Substance Profile for The Challenge

2-Naphthalenecarboxamide, *N*-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy-
(Pigment Red 5)
CAS RN 6410-41-9

Environment Canada
Health Canada

August 2007

Introduction

The *Canadian Environmental Protection Act, 1999* [CEPA 1999] (Canada 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, or of commercial interest, 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, genotoxicity, 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 conclude whether these substances meet 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 (Environment Canada and Health Canada 2006) to submit, within the timelines stated in the Challenge section of this document, specific information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

The substance 2-Naphthalenecarboxamide, *N*-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy- 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 of commercial interest in Canada. The technical human health and ecological information, that formed the basis for concern associated with this substance, is presented in this document.

The Challenge

Respecting direction under section 76.1 of CEPA 1999, and in the absence of additional relevant information as a result of this Challenge, the Ministers are predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic under section 64 of CEPA 1999. As such, the Ministers are prepared to then recommend to the Governor in Council that this substance be added to the List of Toxic Substances in Schedule 1 of CEPA 1999, with the intent of initiating the development of risk management measures taking into account socio-economic considerations.

If it is determined that the substance meets the virtual elimination criteria in subsection 77(4) of CEPA 1999, then subsequent risk management activities will be based on the objective of eliminating the release of any measurable quantity of the substance to the environment. In the absence of further information on existing management practices for a substance, actions will be proposed based on the assumption of worst-case practices. The management actions being considered for such substances at this time include prohibition 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* (Canada 2002) and/or the *Food and Drugs Act* (Canada 1985).

Exceptionally, should no information be identified to indicate that this substance is in commerce in Canada, the Ministers will conclude, based on a screening assessment, that this substance does not satisfy the definition of toxic under section 64 of CEPA 1999. However, given the properties of this substance, there is concern that new activities for the substance that have 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 would be recommended that this 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 that ecological and human health risk assessments are conducted as specified in section 83 of the Act prior to the substance being introduced into Canada.

Section 71 Notice

Under the Challenge, information deemed necessary for improved decision making may be gathered by the Minister of Environment using section 71 of CEPA 1999. This information may be used for the purpose of assessing whether a substance is toxic or is capable of becoming toxic as defined under section 64 of CEPA 1999, or for the purpose of assessing whether to control, or the manner in which to control a substance.

The information mandated through the notices may relate to, among other things; quantity of the substance imported, manufactured, used, or released, concentrations, suppliers, customers, as well as types of uses of the substance.

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

Opportunity to Submit Additional Information to Inform Screening Assessment

The Ministers of Health and Environment are inviting the submission of additional information for consideration during screening assessment of this substance. Data of the types described in the following paragraphs are considered most relevant, although other submitted information will be considered.

Data on the persistence, bioaccumulation, and potential for toxicity of the substance to organisms in different environmental media – Through the categorization exercise, available experimental data were collected up 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 experimental data are preferred, interested parties have an opportunity to provide new or additional relevant experimental study information on the persistence, bioaccumulation, and potential for toxicity of this substance to organisms in different environmental media (air, water, sediment, soil), or on the physical/chemical properties values that were used as input to the QSAR models. Efforts should focus on providing data for the endpoints for which good quality experimental data do not already exist, as demonstrated by the information summarized in the "Ecological Information" or "Physical/Chemical Properties" sections 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" (Government of Canada 2006).

Data on the toxicity of the substance to human health – Through the categorization exercise, the high health priorities for action were those substances identified by a Simple Hazard tool, which identified a potential high health hazard on the basis of classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity. The hazard classifications used were those developed by national or international agencies in which large numbers of substances have been classified for endpoint-specific hazard based on original review and critical evaluation of data, assessments of weight of evidence and extensive peer review. Interested parties have an opportunity to provide new or additional relevant experimental study information on the toxicity of the substance to human health which could inform the screening assessment.

Information submitted in response to the section 71 Notice or as additional information on current uses and existing control measures (see following section) will also be considered when characterizing exposure potential.

Responses to this part of the Challenge for this substance should be received at the address provided below by the date indicated on the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca).

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 website (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 the date indicated on the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca).

