sediment, where they will persist until gradual burial in deeper sediments under reducing conditions. The rate of sediment deposition and the extent of bioturbation vary from site to site, and thus it is very difficult to ascertain the residence time of these dyes in aerobic sediment layers. It is likely, however, that this is greater than 365 days in many cases.

According to ETAD (1995b), with some exceptions, dyes are considered essentially non-biodegradable under aerobic conditions. Repeated evaluation of ready and inherent biodegradability using accepted screening tests following the Organisation for Economic Co-operation and Development (OECD) test guidelines (TGs) have confirmed this for such chemicals (Pagga and Brown 1986; ETAD 1992). Based on the common chemical structures in this class of colourants, it is expected that these Azo Disperse Dyes possess similarly low potential for biodegradation under aerobic conditions.

5.4.2 Degradation and Transformation of Azo Disperse Dyes

As summarized in the Subgrouping Approach and Background Information document (Environment Canada and Health Canada 2013), photodecomposition of dyes under ultraviolet (UV) irradiation has been observed; the reaction rate depends on a number of factors, including oxygen levels, pH and light intensity. The dye structure is also related to the tendency of decomposition. Chu and Ma (1997) reported the UV decoloration of Disperse Yellow 79* and Disperse Blue 142*. These dyes underwent colour losses of 18% and 8%, respectively, after 10 hours of UV irradiation.

Under anaerobic conditions, many Azo Disperse Dyes are vulnerable to chemical-induced and bacteria-mediated cleavage of their azo bonds (Brown and Laboureur 1983; Baughman and Weber 1994; Weber and Adams 1995). A few degradation studies were conducted on Disperse Blue 79:1 and Disperse Blue 79, which are structurally similar to each other. The results of one study suggest that Disperse Blue 79 can undergo rapid reductive cleavage in anoxic bottom sediments, resulting in the release of aromatic amines to the water column (Weber and Adams 1995). In another study, a 98.2% degradation of Disperse Blue 79:1 was reported after 15 days under anaerobic conditions (US EPA 1990). Also, Yen et al. (1991) reported half-lives of 2.9 hours up to 3 days for three disperse dyes in anaerobic sediments (see Table 5-2). These results also confirm rapid degradation under anaerobic conditions.

Table 5-2. Summary of experimental data on abiotic degradation of Azo Disperse Dye analogues in non-aquatic media

C.I. generic name	Degradation endpoint and value	Reference
Disperse Red 1*	Half-life = 2.9 h	Yen et al. 1991
Disperse Red 5*	Half-life = 4.5 h	Yen et al. 1991
Disperse Red 177*	Half-life = 2 days	Yen et al. 1991

5.4.3 Summary of Persistence

Azo Disperse Dyes will not degrade rapidly under aerobic conditions and tend to persist in water, sediment and soil. However, some Azo Disperse Dyes are known to degrade rapidly and release aromatic amines under anaerobic conditions, such as when they are buried in aquatic sediments.

5.5 Potential for Bioaccumulation

In order to assess the bioaccumulation potential of Azo Disperse Dyes, empirical data were obtained from literature searches and data submissions for Azo Disperse Dyes and their analogues. Molecular size–related indicators were taken into consideration when characterizing the bioaccumulation potential of this class of dyes.

Additional information on the potential for bioaccumulation for Disperse Yellow 3 is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015).

5.5.1 Empirical Data for Bioaccumulation

Empirical data have been identified for some Azo Disperse Dyes and their analogues, as summarized in Table 5-3. All available data (over 30 results) show that Azo Disperse Dyes have limited potential for bioaccumulation.

Anliker et al. (1981) reported experimental fish bioaccumulation values for 18 monoazo disperse dyes in tests performed according to methods specified by the Japanese Ministry of International Trade and Industry (MITI). Expressed on the basis of wet body weight of the fish, the measured bioconcentration factor (BCF) is below 57.54 L/kg (originally reported as log BCF from 0 to 1.76). This demonstrates low bioaccumulation potential. However, there are limitations to the interpretation of this study, given that the specific identities of the test substances could not be determined from information included in the publication.

Brown (1987) also reported no significant accumulation of 12 disperse dyes in carp during an 8-week bioaccumulation study. According to the results, no bioaccumulation factor (BAF) or BCF above 5 000 was reported, indicating that the disperse dyes did not demonstrate significant potential for bioaccumulation in the aquatic species.

Anliker et al. (1988) collected bioconcentration data for a few Azo Disperse Dyes and analogues, which demonstrate limited bioaccumulation potential. The reported data are summarized in Table 5-3.

Table 5-3. Empirical data for bioaccumulation of Azo Disperse Dyes and their analogues in fish

C.I. generic name or CAS RN [a]	**Test organisms**	**Bioaccumulation endpoint and value (L/kg)**	**References**
Disperse Red 74:1*	Fish	BCF = 19.95 (originally reported as log BCF = 1.30) MW=471 g/mol	Anliker et al. 1988
Disperse Orange 30	Zebra fish (*Brachydanio rerio*)	28-day BCF < 100	Shen and Hu 2008
6657-33-6*	Fish	BCF = 2.0 (originally reported as log BCF = 0.30) MW=374 g/mol	Anliker and Moser 1987
26630-87-5*	Common carp (*Cyprinus*	42-day BCF = 2.0–6.6 (at 0.2 mg/L)	OECD 2012 (originally

C.I. generic name or CAS RN [a]	Test organisms	Bioaccumulation endpoint and value (L/kg)	References
	carpio)	42-day BCF = 8.0–25 (at 0.02 mg/L)	reported by JETOC 1992)
26630-87-5*	N/A	BCF = 16.52 (originally reported as log BCF = 1.218)	CPOPs 2012
26630-87-5*	N/A	Low bioconcentration[b]	CHRIP ©2008
Disperse Red 167	Golden orfe (*Leuciscus idus*)	72 h BCF = 3150 (originally reported as log BCF = 3.5)	OECD 2012 (originally reported by Freitag et al. 1984)
Disperse Red 167	Common carp (*Cyprinus carpio*)	42-day BCF = 0.699 (originally reported as log BCF = −0.155) MW=520 g/mol	OECD 2012 (originally reported by JETOC 1992)
Disperse Red 167	N/A	Low bioconcentration[b]	CHRIP ©2008
Disperse Red 167	N/A	BCF = 6.26	CPOPs 2012
Disperse Yellow 198*	Fish	BCF < 1 (originally reported as log BCF < 0)	Anliker and Moser 1987
Disperse Yellow 198*	Fish	BAF = 0 (originally reported as log BAF = 0)	Anliker et al. 1988
Disperse Orange 73*	Common carp (*Cyprinus carpio*)	42-day BCF = 11–14	OECD 2012 (originally reported by JETOC 1992)
Disperse Orange 73*	N/A	Low bioconcentration[b]	CHRIP ©2008
Disperse Orange 73*	N/A	42-day BAF = 0.8–14 (at 0.1 mg/L) 42-day BAF < 2.5–11 (at 0.02 mg/L)	MITI 1992
Disperse Orange 73*	N/A	BCF = 6.75	CPOPs 2012
51248-73-8*	Fish	BCF = 3.98 (originally reported as log BCF = 0.60)	Anliker et al. 1988
51249-07-1*	Fish	BAF = 7.94 (originally reported as log BAF = 0.90)	Anliker and Moser 1987

C.I. generic name or CAS RN [a]	Test organisms	Bioaccumulation endpoint and value (L/kg)	References
55290-62-5	Fish	BCF = 5.01 (originally reported as log BCF = 0.70)	Anliker et al. 1988
Disperse Green 9*	Fish	BCF = 6.31 (originally reported as log BAF = 0.80)	Anliker et al. 1988
61038-97-9*	Fish	BCF = 19.95 (originally reported as log BCF = 1.30)	Anliker et al. 1988
62072-81-5*	Fish	BCF = 19.95 (originally reported as log BCF = 1.30)	Anliker et al. 1988
Disperse Yellow 163*	N/A	BCF = 36.48	CPOPs 2012
Disperse Yellow 163*	Common carp (*Cyprinus carpio*)	42-day BCF = 47 L/kg ww (at 0.01 mg/L) 42-day BCF = 49 L/kg ww (at 0.1 mg/L)	OECD 2011 (originally reported by JETOC 1992)
Disperse Yellow 163*	Common carp (*Cyprinus carpio*)	42-day BCF = 2.65–38.1 L/kg ww	OECD 2011 (originally reported by JETOC 1992)
Disperse Yellow 163*	N/A	Low bioconcentration [b]	CHRIP ©2008
Disperse Yellow 163*	N/A	42-day BCF = 30–49 L/kg (at 0.0001 mg/L) 42-day BCF = 26–47 L/kg (at 0.000 01 mg/L)	MITI 1992; ETAD 2005
68110-29-2*	Fish	BCF = 3.98 L/kg (originally reported as log BCF = 0.60)	Anliker et al. 1988
68110-29-2*	Fish	BCF = 3.02 L/kg (originally reported as log BCF = 0.48)	Anliker and Moser 1987
71617-28-2*	Fish	BCF = 57.54 L/kg (originally reported as log BCF = 1.76)	Anliker and Moser 1987
73384-66-4*	Fish	BCF = 2.09 L/kg (originally reported as log BCF = 0.32)	Anliker et al. 1988

Abbreviations: BAF, bioaccumulation factor; BCF, bioconcentration factor; ww, wet weight

[a] An asterisk (*) after the C.I. generic name or the CAS RN indicates that the subject chemical is an analogue.

[b] There is no value reported in CHRIP (©2008); however, the conclusion was made based on the criteria as set in the Chemical Substances Control Law in Japan.

The octanol–water partition coefficient is usually used as a secondary indicator of potential for bioaccumulation. In this case, the moderate to high log K_{ow} values (3.4–5.7) associated with Azo Disperse Dyes are not consistent with experimental bioaccumulation and bioconcentration data, which are preferred as primary indicators. This may be because Azo Disperse Dyes are less bioavailable as either particles or large molecules and hence are not taken up as quickly or readily by organisms. This phenomenon is explained in the next section on size-related indicators.

Another possibility is that after certain Azo Disperse Dyes are absorbed into organisms (e.g., through direct ingestion), they are metabolized, conjugated and excreted; therefore, bioaccumulation is not observed. Enzymatic breakdown of the azo linkage and other reductive/oxidative reactions on fragments are expected. This metabolic cleavage is discussed in greater detail in the Subgrouping Approach and Background Information document (Environment Canada and Health Canada 2013). The metabolites (e.g., aromatic amines) may demonstrate additional effects (mutagenic or cytotoxic) on organisms and will be assessed separately under the Aromatic Azo and Benzidine-based Substance Grouping.

No data on bioaccumulation potential for any Azo Disperse Dyes or their analogues in soil or sediment organisms have been identified. However, given their very low capacity to bioaccumulate in water and the potential for metabolism, bioaccumulation in organisms residing in soil and sediment compartments is not expected.

5.5.2 Size-related Indicators

Azo Disperse Dyes are often expected to exist as particles either alone or in dispersions. In this particulate form, they are expected to have low bioavailability. For the proportion of Azo Disperse Dyes that exist in molecular forms or soluble fractions, molecular size is another chemical-dependent factor affecting their passive transport across cell membranes, particularly across gill membranes from water, thus mitigating their overall bioaccumulation in organisms (DeVito 2000; Muller and Nendza 2007).

Molecular size can be characterized by the maximum molecular diameter (D_{max}). The maximum diameter of a molecule can be principally calculated as the largest distance between two atoms based on their van der Waals radii. Different conformations of the same compound can exist, and the maximum diameters may vary considerably if the subject compound is a flexible molecule. In many circumstances, the effective diameter (D_{eff}) can also be calculated as the effective second largest diameter. In a comparison between D_{max} and D_{eff} for different chemical molecules with different stabilities of conformation, D_{eff} has been found to be less sensitive to changes of conformation, whereas D_{max} depends strongly on conformation (Muller and Nendza 2007).

Measurements of D_{max} and D_{eff} for Azo Disperse Dyes were obtained from CPOPs model v1.1.18 (CPOPs 2012) and are summarized in Table 3-1 in the section on Physical and Chemical Properties.

Recent investigations relating fish BCF data to molecular size parameters (Dimitrov et al. 2002, 2005) suggest that the probability of a molecule crossing cell membranes as a result of passive diffusion declines significantly with increasing D_{max}; the probability decreases appreciably when D_{max} is greater than ~1.5 nm and much more so for molecules having a D_{max} of greater than 1.7 nm. Sakuratani et al. (2008) also investigated the effect of cross-sectional diameter on passive diffusion in a BCF test set of about 1200 new and existing chemicals. They observed that substances that do not have a very high bioconcentration potential (BCF < 5000) often have a D_{max} of > 2.0 nm and a D_{eff} of > 1.1 nm.

In addition, researchers (Muller and Nendza 2007; Arnot et al. 2010) have pointed out that there are no clear relationships for establishing strict molecular size cut-offs for assessing bioaccumulation potential. However, this report does not dispute the notion that a reduction in uptake rate can be associated with increasing cross-sectional diameter, as demonstrated by Dimitrov et al. (2002, 2005). As discussed above, the effect of molecular size on passive diffusion suggests that a potential for a significantly reduced uptake rate from water and reduced *in vivo* bioavailability exists with these dyes.

In a recent review, Arnot et al. (2010) noted that there are uncertainties associated with the thresholds proposed by Dimitrov et al. (2002, 2005) and Sakuratani et al. (2008), since the BCF studies used to derive them were not critically evaluated. Arnot et al. (2010) pointed out that molecular size influences solubility and diffusivity in water and organic phases (membranes), and larger molecules may have slower uptake rates. However, these same kinetic constraints also apply to diffusive routes of chemical elimination (i.e., slow in = slow out). Thus, significant bioaccumulation potential may remain for substances that are subject to slow absorption processes, if they are slowly biotransformed or slowly eliminated by other processes. Consequently, when evaluating bioaccumulation potential as well as assessing the effect to organisms, molecular size information should be considered with care and used together with other relevant lines of evidence in a weight of evidence approach.

5.5.3 Summary of Bioaccumulation Potential

It is noted that these Azo Disperse Dyes possess moderate to high octanol–water partition coefficients (log K_{ow} ranging from 3.4 to 5.7), which is the only line of evidence suggesting a potential for high bioaccumulation. In spite of this, experimental evidence on a number of subject chemicals and analogues indicated no significant potential for bioconcentration from water. While octanol–water partitioning data indicate some potential for bioaccumulation, additional factors indicate an overall low bioaccumulation potential. For example, the particulate nature of Azo Disperse Dyes and their large molecular diameters are likely to mitigate the uptake rate of these dyes across the gill membranes of fish, allowing other internal elimination processes to mitigate total body burdens.

Based on the available experimental bioaccumulation and bioconcentration data, with consideration of size-related factors, Azo Disperse Dyes are not expected to significantly bioaccumulate in environmental organisms.

6. Potential to Cause Ecological Harm

6.1 Ecological Effects Assessment

Ecological effects of Azo Disperse Dyes were characterized based on the empirical data available for these substances. Empirical data on analogues have also been taken into consideration in the assessment. Models were not used to predict the ecotoxicity of any of these substances, as the substances are outside of the domain of applicability. A critical body burden (CBB) approach was also considered as part of the weight of evidence.

6.1.1 Aquatic Compartment

6.1.1.1 Empirical toxicity data

Aquatic and chronic toxicity data for Azo Disperse Dyes have been identified and are summarized in Tables 6-1 and 6-2, additional details are presented in Appendix C. Exact endpoint values were reported from each ecotoxicity study if a lethal or sublethal effect was observed on 50% of the test organisms or if no effect was observed in the highest concentration group. In many cases, the lethal or sublethal effects were observed on less than 50% of the test organisms in the highest concentration group; therefore, the ecotoxicity was characterized by ranges, instead of reporting exact endpoint values.

Azo Disperse Dyes are poorly soluble in water and difficult to test in this medium, as they do not dissolve naturally at higher concentrations. Carriers, solvents or dispersing agents are often used in experiments to facilitate dissolution and support stable dispersions. As a result, the exposure to the test chemicals can occur above their water solubility limits. Many of the higher concentrations used in toxicity tests on Azo Disperse Dyes are not likely realistic with respect to their expected water solubilities in the Canadian environment. However, other factors (e.g., temperature, pressure, co-solvents) in the ambient environment may act to slightly increase the water solubility of the chemicals.

As indicated in an ECETOC (1996) report, the use of any auxiliary agent at a low concentration should not cause additional toxic effects on the test organisms. If ecotoxic effects are apparent, these should be identified and eliminated from the study by using a solvent control group. It has also been noted that toxicity at concentrations in excess of water solubility may be due to artifacts of the test procedure, such as ingestion of particles, which has been noted in some disperse dye toxicity tests, or could be attributed to impurities and transformation products (ECETOC 1996).

In addition, where concentrations of a test substance are far above its water solubility, soluble impurities may also be present whose effects might confuse the interpretation of true substance toxicity (Weyman et al. 2012). Weyman et al. (2012) also indicated that when solvent is used, but the test substance is not completely dissolved, any

undissolved material present in the test medium has the potential to exert adverse (physical) effects on test organisms, such as blocking of fish gill membranes, encapsulation/entrapment of daphnids or the reduction of light intensity in algal tests. All of these factors confound the results of the toxicity tests and need to be taken into consideration when interpreting and evaluating the data. Based on these complicating factors for aquatic toxicity tests on Azo Disperse Dyes, it is prudent to place a higher reliance on studies using low, realistic exposure concentrations close to or within known water solubility limits.

Acute ecotoxicity tests on Azo Disperse Dyes have been conducted using a variety of aquatic organisms. While specific details are not always available, it is assumed that most, if not all, studies were conducted using a chemical of less than 100% purity, mixed with an auxiliary agent to ensure the chemical is dissolved in water. The reported short-term toxicity data for Azo Disperse Dyes are summarized in Table 6-1.

Toxicity test using algae were not included in the tables below. For ecotoxicity studies using algae, the acute algal growth inhibition test is one of the most common tests for determining aquatic toxicity, by measuring changes in the growth rate in response to exposure to test chemicals in water. When testing coloured substances, it has been noted that these substances are capable of attenuating light penetration into the test medium, by light absorption and reflection. Using solvents or emulsifiers to create a homogeneous dispersion in water, attenuation of light is likely to be proportional to the amount of substance added. The inhibition of algal growth due to light attenuation can result in reduced algal population growth in relation to the amount of substance added to the test medium. However, such inhibition is not considered to be a true ecotoxicological effect of the test chemicals (Rufli et al. 1998; Cleuvers and Weyers 2003).

There have been recommendations on how to deal with light attenuation in algal tests with coloured substances. It was suggested that the algae be put back into a test substance–free medium after the end of the exposure period, in order to discriminate between an algistatic and an algicidal effect (Whitehouse and Mallet 1993); a reduced light path through the test solution was also proposed, so that the algal growth rate is not affected (Comber et al. 1995; Cleuvers and Weyers 2003). However, in algae studies identified to assess the ecotoxicological effects of Azo Disperse Dyes and analogues in algae, there is no report of any light attenuation in the studies, and hence no indication as to whether such an impact has been minimized. Therefore, it is suspected that the reported ecotoxicity in the algae studies may not represent the “true” effects of the test dyes on the organisms.

Table 6-1. Summary of acute aquatic toxicity data of Azo Disperse Dyes and analogues in comparison to their molecular weights and molecular sizes

C.I. generic name	Molecular weight (g/mol)	Deff (nm)	Organisms	Toxicity endpoint and value (mg/L)	Reference
Disperse	314	0.86	*Daphnia similis*	48 h EC50 = 0.13	Ferraz et

Red 1*					al. 201b; Vacchi et al. 2013
Disperse Red 1*	314	0.86	*Hydra attenuata*	48 h EC50 = 1.9	Vacchi et al. 2013
Disperse Orange 1*	318	0.87	*Daphnia similis*	48 h NOEC = 0.1	Ferraz et al. 2011a
Disperse Red 13*	349	0.89	*Daphnia similis*	48 h EC50 = 0.019	Ferraz et al. 2011b
Disperse Orange 29	377	0.99	Crustacean (*Daphnia magna*)	48 h EC50 = 70	Brown 1992
Disperse Red 179	394	1.01	Guppy (*Poecilia reticulata*)	96 h LC50 = 10–100	BMG 2003b
DAPEP	404	0.93	Guppy (*Poecilia reticulata*)	96 h NOEC ≥ 100	BMG 2000b
DADM	439	1.17	Zebra fish (*Brachydanio rerio*)	96 h LC0 > 1000	Study Submission 2008b
Disperse Orange 30	450	1.04	Crustacean (*Daphnia magna*)	48 h EC50 = 5.8	Brown 1992
52697-38-8	479	1.08	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC50 > 100	SafePharm 1990a
MATCB	493	1.03	Carp (*Cyprinus carpio*)	96 h LC50 > 100	Kremer 2003
Disperse Blue 79:1	625	1.23	Crustacean (*Daphnia magna*)	24 h EC50 = 16	Brown 1992
Disperse Blue 79	639	1.29	Crustacean (*Daphnia magna*)	48 h EC50 = 4.5	Brown 1992

Ferraz et al. (2011b) and Vacchi et al. (2013) conducted an ecotoxicity study on Disperse Red 1* and Disperse Red 13*. Both substances were reported as demonstrating high toxicity to *Daphnia similis*. The 48-hour EC_{50} for Disperse Red 1* (0.127 mg/L) is slightly below its known water solubility (0.16 mg/L); however, the 48-hour EC_{50} for Disperse Red 13* (0.019 mg/L) is slightly above its water solubility (0.012 mg/L) (Ferraz et al. 2011b). Vacchi et al. (2013) also published an ecotoxicity study on Disperse Red 1* and reported a similar 48-hour EC_{50} (0.13 mg/L) for *Daphnia similis*. However, as specified in the publication, the test chemical is a commercial dye, composed of 60% Disperse Red 1*, 20% subsidiary colourants and 20% dispersing agent as a dyeing auxiliary. Disperse Red 1* was extracted from the commercial dye and studied separately. The authors suggested that the ecotoxicity of the commercial dye seems to arise mainly from the principal component (Disperse Red 1*); the impact of the components of the formulation on bioavailability was not determined or discussed in any detail.

Based on data presented in Table 6-1, Azo Disperse Dyes and associated analogues with smaller molecular weights (314 to 349 g/mol) appear to demonstrate higher aquatic toxicity. Azo Disperse Dyes with larger molecular weights (377 to 639 g/mol) appear to have a lower aquatic toxicity. Chronic or long-term ecotoxicity tests on Azo Disperse Dyes have been conducted on relatively few aquatic organisms. While specific details are not always available, it is assumed that most, if not all, studies were conducted using a chemical of less than 100% purity, mixed with an auxiliary agent to ensure the chemical is dissolved in water. The reported chronic toxicity data for Azo Disperse Dyes are summarized in Table 6-2.

