Substance Profile for The Challenge

1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol
(Pigment Red 4)
CAS RN 2814-77-9

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 1-[(2-chloro-4-nitrophenyl)azo]-2-naphthalenol 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 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).

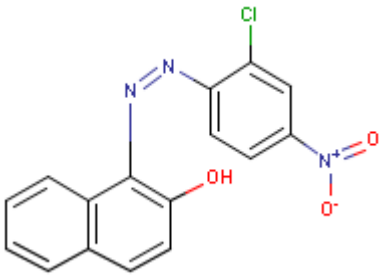
Request for Documents and Submission of Information

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 purposes of this report, this substance will be referred to as Pigment Red 4.

Chemical Abstract Service Registry Number (CAS RN)	2814-77-9
Inventory names	*2-Naphthalenol, 1-[(2-chloro-4-nitrophenyl)azo]-* *1-(2-Chloro-4-nitrophénylazo)napht-2-ol* *1-[(2-chloro-4-nitrophenyl)azo]-2-naphthol* *Pigment Red 4; C.I. pigment red 004*
Other names	*1-(o-Chloro-p-nitrophenylazo)-2-naphthol ; 12094 Red ; 2-Naphthol, 1-(2-chloro-4-nitrophenylazo)- ; C-Red 1 ; 1-(o-Chloro-p-nitrophenylazo)-2-naphthol; 12094 Red; 2-Naphthol, 1-(2-chloro-4-nitrophenylazo)-; ADC Permanent Red Toner R; American Vermilion; Blazing Red; C-Red 1; C.I. 12085; Calcotone Red PR Carnelio Red R; Chlorparanitraniline Red; D and C Red No. 36; D&C Red 36 ; Dainichi Permanent Red RX ; Duplex Permaton Red L 20-7022; Fast Orange 3R; Fast Orange 3RJ; Fast Red R; Fastona Red R; Fire Red Toner; Flame Tones; Flaming Red; Glo-blaze Red R 152; Graphtol Red RL; Hansa Red R; Irgalite Red PRR; Isol Fast Red R; Isol Fast Red RG; Japan Red 228; Kromon Red Rl; Latexol Red J ; Lincoln Red 1002; Lutetia Fast Orange 3R; Monolite Fast Red G; Monolite Fast Red GA; Monolite Fast Red GF; No. 1 Forthfast Red R; Oralith Red; Permanent Red 2B; Permanent Red BFR; Permanent Red F; Permanent Red R; Permanent Red R Extra; Permanent Red RG Extra; Permanent Red Toner R; Permansa Red; Permaton Red; Permaton Red XL 20-7015; Pigment Scarlet Zh; Pyrotone Red Toner RA 5520; Red Extract R; Red No. 228; Rubber Red R Extra; Segnale Light Red PRG; Silopol Red G; Silosol Red GN ; Siloton Red 2G; Syton Fast Red R; Tanager Red X 761; Tiger Orange; Versal Fast Red R; Versal Red R ; Vulcafix Red J; Vulcafor Orange R; Vulcan Red R*
Chemical group	Discrete organic
Chemical sub-group	Azo compounds; naphthalenes
Chemical formula	$C_{16}H_{10}ClN_3O_3$
Chemical structure	
SMILES	N(=O)(=O)c(ccc(N=Nc(c(c(ccc1)cc2)c1)c2O)c3Cl)c3
Molecular mass	327.73 g/mol

Physical and Chemical Properties

Table 1 contains modelled physical-chemical properties of Pigment Red 4 which are relevant to its environmental fate. Experimental data were not available.

Table 1. Physical and chemical properties for Pigment Red 4.

Property	Type	Value	Temperature (°C)	Reference
Boiling Point (°C)	Modelled	480.77		MPBPWIN v1.41
Melting Point (°C)	Modelled	203.61		MPBPWIN v1.41
Log Kow (Octanol-water partition coefficient) (dimensionless)	Modelled	6.55	25	Kowwin v.1.67
Log Koc (Organic carbon-water partition coefficient) (dimensionless)	Modelled	4.38		PCKOCWIN v1.66
Vapour Pressure (Pa)	Modelled	2.066×10^{-8}	25	MPBPWIN v1.41
Henry's Law Constant ($Pa\text{-}m^3/mol$)	Modelled	4.42×10^{-8} , 9.42×10^{-8} ($4.367 \times 10\text{-}^{13}$ $atm\text{-}m^3/mol$, 9.299×10^{-13} $atm\text{-}m^3/mol$)	25	HenryWin v1.90
Water Solubility (mg/L)	Modelled	0.03039	25	WSKOWWIN v1.41

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 3200 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:

04 - Adhesive/binder/sealant/filler
13 - Colourant- pigment/stain/dye/ink
21 - Formulation Component
34 - Polymer additive
56 - Automotive, Aircraft and Watercraft
60 - Cosmetics

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 manufacture and import of the substance.

