

Screening Assessment for the Challenge

**9,10-Anthracenedione, 1-hydroxy-4-[[4-
[(methylsulfonyl)oxy]phenyl]amino]-
(Disperse Violet 57)**

**Chemical Abstracts Service Registry Number
1594-08-7**

**Environment Canada
Health Canada**

February 2009

Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment on 9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]- (Disperse Violet 57), Chemical Abstracts Service Registry Number 1594-08-7. This substance was identified as a high priority for screening assessment and included in the Challenge because it was originally found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms and is believed to be in commerce in Canada.

The substance Disperse Violet 57 was not considered to be a high priority for assessment of potential risks to human health, based upon application of the simple exposure and hazard tools developed by Health Canada for categorization of substances on the *Domestic Substances List*. Therefore, this assessment focuses on information relevant to the evaluation of ecological risks.

Disperse Violet 57 is an organic substance that is used in Canada and elsewhere as an intense violet colorant dye in textiles. The substance is not naturally produced in the environment. Between 100 and 1000 kg of Disperse Violet 57 were imported into Canada in 2006, and between 100 and 1000 kg were imported in 2005, for use mainly in the textile industry. The quantity of Disperse Violet 57 imported into Canada, along with the potentially dispersive uses of this substance, indicate that it could be released into the Canadian environment.

Based on reported use patterns and certain assumptions, most of the substance ends up in waste disposal sites while the remaining portion is estimated to be released to water. Disperse Violet 57 is a dense solid particle with a limited water solubility. For these reasons, Disperse Violet 57 will be likely found mostly in sediments, and to a lesser extent, in soil. It is not expected to be significantly present in other media. It is also not expected to be subject to long-range atmospheric transport.

Based on its physical and chemical properties, Disperse Violet 57 does not degrade quickly in the environment and is therefore expected to be persistent in water, soil and sediments. Recent experimental data for a chemically similar substance show that Disperse Violet 57 has a low potential to accumulate in the lipid tissues of aquatic organisms. The substance therefore meets the persistence criteria but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations*. Empirical acute aquatic toxicity values of analogues of Disperse Violet 57 suggest that the substance is not expected to be highly hazardous to aquatic organisms.

No environmental monitoring data relating to the presence of Disperse Violet 57 in the Canadian environment (air, water, soil, sediment) have been identified. For this screening assessment, a conservative exposure scenario was designed in which it is assumed that all industrial operations (users of the dye) discharge Disperse Violet 57 into the aquatic

environment. The predicted environmental concentration in water was below the predicted no-effect concentration calculated for sensitive aquatic organisms.

This substance will be included in the upcoming *Domestic Substances List* inventory update initiative. In addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.

Based on the information available, it is concluded that Disperse Violet 57 does not meet any of the criteria set out in section 64 of CEPA 1999.

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health. Based on the results of a screening assessment, the Ministers can propose to take no further action with respect to the substance, to add the substance to the Priority Substances List (PSL) for further assessment, or to recommend that the substance be added to the List of Toxic Substances in Schedule 1 of the Act and, where applicable, the implementation of virtual elimination.

Based on the information obtained through the categorization process, the Ministers identified a number of substances as high priorities for action. These include substances that

- met all of the ecological categorization criteria, including persistence (P), bioaccumulation potential (B) and inherent toxicity to aquatic organisms (iT), and were believed to be in commerce; and/or
- met the categorization criteria for greatest potential for exposure (GPE) or presented an intermediate potential for exposure (IPE), and had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

The Ministers therefore published a notice of intent in the *Canada Gazette*, Part I, on December 9, 2006 (Canada 2006), that challenged industry and other interested stakeholders to submit, within specified timelines, specific information that may be used to inform risk assessment, and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as high priorities.

The substance 9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]- (Disperse Violet 57) was identified as a high priority for assessment of ecological risk as it was found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada. The Challenge for Disperse Violet 57 was published in the *Canada Gazette* on August 18, 2007 (Canada 2007). A substance profile was released at the same time. The substance profile presented the technical information available prior to December 2005 that formed the basis for categorization of this substance. As a result of the Challenge, submissions of information were received.

Although Disperse Violet 57 was determined to be a high priority for assessment with respect to the environment, it did not meet the criteria for GPE or IPE and high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity. Therefore,

this assessment focuses principally on information relevant to the evaluation of ecological risks.

Under CEPA 1999, screening assessments focus on information critical to determining whether a substance meets the criteria for defining a chemical as toxic as set out in section 64 of the Act, where

“64. [...] a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

- (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
- (b) constitute or may constitute a danger to the environment on which life depends; or
- (c) constitute or may constitute a danger in Canada to human life or health.”

Screening assessments examine scientific information and develop conclusions by incorporating a weight-of-evidence approach and precaution as required under CEPA 1999.

This screening assessment includes consideration of information on chemical properties, hazards, uses and exposure, including the additional information submitted under the Challenge. Data relevant to the screening assessment of this substance were identified in original literature, review and assessment documents, stakeholder research reports and from recent literature searches, up to March 2008. Key studies were critically evaluated; modelling results may have been used to reach conclusions. When available and relevant, information presented in hazard assessments from other jurisdictions was considered. The screening assessment does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies and lines of evidence pertinent to the conclusion.

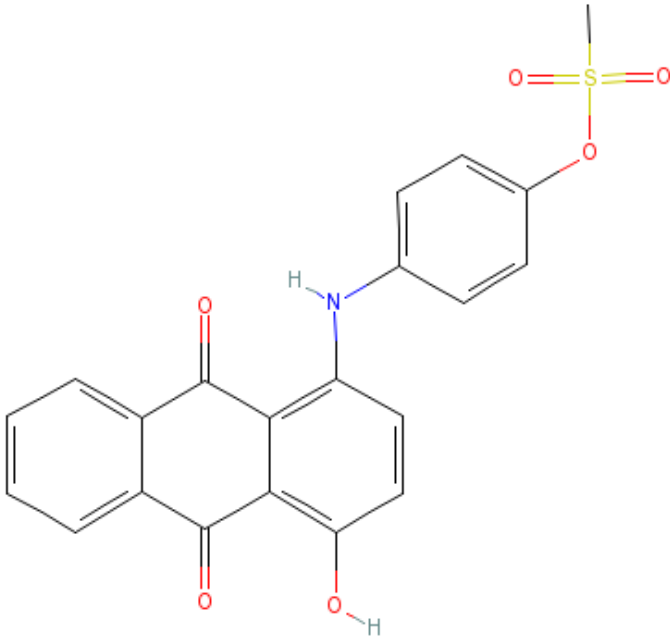
This screening assessment was prepared by staff in the Existing Substances Programs at Health Canada and Environment Canada and incorporates input from other programs within these departments. Additionally, the draft of this screening assessment was subject to a 60-day public comment period. While external 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 assessment is based are summarized below.

