

Screening Assessment for the Challenge

**Ethanol, 2-[[4-[(2, 6-dichloro-4-nitrophenyl)azo]phenyl]methylamino]-
(Disperse Orange 5)**

**Chemical Abstracts Service Registry Number
6232-56-0**

**Environment Canada
Health Canada**

August 2009

Synopsis

Pursuant to section 74 of the *Canadian Environment Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment of Ethanol, 2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]methylamino]- (Disperse Orange 5), Chemical Abstracts Service Registry Number 6232-56-0. The above substance on the *Domestic Substances List* was identified as high priority for screening assessment, to be part of the Challenge, because it met the ecological categorization criteria for persistence (P) and bioaccumulation (B) and inherent toxicity to non-human organisms (iT), under paragraph 73(1)(b) of CEPA 1999, and was believed to be in commerce in Canada. The substance was not considered to be a high priority for assessment of potential risks to human health.

Results from notices issued under paragraph 71(1)(b) of CEPA 1999 in March 2006 and February 2008 revealed no reports of industrial activity (import or manufacture) with respect to this substance in Canada, equal or above the reporting threshold of 100 kg, for the specified reporting years of 2005 and 2006. These results suggest that this substance is currently not in use above the specified reporting threshold, and therefore the likelihood of exposure to the substance in Canada resulting from commercial activity is low. Other sources of entry into the environment have not been identified at this time.

Information received as a result of the above notices issued under paragraph 71(1)(b) of CEPA 1999 and the accompanying questionnaire of February 2008 also revealed no significant new data relevant to the PBiT properties of this substance. Given the lack of any significant commercial activity for the substance, no additional efforts have been made to collect or analyze information relevant to the persistence, bioaccumulation and ecological effects of the substance beyond what was done for categorization. Therefore, the decisions on PBiT properties made during categorization remain unchanged. The substance is considered to be inherently toxic to non-human organisms. It also meets the criteria for both persistence and bioaccumulation as set out in the *Persistence and Bioaccumulation Regulations*.

Based on available information, and until new information is received indicating that this substance is entering, or may enter the environment, from commercial activity or from other sources, it is concluded that the above substance is currently not entering, nor is it likely to enter, the environment as a result of commercial activity in Canada. Therefore, it is proposed to conclude that it does not meet any of the criteria set out in section 64 of CEPA 1999.

As a substance listed on the *Domestic Substances List*, import and manufacture of this substance in Canada are not subject to notification under subsection 81(1). Given the hazardous PBiT properties, there is concern that new activities for the above substance which have not been identified or assessed under the *Canadian Environmental Protection Act, 1999* could lead to the substance meeting the

criteria set out in section 64 of the Act. Therefore, it is recommended that the above substance 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 the substance 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.

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 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 these substances identified as high priorities.

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

CAS RN*	DSL Name	Common Name
6232-56-0	ethanol,2-[[4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]methylamino]-	Disperse Orange 5

*CAS RN = Chemical Abstracts Service Registry Number

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.”

The Notice for the Challenge for the above substance was published in the *Canada Gazette* on February 16, 2008 (Canada 2008). The 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. Based on the outcome of the Challenge, the Ministers of the Environment and of Health have conducted this screening assessment for this substance. The critical information and considerations upon which the assessment is based are summarized below.

Summary of Information Used as Basis for this Screening Assessment

Based on categorization results, the substance listed in this report has been found to meet the ecological criteria for persistence, bioaccumulation and inherent toxicity to non-human organisms (PBiT). This substance was not found to meet the human health categorization criteria (Environment 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, 2006a).

In response to this notice, there were no reports of industrial activity (import or manufacture) with respect to this substance in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2005. However, some companies did identify themselves as having a stakeholder interest in this substance. Therefore, this substance was believed to be potentially in commerce in Canada and was included in the Challenge.

Results from a similar notice issued under paragraph 71(1)(b) of CEPA 1999 on February 16, 2008, as part of the Challenge (Canada 2008) also revealed no reports of industrial activity (import or manufacture) with respect to this substance in Canada, above the reporting threshold of 100 kg, for the specified reporting year of 2006. These results indicate that currently this substance is not in use above the specified reporting threshold, and therefore the likelihood of exposure to this substance in Canada resulting from commercial activity is low. Other sources of entry into the environment have not been identified at this time.

Responses to the above notices and the accompanying questionnaire of February 2008 (Canada, 2006a; Canada 2008) also revealed no new information relevant to the PBiT properties of this substance. Given the lack of any significant commercial activity for this substance, no further collection or analysis relevant to the persistence, bioaccumulation and ecological effects of this substance, beyond

what was done for categorization, has been completed. Therefore, the decisions on PBiT properties made during categorization remain unchanged. The substance is thus considered to be inherently toxic to non-human organisms. It is also 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 the substance is entering, or may enter the environment, from commercial activity or from other sources, it is concluded that the above substance is currently not entering, nor is likely to enter, the environment. Therefore, it is concluded that it does not meet the definition of toxic as set out in section 64 of CEPA 1999.

As a substance listed on the DSL, import and manufacture of this substance in Canada is not currently subject to notification under subsection 81(1). Given its hazardous PBiT properties, there is concern that new activities for the above substance which has not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore, it is recommended that the above substance 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 this substance in quantities greater than 100 kg/year is notified and will undergo ecological and human health assessments as specified in section 83 of the Act, prior to the substance being considered for introduction into Canada.

References

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