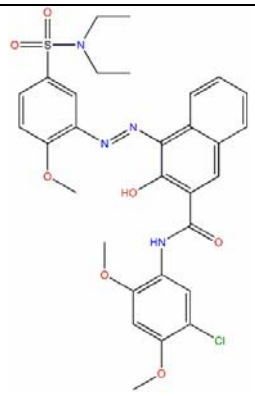
Request for Documents and Submission of Information

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

Substance Identity

For the purpose of this document, this substance will be referred to as Pigment Red 5.

Chemical AbstractsService Registry Number (CAS RN)	6410-41-9
Inventory names	*2-Naphthalenecarboxamide, N-(5-chloro-2,4-dimethoxyphenyl)-4-[[5-[(diethylamino)sulfonyl]-2-methoxyphenyl]azo]-3-hydroxy-* *N-(5-Chloro-2,4-diméthoxyphenyldiméthoxyphenyl)-4-[[5-[(diéthylamino)sulfonyl]-2-méthoxyphenyl]azo]-3-hydroxynaphtalène-2-carboxamide* *Pigment Red 5* *C.I. pigment red 005* *2-Naphthalenecarboxamide, 4-[(2,5-dichlorophenyl)azo]-3-hydroxy-N-(2-methoxyphenyl)-* *C.I. PIGMENT RED 5* *C.I. PIGMENT RED 9*
Other names	*C.I. 12490; C.I. Pigment Red 5; Carmine BST; Carmine Red FB; Chromatex Carmine B; Fast Carmine B; Fast Red Slurry; Fenalac Carmine FB; Fuji Fast Red 7R3300; Graphtol Red FBL; Hostaperm Carmine FB; Irgalite Carmine FB; Irgalite Carmine FBX; Isol Aryl Carmine B; Lake Carmine B; Marcy Red X 2640; Microsol Carmine FBSX; Monlite Fast Carmine BD; Monolite Fast Carmine B; Monolite Fast Carmine BV; Monolite Fast Carmine BVSA; Monolite Red CB; Naftol Red RN 1569; Naphthol Red Deep 10460; PC Carmine B; Permanent Carmine; Permanent Carmine FB; Permanent Carmine FB 01; Permanent Carmine FR; Permanent Red ITR; Pigment Carmine B; Pigment Carmine FFY; Pigment Pink Zh; Pigment Pink ZhTP; Pigment Rose Zh; PV-Carmine B; Sanyo Brilliant Carmine FB Pure CONC; Segnale Light Red FB; Sumitone Carmine B; Symuler Fast Red 4081; Symuler Fast Red 4188N; Symuler Fast Red 4202; Tinofil Red 3BL*
Chemical group	Discrete organics
Chemical sub-group	Monoazo Organic Color Pigments (Naphthol AS pigments III)
Chemical formula	$C_{30}H_{31}ClN_4O_7S$
Chemical structure	

SMILES	O=C(Nc(c(OC)cc(OC)c1Cl)c1)c(c(O)c(N=Nc(c(OC)ccc2S(=O)(=O)N(CC)CC)c2)c(c3ccc4)c4)c3
Molecular mass	627.12 g/mol

Physical/Chemical Properties

Table 1 contains experimental and modelled physical-chemical properties of Pigment Red 5 which are relevant to its environmental fate.

Table 1. Physical and chemical properties for Pigment Red 5

Property	Type	Value	Temperature (C°)	Reference
Boiling point (ºC)	Modelled	827.9		MPBPWIN v1.41
Melting point (ºC)	Modelled	349.8		MPBPWIN v1.41
Vapour pressure (Pa)	Modelled	3.45×10^{-20}	25	MPBPWIN v1.41
Henry's Law constant ($Pa \cdot m^3/mol$)	Modelled	4.42×10^{-16} (4.36×10^{-21} atm-m^3/mole)	25	HenryWin v1.90
Log Kow (Octanol-water partition coefficient) (dimensionless)	Modelled	7.65	25	KOWWIN v.1.67
Water solubility (mg/L)	Modelled	4.38×10^{-5}	25	WSKOWWIN v1.41
Log Koc (Organic carbon-water partition coefficient) (dimensionless)	Modelled	6.13	25	PCKOCWIN v1.66

Sources and Uses

Information from DSL Nomination (1984-1986)

Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 1200 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-86 was 5.