Substance Identity

Disperse Violet 57 is defined by the Colour Index (CII 2002) as a combination of multiple Chemical Abstracts Service Registration Numbers (CAS RNs), including CAS RN 1594-08-7. However, for the purposes of this document, the common name “Disperse Violet 57” refers exclusively to CAS RN 1594-08-7.

Table 1. Substance identity of Disperse Violet 57

Chemical Abstracts Service Registry Number (CAS RN)	1594-08-7
DSL name¹	<i>9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]-</i>
National Chemical Inventories (NCI) names²	<i>9,10-Anthracenedione, 1-hydroxy-4-[[4-[(methylsulfonyl)oxy]phenyl]amino]-</i> (TSCA, AICS, PICCS, ASIA-PAC, NZIoC) <i>1-hydroxy-4-[[4-[(methylsulphonyl)oxy]phenyl]amino]anthraquinone</i> (EINECS) <i>C.I. DISPERSE VIOLET 57</i> (PICCS) <i>9,10-ANTHRACENEDIONE, 1-HYDROXY-4-[[4-[(METHYLSULFONYL)OXY]PHENYL]AMINO]-</i> (PICCS)
Other names	<i>C.I. Disperse Violet 57</i> <i>9,10-Anthracenedione, 1-hydroxy-4-((4-((methylsulfonyl)oxy)phenyl)amino)-</i> <i>Anthraquinone, 1-hydroxy-4-(p-hydroxyanilino)-, 4-</i> <i>methanesulfonate (ester)</i> <i>1-Hydroxy-4-((4-((methylsulphonyl)oxy)phenyl)amino)anthraquinone</i>
Chemical group (DSL stream)	Discrete organics
Major chemical subclass	Anthraquinones
Chemical formula	C ₂₁ H ₁₅ NO ₆ S

Chemical structure	 <p>The image shows the chemical structure of Disperse Violet 57. It consists of a central benzene ring with a hydroxyl group (-OH) at the 4-position and a sulfonamide group (-NH-C6H4-SO2CH3) at the 1-position. This central ring is fused to a naphthalene-like system with two carbonyl groups (=O) at the 2 and 6 positions.</p>
SMILES	<chem>O=C(c(c(C(=O)c1c(O)ccc2Nc(ccc(OS(=O)(=O)C)c3)c3)ccc4)cc4)c12</chem>
Molecular mass	409.42 g/mol

¹ DSL (Domestic Substances List).

² **Source:** National Chemical Inventories (NCI) 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances List); EINECS (European Inventory of Existing Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

Physical and Chemical Properties

With the exception of physical state, no other experimental data are available for Disperse Violet 57. At the Environment Canada-sponsored Quantitative Structure-Activity Relationship (QSAR) Workshop in 1999 (Environment Canada 2000), Environment Canada and other invited modelling experts identified many structural classes of pigment and dyes as difficult to model using QSARs. The inherent properties of many of the structural classes of dyes and pigments (including acid and disperse dyes) are not amenable to model prediction because they are considered “out of the model domain of applicability” (e.g., structural and/or property parameter domains). Therefore, to determine the domain of applicability, Environment Canada reviews the applicability of QSAR models to dyes and pigments on a case-by-case basis. It has been considered inappropriate to use QSAR models to predict the physical and chemical properties of Disperse Violet 57 and consequently a “read-across” approach was used to determine the approximate physical and chemical properties in Table 2.

In order to find acceptable analogues, a review of data for several disperse anthraquinone dyes was performed (Anliker et al. 1981; Anliker and Moser 1987; Baughman and Perenich 1988; ETAD 1992, 1995; Brown 1992). These compounds have higher molecular weights, generally > 300 g/mol, have solid crystalline structures, decompose at greater than 220°C, and are “dispersible” in water (i.e., not truly “soluble”). In addition, they have limited solubility in n-octanol, a negligible vapour pressure and are stable under environmental conditions since they are designed to be so. These properties were subsequently used for further modelling in this assessment.

Table 2 below contains analogue as well as read-across experimental and calculated physical and chemical properties of Disperse Violet 57 that are relevant to its environmental fate.

Table 2. Physical and chemical properties for Disperse Violet 57 (neutral molecule)

Property	Type ¹	Value	Temperature (°C)	Reference
Physical State	Experimental	Violet-Black Powder		MSDS 2004
Melting point² (°C)	Read-across	225		Anliker and Moser 1987
		~ 130 to 330		Baughman and Perenich 1988
Boiling point³ (°C)	Not applicable			
Density (kg/m³)	Not available			
Vapour pressure (Pa)	Read-across	2.7×10^{-11} to 1.3×10^{-7} ₄ (2×10^{-13} to 1×10^{-6} mm Hg)	25	Baughman and Perenich 1988
Henry's Law constant (Pa·m³/mol)	Read-across ⁴	10^{-9} to 10^{-1} (10^{-14} to 10^{-6} atm m ³ /mol)		Baughman and Perenich 1988
Log K_{ow} (Octanol-water partition coefficient) (dimensionless)	Analogue Disperse Violet 26	5.1 ⁵		ETAD 1992
	Analogue Disperse Blue 60	4.1		
	Analogue Disperse Blue 73	3.4		
	Read-across	> 4		Anliker et al. 1981; Anliker and Moser 1987

Property	Type ¹	Value	Temperature (°C)	Reference
Log K_{oc} (Organic carbon partition coefficient) (dimensionless)	Read-across, calculated ⁶	3.4 to 4.2		Baughman and Perenich 1988
Water solubility (mg/L)	Read-across	<0.01	20	Anliker and Moser 1987
		Substantially water insoluble		ETAD 1995
	Analogue Disperse Violet 26	Insoluble		ETAD 1992
	Analogue Disperse Blue 60	0.0 ² (2 x 10 ⁻⁵ g/L) ⁷		
	Analogue Disperse Blue 73	0.2 (2 x 10 ⁻⁴ g/L)		
n-octanol solubility (mg/L)	Read-across	120	20	Anliker and Moser 1987
pK_a (Acid dissociation constant) (dimensionless)	Modelled	7.81 for acid form		ACD/pK _a DB 2005

¹ The extrapolated values used for Disperse Violet 57 are based on evidence on disperse dyes submitted to Environment Canada under the *New Substance Notification Regulations* (ETAD 1995) and available evidence from other disperse dye analogues found in literature.

² The phrase “melting point” is used but this may be better referred to as a “decomposition point” because disperse dyes are known to char at high temperatures (greater than 200°C) rather than melt.

³ “Boiling point” is generally not applicable for disperse dyes. For powder dyes, charring or decomposition occurs at high temperatures instead of boiling. For liquids and pastes, boiling will only occur for the solvent component while the unevaporated solid will decompose or char (ETAD 1995).

⁴ Solubilities of several disperse dyes at 25 and 80°C were used by Baughman and Perenich (1988) to calculate Henry’s Law constants for these dyes. These values are presented here as a range to illustrate the expected Henry’s Law constant for Disperse Violet 57.

⁵ Log K_{ow} was obtained using the high performance liquid chromatography (HPLC) method.

