Substance Profile for The Challenge
N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide
(Pigment Orange 38)
CAS No. 12236-64-5

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) required the Minister of Health and Minister of the Environment to categorize the approximately 23 000 substances on the Domestic Substances List (DSL). Categorization involved identifying those substances on the DSL that are a) considered to be persistent (P) and/or bioaccumulative (B), based on criteria set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000), and "inherently toxic" (iT) to humans or other organisms, or b) that present, to individuals in Canada, the greatest potential for exposure (GPE).

Further to this activity, the Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that meet the categorization criteria. A screening assessment involves a scientific evaluation of available information for a substance to determine whether the substance meets the criteria set out in section 64 of CEPA 1999. Based on the results of a screening assessment, the Ministers can propose taking no further action with respect to the substance, adding the substance to the Priority Substances List (PSL) for further assessment or recommending the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999 and, where applicable, the implementation of virtual elimination of releases to the environment.

A number of substances have been identified by the Ministers as high priorities for action based on the information obtained through the categorization process. This includes substances:

- that were found to meet all of the ecological categorization criteria, including persistence, bioaccumulation potential and inherent toxicity to aquatic organisms (PBiT), and that are known to be in commerce in Canada, and/or
- that were found either to meet the categorization criteria for GPE or to present an intermediate potential for exposure (IPE), and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity.

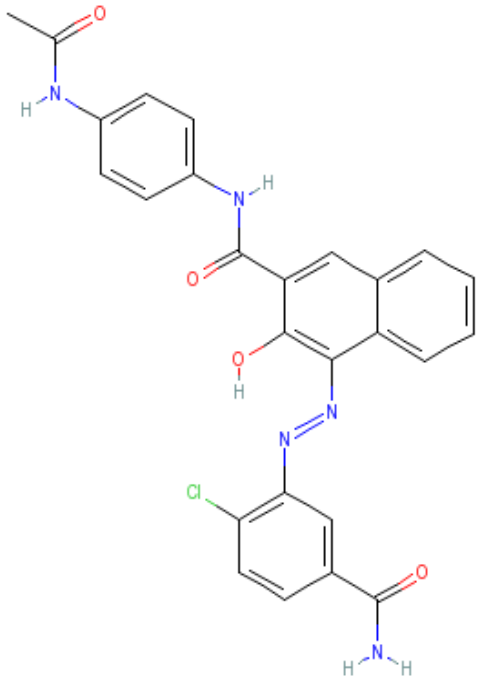
Based on a consideration of the ecological and/or human health concerns associated with these substances, and the requirement under section 76.1 of CEPA 1999 for the Ministers to apply a weight of evidence approach and the precautionary principle when conducting and interpreting the results of an assessment, sufficient data are currently available to consider these substances as meeting the criteria under Section 64 of CEPA 1999.

As such, the Ministers have issued a Challenge to industry and other interested stakeholders through publication in Canada Gazette Part I December 9, 2006 to submit, within the timelines stated in the Challenge section of this document, below, specific information that may be used to develop and benchmark best practices for risk management and product stewardship.

N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide was identified as a high priority for action as it was found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada. The technical human health and ecological information, that formed the basis for concern associated with this substance, is contained in Appendices I and II, respectively.

Substance Identity

For the purpose of this document, this substance will be referred to as Pigment Orange 38.

CAS Registry Number	12236-64-5
Inventory names	2-Naphthalenecarboxamide, N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxy-; N-[4-(Acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphtalene-2-carboxamide (French); N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide; N-[4-(Acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorphenyl]azo]-3-hydroxynaphthalin-2-carboxamid (German); N-[4-(acetilamino)fenil]-4-[[5-(aminocarbonil)-2-clorofenil]azo]-3-hidroxinaftaleno-2-carboxamida (Spanish); Pigment Orange 38; C.I. Pigment Orange 038; C.I. PIGMENT ORANGE 38
Other names	2-Naphthanilide, 4'-acetamido-4-[(5-carbamoyl-2-chlorophenyl)azo]-3-hydroxy-; Novoperm Orange HFG; Novoperm Red HFG; Permanent Red HFG; PV-Red HFG
Chemical group	Discrete organics
Chemical sub-group	Monoazo Organic Color Pigments (Naphthol AS pigments III)
Chemical formula	C26H20ClN5O4
Chemical structure	
SMILES	O=C(Nc(ccc(NC(=O)c(c(O)c(N=Nc(c(ccc1C(=O)N)Cl)c1)c(c2ccc3)c3)c2)c4)c4)C
Molecular mass	501.93 g/mol

Based on information submitted in response to a legal Notice published in 2006 under section 71 of CEPA 1999, Pigment Orange 38 was not manufactured in Canada in 2005 in a quantity meeting the 100 kg reporting thresholds. One company reported importing up to 1,000 kg into Canada in 2005 for activities described as Wholesale Trade/Distribution of Chemical (except agricultural) and Allied Products. It can be used as colourants in printing inks, in rubber and plastic products, and in paints, lacquers and varnishes. It may also present in crayons and wax dispersions.