Use Codes and Description

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

13 - Colourant- pigment/stain/dye/ink
76 - Organic Chemicals, Industrial
84 - Photographic/Photocopier
85 - Pigment, Dye and Printing Ink
94 - Textile, Primary Manufacture

Recent Manufacture and Importation Information

Recent information was collected through an industry survey conducted for the year 2005 under a Canada Gazette Notice issued pursuant to section 71 of CEPA 1999 (Environment Canada 2006a). This Notice requested data on the Canadian manufacture and import of the substance.

No reports of manufacture in or import into Canada of this substance at or above the reporting threshold of 100 kg in the 2005 calendar year were received in response to a Notice published under section 71 of CEPA 1999 (Environment Canada 2006a). However, the Declaration of Non-Engagement and/or Stakeholder Interest form associated with this Notice (found at the Government of Canada's Chemicals website: www.chemicalsubstanceschimiques.gc.ca) further invited any companies to identify themselves as stakeholders if they had an interest in a listed substance. Three Canadian companies and one American Industrial Association have identified a stakeholder interest in this substance.

Human Health Information

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 persistent (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 from a human health perspective, 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 Lowest Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

Exposure Information from Health Related Components of DSL Categorization

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 Red 5 has been determined to be LPE based on a consideration of the DSL nomination information listed in the section on Sources and Uses.

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. . Those

substances identified as a potential high health hazard were based on classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity (Health Canada 2005).

Results of the Application of SimHaz

Pigment Red 5 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 that are considered to be human health 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.

Ecological Information

Data relevant to an ecological screening assessment were identified in original literature, review documents, and commercial and government databases prior to December 2005. Properties and characteristics may also have been estimated using Quantitative Structure Activity Relationship (QSAR) models.

Releases, Fate and Presence in the Environment

Releases

Since there were no reports of import or manufacture at or above the reporting threshold of 100 kg in 2005 in response to a s.71 Notice (Environment Canada 2006a), releases of this substance to the Canadian environment are presumed to be very low.

Fate

The high log K_{ow} and K_{oc} values indicate (Table 1) that Pigment Red 5 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 v 3.12)

	Fraction of Substance Partitioning to Each Medium (%)			
Substance Released to:	**Air**	**Water**	**Soil**	**Sediment**
- Air (100%)	0.03	0.19	85.2	14.6
- Water (100%)	0.00	1.28	0.00	98.7
- Soil (100%)	0.00	0.00	99.8	0.19
- Air, water, soil (33% each)	0.01	0.66	48.50	50.9

If the substance is released solely to air, an estimated vapour pressure of 3.45×10^{-20} Pa and Henry's Law constant of 4.42×10^{-16} Pa-m^3/mole indicate that 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 (< 1 %) due to the substance's low estimated water solubility.

If released to soil, Pigment Red 5 is expected to have extremely high adsorptivity to soil (i.e. expected to be immobile) based upon estimated log K_{oc} of ~ 6. Volatilization from dry or moist soil surfaces seems to be an unimportant fate process based upon the very low estimated Henry's Law constant and vapour pressure. Therefore, if released to soil, Pigment Red 5 will mainly remain in this environmental compartment, which can be illustrated by the results of the Level III fugacity modelling (Table 2).

If released into water, Pigment Red 5 is expected to strongly adsorb to suspended solids and sediment based upon an extremely high value of estimated log K_{oc} (Table 1). Volatilization from water surfaces is expected to be an unimportant fate process based upon this compound's 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, remain in water (Table 2).

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

The Level III Fugacity model indicates negligible partitioning of the substance in air (Table 2). Accordingly, 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 3a. 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 3, Pigment Red 5 is expected to remain primarily in the areas close to its emission sources.

Table 3a. Model Predicted Characteristic Travel Distance (CTD) for Pigment Red 5

Characteristic Travel Distance	Model (Reference)
475 km	TaPL3 (CEMC 2000)

Once released into the environment, Pigment Red 5 appears to be relatively persistent in water, soil and sediments. Since no experimental data on biological degradation of Pigment Red 5 are available, a QSAR-based weight-of-evidence approach (Environment Canada 2007) was applied using the biodegradation models shown in Table 3b. Based on these results, the estimated timeframe and probability for biodegradation indicates that Pigment Red 5 can be considered as persistent in water.