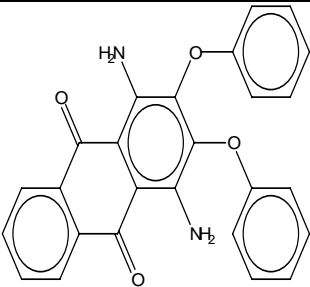
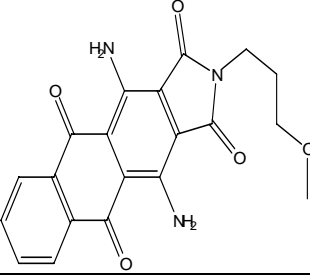
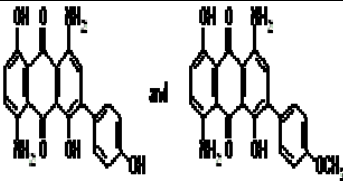
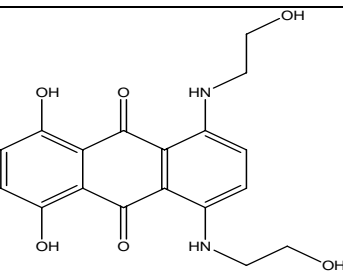
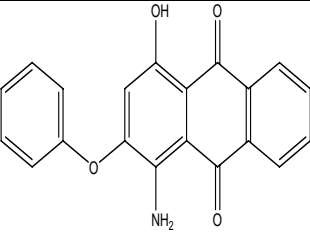
⁶ Log K_{oc} values are based on calculations by Baughman and Perenich (1988) using a range of measured solubilities for commercial dyes and an assumed melting point of 200°C.

⁷ Tested as active ingredient (FAT-36’ 152/C) and not as dispersion.

Structural disperse anthraquinone analogues to Disperse Violet 57 are presented in Table 3 below. Certain physical and chemical properties (see Table 2), empirical bioaccumulation data (Table 6) and empirical toxicity data (see Table 7) of these analogues were used in support of the weight of evidence and decisions in this screening assessment. Specifically, physical and chemical properties were obtained for the following structural analogues: (i) Disperse Violet 26, (ii) Disperse Blue 60 and (iv) Disperse Blue 73. Aquatic bioaccumulation data were available for the analogue (vi)

Disperse Blue 77. Empirical toxicity data were obtained for the following analogues: (i) Disperse Violet 26, (iii) Disperse Blue 73, (iv) Disperse Blue 7 and (v) Disperse Red 60.

Table 3a. Structural analogues for Disperse Violet 57

	CAS RN* or Colour Index number**	Common name	DSL name ¹	Structure of analogue
i.	6408-72-6*	Disperse Violet 26	9,10-Anthracenedione, 1,4-diamino-2,3-diphenoxy-	
ii.	61104**	Disperse Blue 60	1H-Naphth[2,3-f]isoindole-1,3,5,10(2H)-tetrone, 4,11-diamino-2-(3-methoxypropyl)-	
iii.	63265**	Disperse Blue 73	Not available	
iv.	3179-90-6*	Disperse Blue 7	9,10-Anthracenedione, 1,4-dihydroxy-5,8-bis[(2-hydroxyethyl)amino]-	
v.	17418-58-5*	Disperse Red 60	9,10-Anthracenedione, 1-amino-4-hydroxy-2-phenoxy-	

	CAS RN* or Colour Index number**	Common name	DSL name ¹	Structure of analogue
vi.	20241-76-3*	Disperse Blue 77	9,10-Anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-	

¹ Source: National Chemical Inventories (NCI) 2007: Canadian Domestic Substances List (DSL).

It should be noted that there are several uncertainties associated with the use of physical, chemical, toxicological and bioaccumulation data available for the substances presented in Table 3a. All these substances are part of the same chemical class (disperse anthraquinone dyes—with their characteristic three-ring structure with two sets of double-bond oxygen atoms off the middle ring), have similar molecular weights and are used for similar industrial purposes. However, there are differences among these substances associated with their unique functional groups (see Table 3b below). As a result, these analogues have different empirical water solubilities that range from 0.02 to 0.2 mg/L and empirical log K_{ow} values that vary over almost 3 orders of magnitude from 3.4 and 5.1 (see Table 2 above). Due to this variability, which cannot be easily interpreted, caution should be exercised in attributing too much weight to these values, as it would be preferable to utilize empirical water solubility and a log K_{ow} specific to the substance Disperse Violet 57.

Differences between structural analogues for Disperse Violet 57

	CAS RN* or Colour Index number**	Common name	Differences with Disperse Violet 57
i.	6408-72-6*	Disperse Violet 26	Contains an extra phenolic ring attached to an oxygen atom. Contains an extra amine group. Lacks a terminal sulfonyl and an alcohol group.
ii.	61104**	Disperse Blue 60	Contains an extra penta-ring with two double-bond oxygens, a nitrogen atom and a 3-carbon chain with a COH ₃ attached.
iii.	63265**	Disperse Blue 73	Has either 1 or 2 extra alcohol groups, 1 extra amine group and an extra OCH ₃ group. Lacks a terminal sulfonyl group.
iv.	3179-90-6*	Disperse Blue 7	Contains two extra 2-carbon chain side groups that are attached to terminal hydroxyl groups. Has an extra hydroxyl and amine group attached to the three phenol rings. Lacks a phenol and a terminal sulfonyl group.
v.	17418-58-5*	Disperse Red 60	Has an extra oxygen atom, connecting phenol groups. Lacks a sulfonyl group.
vi.	20241-76-3*	Disperse Blue 77	Contains an extra hydroxyl group and nitro group. Lacks a terminal sulfonyl group.

Sources

Disperse Violet 57 is not naturally produced in the environment.

Recent information was collected through an industry survey conducted for the years 2005 and 2006 under *Canada Gazette* notices issued pursuant to section 71 of CEPA 1999 (Canada 2006, 2007). These notices requested data on the Canadian manufacture, import and use of the substance.

One company reported importing a total of between 100 and 1000 kg of the substance in 2006. No companies reported manufacturing Disperse Violet 57 in Canada above the prescribed reporting threshold of 100 kg/year for that year. No companies reported using a total quantity greater than 1000 kg of the substance, whether alone, in a mixture, in a product or in a manufactured item, at any concentration in 2006. In the Declaration of Stakeholder Interest form associated with the section 71 survey for 2006, three companies reported a stakeholder interest in this substance despite not meeting mandatory reporting requirements (Environment Canada 2007a).

In 2005, no companies reported manufacturing Disperse Violet 57 in quantities above the prescribed reporting threshold of 100 kg/year. One company reported importing the substance in the range of 100–1000 kg/year. No companies identified themselves as having a stakeholder interest in the substance.

In the United States, between 4536 kg (10 000 pounds) and 226 796 kg (500 000 pounds) of Disperse Violet 57 were manufactured and/or imported in each of the following years: 1986, 1994, 1998 and 2002 (US EPA 2007). Disperse Violet 57 is an existing chemical in

Europe but is not on the low or high production volume chemicals lists (ESIS 2008). Disperse Violet 57 was in use in Denmark, Sweden and Finland during 1999 to 2005 (SPIN 2007).