Table 6-2. Summary of chronic aquatic toxicity data of Azo Disperse Dyes and analogues in comparison to their molecular weights and molecular sizes

C.I. generic name	Molecular weight (g/mol)	Deff (nm)	Organisms	Toxicity endpoint and value (mg/L)	Reference
Disperse Yellow 7	316	0.86	Fathead minnow (*Pimephales promelas*)	20-day[a] LC50 = 0.025	Parrott et al. 2013
Disperse Yellow 7	316	0.86	Crustacean (*Hyalella azteca*)	14-day LC50 = 0.16 28-day LC50 = 0.12	Bartlett 2013
Disperse Orange 13	352	1.02	Crustacean (*Hyalella azteca*)	14-day LC50 = 1.41 28-day LC50 = 0.61	Bartlett 2013
Disperse Blue 79:1	625	1.23	Rainbow trout (*Oncorhynchus mykiss*)	122-day NOEC ≥ 0.0048	ABC 1991

[a]The 20-day testing period started counting from the exposure to eggs less than 24 hour post-fertilization at 0 day pf, with hatch at 4-5 days pf, and ended at 14 days post-hatch.

In a chronic toxicity study on Disperse Yellow 7 (Parrott et al. 2013), the substance demonstrated a high level of toxicity to the early life stage of fathead minnow (*Pimephales promelas*). Methanol was used as a carrier in this study. A delayed toxic response was observed, as lethality to larval fish occurred 4 to 5 days after hatch. In another chronic toxicity study on Disperse Blue 79:1, new fertilized eggs of rainbow trout (*Oncorhynchus mykiss*) were exposed to the test substance continuing for 122 days post hatch (ABC 1991). No effect on survival or growth of the test organisms was reported at a concentration close to the maximum solubility of the substance. The NOEC was determined to be equal to or greater than the highest measure test concentration of 0.0048 mg/L (ABC 1991).

Significant differences in aquatic toxicities associated with test substances may be related to the bioavailability to the test organisms (Parrott et al. 2013; Bartlett 2013; ABC 1991). Disperse Blue 79:1 has a molecular weight at 625 g/mol, which is almost twice the molecular weight of Disperse Yellow 7 (316 g/mol). Disperse Blue 79:1 also

has a much larger effective cross sectional diameter (D_{eff}) (1.23 nm) when compared to Disperse Yellow 7 (0.86 nm). As discussed in the bioaccumulation section (5.5.2), the size of Disperse Blue 79:1 likely impedes its uptake compared to Disperse Yellow 7. Coupled with biotransformation and elimination, the internal concentration of larger substances in the aquatic organism is likely not high enough to demonstrate an effect, even under a much longer exposure period at its water solubility limit.

The relationship between the molecular weight and the molecular size (D_{eff}) and toxicity may also be observed in chronic toxicity studies using the same species of the aquatic invertebrate (*Hyalella Azteca*) exposed to Disperse Yellow 7 and Disperse Orange 13 for up to 28 days (Bartlett 2013). Preliminary data reported a slightly higher toxicity for Disperse Yellow 7 than it for Disperse Orange 13, which possesses a lower molecular weight and small Deff than the latter one (Table 6-2).

Analysis of cross sectional diameter and the molecular weights of Azo Disperse Dyes appear to align fairly well (Table 6-3). The substances with a molecular weight of 352 g/mol or less had effective cross sectional diameters which were smaller than the substances which had a molecular weight ranging from 377 to 639 g/mol, for the most part. For the remainder of the ecological portion of the assessment, Azo Disperse Dyes will be classified into two size classes; a smaller molecular weight size class composed of substances with molecular weights below 360 g/mol and a larger molecular weight class with substances above 360 g/mol.

Table 6-3. Ranges of molecular sizes aligning with molecular weights for 73 Azo Disperse Dyes and analogues with empirical data

Number of substances	Range of molecular weights (g/mol)	Range of effective cross sectional diameter (Deff) (nm)
8	302-352	0.77 – 1.02
65	377-639	0.99 – 1.29

No empirical toxicity data was available for Disperse Yellow 3. Disperse Yellow 3 is expected to have a comparable toxicity to Disperse Yellow 7. Disperse Yellow 3 has a small effective cross sectional diameter (D_{eff}=0.84 nm), smaller molecular weight (269 g/mol), and is more water soluble (1,800 mg/L) than the 73 substances in this subgroup, indicating that it may be more bioavailable than the other substances in this assessment.

In the Azo Solvent Dyes assessment, toxicities for azo solvent dyes ranged from a 21-day no effect concentration of 0.0071 mg/L for reproduction of *Daphnia magna* to a 48-h LC_{50} of greater than 100 mg/L on the fish *Oryzias latipes*. Additional information on the toxicity of Azo Solvent Dyes is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015). A 96-hour LC50 = 0.23 mg/L on fish (*Oryzias latipes*) was selected as the CTV for Disperse Yellow 3 (see Azo Solvent Dyes assessment for further details (Environment Canada, Health Canada 2015).

Based on the available information, it appears that aquatic organisms are sensitive to smaller sized Azo Disperse Dyes (i.e. molecular weight less than 360 g/mol), while for larger substances (i.e. molecular weight greater than or equal to 360 g/mol), effects would be observed at concentrations greater than the water solubility of the substances. It should be noted that there is a lack of toxicity data for the larger sized Azo Disperse Dyes (greater than 360 g/mol).

6.1.1.2 Estimated Critical Body Burden (CBB) for the Fish

According to their physical and chemical properties, Azo Disperse Dyes are considered to have low water solubilities, low potential to bioaccumulate in environmental organisms and low acute toxicities to fish at saturation in water. However, there is still a question regarding the effects of these substances on aquatic organisms in relation to their water solubility. This is because there may be different solubilities, bioavailabilities and inherent toxicities of Azo Disperse Dyes as raw chemicals compared with other forms containing impurities or in formulations or when auxiliary chemicals are used in aquatic toxicity tests.

To help answer this question, a critical body burden (CBB) or internal critical concentration (ICC) approach can be applied as a "check mechanism," in which the acute external effect concentrations of substances causing the mortality of organisms can be calculated and compared with the results of ecotoxicity studies with pronounced biological effects (i.e., tests with solvents/dispersants) and ecotoxicity classification schemes (i.e., LC_{50}/EC_{50} values reflecting low, moderate or high aquatic toxicity levels).

This approach is described in detail in Appendix D of this report, while calculated external acute effect concentrations for two Azo Disperse Dyes and two analogues, with BCF and lipid contents of test organisms reported, are summarized in Table 6-4.

Table 6-1. Calculated external acute effect concentrations (LC50s) for Azo Disperse Dyes and analogues using CBB approach

C.I. generic name	Molecular weight (g/mol)	BCF_{ww} (L/kg)	Lipid content (%)	BCF_L (L/kg)	External acute effect concentration (LC_{50}) (mg/L)
Disperse Orange 30	450	8.43	0.83	50.78	44
Disperse Red 167	520	1.68	4.3	1.95	1333
Disperse Yellow 163*[a]	417	36.6	3.9	47.31	44
Disperse Orange 73*	443	4.12	4.3	4.79	462

Abbreviations: BCF_{ww}, the whole-body BCF on a wet weight basis; BCF_L, the BCF normalized for lipid content;
[a]An asterisk (*) after the C.I. generic name indicates that the substance is an analogue.

Calculated data indicate that to reach the CBB threshold levels and cause 50% mortality in the test organisms, exposure to the substances must be at least 44 mg/L ($LC_{50} \geq 44$ mg/L). This estimate suggests that these substances are moderately toxic to fish. This is in line with the low bioaccumulation potential in fish, as indicated in the section on Potential for Bioaccumulation, where it was hypothesized that bioavailability was not

expected to be high for substances in this subgroup. Indeed, very low BCFs (i.e., little uptake) for these substances with low water solubility mean less chance for them to demonstrate acute toxic effects, which is confirmed by the above-mentioned CBB-based external effect concentrations and by the lack of significant adverse effects observed in any of the bioconcentration tests. While the results of the CBB approach are relatively consistent with experimental acute fish toxicity results, they do not take into account the bioavailability of individual substance, which is associated with the water solubility and the molecular weight/size. Furthermore, no data was available to calculate the CBB threshold for substances with a molecular weight less than 360 g/mol, including Disperse Yellow 3.

6.1.1.3 Predicted No-Effect Concentrations (PNECs) for the Aquatic Compartment

To predict the no-effect level in the environment that will be used in the risk characterization in the assessment, an assessment factor may be used to account for extrapolation from laboratory to field data, uncertainties related to interspecies variations, differently sensitive biological endpoints and extrapolation from a single species test in the laboratory to ecosystems.

The 20-day LC_{50} of 0.025 mg/L for Disperse Yellow 7 (Parrott et al. 2013) was chosen as a representative toxicity value for Azo Disperse Dyes with molecular weights less than 360 g/mol. This toxicity value is below the water solubility for this substance; furthermore, additional studies reported toxicity values at about the same concentration using other substances and/or test organisms. Using an application factor of 10 to extrapolate lab to field conditions, a PNEC was calculated as 0.0025 mg/L for Azo Disperse Dyes having a molecular weight less than 360 g/mol.

Substances having molecular weights greater than or equal to 360 g/mol are not expected to demonstrate any effect to aquatic organism during any long term exposure at or below their water solubility limits. The PNEC, if calculated, would likely be greater than the water solubility of these substances. Therefore, no PNEC was calculated for substances with a molecular weight greater than or equal to 360 g/mol.

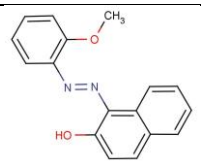
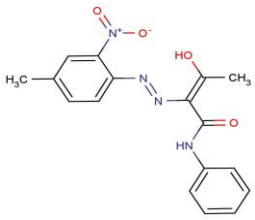
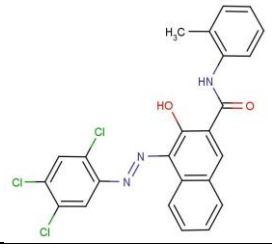
Disperse Yellow 3 has a greater water solubility than 73 Azo Disperse Dyes in this assessment; therefore, the PNEC for Disperse Yellow 3 in water was estimated separately to 73 Azo Disperse Dyes in this subgroup. Based on lines of evidence involving empirical and read-across aquatic ecotoxicity data, a 96-hour LC50 = 0.23 mg/L on fish (*Oryzias latipes*) was selected as the CTV for Disperse Yellow 3 (see Azo Solvent Dyes assessment for further details (Environment Canada, Health Canada, 2015). With the application of an assessment factor of 100 to extrapolate the long term no effect concentration from an acute toxicity endpoint and to extrapolate lab to field, the PNEC for the aquatic environment is 0.0023 mg/L for this substance.

6.1.2 Soil Compartment

There is little information on the effects of these 73 Azo Disperse Dyes and Disperse Yellow 3 in soil. In a screening assessment under the Challenge Initiative, soil toxicity data were identified for a structural analogue (CAS RN 70198-17-3*). A 96-hour LC_{50} of 32 mg/L was reported for flatworms (Health, Safety, and Human Factors Laboratory 1978); however, the reliability of such information cannot be evaluated due to a lack of details in the original submission.

While soil toxicity data on disperse dye analogues are limited, a few structurally similar substances have been identified with relevant ecotoxicity data. These data are used to estimate the effect of Azo Disperse Dyes on soil organisms (see Table 6-5).

Table 6-2. Summary of chronic ecotoxicity data in soil for other classes of dye and pigment

C.I. generic name [a]	Chemical structure	Organism, endpoint value and reference
Solvent Red 1*		Turtle (*Chelydra serpentina*) embryos 21-day NOEC > 625 mg/kg soil (dry weight) (Milani and Intini 2013)
Pigment Yellow 1*		Earthworm (*Eisenia fetida*) 56-day NOEC = 1000 mg/kg soil (dry weight) (Study Submission 2012a) Oat (*Avena sativa*); rape (*Brassica napus*); soybean (*Glycine max*) 21-day NOEC = 1000 mg/kg soil (dry weight) (Study Submission 2012b)
Pigment Red 112*		Oat (*Avena sativa*); rape (*Brassica napus*); soybean (*Glycine max*) 21-day NOEC = 1000 mg/kg soil (dry weight) (ECHA 2012)

[a]An asterisk (*) after the C.I. generic name indicates that the substance is an analogue.

Milani and Intini (2013) conducted a range-finding study and reported ecotoxicity data of Solvent Red 1* on turtle (*Chelydra serpentina*) embryos. Within a series of six concentration groups, a 100% hatching success rate was observed in the groups exposed to 0, 5 and 124 mg/kg soil (dry weight). In the groups exposed to 1, 25 and 625 mg/kg soil (dry weight); the hatching success rate was reported to be 92.5%, 90% and

97.5%, respectively. While assessing potential deformities requires further analysis, these preliminary results indicated very low toxicity in turtles (Milani and Intini 2013).

Three other studies on soil toxicity were found for Pigment Yellow 1* and Pigment Red 112*, which share some structural similarities with Azo Disperse Dyes. The studies indicate that at a loading rate of 1 000 mg/kg of soil, no adverse effects (mortality, reproduction and biomass of organisms for earthworms; shoot height/weight, emergence rate and visual phytotoxic effects for crop plants) were observed following chronic exposures.

A PNEC for the soil compartment is not calculated. Based on the information above, it is expected that these 73 Azo Disperse Dyes are not harmful to soil-dwelling organisms, which most likely can be explained by the low bioavailability of these substances from bulk soil.

For Disperse Yellow 3, the preliminary soil toxicity data has been identified for this substance in the screening assessment for Azo Solvent Dyes substance grouping (Environment Canada, Health Canada 2015). A 21-day NOEC greater than 625 mg/kg-dw in turtle embryos (*Chelydra serpentina*) was reported for Solvent Red 1. This data is preliminary, suggesting that Disperse Yellow 3 is unlikely to be harmful to soil-dwelling organisms, and is considered not suitable to be used as the CTV. Therefore a PNEC is not determined for soil compartment for this substance.

6.1.3 Sediment Compartment

No ecotoxicity data on sediment organisms have been identified for Azo Disperse Dyes. However, Milani and Intini (2013) conducted preliminary studies on the effects of Solvent Red 1* (or Sudan Red G*), an azo dye with low solubility (7.8×10^{-3} mg/L), on mayflies (*Hexagenia* spp.) in a 21-day test and on an oligochaete worm (*Tubifex tubifex*) in a 28-day test in which organisms were exposed to concentrations of Solvent Red 1* in sediments (see Table 6-6). For mayflies, an LC_{50} of > 1 000 µg/g dry weight and an IC_{50} (growth) of > 1 000 µg/g dry weight were reported (nominal concentrations). A slight reduction in growth was noted at the highest concentration tested (1 000 µg/g). *Tubifex tubifex* was more sensitive, with an LC_{25} of 56.3 µg/g and an LC_{50} of 70.5 µg/g. *Tubifex tubifex* reproduction endpoints were more sensitive than survival, with IC_{25}s ranging from 1.0 to 3.3 µg/g. All concentrations reported are nominal, and acetone was used as a carrier. During the tests, it was reported that a spongy mat layer of chemical and solvent formed on the top of the sediment, which may have caused physical effects on the *T. tubifex* by affecting its ability to burrow. This factor may have increased toxicity and adds an element of uncertainty to the interpretation of the preliminary test results.

A PNEC for this compartment is not calculated, but the preliminary results on a solvent dye indicate that Azo Disperse Dyes may be hazardous to sensitive sediment-dwelling species.

Table 6-3. Summary of preliminary chronic ecotoxicity data in sediment for Solvent Red 1* (or Sudan Red G*; Milani and Intini 2013)

Organism	Test type	Endpoint (µg/g)[a]
Oligochaete worm (*Tubifex tubifex*)	28-day LC_{25}	56.3
Oligochaete worm (*Tubifex tubifex*)	28-day LC_{50}	70.5
Oligochaete worm (*Tubifex tubifex*)	28-day IC_{25} (reproduction)	1.0–3.3
Mayfly (*Hexagenia* spp.)	21-day LC_{50}	> 1 000
Mayfly (*Hexagenia* spp.)	21-day IC_{50} (growth)	> 1 000

[a]Nominal concentrations; final concentrations to be confirmed when results are finalized. As indicated in the section on Environmental Persistence, Azo Disperse Dyes may undergo biodegradation in sediment (Yen et al. 1991); however, in deep anoxic sediment, these biodegradation transformation products are not expected to present a high degree of exposure potential for most organisms. This is in part because contact of organisms with anoxic sediment is likely to be limited, and also because the amine degradation products are expected to be tightly bound to sediments, resulting in very low bioavailability (Weber et al. 2001; Colón et al. 2002). Therefore, Azo Disperse Dyes are not likely to present an ecological concern under anaerobic conditions.

The preliminary sediment toxicity data indicate that Disperse Yellow 3 is unlikely to be harmful to soil-dwelling organisms. However no CTV has been determined for the sediment compartment for this substance.

6.2 Ecological Exposure Assessment

Because of difficulties in the determination of different classes of dyes at trace levels in environmental samples, little is known of the environmental occurrence, persistence or fate of dyes used in textile wet processing (Maguire and Tkacz 1991). As already mentioned in the Subgrouping Approach and Background Information document (Environment Canada and Health Canada 2013), there has been only one published investigation of the occurrence of dyes in the Canadian environment (Maguire and Tkacz 1991; Maguire 1992). In an environmental study conducted in 1987, no disperse dyes were detected in water samples from the Yamaska River, Quebec which may receive effluents from nearby textile mills (Canada 2001). Additionally, no disperse dyes were detected in over 100 samples of fish from the river in the same year (Canada 2001). This may be due to the installation of wastewater treatment systems in the major cities and towns in the river basin where sampling was conducted or the sampling did not coincide with the use of the disperse dyes being analysed.

Between 2009 and 2012, samples were collected from wastewater treatment plants across Canada (2012 email from Aquatic Ecosystem Research Protection Division, Water Science and Technology Directorate, Environment Canada, to Environmental Assessment Division, Science and Risk Assessment Directorate, Environment Canada; unreferenced) and analyzed for four Azo Disperse Dyes (Disperse Orange 5, Disperse Orange 13, Disperse Yellow 7 and Disperse Blue 79); none of these dyes were

detected. Of these four dyes, only Disperse Blue 79 was reported to be in commerce according to recent surveys.

Given that limited data on measured environmental concentrations (in water, soil or sediment) of Azo Disperse Dyes in Canada have been identified, environmental concentrations are estimated from available information.

6.2.1 Releases to the Environment

Anthropogenic releases of a substance to the environment depend upon various losses that occur during the manufacture, industrial, consumer and commercial use[4] and disposal of a substance. In order to estimate releases to the environment occurring at different stages of the life cycle of Azo Disperse Dyes, Environment Canada compiled information on the relevant sectors and product lines, as well as emission factors[5] to wastewater, land and air at different life cycle stages, in order to identify the life cycle stages that are the largest contributors to environmental concentrations. Recycling activities and transfer to waste disposal sites (landfill, incineration) were also considered. However, releases to the environment from disposal were not quantitatively accounted for unless reliable specific information on the rate of (or potential for) release from landfills and incinerators was available.

Factors relevant to the life cycle stages of these substances have been considered, uncertainties have been recognized and assumptions have been made, subject to the availability of information. Exposure scenarios for the uses and media of concern have been developed, including the determination of applicable predicted environmental concentrations (PECs).

6.2.2 Identification of Important Exposure Scenarios

Exposure characterization is focused on important exposure scenarios. These scenarios represent major environmental releases and relatively high levels of exposure. In general, the magnitude of releases is a direct function of the quantity of a substance manufactured or used and its applicable emission factors. In cases where

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[4]Commercial use is the use of a chemical substance, or the use of a mixture, product or manufactured item containing a chemical substance, in a commercial enterprise providing saleable goods or services.

[5]An emission factor is generally expressed as the fraction of a substance released to a given medium, such as wastewater, land or air, during a life cycle stage, such as manufacture, processing, industrial application or commercial/consumer use. Sources of emission factors include emission scenario documents developed under the auspices of the OECD, data reported to Environment Canada's National Pollutant Release Inventory, industry-generated data, monitoring data, etc.

industrial releases are similar in a total quantity to consumer and/or commercial releases, the former normally results in higher levels of environmental exposure than the latter. This is because industrial releases are concentrated at a limited number of facilities, whereas consumer and/or commercial releases are dispersed across the country.

Two scenarios were identified as having significant environmental releases of Azo Disperse Dyes in commerce. These scenarios were textile chemicals formulation and textile dyeing. The data from recent CEPA 1999 section 71 surveys (Canada 2006, 2008a, 2008b, 2008c, 2009a, 2009b, 2011) revealed that 13 Azo Disperse Dyes in this subgroup and Disperse Yellow 3 were reported above the 100 kg/year reporting threshold for import and that they were used in textile chemicals formulation and/or textile dyeing. The survey data also indicated that none of these 13 Azo Disperse Dyes, or Disperse Yellow 3 were manufactured in Canada. The total import quantity of these 13 Azo Disperse Dyes and Disperse Yellow 3 was between 10 000 and 100 000 kg/year. The emission factors to wastewater were high, in the range of 0.74–12% for disperse dyes from textile chemicals formulation and textile dyeing (2013 telephone communications between formulation facility and Environment Canada; unreferenced; OECD 2004). These emission factors, combined with the total imported quantity, pointed to textile chemicals formulation and textile dyeing as important sources of environmental releases.

Compared with the releases of dyes from industrial uses, the exposure resulting from the laundering of textile products was expected to be relatively low. This was because releases from the laundering of textile products were dispersed across numerous sites in Canada, and the release amount on a per site basis was much smaller than that from a limited number of industrial facilities. Thus, the consumer and/or commercial uses of textile products were not considered as important a source of release and were therefore not selected for quantitative exposure characterization.

6.2.3 Estimates for Predicted Environmental Concentrations (PECs)

The exposure to Azo Disperse Dyes was estimated in the form of PECs for scenarios of textile chemicals formulation and of textile dyeing. These concentrations are based on available information on the quantities of Azo Disperse Dyes, emission factors to wastewater, the characteristics of the wastewater treatment systems involved and the characteristics of the receiving environment.

Based on the information obtained from recent CEPA 1999 section 71 surveys (Canada 2006, 2008a, 2008b, 2008c, 2009a, 2009b, 2011), fewer than 4 facilities were identified to use Disperse Yellow 3 in the formulation of textile chemicals and 39 facilities were identified to use 13 Azo Disperse Dyes in this subgroup and Disperse Yellow 3 in textile dyeing. One textile dyeing facility confirmed with Environment Canada that it no longer uses any Azo Disperse Dyes in its operations after initial purchases (2013 email from textile dyeing facility to Environment Canada; unreferenced). Therefore, fewer than 4 chemicals formulation facilities and 38 textile dyeing facilities were selected to evaluate

the exposure from the industrial use of Azo Disperse Dyes. The fewer than 4 formulation facilities and 38 textile dyeing facilities were located in three provinces (Nova Scotia, Ontario and Quebec).