THE CHALLENGE

Based on the information presented in Appendix II of this document, it is expected that the screening assessment of this substance will conclude that it satisfies the definition of toxic under section 64 of CEPA 1999 in that it "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". The substance will then be proposed for addition to the List of Toxic Substances in Schedule I of the Act and proposed for virtual elimination of releases to the environment.

Subsequent risk management activities will be based on the objective of eliminating the release of a measurable quantity of a PBiT substance to the environment. In the absence of further information on existing handling practices for these substances, proposed actions would be based on realistic worst case assumptions. At this time, prohibition is being considering through regulations, of the manufacture, use, sale, offer for sale and import of this substance, except for those activities controlled under the *Pest Control Products Act* and/or the *Food and Drugs Act.*

Opportunity to Submit Information on P, B and iT Properties

Through the categorization exercise, available experimental aquatic toxicity information as well as experimental data on the potential for a substance to persist or bioaccumulate in the environment were collected prior to December 2005. Where acceptable experimental data were not available, Quantitative Structure Activity Relationships (QSARs) or read across data were used to fill the data gaps. Since the categorization outcome on P, B, and iT form the basis for prioritizing this substance for action, and experimental data are preferred, interested parties have an opportunity to provide relevant experimental study information on the persistence, bioaccumulation, and inherent toxicity to aquatic organisms for this substance.

Efforts should focus on providing data for the endpoints for which quality experimental data does not already exist, as demonstrated by the information summarized in Appendix II of this document. As submitted data will be evaluated for completeness and robustness, it is recommended that stakeholders follow the guidance for test protocols and alternative approaches for test data, as described in Section 8 of the "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers".[1]

Responses to this part of the challenge for this substance should be received at the address provided below by June 5, 2007.

[1] "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers (version 2005)", Government of Canada, Available from http://www.ec.gc.ca/substances/nsb/eng/cp_guidance_e.shtml

Section 71 Notice

Information needed for improved decision-making with regard to risk assessment and management of this substance is being gathered using section 71 of CEPA 1999. This notice applies to any person who reported pursuant to the *Canadian Environmental Protection Act*, 1999 section 71 Notice with Respect to Selected Substances Identified as Priority for Action, published in the Canada Gazette, Part I, on March 4, 2006.

The 2006 information mandated through the notice relates to, among other things, quantity of the substance imported, manufactured or used, types of uses of the substance, and releases of the substance to the environment.

Copies of the section 71 notice and guidance on how to comply with it are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca), or from the contact provided below.

Responses to the section 71 notice must be received at the address provided below by June 5, 2007.

Opportunity to Submit Additional Information on Current Uses and Existing Control Measures to Inform the Risk Management Approach for this Substance

The Ministers of Health and Environment are inviting the submission of additional information that is deemed beneficial by interested stakeholders, relating to the extent and nature of the management/stewardship of substances listed under the Challenge.

Organizations that may be interested in submitting additional information in response to this invitation include those that manufacture, import, export or use this substance whether alone, in a mixture, in a product or in a manufactured item.

Additional information is being invited in the following areas:

- Import, manufacture and use quantities
- Substance and product use details
- Releases to the environment and spill management
- Current and potential risk management and product stewardship actions
- Existing legislative or regulatory programs controlling/managing the substance
- Information to support the development of a regulatory impact assessment.

A questionnaire is available which provides a detailed template as an example for the submission of this information. Guidance on how to respond to the challenge questionnaire is also available. Interested stakeholders are invited to provide available

additional information, recognizing that not all questions in the questionnaire may be relevant to a particular substance, use, or industrial sector.

Copies of the questionnaire and associated guidance are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca)**,** or from the contact provided below.

Responses to this part of the challenge for this substance should be received at the address provided below by June 5, 2007.

Request for Documents and Submission of Information

Documents and instructions may be requested from the following contact. Information in response to the above Challenge must be submitted to this address.

