Substance Profile for Challenge to Stakeholders

1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate
(PDDAM)
CAS RN 60352-98-9

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-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate 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).

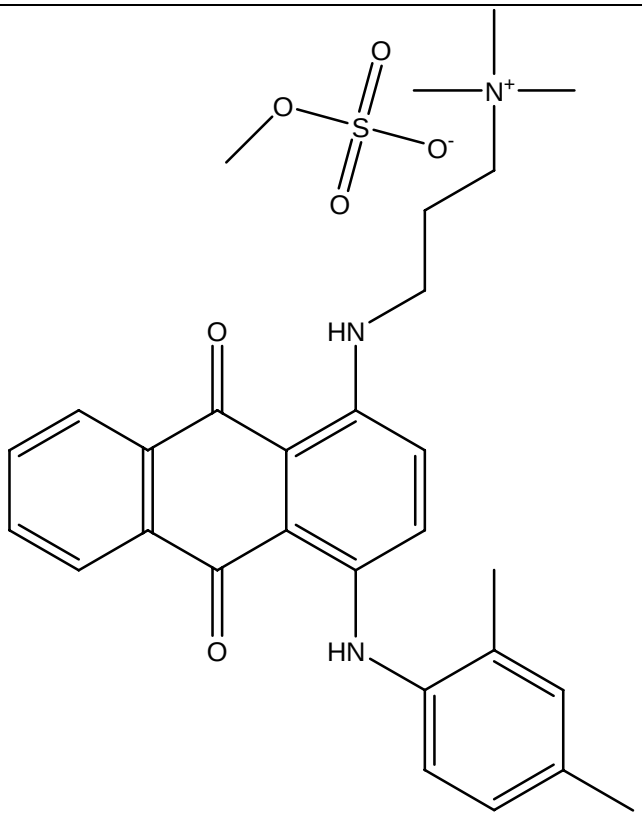
Request for Documents and Submission of Information

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 PDDAM.

Chemical Abstracts Service Registry Number (CAS RN	60352-98-9
Inventory names	*1-Propanaminium, 3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]-N,N,N-trimethyl-, methylsulfate; [3-[[4-[(2,4-dimethylphenyl)amino]-9,10-dihydro-9,10-dioxo-1-anthryl]amino]propyl]trimethylammonium methyl sulphate Sulfate de [3-[[4-[(2,4-diméthylphényl)amino]-9,10-dihydro-9,10-dioxo-1-anthryl]amino]propyl]triméthylammonium et de méthyle*
Other names	
Chemical group	Discrete organics
Chemical sub-group	Anthracenediones
Chemical formula	$C_{28}H_{32}N_3O_2.CH_3O_4S$
Chemical structure	
SMILES	Cc3ccc(c(c3)C)Nc4ccc(c2c4C(=O)c1c(cccc1)C2=O)NCCCN(OS(=O)(=O)OC)(C)(C)C
Molecular mass	442.59 g/mol

Physical/Chemical Properties

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

Table 1. Physical and chemical properties of PDDAM

Property	Type	Value	Temperature (°C)	Reference
Boiling Point (°C)	Modelled	861.53		MPBPWIN v1.41
Melting Point (°C)	Modelled	349.84		MPBPWIN v1.41
log Kow (Octanol-water partition coefficient - dimensionless)	Modelled	5.38	25	Kowwin v.1.67
log Koc (Organic carbon partition coefficient – dimensionless)	Modelled	5.50	25	PCKOCWIN v.1.66
Vapour Pressure (Pa)	Modelled	1.72×10^{-19} (1.29×10^{-21} mm Hg)	25	MPBPWIN v1.41
Henry's Law constant ($Pa \cdot m^3/mol$)	Modelled	5.98×10^{-25} (5.98×10^{-30} $atm \cdot m^3/mol$)	25	HenryWin v1.90
Water solubility (mg/L)	Modelled	6.415×10^{-4}	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 100 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-86 was fewer than 4.

Use Codes and Description

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

13 - Colourant- pigment/stain/dye/ink

Potential Uses in Canada

No other potential uses in Canada were identified through searches of the available scientific and technical literature.

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

PDDAM 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 hazard classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity (Health Canada 2005).

Results of the Application of SimHaz

PDDAM 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

PDDAM is not naturally produced in the environment. Data concerning the environmental releases in Canada are not available. According to its major applications in manufacturing colourant, pigment, stain, dye and ink, it is possible that PDDAM may be released to the environment in a widespread manner. It is assumed that the predominant release route is through use of such products, and to a lesser degree at the end of their life cycle from landfills. The extensive used of PDDAM in manufacturing colourant could lead to release through wastewater treatment plants (STPs). STP treatment and leaching from landfills may lead to soil (through land application of sewage sludge) and ground water exposures.

Fate

The moderate estimated log K_{ow} and very high log K_{oc} values (Table 1) indicate this substance will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicates that if PDDAM is released equally to the three major environmental compartments (air, water, and soil), it will partition in water, sediments, and soil, with the latter one being the predominant compartment (Table 2).

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

Receiving media	% in Air	% in Water	% in Soil	% in Sediment
Air (100%)	0.00	1.82	97.20	0.97
Water (100%)	0.00	65.10	0.00	34.90
Soil (100%)	0.00	0.10	99.80	0.05
Air, water, soil (33.3% each)	0.00	8.16	87.50	4.37

The very high estimated log K_{oc} value of 5.50 and very low water solubility (Table 1) indicates that if released into water, this chemical is expected to strongly adsorb to suspended solids and sediments. Volatilization from water surfaces is not expected based upon an estimated Henry's Law constant of 5.98×10^{-25} $Pa.m^3/mol$ (Table 1). Thus, if water is a receiving medium, PDDAM is expected to mainly partition to sediments and remain in water, which can be illustrated by the results of Level III Fugacity modelling (Table 2).