Uses

In 2006, the importing company gave the use pattern code for “Colorant – pigment – stain – dye – ink” and the NAICS code for “Synthetic Dye and Pigment Manufacturing.” Further research on the trade names reported for this substance suggests that the substance could be used for dyeing and printing textiles (Huntsman 2008). The following use codes were specified for the substance during the DSL nomination: “Colorant - pigment/stain/dye/ink” and “Textile, Primary Manufacture.”

Review of available scientific and technical information indicated that Disperse Violet 57 is an intense violet dyestuff with good heat resistance in most common polymers (Ciba undated). It is suitable for producing deep shades in polymers with high opacity such as high-impact polystyrene (HIPS) and acrylonitrile butadiene styrene (ABS) (Ciba undated). Disperse Violet 57 is suitable for the spin coloration of polyester fibres and selected engineering plastics (Ciba 2004). In Denmark, Disperse Violet 57 is used in the manufacture of textiles (SPIN 2007).

Releases to the Environment

Mass Flow Tool

To estimate potential release of the substance to the environment at different stages of its life cycle, a Mass Flow Tool was used (Environment Canada 2008a). Empirical data concerning releases of specific substances to the environment are seldom available. Therefore, for each identified type of use of the substance, the proportion and quantity of release to the different environmental media are estimated, as is the proportion of the substance chemically transformed or sent for waste disposal. Unless specific information on the rate or potential for release of the substance from landfills and incinerators is available, the Mass Flow Tool does not quantitatively account for releases to the environment from disposal.

Assumptions and input parameters used in making these estimates are based on information obtained from a variety of sources including responses to regulatory surveys, Statistics Canada, manufacturers’ websites and technical databases. Of particular relevance are emission factors, which are generally expressed as the fraction of a substance released to the environment, particularly during its manufacture, processing, and use associated with industrial processes. Sources of such information include emission scenario documents, often developed under the auspices of the Organisation for Economic Co-operation and Development (OECD), and default assumptions used by different international chemical regulatory agencies. It is noted that the level of uncertainty in the mass of substance and quantity released to the environment generally increases further down the life cycle.

Table 4. Estimated releases and losses of Disperse Violet 57 to environmental media, chemical transformation and distribution to management processes, based on the Mass Flow Tool (Environment Canada 2008a).

Fate	Proportion of the mass (%) ¹	Major life cycle stage involved ²
Released to receiving media:		
Soil	0	-
Air	0	-
Sewer ³	16.5	Formulation (into an article), waste disposal
Chemically transformed		
Transferred to waste disposal sites (e.g., landfill, incineration)	83.5	Waste disposal

¹For Disperse Violet 57, information from the following OECD emission scenario documents was used to estimate releases to the environment and the distribution of the substance, as summarized in this table: OECD 2004, OECD 2006 and OECD 2007. Values presented for releases to environmental media do not account for possible mitigation measures that may be in place at some locations (e.g., partial removal by sewage treatment plants). Specific assumptions used in the derivation of these estimates are summarized in Environment Canada 2008a.

²Applicable stage(s): production; formulation (into an article); industrial use; consumer use; service life of article/product; waste disposal.

³Wastewater before any form of treatment.

Results indicate that Disperse Violet 57 can be expected to be found largely in waste management sites (83.5%), due to the eventual disposal of manufactured items containing it. Mass Flow Tool calculations do not quantitatively account for releases of the substance to the environment from waste disposal sites (such as landfills, incinerators) unless specific information on the rate or potential for release is available. No such information has been identified for Disperse Violet 57. A small fraction of solid waste is incinerated, which is expected to result in transformation of the substance. Based largely on information contained in OECD emission scenario documents for processing and uses associated with this substance, it is estimated that 16.5% of Disperse Violet 57 is released to sewer water during the textile dyeing process and 0% is released to both air and soil.

Based on the above, sewer water is the medium receiving the greatest proportion of Disperse Violet 57 emitted during product manufacturing and processing. It is anticipated that the majority of the substance bound in products will be sent to landfills for disposal.

Although no information is available on the total quantity of importation of consumer products containing Disperse Violet 57, it is anticipated that the proportions of releases to the various environmental media would not be significantly different from those estimated here. However, the quantities sent for waste management would be higher if importation of these products were taken into consideration.

Environmental Fate

According to the results of the Mass Flow Tool (Table 4), the substance Disperse Violet 57 is expected to be released to wastewater effluents during industrial processing and use. The moderate to high $\log K_{ow}$ (analogues 3.4, 4.1, 5.1 and read-across > 4) and high $\log K_{oc}$ (3.4 to 4.2) values (see Table 2) and vapour pressure, as well as the substance's tendency to ionize in alkaline environments indicate that this substance may have affinity for solids. However, the $\log K_{oc}$ is a calculated value (see footnote 6 below Table 2) and the adsorption potential of solid crystalline dye structures is generally not well understood; therefore, the degree of this particular behaviour of Disperse Violet 57 is uncertain.

Disperse Violet 57 does not biodegrade fast (see Table 5 below). It may inadvertently be applied to agricultural soils and pasture lands in Canada as a component of biosludge, which is commonly used for soil enrichment (Environment Canada 2006). Moreover, it may also be released from coloured textiles deposited in landfills.

Disperse Violet 57 is a dense solid particle with a limited water solubility (see Table 2). Thus, when released into water, this substance is expected to eventually sink to bed sediments, where it is expected to behave as a particle rather than a soluble organic chemical. It has been concluded by Yen et al. (1989) that disperse dyes tend to accumulate extensively in sediments and biota unless they are degraded at rates comparable to uptake.

The rate of volatilization is proportional to the Henry's Law constant (Baughman and Perenich 1988). The low to negligible read-across Henry's Law constant value (10^{-9} to $0.1 \text{ Pa}\cdot\text{m}^3/\text{mol}$, Table 2) and vapour pressure, as well as the substance's tendency to ionize in alkaline environments indicates that Disperse Violet 57 is essentially non-volatile. Therefore, volatilization is not likely to be an important transport pathway for the loss of this substance from moist and dry soil surfaces as well as aquatic compartments.

Finally, air is not considered to be an important medium for Disperse Violet 57 due to the low volatility of this substance, as indicated by the low to negligible read-across vapour pressure (2.7×10^{-11} to $1.3 \times 10^{-5} \text{ Pa}$, Table 2) and Henry's Law constant. These data are consistent with the physical state (solid crystalline structure) of Disperse Violet 57, which does not make it a likely candidate for volatilization.

Persistence and Bioaccumulation Potential

Environmental Persistence

No environmental monitoring data relating to the presence of Disperse Violet 57 in the Canadian environment (air, water, soil, sediment) have been identified. Furthermore, no experimental biological degradation data for Disperse Violet 57 have been identified.