DSL Surveys Coordinator
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530/819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: DSL.surveyco@ec.gc.ca

Appendix I
Human Health Information to Support the Challenge for N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide (Pigment Orange 38) CAS No. 12236-64-5

Introduction

Under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), Health Canada undertook to categorize all substances on the Domestic Substances List (DSL) to identify those representing the greatest potential for human exposure (GPE) and those among a subset of substances considered persistant (P) and/or bioaccumulative (B) that are also considered to be "inherently toxic" to humans.

In order to efficiently identify substances that represent the highest priorities for screening assessment, Health Canada developed and applied a Simple Exposure Tool (SimET) to the DSL to identify those substances that meet the criteria for GPE, Intermediate Potential for Exposure (IPE) or Low Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

Pigment Orange 38 is considered to meet the criteria for LPE under SimET and does not meet the criteria for high hazard under SimHaz. This document summarizes the currently available information on which the SimET and SimHaz results are based.

Exposure Information from Health Related Components of DSL Categorization

As mentioned above, SimET was developed and used to identify substances on the DSL considered to represent GPE. This approach was based on three lines of evidence: 1) the quantity in commerce in Canada, 2) the number of companies involved in commercial activities in Canada (i.e., number of notifiers), and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an IPE or LPE, based on criteria for quantity and nature of use (Health Canada, 2003).

Results of the Application of SimET

Pigment Orange 38 has been determined to be LPE based on a consideration of the DSL nomination information listed below.

Nomination Information for DSL

Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 1,100 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-1986 was less than 4.

Use Codes and Description

The following DSL use codes have been identified for the substance:

13	Colourant - pigment/stain/dye/ink
85	Pigment, Dye and Printing Ink
86	Plastics

Hazard Information from Health Related Components of DSL Categorization

Simple Hazard Tool (SimHaz)

SimHaz is a tool that has been used to identify, among all of the approximately 23 000 substances on the DSL, those considered to present either high or low hazard to human health based on formalized weight of evidence criteria and/or peer review/consensus of experts. This tool has been developed through extensive compilation of hazard classifications of Health Canada and other agencies and consideration of their robustness based on availability of transparent documentation of both process and criteria (Health Canada, 2005).

Results of the Application of SimHaz

Pigment Orange 38 has not been classified for hazard by any of the agencies considered under the SimHaz tool and therefore does not meet the criteria for high hazard under SimHaz.

Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL considered to be human health related priorities for further consideration. It is recognized that they do not include a number of elements normally considered in a human health risk assessment such as a comprehensive characterization of exposure and hazard, a comparison of exposure metrics to hazard metrics and a detailed analysis of uncertainties.

References

Health Canada. 2003. Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for Human Exposure. http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/existsub/exposure/greatest_potential_human_exposure-risque_exposition_humaine_e.pdf

Health Canada. 2005. Proposed Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999. http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/framework-int-cadre_e.pdf

Appendix II
Ecological Information
to Support The Challenge for
N-[4-(acetylamino)phenyl]-4-[[5-(aminocarbonyl)-2-chlorophenyl]azo]-3-hydroxynaphthalene-2-carboxamide
(Pigment Orange 38)
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The information in this document will form the basis of a screening assessment under section 74 of CEPA, 1999. Data relevant to an ecological screening assessment were identified in original literature, review documents, commercial and government databases prior to December 2005. Properties and characteristics may also have been estimated using Quantitative Structure Activity Relationship (QSAR) models. In addition, an industry survey was conducted for the year 2005 through a Canada Gazette Notice issued pursuant to section 71 of CEPA 1999 (Environment Canada, 2006). This Notice requested data on the Canadian manufacture and import of the substance.

Physical and chemical properties

There is no empirical physical-chemical property data available. Table 1 contains modelled physical-chemical properties of Pigment Orange 38 which are relevant to its environmental fate.

Table 1. Physical and chemical properties

Property	Type	Value	Reference
Boiling point	Modelled	847.96 ^{o}C	MPBPWIN v1.41
Melting point	Modelled	349.84 ^{o}C	MPBPWIN v1.41
Vapour Pressure	Modelled	8.69 x 10^{-21} Pa/ 6.52 x 10^{-23} mm Hg	MPBPWIN v1.41
Henry's Law Constant	Modelled	2.36 x 10^{-23} atm-m^3/mole	HenryWin v3.10
log K_{ow}	Modelled	5.79	Kowwin v.1.67
log K_{oc}	Modelled	4.77	PCKOCWIN v1.66
Water solubility	Modelled	0.01118 mg/L	WSKOWWIN v1.41

Manufacture, Importation, and Uses

Manufacture and Importation

In Canada, no manufacture of Pigment Orange 38 was reported in response to a CEPA section 71 survey notice for the 2005 calendar year in a quantity meeting the 100 kg reporting threshold. In total, one company reported import of this substance in the 100-

1,000 kg/year range (Environment Canada, 2006). Similar quantity was reported to the DSL during the calendar year 1986 (see Appendix I).