6.2.4 Aquatic PECs

The aquatic PEC resulting from the fewer than 4 facilities formulation facilities and each of the 38 facilities was estimated from a number of parameters, including an estimated daily use quantity of Azo Disperse Dyes, emission factor to wastewater, wastewater treatment flow and removal, and receiving water dilution factor. Detailed calculations are given in Appendix E.

6.2.4.1 Textile chemicals formulation

There were fewer than 4 facilities identified using Disperse Yellow 3 in textile chemicals formulation. Based on the information provided by companies involved (2013 communications between companies and Environment Canada; unreferenced), the maximum daily use of Disperse Yellow 3 was up to 440 kg. Considering an emission factor to wastewater as 1.1%, removal rates for the on-site and off-site wastewater treatment as 26.2%, the flow rate of the off-site wastewater system as 24 375 000 L/day, and a high dilution in the receiving water, the aquatic PEC of Disperse Yellow 3 is estimated as 0.011 mg/L.

6.2.4.2 Textile dyeing

The daily use quantity of 13 Azo Disperse Dyes in this subgroup and Disperse Yellow 3 at each textile dyeing facility was determined based on literature data or facility-supplied data. Among 38 textile dyeing facilities, 1 facility in Ontario provided its daily use quantity as being below 15 kg (2013 emails from textile mill to Environment Canada; unreferenced). For the other 37 facilities, the daily use quantity remained unknown and was therefore assumed as 36 kg/day based on literature data (US EPA 1994; Cai et al. 1999).

The emission factor to wastewater for disperse dyes was given in the range of 1–12% for textile dyeing (OECD 2004) and the higher-end value of this range (12%) was applied to daily use quantities and resulted in conservative daily release quantities to wastewater.

These conservative daily release quantities were further assumed to enter local sewer systems without going through on-site wastewater treatment for textile dyeing facilities. Many of these facilities were known to have on-site wastewater treatment, although the type of treatment was unknown for each of the facilities evaluated. As a conservative approximation, it was assumed that dyes were released to the sewer system without being removed by on-site wastewater treatment. This assumption resulted in a conservative estimate for the daily release quantity to the sewer system, which was equal to the daily release quantity to wastewater.

The aquatic PEC from each facility was then calculated based on the characteristics of the local off-site wastewater treatment system and its receiving water. Firstly, the influent concentration of dyes was determined from the daily quantity released to sewer and the flow of the off-site wastewater treatment system. Secondly, the effluent concentration of dyes was determined based on the removal efficiency of the off-site wastewater treatment system, which was estimated by ASTreat (2006) for primary treatment system (21.7–47.1 %) and secondary (26.2–61.1 %) or by STP-EX (2008) for lagoons (8.3–67.3 %). The lower values in each range were used to calculate conservative effluent concentrations. Finally, the aquatic PEC was derived by applying an appropriate receiving water dilution factor to the effluent concentration.

The aquatic PECs derived for the 38 facilities are presented statistically, ranging from 1.2×10^{-4} to 0.11 mg/L (Table 6-4). It should be noted that these estimated PECs were conservative due to the use of the highest emission factor to wastewater, no removal assumed via the on-site wastewater treatment, and the lower removal rates for the off-site wastewater treatment systems. These PECs also did not necessarily reflect the actual level of exposure, because facility-specific data were unavailable for textile dyeing and could not be used in the calculations, except for one textile dyeing facility in Ontario. Nevertheless, the estimated aquatic PECs were indicative of a conservative level of exposure for the industrial use of 13 Azo Disperse Dyes in this subgroup and Disperse Yellow 3.

6.2.5 Sediment PECs

An equilibrium sediment–water partition approach described by the European Chemicals Agency (ECHA 2010) was used to estimate the PECs of Azo Disperse Dyes in sediment. This approach assumes that the concentration in bottom sediment is in equilibrium with the concentration in the overlying water. According to Gobas (2007), the concentration in the overlying water should pertain to the concentration in the aqueous phase and should not include quantities adsorbed to suspended sediment. The concentration in the aqueous phase can be estimated from the aquatic PEC, which is the total concentration in water. Thus, the sediment PEC for each facility was derived from the respective aquatic PEC and standardized to an organic carbon (OC) content of 3% for bottom sediment.

The probabilistic sediment PECs for 38 dyeing facilities are summarized statistically in Table 6-4. Detailed calculations for these sediment PECs are explained in Appendix E.

The probabilistic sediment PECs presented in Table 6-4 are conservative, because the concentrations in the aqueous phase were conservatively estimated. In the water column, the total concentration of Azo Disperse Dyes or the aquatic PEC associated with a given facility was a fixed value. It was split between the aqueous phase and the solids phase (suspended sediment). The concentration in the solids phase depended upon the OC content of the solids phase, and the latter varied from a low of 0.1 kg/kg to a high of 0.2 kg/kg (Gobas 2010). By selecting the low value of 0.1 kg/kg, the minimum concentration in the solids phase resulted, therefore yielding the maximum

concentration in the aqueous phase. This maximum concentration then resulted in the maximum sediment PEC.

An equilibrium sediment-water partition approach described by the European Chemicals Agency (ECHA 2010) was used to estimate the PECs for Disperse Yellow 3 in sediment (sediment PECs). This approach assumes that the concentration in bottom sediment is in equilibrium with the concentration in the overlying water. According to Gobas (2007), the concentration in the overlying water should pertain to the concentration in the aqueous phase and should not include quantities adsorbed to suspended sediment. The concentration in the aqueous phase can be estimated from the aquatic PEC, which is the total concentration in water. Thus, the sediment PECs for the three formulation sites were derived from their respective aquatic PECs and standardized to an organic carbon (OC) content of 3% for bottom sediment.

6.2.6 A sediment PEC of 25.3 mg/kg was calculated for the folrmulation of textile chemicals. More detailed information is available in the Azo Solvent Dye assessment (Environment Canada, Health Canada 2015). Soil PECs

An approach described by the European Chemicals Agency (ECHA 2010) was used to estimate soil PECs for Azo Disperse Dyes resulting from the land application of wastewater biosolids. Using this approach, the amounts of biosolids accumulated within the top 20 cm layer of soil over 10 consecutive years were estimated and used as the basis for soil PECs. One underlying assumption of the approach was that there was no loss due to degradation, volatilization, leaching or soil runoff. In general, this assumption resulted in conservative soil PECs.

Using the above method, the probabilistic soil PECs estimated for 38 textile dyeing facilities are summarized statistically in Table 6-4 and explained in detail in Appendix E. According to their aquatic PECs, the soil PEC associated with use of Disperse Yellow 3 in the dye chemical formulation is within the range of probabilistic soil PECs associated with uses of these dyes in textile dyeing and hence not listed separately.

These soil PECs were based on the amounts of Azo Disperse Dyes sorbed to biosolids. These sorbed amounts were conservatively estimated using the maximum sorption to biosolids determined by computer models. Two models were used: ASTreat (2006) for primary or secondary wastewater treatment systems and STP-EX (2008) for lagoons. The use of the maximum sorption provided additional conservatism in the soil PECs derived.

The soil PECs derived were also a function of the daily biosolids production at a given off-site wastewater treatment system and the biosolids land application rate. The daily biosolids production was determined from the population served by the treatment system and the per capita sludge production found in the literature. The per capita sludge production was given as 0.080 kg/day per person for primary wastewater treatment systems and 0.195 kg/day per person for secondary systems (Droste 1997).

The per capita sludge production for lagoons was not found, but it was assumed to be the same as that for primary systems because of similar sludge removal mechanisms between the two treatment types. The biosolids land application rate varied between different provinces/territories from a low of 1.6 t/ha per year in Ontario (MOE and OMAFRA 1996) to a high of 8.3 t/ha per year in Alberta (Alberta Environment 2009). An appropriate rate was used in the calculations depending upon the location of a given facility.

In calculations of the soil PECs, the biosolids land application was assumed to take place at its maximum allowed rate within the province/territory where a facility was located. It was also assumed in the calculations that the sludge produced was converted into biosolids and subsequently applied to land. This assumption might result in an overestimate for biosolids land application, because not all sludges, lagoon sludges in particular, were converted into biosolids, and not all biosolids were land applied.

Table 6-4. Probabilistic Aquatic, Sediment and Soil PECs from Industrial Use of Azo Disperse Dyes on Textile Dyeing

Percentile	Aquatic PEC (mg/L)	Sediment PEC (mg/kg)	Soil PEC (mg/kg)
0^{th} (minimum)	0.00012	0.15	0.05
5^{th}	0.00012	0.15	0.20
10^{th}	0.000012	0.15	0.29
20^{th}	0.00012	0.15	0.29
30^{th}	0.00012	0.15	0.29
40^{th}	0.00052	0.63	0.29
50^{th}	0.0045	5.5	1.2
60^{th}	0.0062	7.5	4.6
70^{th}	0.021	25.1	5.1
80^{th}	0.035	42.8	13.8
90^{th}	0.056	68.0	132.7
95^{th}	0.097	118.0	136.9
100^{th} (maximum)	0.11	131.4	505.1

6.3 Characterization of Ecological Risk

The approach taken in this ecological screening assessment on Azo Disperse Dyes was to examine various supporting information and develop conclusions based on a weight of evidence approach and using precaution. Lines of evidence considered include available experimental information on physical-chemical properties, potentials for persistence and bioaccumulation, source, releases, environmental fate, ecotoxicity of Azo Disperse Dyes and results from a conservative risk quotient analysis, which are outlined below.

Based on the outcomes from recent surveys, 13 of the 73 Azo Disperse Dyes within this assessment have been identified in commerce in Canada and the total import quantity

of these 13 substances in Canada is between 10 000 and 100 000 kg/year. In addition, Disperse Yellow 3, which was also assessed as part of the Azo Solvent Dyes assessment (as Solvent Yellow 77), was also found to be in commerce.

Azo Disperse Dyes generally have low water solubilities (nanograms to micrograms per litre) but have higher solubilities in octanol. Given their import and use in Canada, potential releases to the aquatic environment and to the terrestrial environment (via wastewater treatment sludge) have been estimated. Azo Disperse Dyes are not volatile and are likely to eventually deposit in sediment if released to water, but they may still be present in the water column at low concentrations. If released to soil, they are expected to remain there.

Experimental data show Azo Disperse Dyes to be persistent under aerobic conditions, but they are expected to degrade in anaerobic environments (e.g., deep sediment). Bioaccumulation and bioconcentration studies consistently show that Azo Disperse Dyes have low potential to bioaccumulate in aquatic organisms.

Ecotoxicity studies have been conducted on four major taxa of aquatic organisms to assess the toxicity of Azo Disperse Dyes. Due to the low water solubilities of Azo Disperse Dyes, a variety of auxiliary agents have been used in the ecotoxicity studies to facilitate dissolution and support stable dispersions. Consequently, exposure to the test chemicals may be higher under such experimental conditions, and most reported acute toxicity endpoint values for Azo Disperse Dyes are in excess of known water solubilities.

Among acute toxicity test organisms for which data are available, *Daphnia* spp. are the most sensitive species. However, chronic toxicity tests at low concentrations within water solubility limits are preferred and available for *Hyalela* spp. and a few fish species (fathead minnow and rainbow trout). Chronic toxicity data show different levels of hazard to aquatic organisms at low concentrations and suggest effects are seen at lower concentrations for substances with lower molecular weights (less than 360 g/mol). The chronic toxicity endpoint of 0.025 mg/L was chosen as the critical toxicity value for Disperse Yellow 7, representing Azo Disperse Dyes with molecular weights below 360 g/mol; using an application factor of 10 to extrapolate for lab to field effects, a PNEC value of 0.0025 mg/L was calculated. No PNEC was calculated for Azo Disperse Dyes with a molecular weight greater than or equal to 360 g/mol, as the PNEC would likely be greater than the maximum solubility of the substances. The PNEC for Disperse Yellow 3 was calculated to be 0.0023 mg/L, based on the read-across toxicity of Solvent Yellow 1 (CAS RN 60-09-3, 96-hour LC50 equal to 0.023 mg/L) on fish (*Oryzias latipes*) with the application factor of 100 to extrapolate the long term no effect concentration from an acute toxicity endpoint and lab to field effects.

While toxicity data have been primarily identified related to pelagic aquatic exposure, soil and sediment may also be important media based on the predicted environmental fate of these substances. Data for sediment and soil are limited and uncertain. While there is some evidence of toxicity at low concentrations in sediment based on

preliminary data for *T. tubifex*, similar substances do not show high levels of toxicity in soil. No PNECs were calculated for sediment or soil.

A risk quotient analysis was conducted by comparing the aquatic PEC values (obtained from the relevant exposure scenario) with the aquatic PNECs (extrapolated from the ecotoxicity data). Aquatic exposure analysis for the textile dyeing scenario was conducted using probabilistic methods. The likelihood of the PECs exceeded the PNECs for Azo Disperse Dyes with a molecular weight less than 360 g/mol was found to be high (55%). However, the molecular weights for the 13 Azo Disperse Dyes in commerce in Canada are 377 g/mol and above. Therefore, since none of the 73 Azo Disperse Dyes with a molecular weight less than 360 g/mol are currently used in Canada, the risk to aquatic organisms from the 73 Azo Disperse Dyes is low based on the current levels of exposure. However, since the molecular weight of Disperse Yellow 3 is below 360 g/mol and it was reported to be used in Canada according to surveys conducted under section 71 of CEPA 1999, this substance does result in a possible concern to the aquatic environment. Furthermore, as indicated above, the 73 Azo Disperse Dyes in this assessment with molecular weight less than 360 g/mol may be harmful to aquatic organisms based on their hazard properties. A list of these substances with environmental health effects of concern based on hazard properties are shown in Appendix F. It should be noted that the use of any azo disperse dye with a molecular weight less than 360 g/mol would likely result in a possible concern to the aquatic environment due to the increased bioavailability for these substances.

A site specific textile formulation scenario was developed for Disperse Yellow 3. The aquatic PEC for this scenario was 0.011 mg/L. A risk quotient analysis was conducted by comparing the PEC to the aquatic PNEC of 0.0023 mg/L. This analysis resulted in a risk quotient of 4.7. The use of Disperse Yellow 3 in textile formulation results in a concern to aquatic organisms.

Given that data for sediment and soil are limited and uncertain, no PNEC is calculated for these media, and risk quotient analyses are not conducted. These 73 Azo Disperse Dyes and Disperse Yellow 3 are associated with low soil and sediment toxicity and are not likely to cause harm to organisms in these two compartments.

6.3.1 Uncertainties in Ecological Risk Assessment

A major area of uncertainty in the ecological risk assessment exists due to a lack of experimental data for most of the Azo Disperse Dyes subject to the screening assessment. For characterizing key physical and chemical properties for Azo Disperse Dyes, notably their solubility in water and octanol–water partition coefficient (log K_{ow}), a read-across approach was used to characterize these parameters for this class of colourant. When applying read-across based on structural similarity, these substances are separated into a few structurally related groups; therefore, characterization on the basis of a certain physical-chemical property is of higher confidence. The evaluation of potential for persistence and bioaccumulation is based on limited experimental data for Azo Disperse Dyes. Available empirical data from relevant analogues were used where

possible in the assessment. Other related structural factors, such as the large cross-sectional diameters and the moderate to high molecular weights, have also been taken into consideration when assessing the bioaccumulation potential. Cross-sectional diameters and molecular weight also appear to influence the bioavailability and toxicity of Azo Disperse Dyes. Toxicity data showed that organisms seem to be more sensitive to substances which have molecular weights ≤ 360 g/mol. However, there is limited toxicity data for substances with molecular weights above 360 g/mol which allows us to further confirm this value.

As discussed above in the assessment, Azo Disperse Dyes are expected to have low solubility in water. Therefore, to improve their dyeing performance in industrial operations, these substances may be sold and used in combination with surfactants; consequently, the distribution of commercial dyes in the environment (the aquatic compartment vs. the sediment compartment) may be different from the theoretical assumptions regarding the pure chemicals. When available, the chemical purity was noted and taken into account in the determination of study reliability.

Many reported values of ecotoxicity endpoints exceed the solubility of Azo Disperse Dyes and their analogues in water. Such experimental concentrations are achieved by using auxiliary agents to increase the solubility of the test substances. Due to the low solubility of dyes, they were mixed with a solubilizing agent to complete the test. This convention can increase the solubility values, which are artificially high, and may affect the results of aquatic toxicity tests as well. Efforts to make the dyes more soluble may increase their bioavailability, but factors in the ambient environment may have a similar effect, however, how this related to factors in the ambient environment is unknown.

Also, regarding ecotoxicity, based on the predicted partitioning behaviour of these chemicals, the significance of soil and sediment as important media of exposure is not well addressed due to a lack of effects data. Although the water column may not be the medium of primary long-term concern, the only effects data identified apply primarily to pelagic aquatic exposures. Data on soil organisms exposed to structurally similar substances have been considered to characterize the ecotoxicity of Azo Disperse Dyes.

The ecotoxicity of Azo Disperse Dyes has been assessed according to their ecological effects on overall survival, growth and reproduction. However, data for the genotoxicity and cytotoxicity of analogues have been reported from laboratory experiments. Germ cell mutation may affect the population fitness of aquatic species. There is a lack of empirical data for assessing the genotoxicity or cytotoxicity of Azo Disperse Dyes in the subgroup.

There is another source of uncertainty related to the degradation of Azo Disperse Dyes, particularly the rate of degradation in anaerobic sediments, the extent to which degradation occurs in these sediments and whether the degradation products (e.g., aromatic amines) would be biologically available. Nevertheless, it is clear that anaerobic degradation of the bioavailable portion of azo dyes in sediments to constitutive amines is much faster (half-lives in the order of days) than aerobic biodegradation. The low

water solubility of Azo Disperse Dyes in this subgroup may limit the biotic reduction to form the degradation products; in contrast, the aromatic amine degradation products are not expected to be biologically available because they form only in relatively deep anoxic sediment and can be irreversibly bound to sediment. The ecological assessment on aromatic amines will be addressed separately under the Aromatic Azo and Benzidine-based Substance Grouping.

An additional uncertainty is associated with a lack of environmental monitoring data for synthetic dyes (including Azo Disperse Dyes). This may be partly due to difficulties in the determination of different classes of azo dyes at trace levels in environmental samples. Also, as some key factors in calculating the environmental releases of dyes from industrial facilities remain unknown, certain factors were estimated.

6.3.2 Azo Disperse Dyes with Ecological Effects of Concern

Overall, ecological risk from the substances in this assessment is low based on the current levels of exposure. However, as indicated above, some of the azo disperse dyes may have ecological effects of concern based on aquatic toxicity. These include eight Azo Disperse Dyes in this subgroup, as well as other azo disperse dyes with a molecular weight less than 360 g/mol. A list of substances with ecological effects of concern based on aquatic toxicity is included in Appendix F.

7. Potential to Cause Harm to Human Health

With respect to human health risk assessment, this Screening Assessment addresses 64 of the 74 substances, among which includes Disperse Yellow 3, 13 substances previously assessed in the Challenge Initiative of the CMP for which significant new information relevant to human health has become available, and one additional substance (ANMOM, CAS RN 59709-38-5) which was part of the Challenge Initiative but not previously concluded on. For 10 of the 74 substances in this assessment, the human health conclusions have not been updated since these 10 substances were previously concluded on under the Challenge Initiative and no significant information relevant to human health were identified. .

7.1 Exposure Assessment

Among the 64 substances being considered for human health in this assessment, there was considered to be direct and prolonged general population exposure potential from textiles for 13 of these substances: Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3, ANMOM, and Disperse Yellow 3. The uses and exposure characterization for Disperse Yellow 3 under the name Solvent Yellow 3 is summarized in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015).

7.1.1 Environmental Media and Food

Due to the very low vapour pressures of these substances, inhalation of the volatile fraction via air is not expected to be a significant route of exposure. Similarly, due to the very low volatilities and water solubilities of Azo Disperse Dyes, these substances are expected to be sorbed onto soil and sediments when released to the environment. Therefore, exposure of the general population to Azo Disperse Dyes through drinking water is expected to be much lower than that based on estimated aquatic PECs (refer to Ecological Exposure Assessment section). In addition, soil PECs were derived from biosolids land application, considering that Azo Disperse Dyes may be present in wastewater biosolids after wastewater treatment. Overall, environmental media are not considered to be a significant source of exposure to the Azo Disperse Dyes.

As summarized in the Uses section, none of the 74 Azo Disperse Dyes was identified to be used in food packaging applications. The Canadian Food Inspection Agency (CFIA) has tested for the presence of synthetic food colours in foods, including Disperse Yellow 7. In the 2009-2010 and 2010-2011 targeted food surveys, CFIA analyzed domestic and imported food samples, including spices, which were selected for their high likelihood of containing food colouring agents (CFIA 2010, 2011). Disperse Yellow 7 was not found in over 1600 analyzed samples across both targeted food surveys. Overall, exposure to Azo Disperse Dyes from food is not expected.

7.1.2 Consumer Products

As indicated above, 64 of the total 74 substances are being evaluated for human health in this assessment, and 13 of these 64 substances was considered to have direct and prolonged general population exposure potential from textiles. Information to support potential exposure from textiles for 10 of the 13 substances is based on section 71 survey information indicating use for dyeing textiles in Canada (see 4.1 Sources, Table 4-1: ANAM, ANMOM, BANAP, Disperse Blue 79, Disperse Blue 79, Disperse Orange 30, Disperse Orange 61, Disperse Red 167, Disperse Yellow 3, and CAS RN 52697-38-8). For an additional 3 of the 13 substances (Disperse Brown 1, Disperse Brown 1:1, CAS RN 63833-78-3) other information provided by ETAD (2010 email from ETAD to Environment Canada; unreferenced) indicated Canadian uses in textile dyeing for these 3 substances (see 4.2 Uses). Therefore, based on information provided in responses to section 71 surveys and also provided by ETAD, 13 of the 64 substances evaluated in this assessment for human health are considered to have direct and prolonged general population exposure potential from textiles

No information was submitted in the section 71 survey or provided by ETAD regarding concentrations of these 13 substances in textile products on the Canadian market. Accordingly, exposure to these 13 substances has been characterized based on a generic exposure scenario for textile products for the general population of Canada. The exposure characterization for 12 of these 13 substances is presented in the sections below. The potential exposure to Disperse Yellow 3 under the name Solvent Yellow 77 is characterized in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015) and therefore is not presented here.

Use of textile products (e.g. clothes, bedding, etc.) that are dyed with Azo Disperse Dyes are expected to result in direct and prolonged exposure via the dermal and/or oral routes. A summary of estimates for oral and dermal exposures from textiles to the 12 substances (excluding Disperse Yellow 3) is provided in Table 7-1. For textile materials, oral exposure is estimated for mouthing of textile objects (e.g., toys and blankets) by infants (0–6 months of age), and dermal exposure is estimated for adults wearing personal apparel and infants wearing baby sleepers, assuming full body coverage (for adults 20–59 years of age and infants 0–6 months of age). These exposure scenarios are expected to represent the predominant sources of exposure based on expected use patterns for textile products and provide conservative estimates using appropriate exposure factors. For example, the assumption of full body coverage is considered to account for exposures from multiple pieces of apparel containing a substance. In addition, the leaching of dyes may be accelerated by wash and wear. The migration rate after 28 hours of simulated wash and wear cycles was observed to be less than one tenth of the value measured for the first migration. The migration fraction of 0.0005, which is one tenth of the peak initial migration (0.5%), is used to reflect exposure after the initial washes.