If released to soil, PDDAM is expected to have extremely high adsorptivity to soil and, therefore, will most likely be virtually immobile based upon an estimated log K_{oc} of 5.50 (Table 1). Volatilization from moist soil surfaces seems to be an unimportant fate process based upon an extremely low Henry's Law constant of 5.98 x 10^{-25} Pa.m^3/mol (Table 1). This chemical will not volatilize from dry soil surfaces based upon estimated vapor pressure which is exceptionally low (1.72 x 10^{-19} Pa). Therefore, if soil is a receiving medium, PDDAM is expected to remain exclusively in soil as indicated by the results of Level III Fugacity modelling (Table 2).

If PDDAM is released solely to air, a vapour pressure of 1.72 x 10^{-19} Pa and Henry's Law constant of 5.98 x 10^{-25} Pa.m^3/mol indicate that the proportion that will remain in air will be negligible. The major two media where PDDAM will partition are soil and sediment (> 97 %) and a very small amount will partition into water (1.82 %) due to the substance's low water solubility.

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

No experimental persistence data have yet been identified for PDDAM.

The Level III Fugacity model indicates negligible partitioning of the substance into air. Accordingly, the long-range transport potential (LRTP) of PDDAM 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 3a, PDDAM is expected to remain primarily in areas close to its emission sources.

Table 3a. Model Predicted Characteristic Travel Distance (CTD) for PDDAM

Characteristic Travel Distance	Model (Reference)
70 km	TaPL3 (CEMC, 2000)

Once released into the environment, PDDAM appears to be persistent in water, soil and sediments. Since no experimental data on biological degradation of PDDAM 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 PDDAM can be considered as persistent in water.

Table 3b. Modelled persistence data for PDDAM

Medium	Fate Process	Degradation Value	Degradation Endpoint	Reference
Water	Biodegradation	182	Half-life (days)	BIOWIN v4.02 , Ultimate survey
Water	Biodegradation	0	Probability	BIOWIN v4.02, MITI Non-linear Probability;

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 PDDAM is expected to be persistent in soil and sediments.

The modelled data (Tables 3b) demonstrate that the PDDAM meets the persistence criteria (half-lives in soil and water greater or equal to 182 days and/or half-lives in sediment greater or equal to 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000; Environment Canada, 2003).

Potential for bioaccumulation

There are no empirical bioaccumulation data available for this substance. The modelled log K_{ow} value for PDDAM 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 66216 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. A very low BCF value of 5.62 (Table 4) is the BCFWIN's default value for the substances which are salts, i.e. this result is not a model-generated bioconcentration factor calculated specifically for PDDAM.

Table 4. Modelled bioaccumulation data for PDDAM

Test Organism	Endpoint	Value wet wt	Reference
Fish	BAF	66216 L/kg	Gobas BAF T2MTL (Arnot & Gobas, 2003)
Fish	BCF	10449 L/kg	Modified Gobas BCF 5% T2LTL (Arnot & Gobas, 2003)
Fish	BCF	31333 L/kg	OASIS Forecast v1.20
Fish	BCF	5.62 L/kg	BCFWIN v2.15

BAF=Bioaccumulation factor
BCF=Bioconcentration factor

The modelled bioaccumulation values do not take into account the metabolism potential of the substance.

The weight of evidence indicates that PDDAM 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 are no empirical ecotoxicity data available for this substance. A range of aquatic toxicity predictions were obtained from the various QSAR models considered. Table 5 list those predictions that were considered reliable and were used in the QSAR weight-of-evidence approach for aquatic toxicity (Environment Canada, 2007). These results indicate a high potential for toxicity to aquatic organisms (i.e. acute LC/EC50<1.0 mg/L and chronic NOEC≤0.1 mg/L).

Table 5. Modelled aquatic toxicity values for PDDAM

Organism	Endpoint	Duration	Concentration (mg/L)	Reference
Mysid Shrimp	LC_{50}	96 h	0.15*	ECOSAR v0.99h, Neutral Org. SAR
Daphnid	EC_{50}	16 d	0.44	ECOSAR v0.99h, Neutral Org. SAR -

LC_{50} – Lethal concentration affecting 50% of the test population
EC_{50} – Effects concentration affecting 50% of the test population
* This value was used as pivotal inherent toxicity value for categorization.

B- 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 toxicity and commercial activity provides a significant indication of its potential to be entering the environment under conditions that may have harmful long term ecological effects (Environment Canada, 2006). 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.

Over 100 kg of PDDAM were imported into Canada in 1986 for use in colourant, pigment, stain, dye and/or ink. Such dispersive use of PDDAM indicates potential for widespread releases into the Canadian environment. Once released in the environment, because of its resistance to degradation, PDDAM 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 PDDAM has the potential to cause ecological harm in Canada.

Uncertainties

Uncertainties exist in the conclusions reached in this document because all P, B, iT evaluations are based on modelled data. There were no empirical studies available relating to the persistence, bioaccumulation and toxicity of PDDAM. Additionally, values for some key physical/chemical properties (Kow, water solubility, Henry's Law Constant) which are used as input into the QSAR models, have also had to be estimated. Information on environmental concentrations of PDDAM in Canada 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 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 PDDAM 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 PDDAM are estimated using such quantitative methods, they are highly uncertain and are likely to be underestimated (Environment Canada, 2006). 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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