According to information from the US Environmental Protection Agency (EPA), the import/production of Pigment Orange 38 was in the order of 4.5 – 225 tonnes during 1986 and 1994, but no consumption was reported in the year of 1990, 1998, and 2002.

The Substances in Preparations in Nordic Countries (SPIN) database indicated its consumption in Denmark decreased from 6.8 tonnes in 2000 to 0.8 tonne in 2001 & 2002. The use was also reported in Sweden during 1999 – 2004 & Denmark in 2003 – 2004, but quantity was not specified (SPIN, 2000).

Uses

There are 3 categories of potential uses for Pigment Orange 38 that have been identified or suggested in Canada and worldwide:

1. Pigment for colouring printing inks - used in the areas of publishing, printing, and reproduction of recorded media (SPIN, 2000).
2. Paint, lacquers and varnishes - used in the areas of treatment and coating of fabricated metal products, machinery and equipment, or in areas of construction industry (SPIN, 2000).
3. Colorant in manufacture of rubber and plastic products. Pigment Orange 38 is primarily used to color PVC, olefins and unsaturated polyester and also finds some use in crayons and wax dispersions (S. Heitzman, Sun Chemical Corporation).

Similar uses were reported to the DSL during the calendar year 1986 (see Appendix I).

Releases, Fate, and Presence in the Environment

Releases

Pigment Orange 38 is not naturally produced in the environment. Data concerning the environmental releases of the pigment in Canada are not available. Since this pigment is not manufactured in Canada, the possible release to waste water effluent during the production phase is negligible. According to its major applications in printing inks, paints, and as plastic colorants, Pigment Orange 38 may be released to the environment in a dispersive manner (Environment Canada 2006). It is assumed that the predominant release route is through weathering of such products, and at the end of their life cycle is to landfills. The de-inking process for paper recycling and residue rinse during the processing phase could lead to release through wastewater treatment plants (STPs). The STP effluents and leaching from landfill may lead to soil and ground water exposure.

Fate

The high log K_{ow} and K_{oc} values indicate this substance will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicates that if this pigment is released equally to the three major environmental compartments (air, water, and soil), it will partition in water, soil, and sediments, with the latter two being the predominant compartments (Table 2), where the chemical has been indicated to persist (see Table 3).

Table 2. Results of the Level III fugacity modelling (EPIWIN V3.12)

	Fraction of Substance Partitioning to Each Medium (%)			
Substance Released to:	**% in Air**	**% in Water**	**% in Soil**	**% in Sediment**
Air (100%)	0.00	0.40	90.30	9.31
Water (100%)	0.00	4.14	0.00	95.9
Soil (100%)	0.00	0.01	99.8	0.16
Air, water, soil (33.3% each)	0.00	1.48	64.30	34.20

If the substance is released solely to air, a vapour pressure of 8.69×10^{-21} Pa and Henry's Law constant of 2.36×10^{-23} atm-m^3/mole indicates its partitioning to air will be negligible. The major two media where these substances will partition are soil and sediment (> 99 %) and a very small amount of the pigment will partition in water (0.4 %) due to the substance's low water solubility.

If released to soil, Pigment Orange 38 is expected to have extremely high adsorptivity to soil (i.e. expected to be immobile) based upon estimated log K_{oc} of ~ 5. Volatilization from dry or moist soil surfaces seems to be an unimportant fate process based upon the low estimated Henry's Law constant and vapour pressure. Therefore, if released to soil, Pigment Orange 38 will mainly partition in this environmental compartment, which can be illustrated by the results of the Level III fugacity modelling (Table 2).

If released into water, Pigment Orange 38 is expected to strongly adsorb to suspended solids and sediment based upon extremely high values of estimated K_{oc}. Volatilization from water surfaces is expected to be an unimportant fate process based upon this compounds' estimated Henry's Law constant. Thus, if water is a receiving medium, this pigment is expected to mainly partition in sediments and, to some extent, in water (Table 2). Pigment Orange 38 is expected to persistent in water with a half-life of more than 182 days according to the model predictions (BIOWIN v4.02, Ultimate survey, Table 3).

