

Screening Assessment for the Challenge

Chemical Abstracts Service Registry Numbers

4395-65-7

60352-98-9

74336-60-0

Environment Canada

Health Canada

February 2009

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 in Canada; 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 2006a), 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 these substances identified as high priorities.

The three substances listed below were identified as high priority for screening assessment and were included in the Challenge because they were found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms and were believed to be in commerce in Canada. These substances were 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 (DSL).

CAS RN*	DSL Name
4395-65-7	9,10-Anthracenedione, 1-amino-4-(phenylamino)-
60352-98-9	1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate
74336-60-0	9,10-Anthracenedione, 1-[(5,7-dichloro-1,9-dihydro-2-methyl-9-oxopyrazolo[5,1-b]quinazolin-3-yl)azo]-

*CAS RN = Chemical Abstracts Service Registry Number

Screening assessments under CEPA 1999 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.”

The Challenge for the above substances was published in the *Canada Gazette* on August 18, 2007 (Canada 2007). Substance Profiles were released at the same time. The Substance Profiles presented the technical information available prior to December 2005 that formed the basis for categorization of these substances. Based on the outcome of the Challenge, the Ministers of the Environment and of Health have conducted the screening assessment below. The draft of this screening assessment was subject to a 60-day public comment period.

Summary of Information Used as Basis for this Screening Assessment

Based on categorization results, the three substances listed in this report have been found to meet the ecological criteria for persistence, bioaccumulation and inherent toxicity to non-human organisms (PBiT). None of these substances was found to meet the human health categorization criteria (Canada, 2006).

To establish whether certain high priority substances, including PBiT substances, were currently being manufactured in or imported into Canada, a survey was conducted by issuing a *Notice with respect to Selected Substances identified as Priority for Action* pursuant to paragraphs 71(1)(a) and (b) of CEPA 1999. The notice was published in Part I of the *Canada Gazette* on March 4, 2006 (Canada, 2006b).

In response to this notice, there were no reports of industrial activity (import or manufacture) in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2005, for two of the substances: CAS RN 4395-65-7 and 74336-60-0. However, some companies did identify themselves as having a stakeholder interest in these substances. Therefore, these substances were believed to be potentially in commerce in Canada and were included in the Challenge. The third substance, with CAS RN 60352-98-9, had not been included in this notice but was included in the Challenge.

Results from a similar Canada Gazette notice issued under paragraph 71(1)(b) of CEPA 1999 on August 18, 2007, as part of the Challenge (Canada 2007) also yielded no reports of industrial activity (import or manufacture) with respect to the three substances in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2006. These results suggest that currently these substances are not in use above the specified reporting threshold, and therefore the likelihood of exposure to these substances in Canada resulting from commercial activity is low.

The above notices and the accompanying questionnaire of August 2007 (Canada, 2006b; Canada 2007) also yielded no new information relevant to the PBiT properties of these substances. Given the lack of any significant commercial activity for these substances, no further collection or analysis of information relevant to the persistence, bioaccumulation and ecological effects of these three substances beyond what was done for categorization, has been conducted. Therefore, the decisions on PBiT properties made during categorization remain unchanged. The substances are considered to be inherently toxic to non-human organisms ($LC_{50}/EC_{50} < 1$ mg/L). They also are considered to meet the criteria for both persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations* (Canada, 2000).

Conclusion

Based on available information, and until new information is received indicating that a substance is entering, or may enter the environment, it is concluded that the above three substances are currently not entering, nor are they likely to enter, the environment as a result of commercial activity in Canada. Therefore, it is concluded that they do not meet the definition of toxic as set out in section 64 of CEPA 1999.

As these substances are listed on the DSL, import and manufacture of these three substances in Canada are not subject to notification as new substances are required under subsection 81(1) of CEPA 1999. Given their hazardous PBiT properties, there is concern that new activities for the above three substances which have not been identified or assessed under CEPA 1999 could lead to the substances meeting the criteria set out in section 64 of the Act. Therefore it is recommended that the above three

substances be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of these substances in quantities greater than 100 kg/year is notified and will undergo ecological and human health risk assessments as specified in section 83 of the Act, prior to the substance being introduced into Canada.

References

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