Table 3b. Modelled data for persistence

Medium	Fate Process	Degradation Value	Degradation Endpoint	Reference
Water	Biodegradation	half-life (days)	> 182	BIOWIN v4.02 (Ultimate Survey model)
Water	Biodegradation	Probability	0	BIOWIN v4.02 (MITI non-linear)

To extrapolate half-life in water to half-lives in soils and sediments, Boethling's extrapolation factors $t_{1/2\ water} : t_{1/2\ soil} : t_{1/2\ sediment} = 1: 1: 4$ (Boethling *et al*. 1995) can be used. Using these factors and the biodegradation model results, it may be concluded that Pigment Red 5 is expected to be persistent in soil and sediments.

The modelled data (Table 3b) demonstrate that Pigment Red 5 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 are no empirical bioaccumulation data available for this substance. The modelled log K_{ow} value for Pigment Red 5 indicates that this substance has the potential to bioaccumulate in the environment.

The Modified GOBAS BAF middle trophic level model produced a BAF value of 3854800 L/kg wet weight, indicating that this substance has the potential to bioaccumulate 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 4. Modelled bioaccumulation data

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	3854800 L/kg	Gobas BAF T2MTL (Arnot & Gobas 2003)
Fish	BCF	16982 L/Kg	Gobas BCF T2LTL (Arnot & Gobas 2003)
Fish	BCF	22751 L/kg	OASIS Forecast v1.20
Fish	BCF	10 L/kg*	BCFWIN v2.15

* Default value for non-ionisable azo pigments.
BCF=bioconcentration factor; BAF=bioaccumulation factor.

The modelled BAF and BCF 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 Red 5 meets the bioaccumulation criterion (BCF, BAF ≥ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

Ecological Effects

A - In the Aquatic Compartment

There is no empirical ecotoxicity data available for this substance.

Table 5. Modelled aquatic toxicity values for Pigment Red 5

Organism	Endpoint	Duration	Concentration (mg/L)	Reference
Fish	LC50	14 d (acute)	0.01	ECOSAR v.0.99h

LC50 – Lethal concentration affecting 50% of the test population

A range of aquatic toxicity predictions were obtained from the various QSAR models considered. Table 5 provides the prediction that was considered reliable and was used in the QSAR weight-of-evidence approach for aquatic toxicity (Environment Canada 2006a). This result indicates that Pigment Red 5 is highly hazardous to aquatic organisms (i.e. acute LC/EC50 ≤ 1.0 mg/L).

B - In Other Media

No effects studies for non-aquatic non-human 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), when taken together with potential for environmental release or formation and potential for toxicity to organisms, provides a significant indication of its potential to be entering the environment under conditions that may have harmful long term ecological effects (Environment Canada 2006b). Substances that are persistent remain in the environment for a long time after being released, 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 information collected to date suggests that Pigment Red 5 has the potential to cause ecological harm if it were to be released in the Canadian environment. Once released into the environment, because of its resistance to degradation, it could remain in water, sediment, and/or soil for a long time. As it persists in the environment, and because of its lipophilic character, it could bioaccumulate and possibly be biomagnified in trophic food chains. It has also demonstrated relatively high toxicity to aquatic organisms. However, the lack of importation or manufacture of Pigment Red 5 in Canada at significant volumes suggests very low releases of this chemical into the Canadian environment.

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 Red 5 is also lacking.

Experimental data for ecotoxicity/degradation/bioaccumulation were not identified during categorization activities, and QSAR's were used to estimate them. There are uncertainties associated with the use of QSAR models to estimate these characteristics. Additionally, values for some key physical/chemical properties (Kow, water solubility, Henry's Law constant), which are used as input to the QSAR models, have also had to be estimated.

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 are often uncertain, toxicity values that exceed solubility estimates by up to a factor of 1000 were accepted during categorization.

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 Red 5 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 (Environment Canada 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.

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