Under the CEPA section 71 Notice with respect to Selected Substances identified as Priority for Action (Environment Canada 2006a), Canadian companies who manufactured or imported (in 2005) greater than 100 kg of a substance listed in the Notice were required to provide specific data regarding the substance to Environment Canada. Information gathered from this survey notice indicate that Pigment Red 4 was not manufactured in Canada in 2005 in a quantity greater than the 100 kg reporting threshold.

In total, 1 company reported import of this substance in the 100-1,000 kg/yr range. In addition, 6 Canadian companies and 1 American Industrial Association identified themselves as having a stakeholder interest in the substance.

Elsewhere, the use of Pigment Red 4 has been reported in the United States under the Inventory Update Rule to be between 4.5 to 225 tonnes per year from 1986 to 1998. It

was not reported under the Inventory Update Rule in 2002. It is a European Union (EU) Low Production Volume Chemical, indicating that production within the EU has been estimated to be in the order of 10 tonnes per year. The database for Substances in Preparations in Nordic Countries indicates that in 2004, approximately 0.8 tonnes were used in Denmark and 2 tonnes were used in Sweden (SPIN 2007).

Known Uses in Canada

Information on use of this substance that was received through the survey conducted under section 71 of CEPA, 1999 (Environment Canada 2006a) has been identified as confidential business information. However, one of the companies that identified a stakeholder interest reported that they imported Pigment Red 4 and identified its business activity as Basic Chemical Manufacturing.

Potential Uses in Canada

The additional information below on potential uses of Pigment Red 4 was identified through searches of the available scientific and technical literature.

Elsewhere, Pigment Red 4 may be used as a color additive in drugs and cosmetics in the European Union and the U.S. (European Commission 2000 and Colorcon 2000). Reported use categories in Sweden and Denmark include colouring agents, paints, laquers and varnishes used in the manufacture of structural metal products (SPIN 2007).

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 4 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 4 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

Pigment Red 4 is not naturally produced in the environment. Releases from anthropogenic sources have not been reported. Given the dispersive type of uses of this chemical, it could potentially be released to the environment.

Fate

The high log Kow and Koc values (Table 1) indicate that this substance will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicate that if the chemical is released equally into the three major environmental compartments (air, water and soil), it will mainly partition into soil and sediments (Table 2) where the chemical has been indicated to persist.

Table 2. Results of the Level III fugacity modelling (EPIWIN v3.12)

	Fraction of Substance Partitioning to Each Medium (%)			
Substance Released to:	**Air**	**Water**	**Soil**	**Sediment**
Air (100%)	0	0.54	80.80	18.70
Water (100%)	0	2.80	0	97.20
Soil (100%)	0	0	99.90	0.09
Air, Water, Soil (33.3% each)	0	1.55	44.70	53.70

The very low estimated vapour pressure and Henry's Law Constant (Table 1) indicate that Pigment Red 4 is not volatile. Therefore, even if released to air, it will quickly sorb to particulate matter and partition to soil and sediment as indicated by the results of Level III fugacity modelling (99%) (Table 2).

Similarly, the very low estimatedwater solubility of 0.03 mg/L (Table 1) indicates that if released to water, Pigment Red 4 will not remain predominantly in the aqueous phase. Again, it will sorb to particulate matter and settle out to sediment (97%).

Pigment Red 4 is expected to have high adsorptivity to soil (i.e. expected to be immobile) based on an estimated log Koc of 4.38 (Table 1). The very low estimated vapour pressure and Henry's Law Constant (Table 1) indicate that volatilization will not occur from soil

surfaces, and the low water solubility indicates that Pigment Red 4 will not be mobilized from the soil phase. Therefore, if released to soil, Pigment Red 4 will remain in this compartment, which can be illustrated by the results of the Level III fugacity modelling (Table 2).

Therefore, if Pigment Red 4 is released to the environment, soil and sediment are expected to be the major media of concern, as illustrated by the results of fugacity modelling (Table 2).

Presence in the Environment

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

Evaluation of P, B and iT Properties

Environmental Persistence

Pigment Red 4 was determined to meet the persistence criteria as a result of a category approach developed for azo pigments. It has been recognized by industries manufacturing pigments and dyes that their substances are persistent as they are designed to be used to colour durable items. Also, Environment Canada gathered solid experimental evidence to the effect that azo compounds are not degradable through chemical, photochemical and biochemical processes in oxic conditions (Environment Canada 2005). Using this approach, it was determined that Pigment Red 4 would have a half life in water and soil exceeding 182 days.