It is not expected that these substances would be present in all consumer products made of textiles in Canada. Therefore, exposures were derived assuming, based on

professional judgement, that there is a 10% probability that a given dye is used in dyeing products made of textile in Canada. This adjustment factor of 10% used in this assessment is similar to the 8% value used in the Danish assessment in estimating exposures to aromatic amines and azo dyes from textile garments in the Dutch apparel market (Zeilmaker et al. 1999). See Appendix G for more details on the exposure scenario and algorithms.

Dermal Absorption

Potential dermal absorption of the Azo Disperse Dyes is expected to be variable due to the large range in molecular sizes and associated physical-chemical properties (e.g. solubility in water and octanol) for these substances. No empirical dermal absorption data were identified for Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3, or ANMOM. However, relevant data from other similar azo disperse dyes are considered to inform dermal absorption for these substances. This information is summarized below. The assumptions regarding dermal absorption for Disperse Yellow 3 under the name Solvent Yellow 77 are presented in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015) and therefore are not presented here.

In estimating exposure to chemicals in clothing, the “Textiles” Working Group at the German Federal Institute for Risk Assessment (BfR 2007) recommended using dermal uptake fractions of 0.01 and 0.02 in areas of high perspiration, as conservative assumptions. This recommendation is based on analysis of studies performed by ETAD (1994, 1995a) on dermal absorption of several disperse dyes, including three azo disperse dyes (Disperse Red 17, Disperse Yellow 3, Disperse Blue 165), using pig skin and human skin probes; flux rates ranging from < 0.007 to 2.59 µg/cm^2 per hour and from < 0.001 to 0.219 µg/cm^2 per hour, respectively, over 55 hours were reported in these studies, indicating low absorption through skin. Although the study designs did not account for skin-bound residues, the data suggest a relatively low degree of dermal absorption for the three azo disperse dyes tested in these studies.

Other information on dermal absorption for two related azo disperse dyes comes from European Scientific Committee on Consumer Safety (SCCS) evaluations. Dermal absorption of Disperse Black 9 was studied in an OECD guideline 428 compliant *in vitro* glass diffusion cell system. Dermatome skin samples of 400 µm thick were obtained from 5 human female donors. Radiolabelled Disperse Black 9 (1%) in hair dye cream formulation was applied for a 30 minute period and sampling continued until 48 hours following application. The mean amount recovered was 104%, and skin washes accounted for over 103%. Total reported mean bioavailable amount and percentage were, 0.128 µg/cm^2 and 0.122%, respectively (P&G, June 2005), indicating minimal absorption.

Dermal absorption of Disperse Red 17 was also studied in an OECD guideline 428 compliant *in vitro* flow-through diffusion cell system by DeLigt (2005). Dermatome

human skin samples of 400 µm thickness were obtained from 3 different female donors. Radiolabelled Disperse Red 17 in non-oxidative hair dye formulations of 0.2% (w/w) and oxidative hair dye formulations of 2.0% (w/w) (oxidative) were applied for a 60 minute period and post-application sampling continued for 23 hours. Mean recoveries reported in non-oxidative and oxidative preparations were greater than 98%. Total reported mean bioavailable amounts and percentages (non-oxidative and oxidative conditions) were 0.41 µg/cm^2 (0.89%) and 0.50 µg/cm^2 (0.11%), respectively.

Low oral absorption of Disperse Blue 79:1 supports a similarly low potential for dermal absorption. An *in vivo* metabolism study of Disperse Blue 79:1, in male and female Sprague-Dawley CD, demonstrated limited oral bioavailability. Animals were administered ^{14}C-labelled Disperse Blue 79:1 at doses of 50 or 500 mg/kg-bw in corn oil by gavage. Total radioactivity recovery at both levels exceeded 90%, with the majority eliminated via the fecal route. At 48 hours post dosing, systemic bioavailability was approximately 6% (Union Carbide Corp. 1991a). Dermal absorption for Disperse Blue 79:1 is not considered greater than absorption by the oral route, and is likely lower (i.e. ≤ 6%).

In contrast to the azo disperse dyes above, dermal absorption for Disperse Yellow 97 (Solvent Yellow 14 also known as Sudan I) was reported to be greater. Dermal absorption of Disperse Yellow 97, which is relatively smaller in terms of molecular size, was evaluated in an *in vitro* flow-through diffusion cell system using human female skin samples. A ^{14}C-radiolabelled Disperse Yellow 97 dose of 5 µg/cm^2 was applied, and the observation period extended for 24 hours. Although total recovery was not reported, total absorbed percentage was 26.4%. Approximately 16% of the absorbed dose was associated with skin residues and less than 10% was detected in receptor fluid (Collier et al. 1993).

The available data suggest that dermal and oral bioavailability of the Azo Disperse Dyes in this assessment is low to moderate. Using BfR's recommended dermal absorption percentage of 2% in areas of high perspiration and the reported 26.4% dermal absorption of Disperse Yellow 97, a dermal absorption range of 2 to 27% was used to estimate dermal exposure to 12 Azo Disperse Dyes (i.e., Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3 and ANMOM).

Table 7-1. Ranges of estimated daily exposures to Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3 and ANMOM

Exposure scenario	Age group	Estimated daily exposure via oral route (mg/kg-bw per day)	Estimated daily exposure via dermal route (mg/kg-bw per day)

Exposure scenario	Age group	Estimated daily exposure via oral route (mg/kg-bw per day)	Estimated daily exposure via dermal route (mg/kg-bw per day)
Textiles—Personal apparel	Adults (20–59 years)	N/A	$5.2x10^{-5}$ to $7.0x10^{-4}$
Textiles—Baby sleeper	Infants (0−6 months)	N/A	$8.0x10^{-5}$ to $1.1x10^{-3}$
Textiles—Mouthing	Infants (0–6 months)	$1.35×10^{-3}$	N/A

Estimated ranges of dermal exposures to these substances (i.e., Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3 and ANMOM) due to direct and prolonged skin contact with textile products in personal apparel and baby sleeper are: $5.2x10^{-5}$ to $7.0x10^{-4}$, and $8.0x10^{-5}$ to $1.1x10^{-3}$ mg/kg-bw per day respectively. The oral exposure for mouthing of textiles by infants was estimated to be $1.35x10^{-3}$ mg/kg-bw per day (see Appendix F). The exposure characterization for 12 of these 13 substances is presented in the sections below. The potential exposure to Disperse Yellow 3 under the name Solvent Yellow 77 is characterized in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015) and therefore is not presented here.

7.2 Health Effects Assessment

Carcinogenicity and genotoxicity are the critical health effects of potential concern for Aromatic Azo and Benzidine-based Substances (Environment Canada and Health Canada 2013). However, non-cancer effect levels are also considered. Aside from Disperse Yellow 3, limited health effects data were identified for most of the disperse dyes considered in this assessment, therefore relevant toxicity data on other related disperse dyeswere also considered for read-across purposes including: Disperse Red 338, Disperse Red 206, Disperse Black 9, Disperse Red 17, and Disperse Yellow 97 (Sudan I/Solvent Yellow 14). Substances used for read-across in the health assessment of the Azo Disperse Dyes are identified in Table 2-8.

Since the health effects data for Disperse Yellow 3 (Solvent Yellow 77) and the read-across substance Disperse Yellow 97 (Sudan I/Solvent Yellow 14) are already characterized in the assessment of Azo Solvent Dyes (Environment Canada and Health Canada 2015), only a summary of this hazard data for these substances is repeated in this section.

The disperse dyes considered in this assessment exhibit considerable variability with respect to molecular structure, physical and chemical properties (Section 3.0). Water solubilities range from negligible (0.000001 mg/L) to low (2.92 mg/L), and molecular weights range from 238 g/mol to 639 g/mol. These differences likely impact oral and

dermal bioavailability, as well as azo cleavage potential, across individual dyes. To conservatively address this variability, the most sensitive health effect levels for parent dyes and their azo cleavage metabolites are used to read-across to the entire grouping.

Azo Bond Cleavage Potential

An important mechanism by which azo and benzidine-based substances exert their toxicity is considered to involve reductive cleavage of the azo bond and the subsequent release of aromatic amines. These aromatic amines can be converted to reactive electrophilic intermediates through metabolic oxidation (Environment Canada and Health Canada 2013). While empirical data are too limited to describe the cleavage potential of all disperse dyes considered in this assessment, it will be inferred based on read-across among (closely) related substances, for which in vitro cleavage assay data exists (Environment Canada and Health Canada 2013).

In the absence of empirical data, the potential for azo bond cleavage *in vitro* was demonstrated for 10 Azo Disperse Dyes in fecal samples and for 4 of those dyes in skin bacteria. 10 Azo Disperse Dyes in anaerobic bacteria (in feces) and on 8 of those 10 dyes in aerobic bacteria were studied (*Staphylococcus epidermidis* and *Micrococcus luteus*, two common skin species). Metabolism of four disperse dyes has been demonstrated in one or both of the skin bacterial species. The postulated azo reduction metabolite, 2-amino-3-bromo-1-cyano-5-nitrobenzene, derived from the dye (CAS RN 2537-62-4), increased over time during incubation with feces; however, postulated azo reduction metabolites were not readily identified for the other test substances (BRI 2012, 2013). The test substances in the *in vitro* metabolism study represent a range of disperse dye structures, including four disazo and six monoazo dyes.

7.2.1 Carcinogenicity and Genotoxicity

Genotoxicity

Genotoxicity data were identified for 20 of the 74 substances in this assessment: *in vitro* studies were available for all 20 of those substances, while *in vivo* data were available for only four. The *in vivo* findings generally failed to support the *in vitro* positive mutagenicity findings in bacterial and mammalian cell assays. No other in vivo data were located for the remaining substances for which only *in vitro* positive reports were available. Of the two additional disperse dyes considered to inform the genotoxic potential of disperse dyes, *in vitro* Ames and mammalian cell data were available for Disperse Black 9 and Disperse Red 17. Information pertaining to the genotoxic potential of Disperse Yellow 3 (Solvent Yellow 77) and Disperse Yellow 97 (Sudan I/Solvent Yellow 14) is summarized separately in the Government of Canada sssessment of Azo Solvent Dyes (Environment Canada and Health Canada 2015).

Twelve substances were tested in Prival-modified Ames assays. Of these, 11 gave positive responses in at least one test strain, both with and without flavin mononucleotide (FMN); only CAS RN 19745-44-9 was negative in all strains and under

all conditions tested (Seifried et al. 2006; BioReliance 2012; ILS 2011, 2012). Four of the 73 disperse dyes, as well as Disperse Black 9 and Disperse Red 17 tested positive in Ames assays under standard conditions, in at least one test strain (Mishra et al. 1981; Clariant Corporation 1982; NTP 1983, 1984, 1988, 1993; Ciba Specialty Chemicals Corp. 1997a; P&G 2005; Sokolowski 2005; Umbuzeiro et al. 2005;).

In vitro mammalian cell assays did not return consistent findings across the grouping. While Disperse Brown 1:1 induced mutations in mouse lymphoma L5178Y cells (Seifried et al. 2006), Disperse Black 9 did not (P&G 2005). Disperse Blue 79 and Disperse Red 17 returned negative results in Chinese Hamster V79 cells (Clarient 1996; Wollny 2005), but Disperse Black 9 induced chromosomal aberrations in Chinese Hamster Ovary-WBL cells (P&G 2005). Disperse Red 17 also failed to significantly increase micronuclei incidence in peripheral lymphocytes harvested from two healthy non-smoking male donors (Whitwell 2005). Disperse Brown 1:1 failed to induce DNA damage in the bacterial umu test (Kosaka and Nakamura 1990, 1991).

Disperse Blue 79:1 was negative in the *in vivo* Drosophila sex-linked recessive lethal test for gene mutations (Foureman 1990). Disperse Blue 79, Disperse Red 17, and Disperse Black 9 were all negative in a mouse micronucleus assay (Honarvar 1982; Clariant 1996; P&G 2005). Neither Disperse Black 9, nor Disperse Red 17 induced UDS in hepatocytes of rats (P&G 2005; Harlan 2010). Also, Disperse Orange 30 failed to induce chromosomal aberrations in mouse bone marrow cells (Baraänski et al. 1992).

Carcinogenicity

Aside from Disperse Yellow 3, limited data were available for the 74 substances in this assessment, and no epidemiological data related to the carcinogenic potential in humans was available. To better understand and characterize the carcinogenic potential of these substances, an expanded literature search was conducted to include information on other azo disperse dyes for the purposes of read-across. Cancer data were identified for Disperse Yellow 3 (Solvent Yellow 77) as well as read-across substance known uses as azo disperse dye Disperse Yellow 97 (Sudan I/Solvent Yellow 14). The hazard data for both of these substances are already characterized in the assessment of Azo Solvent Dyes (Environment Canada and Health Canada 2015) and are only briefly described here.

Disperse Yellow 3 (Solvent Yellow 77) and Disperse Yellow 97 (Sudan I/Solvent Yellow 14) have both been shown to induce hepatic neoplasia in rats. The range of lowest critical adverse effect benchmark dose levels ($BMDL_{10}$s) is: 5.54 to 51.29 mg/kg-bw per day, for Disperse Yellow 97 (Sudan I/Solvent Yellow 14) and Disperse Yellow 3 (Solvent Yellow 77) respectively.

While Disperse Yellow 97 (Sudan I/Solvent Yellow 14) was classified by IARC in 1975 as Group 3, not classifiable as to its carcinogenicity in humans, a NTP (1982a) bioassay clearly demonstrated carcinogenic potential. In the NTP study, groups of 50 male and female F344/N rats were administered 0, 250 or 500 ppm dye , under the name Solvent

Yellow 14, daily, in feed *ad libitum* for 103 weeks. (Male low and high doses were: 14 and 28 mg/kg-bw per day; female low and high doses were: 16 and 33 mg/kg-bw per day). Treated rats exhibited reduced body weights as compared to control animals; however, no differences in survival were reported. While several tumours types developed in both control and treated animals, neoplastic nodules of the liver were significantly increased ($P < 0.001$) in the high dose 30/50 (60%, $P < 0.001$), but not low dose 10/50 (20%, non-sig.) males, as compared to controls 5/50 (10%). Similarly, hepatic neoplastic nodules were increased in high dose 10/48 (21%, $P=0.011$), but not low dose 3/49 (6%, non-sig.) females, as compared to controls 2/50 (4%) (NTP 1982a). The critical effect level is a lower 95th percentile confidence limit of a benchmark dose ($BMDL_{10}$) identifying a 10% hepatic tumourigenesis incidence: 5.54 mg/kg-bw per day; this value was derived from this dataset. Additional information pertaining to the derivation of this $BMBL_{10}$ is summarized separately in the Government of Canada assessment of Azo Solvent Dyes (Environment Canada and Health Canada 2015).

Disperse Yellow 3 (Solvent Yellow 77) was evaluated as part of a NTP (1982b) cancer bioassay, in which the dye was administered to male and female rats in feed *ad libitum*, at either 0, 5000 ppm (males – 297, females – 348 mg/kg-bw per day) and 10000 ppm (males – 672, females – 820 mg/kg-bw per day) for 103 weeks. Neoplastic hepatic nodules or hepatic carcinomas were significantly elevated in low dose 15/50 (30%; $P < 0.001$) and high dose males 11/50 (22%; $P = 0.004$), as compared to controls 2/49 (4%). However, this effect was not observed in females (NTP 1982b). The critical effect level is a lower 95th percentile confidence limit of a benchmark dose ($BMDL_{10}$) identifying a 10% hepatic tumourigenesis incidence: 51.29 mg/kg-bw per day. This value was derived from this dataset. Additional information pertaining to the derivation of this $BMBL_{10}$ is summarized separately in the Government of Canada assessment on Certain Azo Solvent Dyes (Environment Canada and Health Canada 2015).

NTP authors also reported significant reductions in lymphocytic and other leukemias, C-cell (calcitonin secreting cell) thyroid carcinomas, and multiple organ malignant mesotheliomas were observed in rats treated with Disperse Yellow 3 (Solvent Yellow 77). This dye also produced a significant dose-dependent decrease in the incidence of endometrial stromal polyps in female rats. Furthermore, time to tumour appearance (latency) was increased in all treated animals (NTP 1982a,b). These observations are not unique to the studies discussed in this assessment. Similar decreases in spontaneous lymphocytic leukemia incidence rates in treated animals have also been reported in other chronic NTP studies. In fact, it has been suggested that reported anticarcinogenic effects may be related to body weight reductions in treated animals, co-occurrence of splenic toxicity, or reduced survival in dosed animals. In addition, animal strain and stock have also been suggested as factors influencing tumour latency (Haseman and Johnson 1996).

Carcinogenicity and Genotoxicity of Azo Bond Cleavage Products

Azo bond cleavage, a potential metabolic pathway for azo disperse dyes, results in the subsequent release of aromatic amine metabolites. While the variability in physical and

chemical properties of the 73 disperse dyes may influence azo cleavage potential, a conservative approach which considers all possible aromatic amine cleavage products is taken. All available carcinogenicity and genotoxicity data specific to the postulated azo bond cleavage products, of the 13 Azo Disperse Dyes to which Canadians are expected to be exposed, were considered as part of the health effects assessment of the Azo Disperse Dyes.

Analyses of the metabolites resulting from azo cleavage of the 74 substances in this assessment determined that one of two “EU22” aromatic amines, which are considered potentially carcinogenic, may be released from 6 of these substances (Environment Canada and Health Canada 2013). *O*-anisidine (CAS RN 90-04-0, “EU22” aromatic amine) may be released from CAS RN 93805-00-6 and CAS RN 65122-05-6; and *p*-aminoazobenzene (CAS RN 60-09-3, “EU22” aromatic amine) may be released from Disperse Yellow 23, Disperse Yellow 7, CAS RN 58104-55-5 and Disperse Red 151. For three substances (CAS RN 93805-00-6, Disperse Yellow 23 and Disperse Yellow 7), the health effects of concern were communicated in previous assessments (Environment Canada, Health Canada, 2009). Additional information pertaining to *p*-Aminoazobenzene (Solvent Yellow 1) is summarized separately in the Government of Canada assessment on Azo Solvent Dyes (Environment Canada and Health Canada 2015).

A literature search was conducted to identify empirical data on genotoxicity and carcinogenicity for the postulated aromatic amine metabolites for which CAS RN numbers were available. No other aromatic amine metabolites were assigned a cancer classification by a national or international agency.

Most of the empirical genotoxicity data available for the azo bond cleavage products included *in vitro* endpoints, while *in vivo* data were identified for only a limited number of non-EU22 aromatic amine metabolites. A summary of the available empirical data on carcinogenicity and genotoxicity of the aromatic amine cleavage products is shown in Table 7-2. The hazard data for Disperse Yellow 3 (Solvent Yellow 77) including potential azo cleavage metabolites is characterized in the assessment of Azo Solvent Dyes (Environment Canada, Health Canada 2015) and is therefore not presented here.

Table 7-2: Aromatic amine metabolites of Azo Disperse Dyes to which Canadians are expected to be exposed

Azo Disperse Dye C.I. generic name or CAS RN	Aromatic amine metabolite CAS RN[a]	Available data on carcinogenicity and genotoxicity of aromatic amine metabolite
Disperse Blue 79:1; Disperse Blue 79; 52697-38-8	1817-73-8	IN VITRO: positive for mutagenicity in bacteria and mammalian cells (Kawai et al. 1987; Zeiger et al. 1987; Seifried et al. 2006)

Azo Disperse Dye C.I. generic name or CAS RN	Aromatic amine metabolite CAS RN[a]	Available data on carcinogenicity and genotoxicity of aromatic amine metabolite
Disperse Orange 30; Disperse Brown 1	99-30-9	IN VIVO: negative in multiple cancer assays in experimental animals IN VITRO: negative genotoxicity assays (WHO 1998)
ANAM	3531-19-9	IN VITRO: positive for mutagenicity in bacteria and chromosomal aberration assay (Kawai et al. 1987; JETOC 1997)
Disperse Brown 1:1	99-29-6	No data
Disperse Red 167	121-87-9	IN VITRO: positive for mutagenicity in bacteria and chromosomal aberration assay; negative mutagenicity in mammalian cells, and negative for micronuclei, DNA damage and repair assays (Shimizu and Takemura 1984; Kawai et al. 1987; Yoshimi et al. 1988; Palus 1995; JETOC 1996; Matsushima et al. 1999)
BANAP	100-01-6	IN VIVO: negative cancer bioassays in rats and female mice. Equivocal evidence in male mice; negative in all genotoxicity assays. IN VITRO: mixed results in genotoxicity assays. Considered “probably non-genotoxic” by the US EPA (Nair et al. 1990; NTP 1993; US EPA 2009)
Disperse Orange 61	827-94-1	No data
63833-78-3	17420-30-0	IN VITRO: positive for mutagenicity in bacteria and chromosomal aberration assay (JETOC 1997)

[a]Only metabolites with an available CAS RN are shown. Each dye also has a second aromatic amine.

While several cleavage metabolites had positive genotoxic effects *in vitro,* all available *in vivo* findings were negative. Negative and equivocal carcinogenicity findings were reported for the metabolites CAS RN 99-30-9 and CAS RN 100-01-6 respectively (WHO 1998). The US EPA (2009) considers CAS RN 100-01-6 to be “probably non-genotoxic.” Given the available data, there is no evidence to support either the carcinogenic or *in vivo* genotoxic potential of cleavage metabolites released from the disperse dyes to which general population exposure is anticipated.

7.2.2 Other Health Effects

Aside from Disperse Yellow 3, data describing non-cancer health effects for the substances in this assessment are limited, and no epidemiological data were identified. To characterize the potential non-cancer health effects from Azo Disperse Dyes, an

expanded literature search was conducted to include additional disperse dyes: Disperse Black 9, Disperse Red 17, Disperse Red 338, , Disperse Red 206, and Disperse Yellow 97 (Sudan I/Solvent Yellow 14). Additional information pertaining to non-cancer adverse effects in animals for Disperse Yellow 3 (Solvent Yellow 77) and Disperse Yellow 97 (Sudan I/Disperse Yellow 14) are summarized separately in the Government of Canada assessment on Azo Solvent Dyes (Environment Canada and Health Canada 2015).