Presence in the Environment

No monitoring data relating to the presence of the substance in environmental media (air, water, soil, sediment) have yet been identified.

Evaluation of P, B and iT Properties

Environmental persistence

Once released into the environment, Pigment Orange 38 appears to be relatively persistent in water, soil and sediments. The Level III Fugacity model indicates negligible partitioning of the substance in air. For the minimum amount of the pigment that may partition in air, the predicted atmospheric oxidation half-life of 0.535 day (Table 3) suggests that in air, it seems to be rapidly oxidized. The pigment is not expected to react, or react appreciably, with other photo oxidative species in the atmosphere, such as O_3 and NO_3, nor is it likely to degrade via direct photolysis. Therefore, it is expected that reactions with hydroxyl radicals will be the most important fate process in the atmosphere for the substance. With a half-life of about half a day via reactions with hydroxyl radical, Pigment Orange 38 is not persistent in air.

Table 3. Modelled persistence data for Pigment Orange 38

Medium	Fate Process	Degradation Value	Degradation Endpoint	Reference
Air	atm-oxidation	0.535	half-life (days)	AOPWIN v1.91
Water/soil	Biodegradation	182	half-life (days)	BIOWIN v4.02, Ultimate survey
Water/soil	Biodegradation	0	probability	BIOWIN v4.02, MITI Linear Probability
Water/soil	Biodegradation	0	probability	BIOWIN v4.02, MITI Non-linear Probability
Water/soil	Biodegradation	0.041	probability	TOPKAT v6.1

For estimating degradation in water, soil and sediment, a QSAR weight-of-evidence approach (ESD, 2006a) was applied using the models shown in Table 3. Based on these results shown in the table, the estimated timeframes for biodegradation indicate that Pigment Orange 38 can be considered as persistent in water and soil. This substance is not expected to hydrolyse.

To extrapolate to a half-life in sediments, an approach has been developed using Boethling's extrapolation factors (BIOWIN v4.02, which involves extrapolating the half life in sediment from that estimated for water ($t_{1/2\ water} : t_{1/2\ sediment} = 1:4$). Therefore, in sediments, the half-life for Pigment Orange 38 is expected to exceed 728 days.

The long-range transport potential (LRTP) of this pigment from its point of release to air is estimated to be low according to the model prediction presented in Table 4. The TaPL3 model was used to estimate Characteristic Travel Distance (CTD), defined as the maximum distance traveled by 63% of a substance; or in other words, the distance that 37% of the substance may travel beyond. Beyer et al (2000) have proposed CTD's of >2000 km as representing high LRTP, 700-2000 km as moderate, and <700 km as low. Based on the result shown in Table 4, Pigment Orange 38 is expected to remain primarily in the areas close to its emission sources.

Table 4. Model Predicted Characteristic Travel Distance (CTD) for Pigment Orange 38

Characteristic Travel Distance	Model (Reference)
116 km	TaPL3 (CEMC, 2003)

The modelled data (Table 3) demonstrate that Pigment Orange 38 meets the persistence criteria (half-life in soil and water ≥ 182 days, in sediments ≥365 days) as set out in the Persistence and Bioaccumulation Regulations (Government of Canada 2000).

Potential for bioaccumulation

There is no empirical bioaccumulation data available for this substance. The modelled log K_{ow} value for Pigment Orange 38 indicates that this substance has the potential to bioaccumulate in the environment.

The Modified GOBAS BAF middle trophic level model produced BAF values from 269153 L/kg wet weight, indicating that this substance has the potential to bioconcentrate and biomagnify in the environment. The GOBAS BCF and BCF OASIS models also provide a weight-of-evidence to support the bioconcentration potential of the substance.

Table 5. Modelled bioaccumulation data

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	269153 L/kg	Gobas BAF T2MTL (Arnot & Gobas, 2003)
Fish	BCF	21380 L/Kg	Gobas BCF T2LTL (Arnot & Gobas, 2003)
Fish	BCF	51286 L/kg	OASIS, 2005
Fish	BCF	10 L/kg*	BCFWIN v2.15

* Default value for non-ionisable azo pigments.

The modelled bioaccumulation values do not take into account the metabolism potential of the substance. Studies on other structurally similar Naphthol AS pigments demonstrated negligible metabolism of these pigments (Danish EPA, 1998).