According to the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers, with some exceptions, dyes are considered essentially non-biodegradable under aerobic conditions (ETAD 1995). Repeated evaluation of ready and inherent biodegradability using accepted screening tests (see the *OECD Guidelines for the Testing of Chemicals* website) have confirmed this assumption (Pagga and Brown 1986; ETAD 1992). Based on the chemical structure of Disperse Violet 57, there is no reason to suspect that biodegradation will be other than that described for dyes generally (ETAD 1995). As described below, modelled data in Table 5 support this assumption of non-degradability.

Given the expected environmental fate of Disperse Violet 57 resulting from release into aqueous waste streams, persistence in water was primarily examined using predictive quantitative structure-activity relationship (QSAR) models for biodegradation assuming the substance could exist in a non-crystalline state. Disperse Violet 57 does not contain functional groups expected to undergo hydrolysis, as dyes are large, complex branched structures that are designed to be stable in aqueous conditions (ETAD 1995).

Table 5 summarizes the results of available QSAR models for biodegradation in water.

Table 5. Modelled data for biodegradation of Disperse Violet 57

Model	Model basis	Medium	Value	Interpretation	Extrapolated half-life (days)	Extrapolation reference and/or source
BIOWIN1 v4.1 (2000)	Linear probability	water (aerobic)	0.45	Does not biodegrade fast	n/a	
BIOWIN2 v4.1 (2000)	Non-linear probability	water (aerobic)	0.01	Does not biodegrade fast	n/a	
BIOWIN3 v4.1 (2000)	Expert Survey (ultimate biodegradation)	water (aerobic)	2.17	Ultimate degradation in months	60	US EPA 2002
BIOWIN4 v4.1 (2000)	Expert Survey (primary biodegradation)	water (aerobic)	3.14	Primary biodegradation in weeks	15	US EPA 2002
BIOWIN5 v4.1 (2000)	MITI linear probability	water (aerobic)	-0.28	Does not biodegrade fast	n/a	
BIOWIN6 v4.1 (2000)	MITI non-linear probability	water (aerobic)	0.00	Does not biodegrade fast	n/a	
BIOWIN7 v4.1 (2000)	Linear probability	anaerobic	-1.18	Does not biodegrade fast	n/a	
BIOWIN Overall Conclusion	BIOWIN 3 + BIOWIN 5	water (aerobic)	no	Not ready biodegradable	n/a	

Model	Model basis	Medium	Value	Interpretation	Extrapolated half-life (days)	Extrapolation reference and/or source
TOPKAT 2004	Probability (MITI 1)	water (aerobic)	0	Persistent	> 182	First order rate kinetics
CATABOL v5.100 (2008)	% BOD (OECD 301C)	water (aerobic)	8.5	Persistent	> 182	First order rate kinetics

*BIOWIN 1–7 are outputs obtained from the predictive model BIOWIN (2000). BIOWIN estimates aerobic and anaerobic biodegradability of organic chemicals using 7 different models.

¹ Based on outcome of BIOWIN 3 and BIOWIN 5.

The results from Table 5 show that the majority of the probability models (BIOWIN 1, 2, 5, 6 and 7) suggest this substance does not biodegrade fast. In fact, all probability results except for BIOWIN1 are less than 0.3, the cut-off suggested by Aronson et al. (2006) identifying substances as having a half-life > 60 days (based on the MITI probability models) and all are less than 0.5, the cut-off suggested by the model developers for slow biodegradation. The half-life from the primary survey model (BIOWIN 4) result of “weeks” is suggested to mean approximately 15 days (US EPA 2002; Aronson et al. 2006) and the ultimate survey model (BIOWIN 3) result of “months” is suggested to mean approximately 60 days by the US EPA (2002) and 120 days by Aronson et al. (2006). The substance is also not expected to degrade rapidly under anaerobic conditions. The overall conclusion from BIOWIN is not ready biodegradable.

Two other ultimate degradation models, CATABOL (2008) and TOPKAT (2004), predict that Disperse Violet 57 does not undergo mineralization in a 28-day timeframe with a probability or percent biodegradation value in the range of very persistent chemicals. TOPKAT, which simulates the Japanese MITI 1 28-day biodegradation test, produced a probability of 0, which is less than the suggested cut-off for persistent substances in this model (< 0.3) (TOPKAT 2004). CATABOL predicted only 8.5% biodegradation based on the OECD 301 28-day ready biodegradation test (% BOD), which has been suggested to mean likely persistent (Aronson and Howard 1999) and having a half-life in water of > 182 days (assuming first-order-rate kinetics).

When the results of the BIOWIN models, and of TOPKAT and CATABOL are considered, the weight of evidence suggests that the ultimate degradation half-life in water is > 182 days, which is consistent with what would be expected for this chemical structure (i.e., few degradable functional groups, solid particle). Although it is possible that this substance will undergo faster primary degradation (based on results of BIOWIN 4), there are significant uncertainties (e.g., dyes are manufactured to be durable), and there is no information on the identity of possible degradation products.

Using a 1:1:4 for a water:soil:sediment half-life extrapolation (Boethling et al. 1995), the ultimate degradation half-life in soil is also > 182 days and the half-life in sediments is > 365 days.

Based on the results of predictive modelling, Disperse Violet 57 meets the persistence criteria for water and soil (half life in soil and water \geq 182 days) as well as sediments

(half-life in sediments ≥ 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential for Bioaccumulation

Since there are no specific experimental bioaccumulation studies for Disperse Violet 57, analogue and read-across data were used in the weight of evidence for this section. Bioaccumulation predictions as well as $\log K_{ow}$ for Disperse Violet 57 were obtained using predictive QSAR models; however, these results were considered unreliable. The structural and/or property domains of disperse dyes, including Disperse Violet 57, such as structural and/or property domains, fall outside of the models' domain of applicability. Hence, many pigment and dye classes, including disperse dyes, are considered as difficult to model using predictive QSAR models.

A recent empirical fish bioconcentration test of a structural analogue for Disperse Violet 57 (Disperse Blue 77) was submitted to Environment Canada (Hu and Shen, 2008). This test was performed according to *OECD Guidelines for the Testing of Chemicals* No. 305B-1996, Bioconcentration: Semi-Static Fish Test. The bioconcentration effect of Disperse Blue 77 to Zebra fish (*Brachydanio rerio*) was determined in a 28-day semi-static test with a test-medium renewal every two days. An exposure test at the concentration of 20 mg/L (mean measured concentration < 0.023 mg/L) was performed in accordance with the result of the fish acute toxicity test to determine the bioconcentration capacity of the test substance on the test organisms. Samples from the test solutions and test organisms were taken daily from the 26th day to the last day during the exposure period. The lipid component was extracted from the test fish and the concentrations taken from test solution. The measured concentration of test substance, fish lipid content and BCF calculation are reported in Table 6a. Based on the measured concentrations in the exposure test medium and the test organism, the bioconcentration factor (BCF) of Disperse Blue 77 to Zebra fish was calculated as < 100 .