Reproduction and Development

While Disperse Blue 79:1 produced no reproductive or developmental toxicity in rats (Tyl et al. 1990; Union Carbide Corp. 1991b) at doses up to 2500 mg/kg-bw per day, Disperse Blue 79:1 was reported to decrease maternal gestational and fetal (secondary to maternal effect) body weights in New Zealand White rabbits (ETAD 1991). Disperse Black 9 produced similar effects in rats (P&G 2005), while Disperse Red 17 treatment was reported to decrease only maternal body weight and feed consumption (Chandler 1997). The most sensitive effect was hemosiderin deposition in the female rat spleen; the (formulation adjusted) NOAEL is 10 (3.1) mg/kg-bw per day (Ehling 2005).

In this OECD 415 compliant study, 28 male and 28 female Sprague Dawley HSD:SD (SPF) rats per dose were administered Disperse Red 17 (31% formulation) at 0, 10, 30 or 200 mg/kg-bw per day via oral gavage, for 10 weeks in males and 2 weeks in females, prior to mating. Males dosed at 30 mg/kg-bw per day and all animals dosed at 200 mg/kg-bw per day exhibited stained fur and urine. Body weight, but not feed consumption decreases were observed in high dose animals. Dams exposed to 200 mg/kg-bw exhibited fewer implantations and live pups/litter, but birth indices were not significantly affected. Hemosiderin deposition was reported in the spleens of females administered 30 and 200 mg/kg-bw per day (Ehling 2005).

Short-term Effects

Structural and/or functional changes in the thyroid, liver, kidney and blood have been reported in rats subjected to short term disperse dye treatment. Disperse Red 338 produced slight hyperplasia and thickening of the thyroid follicular epithelium over 11 days of exposure (Eastman Kodak Co. 1992). Disperse Black 9 caused renal and hepatic dysfunction and injury, evidenced by elevations in blood urea nitrogen, creatinine, electrolyte imbalance, increased ASAT (AST/aspartate aminotransferase), ALAT (ALT/alanine aminotransferase) and gamma-GT (GGT/gamma-glutamyl transferase) in animals dosed over 16 days (P&G, 2004). Disperse Red 206 decreased hematocrit and mean corpuscular hemoglobin following 28 day exposures (MHLW 2012).

Supplementary information on other disperse dye analogues further supports findings in short-term repeat dose effects in hepatic, renal and hematopoietic tissues, including: elevations in serum ASAT and ALAT, renal tubular degeneration and necrosis, hyaline droplet formation, as well as decreased circulating erythrocytes, hemoglobin and hematocrit (personal communication, email from the New Substances Assessment and

Control Bureau [Health Canada] to the Existing Substances Risk Assessment Bureau [Health Canada], dated September 18, 2014; unreferenced)

Long-term Effects

Chronic treatments with Disperse Yellow 3 (Solvent Yellow 77) or Disperse Yellow 97 (Sudan I/Solvent Yellow 14) have been reported to affect the liver and kidneys in mice; hepatic degeneration and hemosiderosis, as well as renal hemosiderosis were observed (NTP 1982a,b). Necrosis of the cortical renal tubular epithelium with subsequent epithelial regeneration was reported in Disperse Yellow 97 treated mice (Sudan I/Solvent Yellow 14) (NTP 1982a).

Some disperse dyes have been shown to impact the spleen; secondary to splenic iron overload resulting from increased erythrocyte turnover. Disperse Yellow 97 (Sudan I/Solvent Yellow 14) and Disperse Yellow 3 (Solvent Yellow 77) were reported to induce splenic hemosiderosis in mice (NTP 1982 a,b). In addition, Disperse Red 17 increased spleen weight in treated rats (Brownlie 1998).

The most sensitive non-cancer chronic effect identified, in an OECD 408 compliant study, was increased spleen weights in male Sprague Dawley rats administered Disperse Red 17 in purified water for 13 weeks; the (formulation adjusted) NOAEL is 10 (4) mg/kg-bw per day. Ten male and ten female Sprague Dawley and Crl:CD(SD)BR rats were administered 0, 10 or 30 mg/kg-bw per day of 41.2% dye. Two deaths in the high dose group were reported on days 14 and 43. Increased spleen weights were observed only in high dose males.

7.3 Characterization of Risk to Human Health

Of the 74 substances in this assessment, 64 of them being considered for human health, while 10 were previously assessed in the Challenge initiative and the health conclusions for these substances are not being updated as no significant new information relevant to human health were identified for these 10 substances. Among the 64 substances being assessed for human health, direct and prolonged exposure potential from textiles is considered to occur for 13 of these substances based on data submitted from recent surveys under section 71 (see 4.1 Sources, Table 4-1: ANAM, ANMOM, BANAP, Disperse Blue 79, Disperse Blue 79, Disperse Orange 30, Disperse Orange 61, Disperse Red 167, Disperse Yellow 3, and CAS RN 52697-38-8) as well as from information provided by industy (2010 email from ETAD to Environment Canada; unreferenced: Disperse Brown 1, Disperse Brown 1:1, CAS RN 63833-78-3). The use of textiles (e.g. in clothing and other products) dyed with these substances could lead to direct and prolonged exposure of the general population. Estimated ranges of dermal exposures to Azo Disperse Dyes due to direct and prolonged skin contact with textile products in personal apparel (adults) and baby sleeper (infants) are: $5.2x10^{-5}$ to $7.0x10^{-4}$, and $8.0x10^{-5}$ to $1.1x10^{-3}$ mg/kg-bw per day respectively. The oral infant exposure from mouthing of textiles was estimated to be 1.35×10^{-3} mg/kg-bw per day. Exposure of the general population of Canada to the remaining substances, considered in this

assessment, is not expected. Note: the exposure and risk characterization for Disperse Yellow 3 (under the name Solvent Yellow 77) is in the assessment of Azo Solvent Dyes and therefore only a brief summary of information on Disperse Yellow 3 is presented here to inform the risk characterization of the other Azo Disperse Dyes in this assessment.

Since most of the 74 substances in this Screening Assessment lack empirical data on health effects, data from additional disperse dyes outside of this grouping were included to inform the hazard characterization to conservatively address the variability in physical and chemical properties across these 74 substances. The most sensitive health effect levels identified from among the 74 Azo Disperse Dyes and additional read-across substances are used to represent the range of potential hazard for the entire grouping. Dermal exposure toxicity studies for the 74 Azo Disperse Dyes were not identified.

The lowest critical adverse effect levels for carcinogenicity were based on a range of $BMDL_{10}$ from 5.54 to 51.29 mg/kg-bw per day for the read-across substance Disperse Yellow 97 (Sudan I/Solvent Yellow 14) and Disperse Yellow 3 (Solvent Yellow 77) respectively. Both critical effect levels are based on chronic studies that identified significantly increased liver tumour incidence in male rats administered these two dyes in feed.

Comparison of the estimated daily dermal exposure range of adults to apparel textiles with the range of critical adverse effect dose levels, results in a MOE range of 7,900 to 986,300. Comparison of the estimated daily dermal exposure range of infant contact, with textiles in baby sleepers with the same critical range, results in a MOE range of 5,000 to 641,100. Comparison of the estimated daily oral exposure of infants with the same critical range results in a margin of exposure MOE range of 4,100 to 38,000. All carcinogenicity MOE ranges are considered adequate to address uncertainties in the exposure and health effects databases (Table 7-3).

Table 7-3: Carcinogenicity MOE ranges for daily exposure to disperse dyes

Exposure route	**Exposure scenario (age group)**	**Estimated daily exposure ranges (mg/kg-bw per day)**	**Critical effect level ranges: $BMDL_{10}$ (mg/kg-bw per day)**	**MOE ranges**
Dermal	Textiles – Personal apparel (adult)	$5.2x10^{-5}$ to $7.0x10^{-4}$	5.54 to 51.29	7,900 to 986,300
Dermal	Textiles – Baby sleeper (infant)	$8.0x10^{-5}$ to $1.1x10^{-3}$	5.54 to 51.29	5,000 to 641,100

Exposure route	Exposure scenario (age group)	Estimated daily exposure ranges (mg/kg-bw per day)	Critical effect level ranges: $BMDL_{10}$ (mg/kg-bw per day)	MOE ranges
Oral	Mouthing of textile objects (infant)	$1.35x10^{-3}$	5.54 to 51.29	4,100 to 38,000

The lowest disperse dye critical effect level protective of non-cancer effects associated with infant daily dermal contact with a baby sleeper, is a chronic NOAEL of 10 (formulation adjusted, 4.0) mg/kg-bw per day. This is based on a chronic oral study that demonstrated increased spleen weights in male rats dosed with Disperse Red 17 at 30 (formulation adjusted, 12.4) mg /kg-bw per day.

The lowest disperse dye critical effect level protective of non-cancer effects associated with adult daily dermal contact with textiles in apparel, is a NOAEL of 3.1 mg /kg-bw per day, based on reproductive toxicity in female rats. In dams, hemosiderin deposition in the spleen was observed following oral administration of Disperse Red 17 at 30 (formulation adjusted, 9.3) mg/kg-bw per day.

Comparison of the estimated daily adult dermal exposure range via contact with textiles in personal apparel, with the Disperse Red 17 critical effect level associated with splenic hemosiderin deposition results in a MOE range of 4400 to 59600. Comparison of the estimated daily infant dermal exposure range via contact with textiles in baby sleeper, with the Disperse Red 17 critical effect level associated with increased spleen weight, results in a MOE range of 3600 to 50000. Comparison of the estimated daily infant oral exposure via mouthing of textile products with the Disperse Red 17 critical effect level associated with increased spleen weight results in a MOE of 3000. These non-cancer MOE (ranges) are considered adequate to address uncertainties in the exposure and health effects databases (Table 7-4).

Table 7-4: Other health effect MOE ranges for daily exposure to disperse dyes

Exposure route	Exposure scenario (age group)	Estimated daily exposure range (mg/kg-bw per day)	Critical effect level: NOAEL (mg/kg-bw per day)	MOE range(s)
Dermal	Textiles – Personal apparel (adult)	$5.2x10^{-5}$ to $7.0x10^{-4}$	3.1	4,400 to 59,600
Dermal	Textiles – Baby	$8.0x10^{-5}$ to	4.0	3,600 to 50,000

Exposure route	Exposure scenario (age group)	Estimated daily exposure range (mg/kg-bw per day)	Critical effect level: NOAEL (mg/kg-bw per day)	MOE range(s)
	sleeper (infant)	$1.1x10^{-3}$		
Oral	Mouthing of textile objects (infant)	$1.35x10^{-3}$	4.0	3,000

In addition, as reported in the Azo Solvent Dyes assessment for CAS RN 2832-40-8, Disperse Yellow 3 (Solvent Yellow 77) MOEs for chronic oral and dermal exposure from textile uses are considered adequate to address uncertainties in the health effects and exposure databases and the risk from incidental oral exposure to ingestion from dyed paper is considered low. See the assessment of Azo Solvent Dyes for additional detail (Environment Canada, Health Canada 2015).

7.3.1 Uncertainties in Human Health Risk Characterization

There is uncertainty with respect to the textile exposure estimates as they are based on generic assumptions for textile dye content that are not specific to any one of the Azo Disperse Dyes assessed. However, confidence is high that the assumptions applied are conservative and therefore do not underestimate exposure.

The *in vivo* oral and dermal bioavailabilities of the disperse dyes considered in this assessment are not known, but are likely quite dissimilar given the variability in physical and chemical properties (e.g. molecular weights). This represents a source of uncertainty for the Azo Disperse Dyes assessment. I*n vivo* and *in vitro* evidence indicates poor to modest dermal bioavailability (less than 1% to 27%) of three azo disperse dyes, and limited oral absorption (6%) of a relatively larger molecular weight dye. However, short term, chronic and carcinogenicity studies demonstrate adverse biological effects following exposure to relatively smaller molecular weight dyes, thereby indirectly supporting oral bioavailability as being toxicologically significant.

Ultimately, because read across, for health effects, was used there is uncertainty surrounding the type and degree of health effects that could result from exposure to each specific disperse dyes, or its metabolites. Nevertheless, confidence is high that the current approach identified the most sensitive health effect levels in the available data, which were used to inform this risk assessment.

7.3.2 Azo Disperse Dyes with Human Health Effects of Potential Concern

Overall, human health risk from the substances in this assessment is low based on the current levels of exposure. However as indicated in this assessment, some of the Azo Disperse Dyes are suspected of having effects of concern based on potential carcinogenicity (Appendix F).

8. Conclusion

Considering all available lines of evidence presented in this Screening Assessment, there is low risk of harm to organisms and the broader integrity of the environment from the 73 of the 74 Azo Disperse Dyes in this assessment. It is concluded that these Azo Disperse Dyes do not meet the criteria under paragraphs 64*(a)* or 64*(b)* of CEPA 1999, as they are not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

An additional azo disperse dye, CAS RN 2832-40-8 (Disperse Yellow 3), was assessed for ecological concerns for its use in textile dye formulation and textile dyeing as part of the Azo Disperse Dye assessment. Considering all available lines of evidence presented in this Screening Assessment and in the Screening Assessment for Azo Solvent Dyes (in which this substance was referred to as Solvent Yellow 77), it is concluded that CAS RN 2832-40-8 meets the criteria under paragraph 64*(a)* of CEPA 1999 as it is entering or may enter the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity. However, this substance does not meet the criteria under paragraph 64(*b*) of CEPA 1999 as it is not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to the environment on which life depends.

Based on the information presented in this Screening Assessment, and based on information for Disperse Yellow 3 (Solvent Yellow 77) presented in the Azo Solvent Dyes Screening Assessment, it is concluded that 64 of the 74 substances in this assessment do not meet the criteria under paragraph 64*(c)* of CEPA 1999, as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health. In addition, there are no updates to the conclusions made with respect to paragraph 64*(c)* for 10 substances previously considered by the Government of Canada under the Challenge Initiative of the CMP.

It is concluded that 73 of the 74 Azo Disperse Dyes identified above do not meet any the criteria set out in section 64 of CEPA 1999.

It is concluded that CAS RN 2832-40-8 (Disperse Yellow 3) meets one or more of the criteria set out in section 64 in CEPA 1999. The information supporting the human health assessment for this substance under the name Solvent Yellow 77 appears in the Screening Assessment of Azo Solvent Dyes.

It has been determined that CAS RN 2832-40-8 (Disperse Yellow 3) meets the persistence criteria but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* of CEPA 1999.

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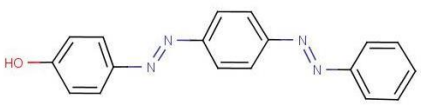
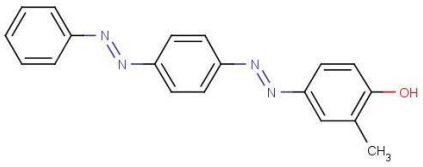
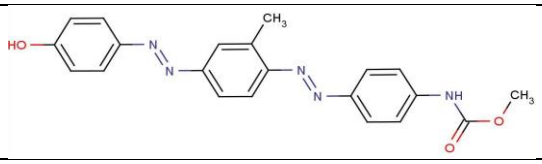
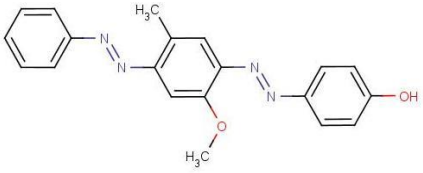
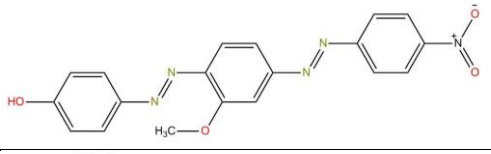
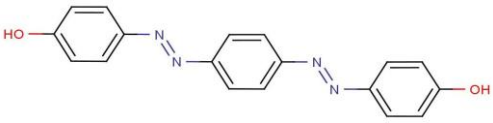
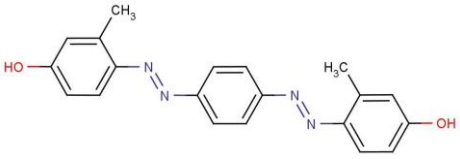
Appendices

Appendix A. Summary of Physical and Chemical Properties—Part 1: Water Solubility and Octanol–Water Partition Coefficient

Seventy-three Azo Disperse Dyes and their structural analogues were sorted into seven structurally related groups, as indicated in Section 2 Identity of Substances. Water solubility (WS) and octanol–water partition coefficient (log K_{OW}) identified are presented in Tables A1 to A7. If empirical data is not available for a substance, read-across is applied using the available information of a substance or an analogue in the same structurally related group or as specified in the table.

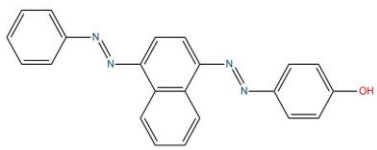
Table A1. Eight Azo Disperse Dyes in Structurally Related Group 1 that have two azo bonds and three aromatic rings with no naphthalene or halogenated ring in the chemical structures

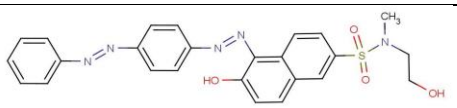
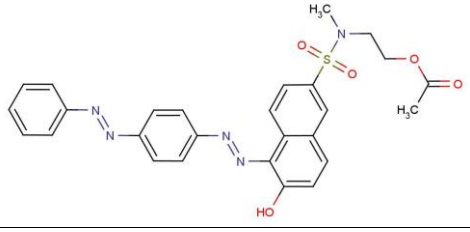
C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Yellow 23		NA	NA

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Yellow 7		NA	NA
6465-02-7		NA	NA
6657-00-7		NA	NA
Disperse Orange 29		0.0037–0.027 (Baughman et al. 1996 and Balakrishnan 2013)	4.58 (Brown 1992 and Study Submission 2008a)
Disperse Yellow 68		NA	NA
27184-69-6		NA	NA
93805-00-6		NA	NA

Abbreviation: NA, not available.

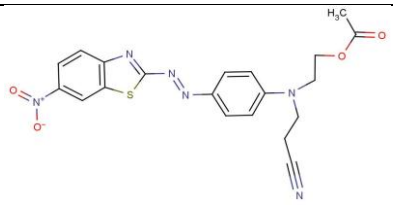
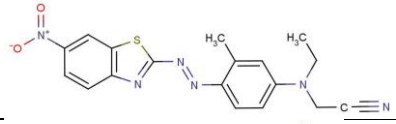
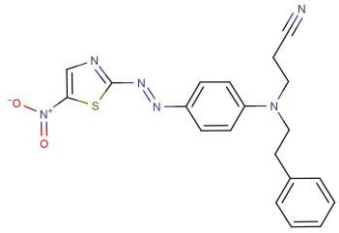
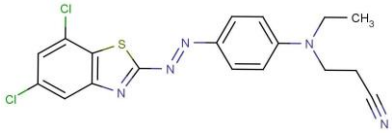
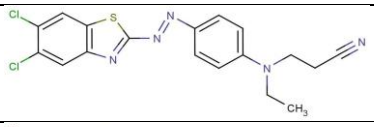
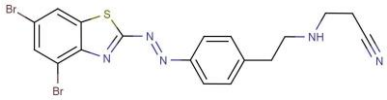
Table A2. Water solubility and octanol–water partition coefficients of Azo Disperse Dyes in Structurally Related Group 2, which includes three dyes that have two azo bonds and four aromatic rings, including one naphthalene ring in the chemical structures

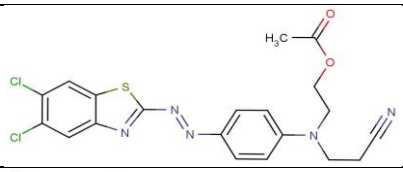
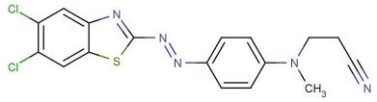
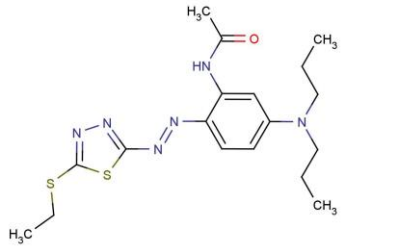
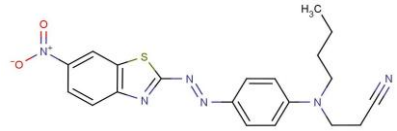
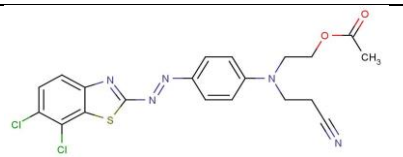
C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Orange 13		0.00022 – 0.345 (Kuroiwa and Ogasawara 1973, and Balakrishnan 2013)	4.58 (read-across of Disperse Orange 29)

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
58104-55-5		NA	NA
Disperse Red 151		NA	NA

Abbreviation: NA, not available.

Table A3. Water solubility and octanol–water partition coefficients of Azo Disperse Dyes in Structurally Related Group 3, which includes 10 dyes and one analogue that have one azo bond, one aromatic ring and one heteroaromatic ring

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Red 177*		0.0079 - 0.79 (Yen et al. 1989, Sijm et al. 1999, and Baughman and Weber 1991)	4.08 – 4.6 (Sijm et al. 1999 and Yen et al. 1989)
Disperse Red 179		NA	NA
19745-44-9		NA	NA
25150-28-1		NA	NA
DAPEP		NA	NA
28824-41-1		NA	NA

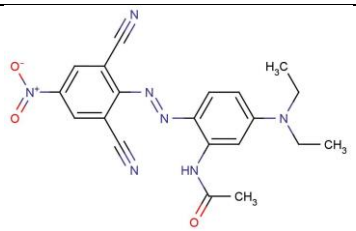
C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
33979-43-0		NA	NA
41362-82-7		NA	NA
Disperse Red 338		NA	NA
67905-67-3		NA	NA
127126-02-7		NA	NA

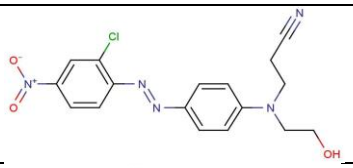
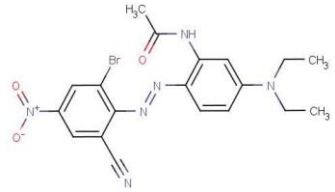
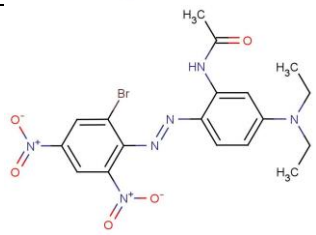
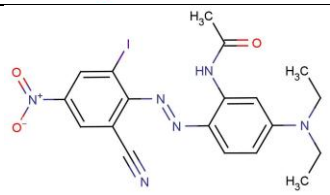
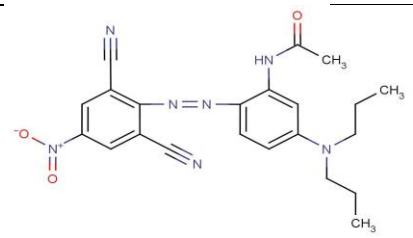
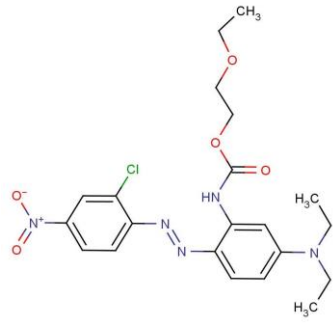
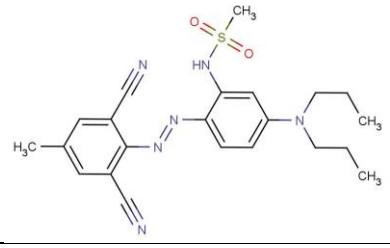
Abbreviation: NA, not available.