The weight of evidence indicates that Pigment Orange 38 meets the bioaccumulation criterion (BCF, BAF ≥ 5000) as set out in the Persistence and Bioaccumulation Regulations (Government of Canada 2000).

Ecological Effects

In the Aquatic Compartment

There is no empirical ecotoxicity data available for this substance. The models suggest that this substance causes harm to aquatic organisms at relatively low concentrations (e.g., acute LC50 < 1 mg/L).

Table 6. Modeled aquatic toxicity values for Pigment Orange 38

Organism	Endpoint	Duration	Concentration (mg/L)	Reference
Fish	LC50	96 h	0.189667	ASTER, 1993
Fish	LC50	96 h	6.23732	AI Expert, 2005
Fish	LC50	96 h	0.341	ECOSAR v.0.99h
Fish	LC50	14 d	0.003369405	ECOSAR v.0.99h
Green Algae	EC50	96 h	0.11	ECOSAR v.0.99h

A range of aquatic toxicity predictions were obtained from the various QSAR models considered. Table 6 lists those predictions that were considered reliable and were used in the QSAR weight-of-evidence approach for aquatic toxicity (ESD, 2006a). These results indicate that Pigment Orange 38 is highly hazardous to aquatic organisms (i.e. acute LC/EC50 $\leq$ 1.0 mg/L).

In Other Media

No effects studies for non-aquatic non-mammalian organisms were found for this compound.

Potential to Cause Ecological Harm

Evidence that a substance is highly persistent and bioaccumulative as defined in the Persistence and Bioaccumulation Regulations of CEPA 1999 (Government of Canada, 2000) together with evidence of commercial activity provides a significant indication of its potential to be entering the environment under conditions that may have harmful long term ecological effects (ESD, 2006b). Substances that are persistent remain in the environment for a long time, increasing the potential magnitude and duration of exposure. Substances that have long half-lives in mobile media (air and water) and partition into these media in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially for top predators. Evidence that a substance is both highly persistent and bioaccumulative, when taken together with other information (such as evidence of toxicity at relatively low concentrations, and evidence of uses and releases) may therefore be sufficient to indicate that the substance has the potential to cause ecological harm.

The volume of Pigment Orange 38 imported into Canada is in of the range of 1 tonne per year. The quantities of the pigment contained in imported printing and painted materials, coloured plastics, etc. are not available. The dispersive use of the pigment indicates potential for releases into the Canadian environment. Once released in the environment, because of its resistance to degradation, Pigment Orange 38 will remain in water, sediment and soil for long times. As it persists in the environment, it will likely

bioaccumulate and may be biomagnified in trophic food chains. It has also demonstrated relatively high toxicity. This information suggests that Pigment Orange 38 has the potential to cause ecological harm in Canada.

Uncertainties

The uncertainties exist in the conclusions reached in this document because all P, B, iT evaluations are based on model data. There were no empirical studies available relating to the persistence, bioaccumulation and toxicity of the pigment. The information on environmental concentration or monitoring data in Canada and long term low level exposure of Pigment Orange 38 is also lacking.

The experimental or predicted concentrations, associated with inherent toxicity for aquatic organisms, may have an additional source of uncertainty in some situations, e.g. where these concentrations exceed the solubility of the chemical in water (either experimental or predicted). Given that concentrations for both the toxicity and water solubility often vary considerably (up to several orders of magnitude), it is acknowledged that these uncertainties exist.

Regarding toxicity, based on the predicted partitioning behaviour of the substance, the significance of soil and sediments as important media of exposure is not well addressed by the effects data available. Indeed, the only effects data identified apply primarily to pelagic aquatic exposures, although the water column may not be the medium of primary concern based on partitioning estimates.

There is also uncertainty associated with basing the overall conclusion that Pigment Orange 38 may be causing ecological harm, solely on information relating to its persistence, bioaccumulation, relative toxicity and use pattern. Typically quantitative risk estimates (i.e., risk quotients or probabilistic analyses) are important lines of evidence when evaluating a substance's potential to cause environmental harm. However, when risks for persistent and bioaccumulative substances such as this pigment are estimated using such quantitative methods, they are highly uncertain and are likely to be underestimated (ESD, 2006b). Given that long term risks associated with persistent and bioaccumulative substances cannot at present be reliably predicted, quantitative risk estimates have limited relevance. Furthermore, since accumulations of such substances may be widespread and are difficult to reverse, a conservative response to uncertainty (that avoids underestimation of risks) is justified.

References

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