To extrapolate to a half-life in sediments, an approach has been developed using Boethling's extrapolation factors, which involves extrapolating the half life in sediment from that estimated for water ($t_{1/2\ water} : t_{1/2\ sediment} = 1:4$)(Boethling et al. 1995). Therefore, based on a water half-life of greater than 182 days, the half-life in sediments is expected to exceed the 365-day criteria for persistence in sediments as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

The long-range transport potential (LRTP) of Pigment Red 4 from its point of release to air is estimated to be low according to the model prediction presented in Table 3. The TaPL3 model was used to estimate Characteristic Travel Distance (CTD), defined as the maximum distance traveled by 63% of the substance; or in other words, the distance that 37% of the substance may travel beyond. Beyer et al (2000) have proposed CTDs 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, this substance is expected to remain primarily in the areas close to its emission sources.

Table 3. – Model Predicted Characteristic Travel Distance (CTD) for Pigment Red 4

Characteristic Travel Distance	Model (Reference)
328 km	TaPL3 v2.10 (CEMC 2000)

Experimental data on the persistence of azo pigments demonstrate that Pigment Red 4 meets the persistence criteria (half-lives in water and soil ≥ 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 Pigment Red 4. The high modelled log Kow value of 6.55 (Table 1) indicates that this chemical has the potential to bioaccumulate in biota.

The Modified Gobas BAF middle trophic level model for fish produced a Bioaccumulation Factor (BAF) of approximately 1,800,000 L/kg (Table 4), indicating that Pigment Red 4 is expected to bioaccumulate in aquatic organisms. Two BCF models (Gobas BCF and OASIS) provide a weight-of evidence to support the high bioconcentration potential of this substance. Metabolism information for this substance was not available, nor was it considered in the BAF models.

Table 4. Modelled data for bioaccumulation

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	1,760,933 L/kg	Gobas BAF T2MTL (Arnot and Gobas 2003)
Fish	BCF	40,484 L/kg	Gobas BCF T2LTL (Arnot and Gobas 2003)
Fish	BCF	66,815 L/kg	OASIS Forecast v1.20
Fish	BCF	10 L/kg*	BCFWIN v2.15

*Default value for aromatic azo pigments recommended by BCFWIN

Therefore, the weight of evidence indicates that the substance meets the bioaccumulation criteria (BCF, BAF ≥5000) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

Ecological Effects

A - In the Aquatic Compartment

There are no empirical acute fish toxicity data available for this substance.

There is modelled evidence (Table 5) that the substance is expected to cause harm to aquatic organisms at relatively low concentrations (e.g. acute LC50≤1mg/L). A range of aquatic toxicity predictions were obtained from the various QSAR models considered.

Table 5 lists those predictions that were considered reliable and were used in the QSAR weight-of-evidence approach for aquatic toxicity (Environment Canada 2007). Since most of the modelled acute ecotoxicity values are well below 1 mg/L, it is expected that the substance is highly hazardous to aquatic organisms.

Table 5. Modelled data for aquatic toxicity

Test Organism	Type of Test	Endpoint	Value (mg/L)	Reference
Fish	Acute	LC50	0.076	ECOSAR v0.99h (Phenols)
Fish	Acute	LC50	0.066429	ASTER
Fish	Acute	LC50	3.037	Artificial Intelligence Expert System v1.25
Fish	Acute	LC50	0.048	ECOSAR v0.99h (Neutral Organic SAR)

LC50 – Lethal concentration affecting 50% of the test population

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.

If released in the environment, Pigment Red 4 will mainly partition to sediment and soil where it is also found to persist. As it persists in the environment, it will likely bioaccumulate and may biomagnify in the trophic food chain. Given its relatively high toxicity, it may affect the survival and reproduction of aquatic, benthic and terrestrial organisms. Given its persistence, bioaccumulation and inherent toxicity, it is considered that releases could lead to environmental exposures or accumulation in organisms to levels that may be of concern.

Uncertainties

Information on concentrations of Pigment Red 4 in the Canadian environment is currently lacking. Yet, the evidence of commercial activity indicates that there is potential for release to the Canadian environment.

Although experimental data were not available for Pigment Red 4, there is strong evidence suggesting that it is persistent as empirical studies indicate that azo compounds are not degradable through chemical, photochemical and biochemical processes in oxic conditions. There is also uncertainty associated with the bioaccumulation potential and inherent toxicity of the substance, as experimental data was not available. Modelled evidence indicates that Pigment Red 4 has a high potential for bioaccumulation and can harm organisms at low exposure concentrations.

The effects data do not address toxicity in soil and sediments, which have been identified as the primary media of concern based on partitioning estimates. The only effects data identified apply to pelagic aquatic exposures, although the water column is not the medium of primary concern.

Experimental data for ecotoxicity and 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 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. 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.

There is also uncertainty associated with basing the overall conclusion that Pigment Red 4 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 Pigment Red 4 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.

References

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