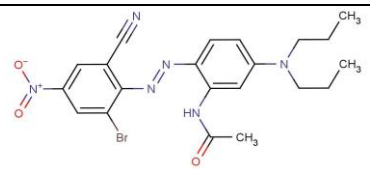
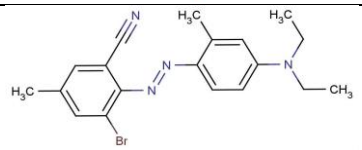
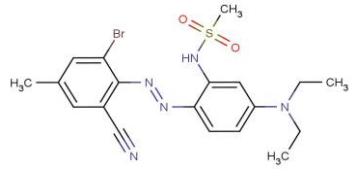
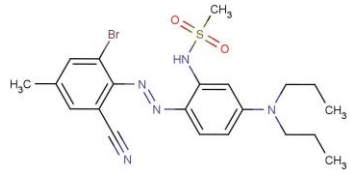
Table A4. Water solubility and octanol–water partition coefficients of Azo Disperse Dyes in Structurally Related Group 4, which includes 40 dyes and their structural analogues that have one azo bond and two aromatic rings with a variety of substituent groups in the chemical structures

To enhance structural similarity between substances to apply read-across, these 40 disperse dyes are further separated into 12 small groups.

(1) 10 monoazo disperse dyes and 2 structural analogues

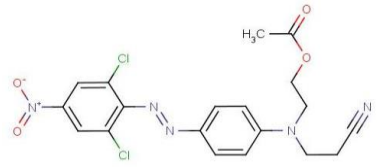
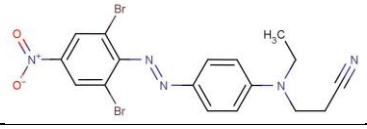
C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Blue 165*		0.058 – 1.3 (Sijm et al. 1999)	NA

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
6657-33-6*		NA	4 (Baughman and Weber 1991)
2537-62-4		NA	NA
52697-38-8		NA	NA
55252-53-4		NA	NA
56532-53-7		NA	NA
68214-66-4		NA	NA
DADM		NA	NA

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
83249-47-2		NA	NA
83249-49-4		NA	NA
83249-53-0		NA	NA
83249-54-1		NA	NA

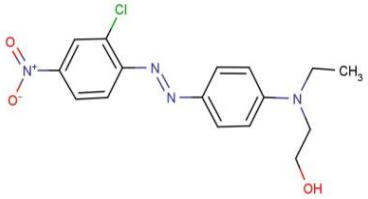
Abbreviation: NA, not available.

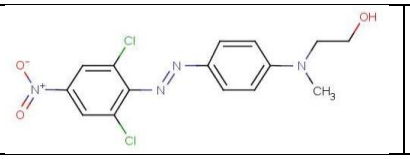
(2) Two monoazo disperse dyes based on a dihalogenated aromatic amine

C.I. generic name	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Orange 30		0.07 (Brown 1992)	4.21 (Brown 1992)
Disperse Orange 61		NA	NA

Abbreviation: NA, not available.

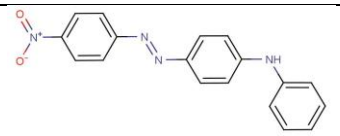
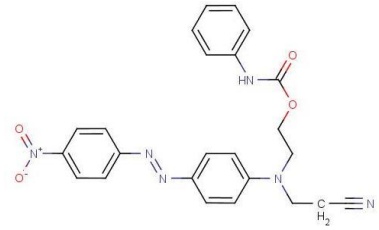
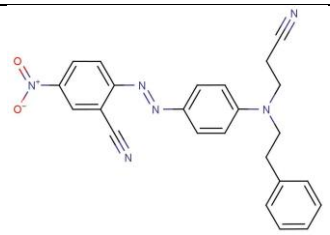
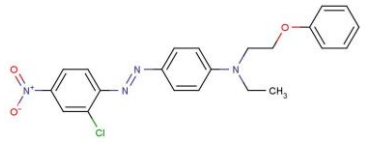
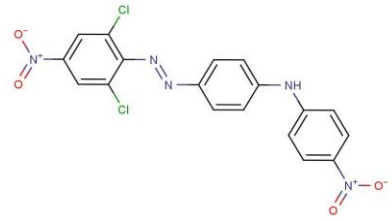
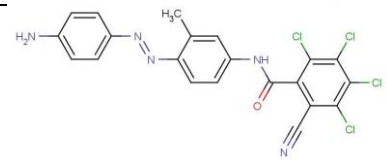
(3) One monoazo disperse dye and one structural analogue

C.I. generic name	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Red 13*		0.012 – 0.1 (OECD 2011, Baughman and Perenich 1988, and Bird 1954)	4.21 (calculated) (Baughman and Perenich 1988)

Disperse Orange 5		NA	4.34 (calculated) (Baughman and Perenich 1988)

Abbreviation: NA, not available.

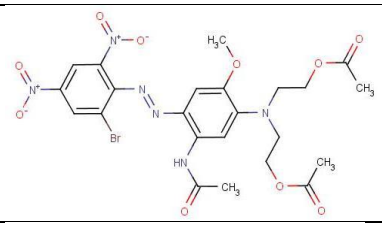
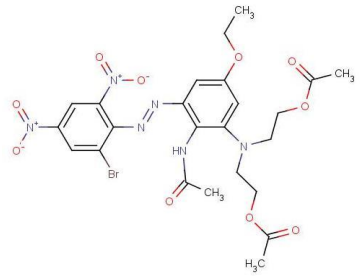
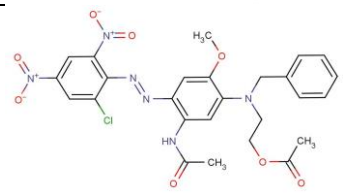
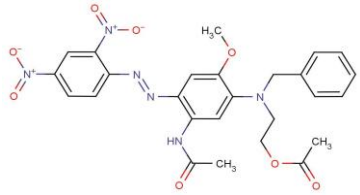
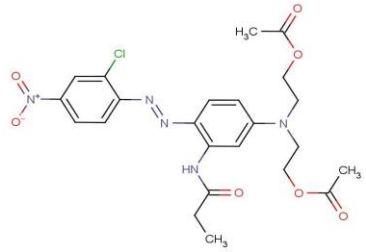
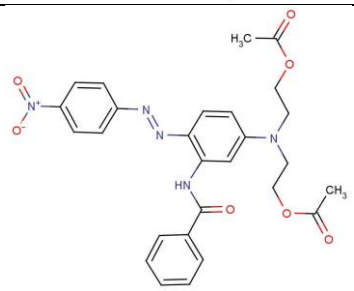
(4) Five monoazo disperse dyes and one structural analogue

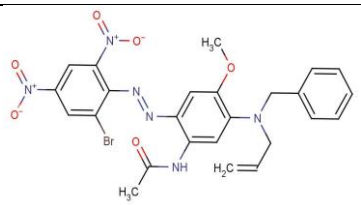
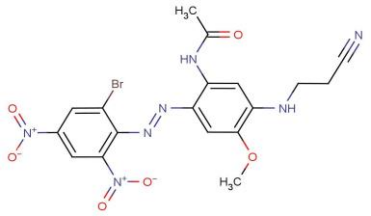
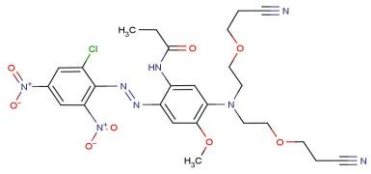
C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Orange 1*		0.00955 (Baughman and Perenich 1988)	5.07 (calculated) (Baughman and Perenich 1988)
15958-27-7		NA	NA
24610-00-2		NA	NA
31030-27-0		NA	NA
72927-94-7		NA	NA
MATCB		NA	NA

Abbreviation: NA, not available.

(5) Nine monoazo disperse dyes

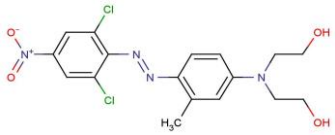
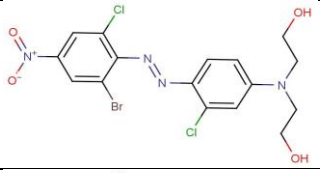
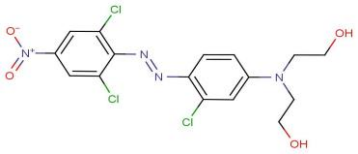
C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Blue 79:1		0.022 (Sijm et al. 1999)	4.44 – 4.8 (Sijm et al. 1999 and Yen et al. 1989)
Disperse Blue 79		0.0003 – 0.0054 (Brown 1992, Baughman and Perenich 1988, Yen et al. 1989, Zhibo et al. 1984, and Clariant 1996)	3.56 – 4.1 (Zhibo et al. 1984, Brown 1992, and Clariant 1996)
ANAM		NA	NA
16421-41-3		NA	NA
Disperse Red 167		NA	NA
BANAP		NA	NA

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
42852-92-6		NA	NA
53950-33-7		NA	NA
Disperse Blue 125		NA	NA

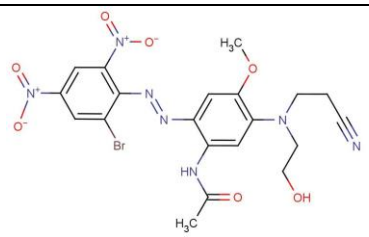
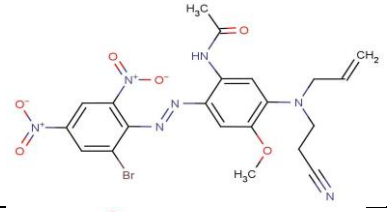
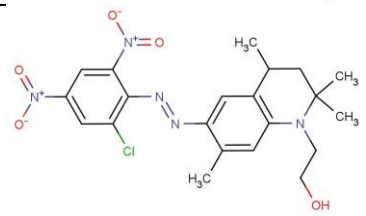
Abbreviation: NA, not available.

(6) Two dihalogenated monoazo disperse dyes with bis-hydroxyethyl side chains and one structural analogue

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
58528-60-2*		0.454 (Bird 1954)	4.12 – 4.98 (calculated) (Baughman and Perenich 1988 and ChemIDplus 1993–)
Disperse Brown 1:1		NA	NA
Disperse Brown 1		NA	NA

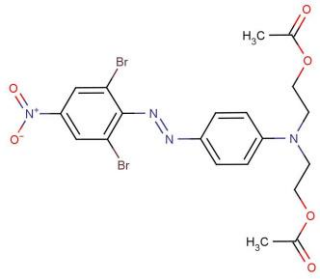
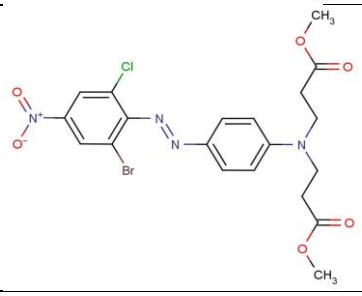
Abbreviation: NA, not available.

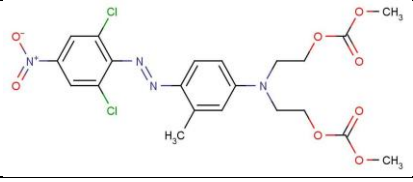
(7) Three monoazo disperse dyes

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Blue 94		NA	NA
68877-63-4		0.000 688 (Yen et al. 1989)	5.4 (Yen et al. 1989)
63133-84-6		NA	NA

Abbreviation: NA, not available.

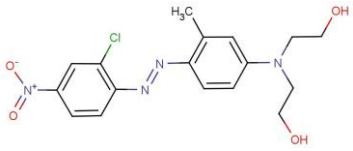
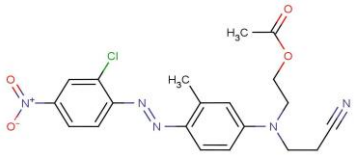
(8) Three monoazo disperse dyes derived from dihalogenated aromatic amines and couplers having bis-acetoxyethyl side chains

CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
55619-18-6		NA	NA
ANMOM		0.055 (calculated) (calculated value from the experimental log K_{ow})	4.1 (Anliker and Moser 1987)

CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
73003-64-2		NA	NA

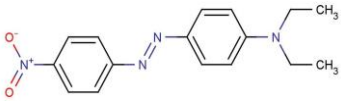
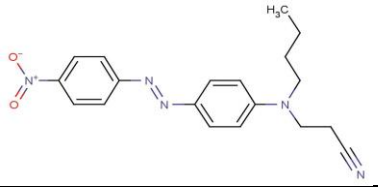
Abbreviation: NA, not available.

(9) One monoazo disperse dye and one structural analogue

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
Disperse Red 5*		0.097 – 0.2 (Shibusawa et al. 1977 (cited in Baughman and Perenich 1988), Baughman and Weber 1991, Bird 1954 (cited in Baughman and Perenich 1988), and Bird 1954)	4.3 (Baughman and Weber 1991, and Hou et al. 1991)
68516-64-3		NA	NA

Abbreviation: NA, not available.

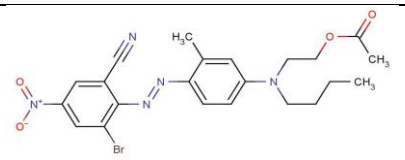
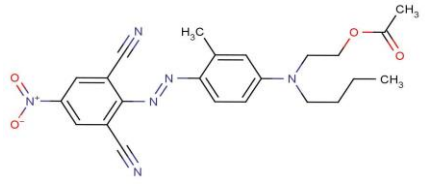
(10) One monoazo disperse dye derived from *p*-nitroaniline and one structural analogue

CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
3025-52-3*		0.000 011 9 (Biedermann and Datyner 1981)	4.34 – 4.69 (calculated) (Biedermann and Datyner 1981, and Baughman and Perenich 1988)
69472-19-1		NA	NA

Abbreviation: NA, not available.

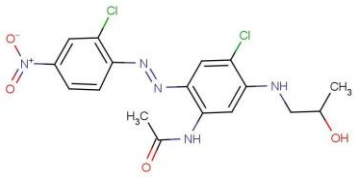
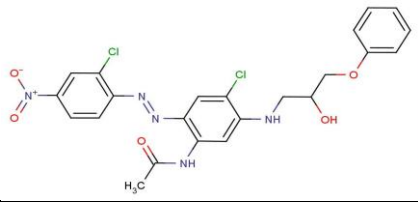
(11) Two monoazo disperse dyes

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	Log K_{ow}

72828-63-8		NA	NA
Disperse Blue 287		0.000 59 (Yen et al. 1989)	5.5 (Yen et al. 1989)

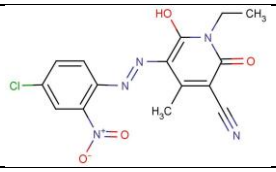
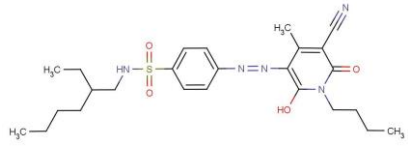
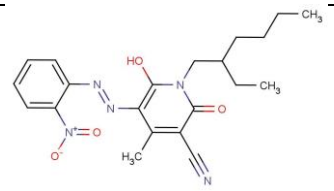
Abbreviation: NA, not available.

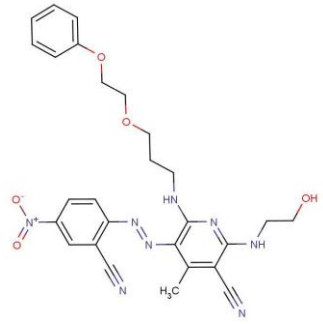
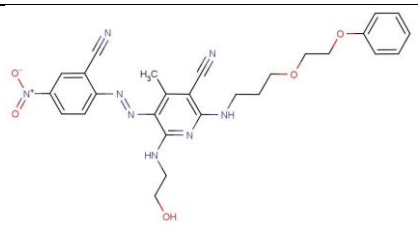
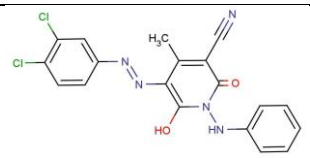
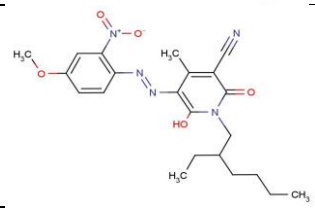
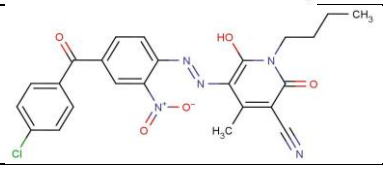
(12) One monoazo disperse dye and one structural analogue

C.I. generic name or CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
71617-28-2*		0.298 (calculated) (calculated based on the experimental log K_{ow})	4.0 (Anliker and Moser 1987)
Disperse Red 349		NA	NA

Abbreviation: NA, not available.

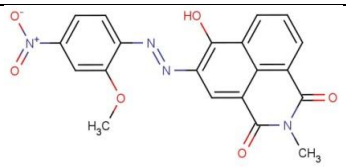
Table A5: Water solubility and octanol–water partition coefficients of Azo Disperse Dyes in Structurally Related Group 5, which includes seven dyes that have one azo bond and one 3-pyridinecarbonitrile in the chemical structures, and one structural analogue

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Yellow 211*		0.0739 (Baughman and Weber 1991, and Baughman et al. 1996)	3.4 (Anliker and Moser 1987)
55290-62-5		0.0019 (calculated based on the experimental log K_{ow})	5.7 (Environment Canada 2014)
51249-07-1		NA	NA

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
61799-13-1		NA	NA
63833-78-3		NA	NA
68214-63-1		NA	NA
68992-01-8		NA	NA
90729-40-1		NA	NA

Abbreviation: NA, not available.

Table A6: Water solubility and octanol–water partition coefficients of Azo Disperse Dyes in Structurally Related Group 6, which includes two dyes that have one azo bond, one aromatic ring and one 1H-benz[de]isoquinoline-1,3(2H)-dione in the chemical structures

CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
42357-98-2		0.345 (read-across of Disperse Orange 13)	4.58 (read-across of Disperse Orange 29)

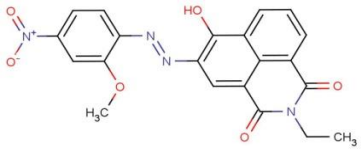
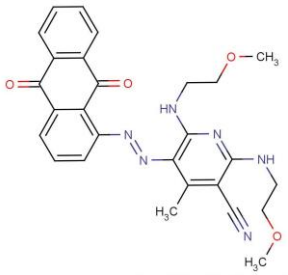
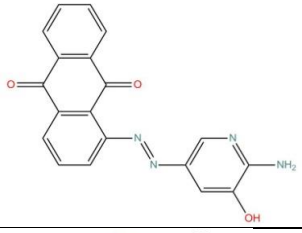
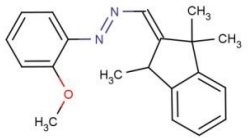
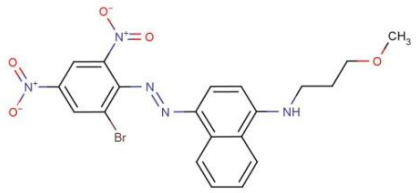
CAS RN	Chemical structures	WS (mg/L)	log K_{ow}
42358-36-1		0.345 (read-across of Disperse Orange 13)	4.58 (read-across of Disperse Orange 29)

Table A7: Water solubility and octanol–water partition coefficients of three Azo Disperse Dyes that have unique chemical structures and the available structural analogue

C.I. generic name or CAS RN	Chemical structure	WS (mg/L)	log K_{ow}
Disperse Brown 21		NA	4.5 (read-across of CAS RN 51249-07-1)
Unknown analogue for Disperse Brown 21		0.000 001 (at 21°C) (Baughman et al. 1996)	4.5 (read-across of CAS RN 51249-07-1)
65122-05-6		NA	4.5 (read-across of CAS RN 51249-07-1)
70660-55-8		NA	4.5 (read-across of CAS RN 51249-07-1)

Abbreviation: NA, not available.

Appendix B. Physical and Chemical Properties of 73 Disperse Dyes and Their Structural Analogues—Part 2: Additional Information on Other Parameters

Empirical data on melting point, vapour pressure, density and *n*-octanol solubility are listed in Table B1 and used to characterize such properties for Azo Disperse Dyes.

Table B1: Empirical data on melting point, vapour pressure, density and *n*-octanol solubility for Azo Disperse Dyes and their structural analogues

C.I. generic name, Abbreviation, or CAS RN	Melting point (°C)	Vapour pressure (Pa)	Density (g/cm^3)	*n*-Octanol solubility (mg/L)
Disperse Red 1*	NA	1.33×10^{-11} (originally reported as 1×10^{-13} mmHg in Baughman and Perenich 1988) 5.32×10^{-12} (originally reported as 4×10^{-14} mmHg in OECD 2011)	1.34 (calculated) (Kojima and Iijima 1975)	NA
3025-52-3*	152 (Baughman and Perenich 1988)	1.06×10^{-8} (originally reported as 8×10^{-11} mmHg in Baughman and Perenich 1988)	NA	NA
Disperse Red 13*	133 (Baughman and Perenich 1988)	NA	1.37 (calculated) (Kojima and Iijima 1975)	NA
Disperse Blue 79:1	≥ 138 (Sandoz Chemicals 1989) 149–151 (CHRIP	NA	NA	14.1 (Sijm et al. 1999)

C.I. generic name, Abbreviation, or CAS RN	Melting point (°C)	Vapour pressure (Pa)	Density (g/cm^3)	*n*-Octanol solubility (mg/L)
	©2008) 132 (OECD 2012)			
Disperse Orange 30	NA	NA	576 (ETAD 2005)	NA
Disperse Orange 5	NA	NA	1.48 (calculated) (Kojima and Iijima 1975)	NA
6657-00-7	NA	NA	1.19 (Guidechem 2012)	NA
6657-33-6*	NA	1.07×10^{-13} mmHg (estimated) (ChemIDplus 1993–)	NA	2100 (20°C) (Anliker and Moser 1987)
Disperse Blue 79	NA	3.40×10^{-9} (IUCLID 2001) 4.53×10^{-7} (Clariant 1996)	NA	NA
Disperse Orange 29	NA	NA	NA	5086 (ETAD 2005)
DAPEP	NA	NA	1.39 (Guidechem 2012)	
Disperse Red 167	NA	NA	NA	450 (water content 47.5% w/w) (ETAD 2005)

C.I. generic name, Abbreviation, or CAS RN	**Melting point (°C)**	**Vapour pressure (Pa)**	**Density (g/cm^3)**	***n*-Octanol solubility (mg/L)**
30449-81-1*	NA	NA	NA	800 (at 20°C) (experimental) (Anliker and Moser 1987)
40690-89-9*	NA	NA	NA	130 (water content 0.3% w/w) (ETAD 2005)
51249-07-1	NA	NA	NA	2430 (experimental) (at 20°C) (Anliker and Moser 1987)
52697-38-8	NA	NA	1.55 (ChemNet 2012; LookChem 2012)	NA
58528-60-2*	NA	8.05×10^{-15} mmHg (estimated) (ChemIDplus 1993–)	NA	NA
ANMOM	NA	NA	NA	1670 (20°C) (experimental) (Anliker and Moser 1987)
65125-87-3*	NA	NA	1.49 (Guidechem 2012)	NA
Disperse Red 177*	NA	1.55×10^{-13} mmHg (estimated)	NA	66 ± 6 (Sijm et al.