Table 6. Measured concentration of Disperse Blue 77, fish lipid content and BCF calculation

		Sampling time		
		26th day	27th day	28th day
Treatments (20 mg/L)	Measured concentration of the test substance in extracted solutions (mg/L)	< 0.02	< 0.02	< 0.02
	Content of the test substance in the fish (mg)	< 0.002	< 0.002	< 0.002
	Fish total weight (g)	3.07	3.47	3.11
	Concentration of the test substance in the fish C_f (mg/kg)	< 0.65	< 0.58	< 0.64
	Measured concentration of the test substance in the water C_w (mg/L)	< 0.023	< 0.023	< 0.023
	Fish lipid content (%)	1.37	1.95	1.47
	BCF	< 100	< 100	< 100

	Average BCF	< 100
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The Hu and Shen (2008) study has been reviewed and considered robust (see Appendix 1). The reported BCF value of < 100 reflects the limits of solubility of Disperse Blue 77 in both water and lipid extract and likely reflects the limit of detection in these media in this study. Lack of detection in fish extracts (< 0.02 mg/L) suggests a limited solubility in lipids and/or partitioning behaviour in aqueous systems, more likely both. However, there is some uncertainty associated with limit-bounded values in any study because the “true” value is not easily known. But given the structure and likely behaviour of this class of disperse dye in aqueous systems, the BCF result is not unexpected. Most disperse dyes, as their name would suggest, exist as fine dispersible particles with limited truly soluble fractions. Solubility, however, can be increased by adding polar functional groups to the molecule. While Disperse Violet 57 contains some of these solubilizing functional groups (sulfonyl, amino, phenolic and hydroxyl), experimental solubility values for analogues containing many of the same groups remain quite low.

Anliker et al. (1981) also report results from experimental fish bioaccumulation tests for disperse anthraquinone dyes, performed according to test methods specified by the Japanese Ministry of International Trade and Industry (MITI). The value reported represents pooled results from several unspecified disperse anthraquinone dyes obtained by the ETAD member companies seeking to register new dyestuffs in Japan. The reported log bioaccumulation factor (BCF) is < 0.7, and it is expressed on the basis of wet body weight of the fishes (Anliker et al. 1981; Anliker and Moser 1987). A log K_{ow} of > 4 is also reported. The reason for the discrepancy between the high log K_{ow} and low log BCF reported by Anliker et al. 1981 is unknown. The authors suggest that the high molecular weight of disperse dyestuffs (at 450–550 g/mol) may make transport across the fish membranes difficult. It is also likely that the lack of bioavailability and limited partitioning behaviour under BCF test conditions limits accumulation in fish lipids. It has also been concluded by Anliker and Moser (1987) that for disperse dyes with substantially higher octanol solubilities, low water solubilities (< 2 mg/L) and relatively high log K_{ow} (> 3), bioaccumulation may reach much higher levels that may warrant the execution of a fish accumulation test. The BCF study from Hu and Shen (2008) addresses this need.

Disperse dyes, including the class of anthraquinones, have been shown to have partition coefficients and solubilities of a magnitude that, when taken alone, suggest a significant potential for bioaccumulation (Baughman and Perenich 1988). The experimental read-across log K_{ow} values for disperse anthraquinone-type dyes are > 4, 5.1, 4.1 and 3.4 respectively (Anliker et al 1981; Anliker and Moser 1987; ETAD 1992, see Table 2). These values indicate that Disperse Violet 57 may have the potential to bioaccumulate in organisms according to the log K_{ow} value alone. However, log K_{ow} > 4 is likely a limit value (reflecting a limit of detection in water and thus an unknown upper limit of log K_{ow}). Additionally, the high log K_{ow} value of 5.1 may be questioned as it was experimentally derived using a procedure called high-performance liquid chromatography (HPLC). HPLC is an indirect method to derive log K_{ow} data, as it

depends upon the relationship between the studied substance and a similar chemical standard (Finizio et al 1997). Unfortunately, few if any HPLC standards exist for pigments and dyes. Also, this method is often used when the substance in question is so insoluble that a traditional log K_{ow} test is not possible. Without more detailed analytical information, it is difficult to ensure that this high log K_{ow} value is a credible value. The other two log K_{ow} values (3.4 and 4.1) seem more reasonable, given the other physical and chemical characteristics of disperse dyes, but are also not completely reliable given lack of information regarding the calculation method. Thus, there is uncertainty associated with these data and it is difficult to determine bioaccumulation potential solely based on these Log K_{ow} values results or when using them in bioaccumulation models.

The experimental details, the identities of the dyes as well as their corresponding Chemical Abstracts Service Registry Numbers (CAS RN) are not reported by Anliker et al. (1981) for both log K_{ow} and log BCF values. This lack of supporting information has also been noted by other authors (Baughman and Perenich 1988). This adversely affects the certainty of usefulness of these data. However, as few bioaccumulation data have been identified for disperse anthraquinone dyes in general, these data were still considered for determining the bioaccumulation potential of Disperse Violet 57. However, the uncertainty inherent in the Anliker et al. (1981) and Anliker and Moser (1987) data results in a lower weight given to these studies.

It has been stated by ETAD (1995) that the molecular characteristics indicating the absence of bioaccumulation are a molecular weight of > 450 g/mol and a cross-sectional diameter of > 1.05 nm. Recent investigation by Dimitrov et al. (2002), Dimitrov et al. (2005) and the BBM (2008) suggests that the probability of a molecule crossing cell membranes as a result of passive diffusion declines significantly with increasing maximum cross-sectional diameter (D_{max}). The probability of passive diffusion lowers appreciably when cross-sectional diameter is $> \sim 1.5$ nm and more significantly so for molecules having a cross-sectional diameter of > 1.7 nm. Sakuratani et al. (2008) have also investigated the effect of cross-sectional diameter on passive diffusion from a test set of about 1200 new and existing chemicals also observing that substances not having a very highly bioconcentration potential often have a D_{max} (> 2.0 nm) and an effective diameter (D_{eff}) > 1.1 nm.

Disperse Violet 57 has a molecular weight of 409.42 g/mol (see Table 1) and its molecular structure is relatively uncomplicated; both these characteristics indicate a bioaccumulation capability of this substance if molecular weight is used as the only parameter. In addition, an Environment Canada (2007b) report points out that there are no clear relationships for establishing strict molecular size cut-offs for assessing bioaccumulation potential. However, the 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. (2005). The maximum diameter of Disperse Violet 57 and its conformers ranges from 13.7 to 18.9 angstroms (1.37 to 1.89 nm) (BBM 2008) suggesting that a potential for a reduced uptake rate from water and in vivo bioavailability exists with this dye.

