Screening Assessment for the Challenge

Acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]-

Chemical Abstracts Service Registry Number
52697-38-8

Environment Canada
Health Canada

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Synopsis

Pursuant to section 74 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999), the Ministers of the Environment and of Health have conducted a screening assessment on acetamide, *N*-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]- (BDAP), Chemical Abstracts Service Registry Number 52697-38-8. This substance was identified as a high priority for screening assessment and included in the Challenge because it had been found to meet the ecological categorization criteria for persistence, bioaccumulation potential and inherent toxicity to non-human organisms and is believed to be in commerce in Canada.

The substance BDAP was not considered to be a high priority for assessment of potential risks to human health, based upon application of the simple exposure and hazard tools developed by Health Canada for categorization of substances on the *Domestic Substances List*. Therefore, this assessment focuses on information relevant to the evaluation of ecological risks.

BDAP is an organic substance that is used in Canada primarily as a black dye in textiles and fabrics. The substance is not naturally produced in the environment. It is not reported to be manufactured in Canada; however, between 10 000 and 100 000 kg of the dye were imported into the country in 2006 for use in the textile and fabric finishing industry.

Based on reported use patterns in Canada and certain assumptions, most of the substance ends up in solid waste disposal sites. A significant amount is however estimated to be released to sewer water (14.8%). BDAP is not expected to be soluble in water or volatile, but is expected to partition to particles because of its hydrophobic nature. For these reasons, after release to water BDAP will likely end up mostly in sediments, and possibly to a much lesser extent, in agricultural soil that has been amended with sewage sludge. It is not expected to be significantly present in other media. It is also not expected to be subject to long-range atmospheric transport.

Based on its physical and chemical properties, BDAP is expected to be persistent in the environment (in water, sediment and soil). However, new experimental data relating to the bioaccumulation potential of a relatively close structural analogue suggests that this dye has a low potential to accumulate in the lipid tissues of organisms. The substance therefore meets the persistence criteria but does not meet the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations*. In addition, experimental toxicity data for chemical analogues suggest that BDAP does not harm aquatic organisms exposed at low concentrations.

For this screening assessment, a very conservative exposure scenario was developed in which an industrial operation (i.e. the largest importer of the dye) discharges BDAP into a relatively small receiving water body at one discharge point. The predicted environmental concentration in water was below the predicted no-effect concentration

calculated for sensitive aquatic species. Additionally, since BDAP may be used in consumer products, a conservative consumer release scenario was also developed based on an estimate of the quantity of BDAP in Canadian commerce. This scenario indicated that all modelled watercourses would have predicted environmental concentrations in water below the predicted no-effect concentration for sensitive aquatic species.

This substance will be included in the upcoming *Domestic Substances List* inventory update initiative. In addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.

Based on the information available, it is concluded that BADAP does not meet any of the criteria set out in section 64 of CEPA 1999.

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that have met the categorization criteria set out in the Act to determine whether these substances present or may present a risk to the environment or human health. Based on the results of a screening assessment, the Ministers can propose to take no further action with respect to the substance, to add the substance to the Priority Substances List (PSL) for further assessment, or to recommend that the substance be added to the List of Toxic Substances in Schedule 1 of the Act and, where applicable, the implementation of virtual elimination.

Based on the information obtained through the categorization process, the Ministers identified a number of substances as high priorities for action. These include substances that

- met all of the ecological categorization criteria, including persistence (P), bioaccumulation potential (B) and inherent toxicity to aquatic organisms (iT), and were believed to be in commerce in Canada; and/or
- met the categorization criteria for greatest potential for exposure (GPE) or presented an intermediate potential for exposure (IPE), and had been identified as posing a high hazard to human health based on classifications by other national or international agencies for carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

The Ministers therefore published a notice of intent in the *Canada Gazette*, Part I, on December 9, 2006 (Canada 2006a), that challenged industry and other interested stakeholders to submit, within specified timelines, specific information that may be used to inform risk assessment, and to develop and benchmark best practices for the risk management and product stewardship of those substances identified as high priorities.

The substance acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]- (BDAP) was identified as a high priority for assessment of ecological risk as it had been found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada. The Challenge for this substance was published in the *Canada Gazette* on February 16, 2008 (Canada 2008). A substance profile was released at the same time. The substance profile presented the technical information available prior to December 2005 that formed the basis for categorization of this substance. As a result of the Challenge, submissions of information pertaining to the toxicity and uses of the substance were received.

Although BDAP was determined to be a high priority for assessment with respect to the environment, it did not meet the criteria for GPE or IPE and high hazard to human health based on classifications by other national or international agencies for carcinogenicity,

genotoxicity, developmental toxicity or reproductive toxicity. Therefore, this assessment focuses principally on information relevant to the evaluation of ecological risks.

Under CEPA 1999, screening assessments focus on information critical to determining whether a substance meets the criteria for defining a chemical as toxic as set out in section 64 of the Act, where

> "64. […] a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that
>
> (*a*) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
>
> (*b*) constitute or may constitute a danger to the environment on which life depends; or
>
> (*c*) constitute or may constitute a danger in Canada to human life or health."

Screening assessments examine scientific information and develop conclusions by incorporating a weight of evidence approach and precaution.