C.I. generic name, Abbreviation, or CAS RN	Melting point (°C)	Vapour pressure (Pa)	Density (g/cm^3)	*n*-Octanol solubility (mg/L)
		(PhysProp 2006)		1999)
Disperse Yellow 163*	NA	NA	NA	90 (water content 0.9% w/w) (ETAD 2005)
68877-63-4	NA	NA	1.52 (Guidechem 2012)	81 (20°C) (Anliker and Moser 1987)
Disperse Yellow 211 *	NA	NA	1.49 (ChemBlink 2012)	100 (at 20°C) (experimental) (Anliker and Moser 1987)
71617-28-2*	NA	NA	NA	950 (at 20°C) (experimental) (Anliker and Moser 1987)
Disperse Blue 287	NA	NA	NA	410 (at 20°C) (Anliker and Moser 1987)

Appendix C. Experimental Ecotoxicity Data on Aquatic Species for Azo Disperse Dyes and their Analogues

Table C1: Summary of experimental ecotoxicity data on aquatic species for Azo Disperse Dyes and their analogues

C.I. generic name	Molecular weight (g/mol)	D_{eff} (nm)	Organisms	Toxicity endpoint and value (mg/L) (reference)
Disperse Yellow 23	302	0.77	Rainbow trout (*Oncorhynchus mykiss*)	48 h LC_{50} > 1000 (Environment Canada 2008b)
Disperse Red 179	394	1.01	Guppy (*Poecilia reticulata*)	96 h LC_{50} = 10–100 96 h NOEC = 10 48 h LC_{100} = 100 (BMG 2003b)
Disperse Orange 29	377	0.99	Zebra fish (*Brachydanio rerio*)	96 h LC_{50} = 480 (Brown 1992)
DAPEP	404	0.93	Guppy (*Poecilia reticulata*)	96 h NOEC ≥ 100 (BMG 2000b)
DADM	439	1.17	Zebra fish (*Brachydanio rerio*)	96 h LC_0 > 1000 (Study Submission 2008b)
DADM	439	1.17	Rainbow trout (*Oncorhyncus mykiss*)	96 h LC_0 > 1000 (Study Submission 2008b)
Disperse Orange 30	450	1.04	Rainbow trout (*Oncorhynchus mykiss*)	48 h LC_{50} > 700 (Sandoz 1975)
Disperse Orange 30	450	1.04	Zebra fish (*Brachydanio rerio*)	96 h LC_{50} = 710 (Brown 1992)
Disperse Orange 30	450	1.04	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC_{50} > 100 (SafePharm 1990a)
52697-38-8	479	1.08	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC_{50} > 100 (SafePharm 1990a)
MATCB	493	1.03	Carp (*Cyprinus carpio*)	96 h LC_{50} > 100 (Kremer 2003)
Disperse Blue 79	639	1.29	Zebra fish (*Brachydanio rerio*)	96 h LC_{50} = 340 (Brown 1992)
Disperse Blue 79	639	1.29	Rainbow trout (*Oncorhynchus mykiss*)	96 h LC_{50} > 100 (SafePharm 1990a)
Disperse Blue 79	639	1.29	Golden orfe (*Leuciscus idus*)	96 h LC_{50} = 100–200 (BASF 1990)

Disperse Orange 29	377	0.99	Crustacean (*Daphnia magna*)	48 h EC_{50} = 70 (Brown 1992)
Disperse Orange 30	450	1.04	Crustacean (*Daphnia magna*)	48 h EC_{50} = 5.8 (Brown 1992)
Disperse Blue 79:1	625	1.23	Crustacean (*Daphnia magna*)	24 h EC_{100} > 50 24 h EC_{50} = 16 24 h NOEC = 1.6 (acute immobilization) (Brown 1992)
Disperse Blue 79:1	625	1.23	Crustacean (*Daphnia magna*)	24 h EC_{50} = 10–100 (immobilization) (Study Submission 2012c)
Disperse Blue 79	639	1.29	Crustacean (*Daphnia magna*)	48 h EC_{50} = 4.5 (Brown 1992)
Disperse Orange 29	377	0.99	Bacteria (activated sludge)	30 min EC_{50} > 100 (Brown 1992)
DAPEP	404	0.93	Activated sludge microorganisms	3 h EC_{20}, EC_{50}, EC_{80} > 4000 (BMG 2000a)
Disperse Red 179	394	1.01	Activated sludge microorganisms	3 h EC_{20}, EC_{50}, EC_{80} > 1000 (BMG 2003b)
DADM	439	1.17	Bacteria (species not specified)	3 h EC_{50} > 10 000 (Study Submission 2008b)
Disperse Orange 30	450	1.04	Bacteria (species not specified)	IC_{50} > 100 (Brown 1992)
52697-38-8	479	1.08	E342 Bacteria toxicity (respiration inhibition)	3 h IC_{50} > 10 (Study Submission 2005a)
MATCB	493	1.03	Bacteria (species not specified)	96 h IC_{50} > 100 (Kremer 2003)
Disperse Blue 79:1	625	1.23	Wastewater bacteria	IC_{50} > 100 (Study Submission 2012c)
Disperse Blue 79	639	1.29	Bacteria (species not specified)	IC_{50} > 100 (Brown 1992)
Disperse Orange 1*[a]	318	0.87	*Daphnia similis*	48 h NOEC = 0.1 (immobilization) 48 h LC_{25} = 10 (Ferraz et al. 2011a)
Disperse Red 1*	314	0.86	*Daphnia similis*	48 h EC_{50} = 0.127 48 h NOEC = 0.01 (immobility) (Ferraz et al. 2011b)
Disperse Red 1*	314	0.86	*Daphnia similis*	48 h EC_{50} = 0.13 (immobilization) (Vacchi et al. 2013)
Disperse Red 1*	314	0.86	*Hydra attenuata*	48 h EC_{50} = 1.9 (immobilization)

				(Vacchi et al. 2013)
Disperse Red 17*	344		*Daphnia magna*	48 h EC_{50} = 98 (Brown 1992)
Disperse Red 13*	349	0.89	*Daphnia similis*	48 h EC_{50} = 0.019 48 h NOEC = 0.001 (immobility) (Ferraz et al. 2011b)
Disperse Red 73*	348	0.95	*Daphnia magna*	48 h LC_{50} = 110 (Brown 1992)
70198-17-3*	403		Daphnids	96 h LC_{50} = 0.12 (Health, Safety, and Human Factors Laboratory 1978)
Disperse Yellow 7	316	0.86	Fathead minnow (*Pimephales promelas*)	14-day LC_{50} = 0.025 (Parrott et al. 2013)
Disperse Blue 79:1	625	1.23	Rainbow trout (*Oncorhynchus mykiss*)	122-day NOEC ≥ 0.0048 (ABC 1991)
Disperse Yellow 7	316	0.86	Crustacean (*Hyalella azteca*)	14-day LC_{50} = 0.16 28-day LC_{50} = 0.12 28-day EC_{50} > 0.2 (Bartlett 2013)
Disperse Orange 13	352	1.02	Crustacean (*Hyalella azteca*)	14-day LC_{50} = 1.41 28-day LC_{50} = 0.61 28-day EC_{50} = 1.17 (Bartlett 2013)
Disperse Orange 29	377	0.99	Alga (*Scenedesmus subspicatus*)	72 h EC_{50} = 6 (biomass) 72 h EC_{50} = 86 (growth) (Brown 1992)
Disperse Orange 30	450	1.04	Alga (*Scenedesmus subspicatus*)	72 h EC_{50} = 3.4 (biomass) 72 h EC_{50} = 6.7 (growth) (Brown 1992)
Disperse Blue 79:1	625	1.23	Alga (*Scenedesmus subspicatus*)	72 h EC_{50} = 15 (biomass) 72 h EC_{50} = 9.5 (growth rate) (Brown 1992)
Disperse Blue 79	639	1.29	Alga (*Scenedesmus subspicatus*)	72 h EC_{50} = 7 (growth) (Brown 1992)
Disperse Blue 79	639	1.29	Alga (*Scenedesmus subspicatus*)	72 h EC_{50} = 15 (biomass) 72 h EC_{50} = 9.5 (growth) (Brown 1992)

Appendix D. Critical Body Burden (CBB) Approach for Azo Disperse Dyes

In terms of aquatic toxicity, the critical body burden (CBB) concept shows that an aquatic organism that takes up a chemical from water may accumulate this chemical until a certain critical body burden has been attained, which then causes the mortality of the organism. McCarty (1986, 1987a, b, 1990), McCarty and Mackay (1993), McCarty et al. (1985, 1991) and Van Hoogen and Opperhuizen (1988) have indeed shown that internal concentrations of halogenated organic chemicals in fish causing death are fairly constant: about 2–8 mmol/kg.

Sijm and Hermens (2000) indicated that McCarty (1987a, b) and McCarty et al. (1991) have mathematically explained this as follows. The fairly constant internal effect concentration or lethal body burden (LBB, which is the critical body burden associated with a lethal effect) is the result of the bioconcentration factor (BCF), which increases with octanol–water partition coefficient (K_{ow}), and the external effect concentration (median lethal concentration, or LC_{50}), which decreases with K_{ow}:

$$LBB = LC_{50} \times BCF$$

Therefore:

$$\log LBB \approx \log (LC_{50}) + \log (BCF) \approx (-\log K_{ow} + b_1) + (\log K_{ow} + b_2)$$

$$\approx b_1 + b_2 \approx \text{constant}$$

where b_1 and b_2 are constants.

Having analyzed the literature data, Sijm and Hermens (2000) emphasized that for narcotic (e.g., polychlorinated benzenes and biphenyls) and polar-narcotic compounds (e.g., chlorinated phenols and anilines), sufficient information is available to study this assumption. The authors came to the conclusion that for different organisms, the lethal body burdens for polar narcotics vary by approximately two orders of magnitude, and thus again show a significant reduction in the variation of the ecotoxicological effect concentrations, compared with the more than five orders of magnitude differences that are found in external effect concentrations for this type of mechanism of action.

While applying a CBB approach for Azo Disperse Dyes, the following assumptions have been made: 1) these substances are not reactive or specifically acting reactive chemicals, i.e., they provoke toxicity only through non-specific mechanisms (i.e., narcotic mode of action); 2) there are no dye–dispersant (or dye–solvent) interactions; 3) the purity of these substances is very high; 4) for lethal effects, once the aquatic organism has reached the lethal body burden (LBB), it dies; and 5) the average acute LBB threshold for a lethal effect is 5 mmol/kg.

Lethal Body Burden (LBB) and External Effect Concentration (EEC) Calculations

As indicated above, LBB = LC_{50} × BCF. Therefore, the expected external acute effect concentration (LC_{50}) can be back-calculated as:

$$LC_{50}\ (mmol/L) = \frac{LBB\ (mmol/kg)}{BCF\ (L/kg)} \frac{CBB\ (mmol/kg)}{BCF\ (L/kg)}$$

Using Disperse Orange 30 as an example, the experimental whole-body BCF is 8.43 L/kg (Shen and Hu 2008), calculated by averaging the measured values at three sampling times.

At the same time, the BCF in fish is usually normalized for the 5% lipid content of the organism:

$$BCF_L = \frac{BCF_{wb\ ww}}{L_f} \times 5\%$$

where BCF_L is the lipid-normalized bioconcentration factor, $BCF_{wb\ ww}$ is the whole-body BCF (wet weight basis), L_f is the lipid content (fraction) in the organism and 5% is the generally accepted lipid level for lipid-normalized BCF.

The lipid content (L_f) in fish in the bioaccumulation study on Disperse Orange 30 is 0.83% (Shen and Hu 2008). Therefore, the lipid-normalized BCF is:

$$BCF_L = \frac{8.43\ (L/kg)}{0.0083} \times 0.05 \approx 50.78\ L/kg$$

Therefore, considering the average acute CBB threshold of 5 mmol/kg, the external effect concentration can be calculated as:

$$\text{Acute } LC_{50} = \frac{LBB\ (mmol/kg)}{BCF\ (L/kg)} = \frac{5\ (mmol/kg)}{50.78\ (L/kg)} = 0.098\ mmol/L$$

Using the molecular weight of Disperse Orange 30 (~450 g/mol or 450 mg/mmol), the external acute effect concentration for this substance, expressed in mg/L, is:

0.098 mmol/L × 450 mg/mmol = 44 mg/L

Applying the same approach, external acute effect concentrations have been calculated for a few other Azo Disperse Dyes in this subgroup and analogues, based on the available information. The results are presented in Table 13.

Appendix E. Ecological Exposure Calculations for Azo Disperse Dyes

The ecological exposure to Azo Disperse Dyes was estimated based on their use patterns. Azo Disperse Dyes were used in two types of industrial operations, textile chemicals formulation and textile dyeing. The aquatic exposure was estimated based on estimated quantities released from industrial facilities to receiving waters via wastewater treatment systems. The exposure in sediment was then derived from the aquatic exposure results using an equilibrium approach. Finally, the exposure in soil was calculated based on the land application of wastewater biosolids. These exposure estimates are summarized statistically in Table 6-4.

Predicted Environmental Concentrations (PECs) in Water for Textile Chemicals Formulation

The aquatic PECs for textile chemicals formulation were estimated based on the daily quantities of Azo Disperse Dyes used. Other parameters considered included emission factor to wastewater, wastewater treatment removal, wastewater flow and receiving water dilution. It was found that the formulation took place at fewer than 4 facilities and involved only one Azo Disperse Dye (Disperse Yellow 3). As a result, the aquatic exposure was estimated based on this specific dye under the conditions of these specific facilities. The approach used in the calculations was to determine the concentration of Disperse Yellow 3 in receiving water near the wastewater treatment system's effluent discharge point based on the wastewater flow and receiving water dilution.

The daily quantity of Disperse Yellow 3 used for the formulation of textile chemicals was determined by companies involved (2013 communications between companies and Environment Canada; unreferenced). Although it varied, the maximum was up to 440 kg/day. This maximum was used to derive the aquatic PEC:

Daily use quantity of Disperse Yellow 3 = 440 kg/d

The emission factor to wastewater for the formulation of textile chemicals was provided by the company involved (2013 telephone communications between company and Environment Canada; unreferenced). It varied between 0.7% and 1.1%. The higher-end value (1.1%) was used.

Emission factor to wastewater = 1.1%

The daily release quantity of Disperse Yellow 3 to wastewater was estimated by multiplying the daily use quantity by the emission factor to wastewater.

Daily release quantity of Disperse Yellow 3 to wastewater

= Daily use quantity of Disperse Yellow 3 × Emission factor to wastewater

= 440 kg/day × 1.1%

= 4.84 kg/day

For the given formulation facilities, the on-site wastewater treatment consisted of pH adjustment, solids settling and aeration (2013 telephone communications between companies and Environment Canada; unreferenced). This treatment was equivalent to a secondary wastewater treatment system at best.

The removal efficiency of a secondary wastewater treatment system was estimated by the model ASTreat (2006). The estimate was based on the physical and chemical properties of Disperse Yellow 3. This dye was non-volatile and was assumed not to biodegrade through wastewater treatment, due to a lack of biodegradation data. The removal efficiency estimated was 26.2% as a result of sludge sorption only.

On-site wastewater treatment removal = 26.2%

The daily release quantity of Disperse Yellow 3 to the sewer system was then estimated from the daily release quantity to wastewater and the on-site wastewater treatment removal.

Daily release quantity of Disperse Yellow 3 to sewer system

= Daily release quantity of Disperse Yellow 3 to wastewater × (1 – On-site wastewater treatment removal)

= 4.84 kg/day × (1 − 0.262)

= 3.57 kg/day

The off-site wastewater treatment system receiving the treated wastewater from the formulation facility was a secondary system and had a flow of 24 375 000 L/day. The concentration of Disperse Yellow 3 in the off-site wastewater treatment influent was then estimated:

Concentration of Disperse Yellow 3 in off-site wastewater treatment influent

= Daily release quantity of Disperse Yellow 3 to sewer system / Flow of off-site wastewater treatment system

= 3.57 kg/day / 24 375 000 L/day = 1.46×10^{-7} kg/L = 146 µg/L

The removal of the off-site wastewater treatment system was estimated by ASTreat (2006) and the result was the same as the removal (26.2%) of the on-site wastewater treatment of the formulation facilities.

The concentration of Disperse Yellow 3 in the off-site wastewater treatment effluent was estimated from the concentration in the influent and the removal of the off-site wastewater treatment system.

Concentration of Disperse Yellow 3 in off-site wastewater treatment effluent

= Concentration of Disperse Yellow 3 in off-site wastewater treatment influent × (1 − Off-site wastewater treatment removal)

= 146 µg/L × (1 − 0.262) = 108 µg/L

The aquatic PEC was estimated by dividing the effluent concentration by the dilution factor of the receiving water. Since the aquatic PEC is determined near the discharge point, the receiving water dilution selected should be applicable to this requirement. The full dilution potential of a river is considered appropriate if it is between 1 and 10. Otherwise, the 10-fold dilution is used for both large rivers and still waters. The receiving water for the off-site wastewater treatment system is a large river. Thus, the 10-fold dilution was used in the calculation of the aquatic PEC.

Aquatic PEC

= Concentration of Disperse Yellow 3 in off-site wastewater treatment effluent / Receiving water dilution factor

= 108 µg/L / 10 = 10.8 µg/L = 0.011 mg/L

Predicted Environmental Concentrations (PECs) in Water for Textile Dyeing

The aquatic for textile dyeing was estimated near the discharge points of wastewater treatment effluents. The PECs were derived from estimated releases from individual textile dyeing facilities, wastewater treatment removal for AzoDisperse Dyes, wastewater treatment flows and receiving water dilution capacities.

Thirty-nine textile dyeing facilities were identified as using Azo Disperse Dyes from recent CEPA 1999 section 71 surveys (Canada 2006, 2008a, 2008b, 2008c, 2009a, 2009b, and 2011). These facilities were the major customers of the importers of this class of dyes. They therefore represented the major sources of environmental releases and exposure for the textile dyeing sector. One textile dyeing facility confirmed with Environment Canada that it no longer used any of Azo Disperse Dyes in its operations after initial purchases (2013 email from textile mill to Environment Canada; unreferenced). Therefore, 38 textile dyeing facilities were selected to evaluate the exposure from the textile dyeing scenario. These 38 facilities were located in three provinces (Ontario, Quebec and Nova Scotia).

The daily use quantity of Azo Disperse Dyes at each facility was unknown except for one facility in Ontario and was therefore estimated from literature data. According to US

EPA (1994), a typical dyelot consisted of 454 kg of textile and was completed within 6 hours from batch dyeing or 8 hours from continuous dyeing. When a facility operated three shifts daily or 24 hours/day, the maximum number of dyelots completed per day would be four, and the quantity of textile dyed would be 1816 kg/day (454 kg/dyelot × 4 dyelots/day), as determined for batch dyeing. For a typical dye use rate of 0.02 kg of dyes per kilogram of textile (Cai et al. 1999), the daily use quantity of Azo Disperse Dyes used at one facility was estimated:

Daily use quantity of disperse dyes used at one facility

= Daily quantity of textile dyed × Dye use rate

= 1816 kg × 0.02 kg/kg = 36 kg/day

The daily use quantity of Azo Disperse Dyes for one facility in Ontario was provided by the facility to be less than 15 kg (2013 email from textile dyeing facility to Environment Canada; unreferenced). The daily use quantity of 15 kg was used in the derivation of the aquatic PEC associated with this facility.

The daily release quantity of Azo Disperse Dyes to the sewer system was estimated based on their emission factors to wastewater. The emission factors for disperse dyes were in the range of 1–12% (OECD 2004). The highest value in this range, 12%, was used to calculate a conservative daily release quantity of Azo Disperse Dyes to the sewer system:

Daily release quantity of disperse dyes to sewer system from one facility

= Daily use quantity of disperse dyes at one facility × Emission factor to wastewater

= 36 kg/day × 12% = 4.32 kg/day

Many textile dyeing facilities were known to have on-site wastewater treatment, but the type of treatment was unknown for each of the facilities evaluated. As a conservative approximation, it was assumed that Azo Disperse Dyes were released to the sewer system without being removed by on-site wastewater treatment. This assumption resulted in a conservative estimate for the daily release quantity to the sewer system, which was equal to the daily release quantity to wastewater.

The concentration of Azo Disperse Dyes in wastewater influent was calculated by dividing the daily release quantity by the wastewater flow (L/day) of an off-site wastewater treatment system. For example, the flow of one off-site wastewater treatment system in Quebec was 53 829 647 L/day. The concentration of Azo Disperse Dyes in the influent was then calculated accordingly:

Concentration of disperse dyes in wastewater influent

= Daily release quantity of disperse dyes to sewer from one facility / Flow of the off-site wastewater treatment system

= 4.32 kg/day / 53 829 647 L/day = 80.3 × 10^{-9} kg/L = 80.3 µg/L

Two computer models were used to estimate removal efficiencies of the off-site wastewater treatment systems for Azo Disperse Dyes. One model was ASTreat (2006) for primary or secondary wastewater treatment systems. The other model was STP-EX (2008) for lagoons. In the estimation, it was assumed that Azo Disperse Dyes did not biodegrade through wastewater treatment. Considering this assumption and the non-volatile nature of Azo Disperse Dyes, the removal derived from the models was driven by sludge sorption only. The principal model input parameter influencing the sludge sorption was the octanol–water partition coefficient (K_{ow}) or the solids–water partition coefficient. For Azo Disperse Dyes (14 in total) found in Canadian commerce, the logarithm of K_{ow} varied from 3.6 to 5.1. Hence, the removal estimated was in the range of 21.7–47.1 % by ASTreat for primary treatment systems, 26.2–61.1 % also by ASTreat for secondary treatment systems and 8.3–67.3 % by STP-EX for lagoons. The lower value in each range was used to derive conservative aquatic PECs.