Considering the information discussed above, there is some uncertainty regarding the bioaccumulation potential of Disperse Violet 57. Evidence is presented that both supports and argues against the bioaccumulation potential. However, greater reliability and thus weight has been assigned to the empirical BCF study from Hu and Shen (2008). Although given lower weight due to lack of sufficient study details, the BCF result from Anliker et al. (1981) and Anliker and Moser (1987), supports this conclusion. The potential for reduced uptake according to maximum cross-sectional diameter is also important and agrees with the BCF results. These data suggest a low bioaccumulation potential of Disperse Violet 57. The only evidence for a higher bioaccumulation potential comes from three relatively high log K_{ow} values for two structural analogue substances (4.1 and 5.1) and one unbounded log K_{ow} value from Anliker (1981), which was also given a low overall weight when evaluating the evidence. Therefore, when considering the overall weight of evidence, Disperse Violet 57 is considered not to meet the bioaccumulation criterion (BCF, BAF \geq 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential to Cause Ecological Harm

Ecological Effects Assessment

A - In the Aquatic Compartment

No experimental toxicity data for Disperse Violet 57 were found. A range of aquatic toxicity predictions were obtained from the various QSAR models considered for Disperse Violet 57 and its analogues. However, as with previously discussed data for physical and chemical properties and bioaccumulation, these QSAR ecotoxicity predictions for Disperse Violet 57 are not considered reliable because the structural and/or physical and chemical properties that fall outside of the models' domain of applicability.

In general, due to their poor solubility in water (< 1 mg/L), disperse dyes have low acute ecological impact (Hunger 2003). In particular, acute toxicity for aquatic life is generally low.

In a study summary submitted to Environment Canada on behalf of ETAD (Brown 1992), 11 disperse dyes were tested on some of the following organisms: Zebra fish, *Daphnia magna*, algae and bacteria. The disperse dyes were tested as a dispersion using a standard (non-toxic) dispersing agent. From the 11 disperse dyes tested by ETAD (1992), 3 are anthraquinone analogues of Disperse Violet 57 (ETAD 1992). These are Disperse Violet 26, Disperse Blue 73 and Disperse Blue 60. However, the aquatic toxicity data available for Disperse Blue 60 were considered unacceptable for presentation in the screening assessment due to ambiguity in the reported values.

Additional empirical toxicity data were also obtained for two additional suitable anthraquinone dye analogues: Disperse Blue 7 and Disperse Red 60. Empirical aquatic toxicity data for Disperse Violet 57 analogues are presented in Table 7 below.

Table 7. Empirical data for aquatic toxicity of Disperse Violet 57 analogues

Common name	Test organism	Endpoint	Value (mg/L)	Reference
Disperse Violet 26	Zebra fish	96-hr LC ₅₀ ¹	> 500 (no effect)	ETAD 1992
	<i>Daphnia magna</i>	48-hr EC ₅₀ ²	> 200 (no effect)	
Disperse Blue 73	Zebra fish	96-hr LC ₅₀	> 500 (no effect)	
	<i>Daphnia magna</i>	48-hr EC ₅₀	200	
Disperse Blue 7	Fathead minnow (<i>Pimephales promelas</i>)	24-hr LC ₅₀	> 180 (no effect)	Little et al. 1974
		48-hr LC ₅₀	142	
		96-hr LC ₅₀	52	
		96-hr LC ₅₀	52	Little and Lamb 1973
Disperse Red 60	Fathead minnow (<i>Pimephales promelas</i>)	24-hr, 48-hr, 96-hr LC ₅₀	> 180 (no effect)	Little et al. 1974
		96-hr LC ₅₀	> 180 (no effect)	Little and Lamb 1973

¹ LC₅₀ – The concentration of a substance that is estimated to be lethal to 50% of the test organisms.

² EC₅₀ – The concentration of a substance that is estimated to cause some toxic sublethal effect on 50% of the test organisms.

The acute aquatic toxicity of Disperse Violet 57 analogues presented in Table 7 ranged from moderate to low (52 to > 500 mg/L) as indicated by the acute LC₅₀ values obtained from tests performed for the duration of 24, 48 and 96 hours. All toxicity values exceeded 100 mg/L except for one 96-hr Fathead minnow LC₅₀ study (52 mg/L). Although there are some differences in functional groups, the toxicity of Disperse Violet 57 is expected to be comparable due to overall similarity in molecular structure. Therefore, these aquatic toxicity values also suggest that Disperse Violet 57 is not hazardous to aquatic organisms at relatively low concentrations (i.e., acute LC_{50s} > 1 mg/L).

It should be noted that the experimental details for the dyes Disperse Violet 26 and Disperse Blue 73 (ETAD 1992) were not provided, greatly limiting evaluation of these studies. Also, it is important to note that all of the toxicity values presented exceed the solubility of the anthraquinone analogues presented in Table 2. This complicates the interpretation of the toxicity results considerably. Primarily, it must be considered that a different mode of action that may involve suspended particles instead of only the dissolved substance could be causing some negative effects. This would not be unreasonable, given the solid nature of disperse dyes, which could impair biota by clogging pores and perhaps gills. These data were nevertheless considered usable and are included in this screening assessment as contributing to the overall weight of evidence suggesting low potential to cause toxicity.

In conclusion, results of the available aquatic toxicity data for disperse anthraquinone dyes indicate that the substance Disperse Violet 57 is not highly hazardous to certain aquatic organisms at relatively low concentrations (i.e., acute LC_{50s} > 1.0 mg/L).

B - In Other Environmental Compartments

Because of the physical and chemical properties of Disperse Violet 57 there is potential for accumulation in sediment. However, no suitable toxicity data were found for sediment-dwelling organisms..

Ecological Exposure Assessment

No data concerning concentrations of this substance in water in Canada have been identified. Environmental concentrations are, therefore, estimated from available information, including estimated substance quantities, release rates and receiving water bodies. Environment Canada's Industrial Generic Exposure Tool – Aquatic (IGETA) was used to estimate the (reasonable worst case) concentration of the substance in a generic watercourse receiving industrial effluents (Environment Canada 2008b). The generic scenario is designed to provide these estimates based on conservative assumptions regarding the amount of chemical processed and released, the number of processing days, the sewage treatment plant removal rate and the size of the receiving watercourse. The tool models an industrial-release scenario based on loading data from sources such as industrial surveys and knowledge of the distribution of industrial discharges in the country and calculates a predicted environmental concentration (PEC). The equation and inputs used to calculate the PEC in the receiving watercourse are described in the Environment Canada (2008b). The maximum mass of chemical used at a single facility is assumed to be the threshold reporting value of 1000 kg for the 2006 section 71 notices, which was not reached by any company. As a conservative estimate, handling and processing losses were assumed to be 16.5%. The receiving body information is highly conservative, assuming the chemical is released to a very small river without treatment. The conservative PEC for water was calculated to be 0.019 mg/L (Environment Canada 2008c).

Characterization of Ecological Risk

The approach taken in this ecological screening assessment was to examine various supporting information and develop conclusions based on a weight-of-evidence approach and using precaution as required under CEPA 1999. Particular consideration was given to risk quotient analysis, persistence, bioaccumulation, toxicity, sources and fate in the environment.

A predicted no-effect concentration (PNEC) was estimated based on the nominal lethal concentration (LC₅₀) to fish (*Pimephales promelas*). The 96-hour LC₅₀ for Disperse Blue 7 (CAS RN 3179-90-6), an analogue of Disperse Violet 57, was 52 mg/L (Table 7). A factor of 100 was then applied to account for uncertainty in extrapolating acute to chronic (long-term) toxicity and from laboratory results to the field. The resulting PNEC is 0.52 mg/L. This value is close to the upper bound of the estimated range of solubility of the substance (0.2 mg/L; Table 2). When compared to the conservative PEC calculated for water above, the resulting risk quotient (PEC/PNEC) is $0.019/0.52 = 0.037$. The calculated risk coefficient is less than one, therefore indicating a low potential for ecological harm resulting from local exposure to a point source industrial release to the

aquatic environment associated with calculation of the PEC and PNEC. Given that IGETA provides a conservative estimate of exposure and risk, a more detailed evaluation of risk resulting from this type of source is not considered necessary.

Based on the available information, Disperse Violet 57 is expected to be persistent in water, soil and sediment. It is also expected to have a low bioaccumulation potential. The low importation volumes of Disperse Violet 57 into Canada, along with information on its uses, indicate a low potential for releases into the Canadian environment. Once released into the environment, it will be found mainly in water, but will eventually transfer to sediment. It has also been demonstrated to have a low to moderate potential for inherent toxicity to aquatic organisms. Risk quotients for aquatic exposures indicate that Disperse Violet 57 concentrations likely do not exceed concentrations associated with harmful effects, even when using conservative scenarios and assumptions. Therefore Disperse Violet 57 is unlikely to be causing harm to populations of aquatic organisms in Canada.

Uncertainties in Evaluation of Ecological Risk

The persistence assessment is limited by the lack of experimental biodegradation data, which necessitated the generation of model predictions.

Uncertainties also exist because of the lack of information on environmental concentrations (e.g., monitoring data) in Canada for Disperse Violet 57. However, the lack of importation or manufacture of Disperse Violet 57 in Canada at significant volumes suggests very low releases of this chemical into the Canadian environment.

Uncertainties are also associated with the fraction of substance in commerce that is released, and with the fraction that is removed in sewage treatment plants.

Regarding toxicity, based on the anticipated release pattern for the substance, the significance of soil as a medium of exposure is not well addressed by the effects data available. Indeed, the only effects data identified apply primarily to pelagic aquatic exposures.

For the exposure assessment, the predicted environmental concentration (PEC) accounts for concentrations in water only, so exposure through soils, suspended solids and sediments is not considered. However, given the current release scenarios and quantities used in Canada, overall exposure is not likely to be significant at this time.

Conclusion

Based on the information presented in this screening assessment, Disperse Violet 57 is considered to not be 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.

It is therefore concluded that Disperse Violet 57 does not meet the definition of “toxic” as set out in section 64 of CEPA 1999. Additionally, Disperse Violet 57 does not meet criteria for bioaccumulation potential but meets criteria for persistence as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

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Appendix 1. Robust study summary

Robust Study Summary Form: Aquatic B				
No.	Item	Weight	Yes/No	Specify
1	Reference: Hu, Shuangqing and Shen, Genxiang (Environmental Testing Laboratory, Shanghai Academy of Environmental Sciences, Shanghai, China). 2008. Bioconcentration Test of C.I. Disperse Blue 77 in Fish. Prepared for Dystar in the name of Ecological and Toxicological Association of the Dyes and Organic Pigments Manufacturers (ETAD) Basel, Switzerland. Report No. S-071-2007. Submitted to Environment Canada on April 2008.			
2	Substance identity: CAS RN	n/a	Y	20241-76-3
3	Substance identity: chemical name(s)	n/a	Y	9,10-anthracenedione, 1,8-dihydroxy-4-nitro-5-(phenylamino)-
4	Chemical composition of the substance	2	Y	
5	Chemical purity	1	N	
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
7	If test material is radio-labelled, were precise position(s) of the labelled atom(s) and the percentage of radioactivity associated with impurities reported?	2		
	Method			
8	Reference	1	Y	
9	OECD, EU, national, or other standard method?	3	Y	
10	Justification of the method/protocol if a non-standard method was used	2		
11	GLP (good laboratory practice)	3	N	
	Test organism			
12	Organism identity: name	n/a	Y	Zebra fish, <i>Brachydanio rerio</i>
13	Latin or both Latin and common names reported?	1	Y	
14	Life cycle age / stage of test organism	1	N	
15	Length and/or weight	1	Y	
16	Sex	1	N	
17	Number of organisms per replicate	1	Y	7
18	Organism loading rate	1	Y	
19	Food type and feeding periods during the acclimation period	1	Y	
	Test design / conditions			
20	Experiment type (laboratory or field)	n/a	Y	Laboratory
21	Exposure pathways (food, water, both)	n/a	Y	Water
22	Exposure duration	n/a	Y	28 days
23	Number of replicates (including controls)	1	Y	
24	Concentrations	1	Y	20 mg/L
25	Food type/composition and feeding periods during the test	1	Y	
26	If BCF/BAF derived as a ratio of chemical concentration in the organism and in water, was experiment duration equal to or longer than the time required for the chemical concentrations to reach steady state?	3	Y	

27	If BCF/BAF derived as a ratio of chemical concentration in the organism and in water, were measured concentrations in both water and the organism reported?	3	Y	
28	Were concentrations in the test water measured periodically?	1	Y	
29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	Y	
30	Photoperiod and light intensity	1	Y	
31	Stock and test solution preparation	1	Y	
32	Analytical monitoring intervals	1	Y	
33	Statistical methods used	1	Y	
34	Was solubilizer/emulsifier used, if the chemical was unstable or poorly soluble?	n/a	N	
	Information relevant to the data quality			
35	Was the test organism relevant to the Canadian environment?	3	Y	
36	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	Y	
37	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and the organism's nature/habits?	2	Y	
38	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1	Y	
39	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	Y	
40	Was lipid content (or lipid-normalized BAF/BCF) reported?	2	Y	
41	Were measured concentrations of a chemical in the test water below the chemical's water solubility?	3	N	
42	If radio-labelled test substance was used, was BCF determination based on the parent compound (i.e., not on total radio-labelled residues)?	3		
	Results			
43	Endpoints (BAF, BCF) and values	n/a	n/a	BCF
44	BAF or BCF determined as: 1) the ratio of chemical concentration in the organism and in water, or 2) the ratio of the chemical uptake and elimination rate constants	n/a	n/a	1
45	Whether BAF/BCF was derived from a 1) tissue sample or 2) whole organism?	n/a	n/a	2
46	Whether 1) average or 2) maximum BAF/BCF was used?	n/a	n/a	1
47	Score: ... %	79.2		
48	EC reliability code:	2		
49	Reliability category (high, satisfactory, low):	Satisfactory Confidence		
50	Comments	<i>The present procedure is based on semi-static conditions (renewal of test solutions every 2 days). Therefore, test chemicals with very low water solubility like Disperse Violet 57 can also be characterized as to their bioconcentration potential without adding solvents or other auxiliary substances that may affect the results.</i>		