Primary wastewater treatment removal for disperse dyes = 21.7 %

Secondary wastewater treatment removal for disperse dyes = 26.2 %

Lagoon treatment removal for disperse dyes = 8.3 %

The off-site wastewater treatment system in Quebec, which was used as an example, was a secondary system. Thus, the concentration of Azo Disperse Dyes in wastewater effluent was estimated by applying the secondary wastewater treatment removal (26.2 %):

Concentration of disperse dyes in wastewater effluent

= Concentration of disperse dyes in wastewater influent × (1 − Wastewater treatment removal)

= 80.3 µg/L × (1 − 0.26) = 59.3 µg/L

The aquatic PEC was estimated by dividing the effluent concentration by an appropriate dilution factor for the receiving water. Since the aquatic PEC was assessed near the discharge point, the receiving water dilution selected should be applicable to this requirement. The full dilution potential of a river is considered appropriate if it is between 1 and 10. Otherwise, the dilution is kept at 10 for both large rivers and still waters. The receiving water for the off-site wastewater treatment system in Quebec used as an example is a large river (St-François River). Thus, a 10-fold dilution factor was used in the calculation for the aquatic PEC:

Aquatic PEC

= Concentration of disperse dyes in wastewater effluent / Dilution factor of receiving water

= 59.3 µg/L / 10 = 5.9 µg/L

The aquatic PECs for all other facilities were estimated according to the above method.

Predicted Environmental Concentrations (PECs) in Sediment

An equilibrium sediment–water partition approach described by the European Chemicals Agency (ECHA 2010) was used to estimate the concentration of Azo Disperse Dyes in sediment. This approach assumes that the concentration in bottom sediment is in equilibrium with the concentration in the overlying water. At equilibrium, the PEC in bottom sediment can linearly correlate with the concentration in the aqueous phase of the overlying water as follows.

Sediment PEC = $K_{sw}C_w$

where:

K_{sw}: sediment–water partition coefficient (L/kg)

C_w: chemical concentration in aqueous phase (mg/L)

The sediment–water partition coefficient (K_{sw}, L/kg) can be estimated from the organic carbon (OC) fraction of sediment (F_{oc}, kg OC/kg), the sorptive capacity of sediment's OC (A_{oc}, L/kg OC) and a substance's octanol–water partition coefficient (K_{ow}, unitless) (Gobas 2010):

$K_{sw} = F_{oc}A_{oc}K_{ow}$

The sediment PEC can then be calculated from the equation:

Sediment PEC = $F_{oc}A_{oc}K_{ow}C_w$

The concentration in the aqueous phase (C_w, mg/L) can be estimated from the aquatic PEC (mg/L). There are three distinctive phases in the water column: aqueous, particulate suspended sediment and dissolved suspended sediment (Gobas 2007). Accordingly, the total concentration in the water column or the aquatic PEC (mg/L) can be expressed as a sum of the concentrations in the aqueous phase (C_w, mg/L), particulate suspended sediment (C_{ps}, mg/L) and dissolved suspended sediment (C_{ds}, mg/L):

Aquatic PEC = $C_w + C_{ps} + C_{ds}$

When the OC phase in particulate or dissolved suspended sediment is the phase of sorption for a substance, the above equation can be converted to an expression for estimating the ratio of the aquatic PEC (mg/L) to the concentration in the aqueous phase (C_w, mg/L) (Gobas 2007):

$$\text{Aquatic PEC}/C_w = 1 + (X_{ps}F_{poc}A_{poc} + X_{ds}F_{doc}A_{doc})K_{ow}$$

where:

X_{ps}: content of particulate suspended sediment in water column (kg/L)

F_{poc}: OC fraction of particulate suspended sediment (kg OC/kg)

A_{poc}: sorptive capacity of particulate OC relative to octanol (L/kg OC)

X_{ds}: content of dissolved suspended sediment in water column (kg/L)

F_{doc}: OC fraction of dissolved suspended sediment (kg OC/kg)

A_{doc}: sorptive capacity of dissolved OC relative to octanol (L/kg OC)

K_{ow}: octanol–water partition coefficient (unitless)

In Canada, the middle level for the content of particulate suspended sediment in the water column (X_{ps}) was 47 mg/L. This value was used in the derivation of the sediment PECs at the sites evaluated.

$X_{ps} = 47 \text{ mg/L} = 4.7 \times 10^{-5} \text{ kg/L}$

According to Gobas (2010), the OC fraction of particulate suspended sediment varied from 0.1 to 0.2 kg OC/kg sediment. The lower end of this range was used in order to be conservative for the sediment PECs derived.

$F_{poc} = 0.1 \text{ kg OC/kg}$

Karickhoff (1981) proposed a value of 0.41 L/kg OC for the sorptive capacity of sediment's OC based on a set of 17 sediment and soil samples and various hydrophobic non-polar organic compounds. This value was used for the sorptive capacity of particulate OC (A_{poc}).

$A_{poc} = 0.41 \text{ L/kg OC}$

In Canada, the dissolved OC content in the water column averaged 2.7 mg OC/L This value was used in the derivation of the sediment PECs at the sites evaluated. Note that this OC content equals the product of the content of dissolved suspended sediment X_{ds} (mg/L) and the OC fraction of dissolved suspended sediment F_{doc} (kg OC/kg).

$X_{ds}F_{doc}$ = 2.7 mg OC/L = 2.7×10^{-6} kg OC/L

Gobas (2007) provided an estimate of 0.08 L/kg OC for the sorptive capacity of dissolved OC. This estimate was used.

A_{doc} = 0.08 L/kg OC

The dependence of the sediment PEC on the octanol–water partition coefficient (K_{ow}) was derived by combining the equation for the sediment PEC with the expression for the ratio of the aquatic PEC to the concentration in the aqueous phase (Aquatic PEC/C_w).

$$\text{Sediment PEC} = \frac{F_{oc}A_{oc}}{\frac{1}{K_{ow}} + X_{ps}F_{poc}A_{poc} + X_{ds}F_{doc}A_{doc}} \text{ Aquatic PEC}$$

This dependence indicates that the sediment PEC approaches zero for water soluble substances with low K_{ow} and approaches a maximum for highly hydrophobic substances with high K_{ow}.

The logarithm of K_{ow} for Azo Disperse Dyes (14 in total) found in Canadian commerce was in the range of 3.6-5.1. The higher end (log K_{ow} = 5.1) of this range was used to derive protective estimates for the sediment PEC.

log K_{ow} = 5.1, or K_{ow} = 125 893

The ratio of the aquatic PEC to the concentration in the aqueous phase (C_w) was calculated:

Aquatic PEC/C_w = 1 + ($X_{ps}F_{poc}A_{poc}$ + $X_{ds}F_{doc}A_{doc}$)K_{ow}

= 1 + [(4.7×10^{-5} kg/L × 0.1 kg OC/kg × 0.41 L/kg OC) + (2.7×10^{-6} kg OC/L × 0.08 L/kg OC) × 125 893]

= 1 + 0.27 = 1.27

As an example, the aquatic PEC associated with one facility in Quebec was estimated as 5.6 µg/L. The concentration in the aqueous phase (C_w) was then calculated from the ratio of the aquatic PEC to C_w:

C_w = Aquatic PEC/1.27 = 5.6 µg/L / 1.27 = 4.41 µg/L

Gobas (2010) suggested a default value of 0.01–0.03 kg OC/kg for the OC fraction of bottom sediment in rivers. The higher end of this range was selected as a standard for the sediment PECs derived.

F_{oc} = 0.03 kg OC/kg

As for particulate suspended sediment, the sorptive capacity of bottom sediment's OC was taken as 0.41 L/kg OC, based on the work from Karickhoff (1981).

A_{oc} = 0.41 L/kg OC

The sediment PEC for the facility in Quebec used as an example was then estimated from the above values:

Sediment PEC = $F_{oc}A_{oc}K_{ow}C_w$

= 0.03 kg OC/kg × 0.41 L/kg OC × 125 893 × 4.41 µg/L

= 1548 L/kg × 4.41 µg/L

= 6867 µg/kg

= 6.9 mg/kg

The sediment PECs for all other facilities were estimated according to the above method.

Predicted Environmental Concentrations (PECs) in Soil

An approach described by the European Chemicals Agency (ECHA 2010) was used to estimate PECs in soil resulting from the land application of wastewater biosolids. This approach employed the quantity of biosolids accumulated within the top 20 cm layer (ploughing depth) of soil over 10 consecutive years as the basis for soil PECs. One underlying assumption of the approach was that substances were subject to no loss due to degradation, volatilization, leaching, or soil runoff upon their entry into soil via biosolids land application. This assumption therefore yielded conservative soil PECs.

When the above conservative approach was applied to Azo Disperse Dyes, their concentrations of the disperse dyes in biosolids was first estimated at each site. The data required for this estimate included the daily quantity of Azo Disperse Dyes released to the sewer system from a facility, the sludge removal efficiency of the related wastewater treatment system, the per capita sludge production rate and the population served by the wastewater treatment system.

The daily quantity of Azo Disperse Dyes released to the sewer system from a facility was estimated previously in the aquatic PEC calculations. This quantity was 3.57 kg/day for the formulation of textile chemicals and 4.32 kg/day for textile dyeing facilities excluding one in Ontario, which had a lower daily release quantity of 1.8 kg/day (15 kg/day × 12%).

Daily release quantity of disperse dyes to sewer system from a textile chemicals formulation facility = 3.57 kg/day

Daily release quantity of disperse dyes to sewer system from a textile dyeing facility = 4.32 kg/day (excluding one which released 1.8 kg/day)

Two computer models were used to estimate sludge removal efficiencies of wastewater treatment systems for Azo Disperse Dyes. One model was ASTreat (2006) for primary or secondary wastewater treatment systems. The other model was STP-EX (2008) for lagoons. The principal model input parameter influencing the sludge removal was the octanol–water partition coefficient (K_{ow}) or the solids–water partition coefficient. For the 14 disperse dyes found in Canadian commerce, the logarithm of K_{ow} varied from 3.6 to 5.1. Hence, the removal estimated was in the range of 21.7–47.1% by ASTreat for primary treatment systems, 26.2–61.1% also by ASTreat for secondary treatment systems and 8.3–67.3% by STP-EX for lagoons. The higher value in each range was used to derive conservative soil PECs.

Primary wastewater treatment sludge removal for disperse dyes = 47.1%

Secondary wastewater treatment sludge removal for disperse dyes = 61.1%

Lagoon treatment sludge removal for disperse dyes = 67.3%

As an example, the wastewater treatment system for one facility in Quebec was a secondary system, so its sludge removal was 61.1 %.

The daily quantity of Azo Disperse Dyes sorbed to sludge was estimated by multiplying the daily release quantity by the sludge removal. For the facility used as an example,

Daily quantity of disperse dyes sorbed to sludge

= Daily release quantity of disperse dyes to sewer system from a facility × Wastewater treatment sludge removal

= 4.32 kg/day (textile dyeing facility) × 61.1 %

= 2.64 kg/day

The per capita sludge production rate depends upon the type of the off-site wastewater treatment. This rate was reported to be 0.080 kg/day per person for primary sludge and 0.115 kg/day per person for secondary sludge (Droste 1997). In other words, the per capita sludge production rate was 0.080 kg/day per person from primary systems and 0.195 kg/day per person from secondary systems (primary sludge rate at 0.080 kg/day per person + secondary sludge rate at 0.115 kg/day per person). The higher rate from secondary systems was mainly attributed to the biomass production during biological treatment. No data were found for lagoons, but large settling pond lagoons were

expected to have similar solids removal to primary clarifiers. The sludge production rate from lagoons was therefore approximated as the rate from primary systems.

Per capita sludge production rate from primary systems = 0.080 kg/day per person

Per capita sludge production rate from secondary systems = 0.195 kg/day per person

Per capita sludge production rate from lagoons = 0.080 kg/day per person

As an approximation, the daily quantity of biosolids produced from an off-site wastewater treatment system was assumed to equal the daily quantity of sludge produced. This daily quantity was calculated by multiplying the sludge production rate by the population served by the off-site wastewater treatment system. For example, the off-site wastewater treatment system for the facility used as an example was a secondary system and served a population of 53 900 persons. The daily quantity of biosolids produced is estimated below:

Daily quantity of biosolids produced from a secondary system

= Per capita sludge production rate from a secondary system × Population served by the system

= 0.195 kg/day per person × 53 900 persons

= 10 511 kg/day

The concentration of Azo Disperse Dyes in biosolids was obtained by dividing the daily quantity of Azo Disperse Dyes sorbed to sludge by the daily quantity of biosolids produced from a wastewater treatment system.

Concentration of disperse dyes in biosolids

= Daily quantity of disperse dyes sorbed to sludge ÷ Daily quantity of biosolids produced

= 2.64 kg/day ÷ 10 511 kg/day

= 0.000 25 kg/kg

= 0.25 g/kg

The annual quantity Azo Disperse Dyes entering soil via biosolids land application is a function of not only the concentration of Azo Disperse Dyes in biosolids, but also the biosolids application rate. In Canada, the use of biosolids is regulated by the provinces

and territories. The rate at which biosolids are land applied can therefore vary between different provinces and territories. Summarized in E1 are biosolids application rates found for four provinces.

Table E1: Land application rates for wastewater biosolids in Canada

Province	Application rate (t/ha)	Application period (years)	Annual application rate (t/ha per year)	Reference
Ontario	8	5	1.6	MOE and OMAFRA 1996
Quebec	22	5	4.4	MENV 2004
British Columbia	17	5	3.4	McDougall and Van Ham 2002
Alberta	25	3	8.3	Alberta Environment 2009

The annual quantity of the disperse dyes entering soil via biosolids land application was calculated by multiplying the concentration of the disperse dyes in biosolids by the annual application rate of the province/territory where the biosolids were generated. The underlying assumption in this calculation was that biosolids were used in nearby areas at their maximum allowed quantity. For locations such as those in Nova Scotia, where application rates were not available, the maximum rate given in Table E1, i.e., 8.3 t/ha per year in Alberta, was used as a conservative estimate. For the facility in Quebec used as an example, the applicable rate was 4.4 t/ha per year, and the annual quantity of Azo Disperse Dyes entering soil from the biosolids produced at this site was calculated:

Annual quantity of disperse dyes entering soil

= Concentration of disperse dyes in biosolids × Applicable biosolids annual application rate

= 0.25 g/kg × 4.4 t/ha per year

= 0.25 g/kg × 0.44 kg/m^2 per year

= 0.11 g/m^2 per year

According to the approach described by the European Chemicals Agency (ECHA 2010), a period of 10 consecutive years was used to determine the quantity of Azo Disperse Dyes accumulated over this period.

Quantity of disperse dyes accumulated in soil over 10 years

= Annual quantity of disperse dyes entering soil × 10 years

= 0.11 g/m^2 per year × 10 years

= 1.1 g/m^2

To derive the concentration of the disperse dyes in soil, the quantity of soil within the top 20 cm or 0.20 m layer as per the European Chemicals Agency (ECHA 2010) was estimated from a dry soil density of 1200 kg/m^3 (Williams 1999):

Quantity of soil = Soil depth × Soil density

= 0.20 m × 1200 kg/m^3

= 240 kg/m^2

The soil PEC associated with a facility was then estimated by dividing the quantity of Azo Disperse Dyes accumulated in soil over 10 years by the quantity of soil. For Site 19:

Soil PEC of disperse dyes

= Quantity of disperse dyes accumulated in soil over 10 years / Quantity of soil

= 1.1 g/m^2 / 240 kg/m^2

= 0.0046 g/kg

= 4.6 mg/kg

The soil PECs for all other facillities were estimated according to the above method.

Appendix F. Azo Disperse Dyes with Effects of concern

Ecological Effects of Concern

Based on the available empirical toxicity data, it is considered that aquatic organisms are sensitive to azo disperse dyes with a molecular weight less than 360 g/mol that may demonstrate effects in aquatic organisms at or below their water solubiltity limits. Among 73 Azo Disperse Dyes in this subgroup, there are 8 substances having molecular weights below 360 g/mol. None of them have been identified in commerce in Canada and hence cause no environmental exposure. However these eight substances, along with other azo disperse dyes on the DSL with a molecular weight less than 360 g/mol are considered to be associated with effects of concern, based on their hazard properties. These substances are likely to cause ecological harm if used in Canada.

Table F-1. 8 Azo Disperse Dyes in this subgroup with effects of concern

CAS RN	C.I. Name	Molecular Weight (g/mol)
6250-23-3	Disperse Yellow 23	302
65122-05-6	NA	306
6300-37-4	Disperse Yellow 7	316
21811-64-3	Disperse Yellow 68	318
27184-69-6	NA	346
6657-00-7	NA	346
69472-19-1	Disperse Orange 33	351
6253-10-7	Disperse Orange 13	352

Abbreviation: NA, not available.

Human Health Effects of Concern

Some of the Azo Disperse Dyes in this assessment are suspected of having human health effects of concern based on potential carcinogenicity. The details for supporting the potential carcinogenicity for these substances are outlined in section 7.2.1 Health Effects Assessment (see specific sub-sections), and generally based on one or more of the following lines of evidence:

- Classifications by national or international agencies for carcinogenicity (may be a group classification).
- Evidence of carcinogenicity in animal studies and/or human epidemiology based on the specific substance.
- Potential to release one or more of the EU22 aromatic amines by azo bond cleavage.
- Read-across to related substances for which one or more of the above lines of evidence apply.

Table F2. Azo Disperse Dyes with effects of concern based on potential carcinogenicity

Substance Names and CAS RN	Classification for carcinogenicity[b]	Evidence of carcinogenicity from animal studies and/or human epidemiology	Release of EU22 aromatic amine by azo bond cleavage[a]	Read-across
58104-55-5[a]	-	-	*p*-Aminoazobenzene	-
65122-05-6[a]	-	-	*o*-Anisidine	-
Disperse Red 151 70210-08-1[a]	-	-	p-Aminoazobenzene	-

[a]There is uncertainty with respect to the extent of azo bond reduction and the identity of any metabolites released *in vivo* (See Section 7.3.1 Uncertainty in Health Effects Assessment).
[b]Classifications used for carcinogenicity are described in Environment Canada, Health Canada 2014.

Appendix G. Conservative Exposure Estimates to Azo Disperse Dyes via use of Textiles and Leather Products

Dermal Exposure from Textiles: Personal Apparel Worn by Adults and Baby Sleeper

A conservative exposure estimate to Azo Disperse Dyes is based on full body coverage from wearing clothing, assuming to account for exposures from multiple pieces of apparel that cover the entire surface area of the body.

Estimated Daily Exposure via Dermal Route from Textile Apparel & Baby Sleeper

$$= \frac{SA \times AW \times SCF \times C \times M \times F \times P \times DA}{BW}$$

Oral Exposure from Mouthing of Textile Objects by Infants

Oral exposure to Azo Disperse Dyes is estimated based on a scenario assuming that the infant is mouthing a textile object (e.g., blanket, textile toy) that may release Azo Disperse Dyes. Conservatism is built in exposure factors described below.

Estimated Daily Exposure via Oral Route from Mouthing Textile Object

$$= \frac{SA \times AW \times C \times M \times F \times P}{BW}$$

Exposure Factors

SA: Total surface area (dermal) = 18 200 cm^2 (adult), 3020 cm^2 (infant) (Health Canada 1995)

Total surface area (oral: textile object mouthed) = 20 cm^2 (Zeilmaker et al. 1999)

AW: Area weight of textile = 20 mg/cm^2 (US EPA 2012a)

The area weight of textiles can vary greatly depending on the type of material. An area weight of 20 mg/cm^2 for cotton textiles is recommended by the US EPA in "Standard Operating Procedures for Residential Pesticide Exposure Assessment" (US EPA 2012a).

SCF: Skin contact factor = 1

Based on a conservative estimate that the 100% of the full body coverage of clothing being in direct contact with the skin (i.e., SCF = 1).

C: Concentration in textile = 0.01 (unitless) (BfR 2007)

Based on the default model developed by the "Textiles" Working Group established at the German Federal Institute for Risk Assessment (BfR 2007), assuming that a standard textile garment of 100 g/m^2 is dyed with 1% active dye ingredient.

M: Migration fraction = 0.0005 (BfR 2007)

The migration of azo dyes from textiles varies considerably depending on the type of fibre, the type of dye used, the dye load, dyeing technology and colour intensity and after treatment. The dermal exposure from textiles is partly dictated by the amount of dye that migrates from textile material onto human skin (ETAD 1983b). The "Textiles" Working Group (BfR 2007) uses a peak initial migration of 0.5% to estimate exposure to dyes from newly bought unwashed garments. The migration rate after 28 hours of simulated wash and wear cycles was observed to be less than one-tenth of the value measured for the first migration. The migration fraction of 0.0005 which is one-tenth of the peak initial migration (0.5%) is used to reflect exposure after the intial washes. It is assumed that the sweat migration rate is similar to the salivary migration rate; this is consistent with observations of leaching behaviours of dyes from textiles reported by Zeilmaker et al. (1999).

F: Exposure frequency = 1×/day

P: Probability that an Azo Disperse Dye is present in textiles = 10%.

In the RIVM risk assessment of azo dyes and aromatic amines from garments and footwear (Zeilmaker et al. 1999), the authors derived a chance of 8% for the appearance of carcinogenic azo dyes and aromatic amines in garments based on four European studies. Presumably, there would be a higher prevalence in the use of non-EU22 amines and their dyes, compared to EU22 amines and related dyes, since the former are not prohibited. Disperse Blue 79:1, Disperse Orange 30, Disperse Blue 79, ANAM, Disperse Brown 1:1, Disperse Brown 1, Disperse Red 167, BANAP, CAS RN 52697-38-8, Disperse Orange 61, CAS RN 63833-78-3 and ANMOM do not derive from EU22 amines; the prevalence of these dyes is not clear because there is relatively limited product testing and monitoring on non-EU22 amines and associated dyes. Based on data available (Danish EPA 1998; Kawakami 2012; Health Canada 2013), the prevalence of certain non-EU22 amines was found to range from 0% to 23.7% (aniline). Since several dyes can derive from a given aromatic amine, the prevalence of an associated dye would be lower. Given the conservatism used in other parameters in this exposure scenario (e.g. full body coverage), the probability that a given dye is present in a textile is assumed to be 10% in this Screening Assessment based on professional judgement. This is considered reasonable since the chances of an individual's outfit containing the same dye every day are low.

DA: Dermal Absorption Uptake Fraction = 0.02 to 0.27

Using BfR's recommended dermal absorption percentage of 2% in areas of high perspiration (BfR 2007) and the relatively higher reported dermal absorption of 26.4% for Disperse Yellow 97 (Collier et al. 1993), a reasonable range of 2 to 27% was used to estimate dermal exposure in this Screening Assessment.

BW: Body weight = 70.9 kg for adult, 7.5 kg for infant (Health Canada 1998)

Estimated Daily Exposures to Azo Disperse Dyes from Textiles via the Dermal Route

Baby Sleeper: 4.0×10^{-2} mg/kg-bw per day

Personal Apparel: 2.6×10^{-2} mg/kg-bw per day

Estimated Daily Exposure to Azo Disperse Dyes via Oral Route for Infants

2.7×10^{-4} mg/kg-bw per day