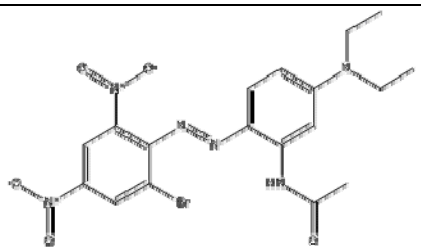
This screening assessment includes consideration of information on chemical properties, hazards, uses and exposure, including the additional information submitted under the Challenge. Data relevant to the screening assessment of this substance were identified in original literature, review and assessment documents, stakeholder research reports and from recent literature searches, up to August 2008 for exposure, effects and ecological sections of the document. Key studies were critically evaluated and generally only results from studies of good quality were used to reach conclusions, although other studies and modelling results may have been considered as part of the weight of evidence. When available and relevant, information presented in hazard assessments from other jurisdictions was considered. The screening assessment does not represent an exhaustive or critical review of all available data. Rather, it presents the most critical studies and lines of evidence pertinent to the conclusion.

This screening assessment was prepared by staff in the Existing Substances Program at Health Canada and Environment Canada and it incorporates input from other programs within these departments. The assessment has undergone external written peer review. While external comments were taken into consideration, the final content and outcome of the screening risk assessment remain the responsibility of Health Canada and Environment Canada. Additionally, the draft of this screening assessment was subject to a 60-day public comment period. The critical information and considerations upon which the assessment is based are summarized below.

Substance Identity

For the purposes of this document, the substance acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]- will be referred to as BDAP. Information on substance identity is included in Table 1.

Table 1. Substance Identity

Chemical Abstracts Service Registry Number (CAS RN)	52697-38-8
DSL name	acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]-
Inventory names[1]	*Acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]- (TSCA, DSL, AICS, PICCS, ASIA-PAC, NZIoC); N-[2-[(2-Bromo-4,6-dinitrophenyl)azo]-5-diethylamino)phenyl]acetamide (English, French) (DSL, EINECS, ECL); 2'-[(2-Bromo-4,6-dinitrophenyl)azo]-5'-(diethylamino)acetanilide (ENCS); Acetamide, N-[2-[(2-bromo-4,6-dinitrophenyl)azo]-5-(diethylamino)phenyl]- (PICCS); ACETAMIDE, N-(2-((2-BROMO-4,6-DINITROPHENYL)AZO) -5-(DIETHYLAMINO)PHENYL)- (PICCS)*
Other names	*2-Bromo-4,6-dinitro-1-[[2-(acetylamino)-4-(diethylamino)phenyl]azo]benzene; Acetanilide, 2-(2,4-dinitro-6-bromophenylazo)-5-N,N-diethylamino-; Disperse Violet 93*
Chemical group	Azo compounds
Chemical sub-group	Monoazo compounds 2
Chemical formula	$C_{18}H_{19}BrN_6O_5$
Chemical structure	
SMILES[2]	O=C(Nc(c(N=Nc(c(cc(N(=O)(=O))c1)Br)c1N(=O)(=O))ccc2N(CC)CC)c2)C
Molecular mass	479.29 g/mol

[1] NCI 2006: *AICS (Australian Inventory of Chemical Substances), ASIA-PAC (Asia-Pacific Substances Lists), ECL (Korean Existing Chemicals List), EINECS (European Inventory of Existing Chemical Substances), ENCS (Existing and New Chemical Substances), PICCS (Philippine Inventory of Chemicals and Chemical Substances), TSCA (U.S. Toxic Substances Control Act Chemical Substance Inventory), NZIoC (New Zealand Inventory of Chemicals).*

[2] Simplified Molecular Line Input Entry System

Physical and Chemical Properties

With the exception of melting point, few experimental data are available for BDAP. At the Environment Canada-sponsored Quantitative Structure-Activity Relationship (QSAR) Workshop in 1999 (Environment Canada 2000), Environment Canada and other invited modelling experts identified many structural classes of pigments and dyes as "difficult to model" using QSARs. The physical and chemical properties of many of the structural classes of dyes and pigments (including acid and disperse dyes) are not amenable to model prediction because they are considered "out of the model domain of applicability" (e.g., structural and/or property parameter domains). Therefore, the domains of applicability of QSAR models to dyes and pigments are assessed on a case-by-case basis to determine the potential utility of the QSAR models. Environment Canada has considered it generally inappropriate to use QSAR models to predict the physical and chemical properties of BDAP. Consequently, a number of analogues were identified and "read-across" data has been used to determine the approximate physical and chemical properties in Table 2. These properties were subsequently used for further modeling and lines of evidence in this assessment.

An analogue is a chemical which is structurally similar to the substance under assessment and is therefore expected to have similar physical-chemical properties, behaviour in the environment and/or toxicity. Where there are experimental data for a given parameter for an analogue substance, these can be used directly or with adjustment as an estimate of that parameter value for the substance under assessment.

In order to find acceptable analogues, a review of data for several disperse azo dyes was performed (Anliker *et al*. 1981, Anliker and Moser 1987, Baughman and Perenich 1988, ETAD 1995, Brown 1992, Yen *et al*. 1989, Sijm *et al*. 1999). These compounds have structural similarities to BDAP but also share other important attributes that contribute to their suitability as analogues. This includes properties affecting their fate in the environment such as high molecular weights (generally >300 g/mol), similar cross sectional diameters (1.31 – 2.05 nm), solid particulate structures, decomposition at greater than 74 ^{o}C (to 236 ^{o}C), and "dispersibility" in water (i.e. not truly soluble). In addition, they have low to moderate solubility in n-octanol, a negligible vapour pressure and are stable under environmental conditions.

Table 2 contains experimental, analogue as well as read-across experimental and calculated physical and chemical properties of BDAP that are relevant to its environmental fate.

Table 2. Physical and chemical properties for BDAP and some chemical analogues.

Property	Type[1]	Value	Temperature (°C)	Reference

Property	Type[1]	Value	Temperature (°C)	Reference
Physical state		Powder		Canada 2008
Melting point[2] (ºC)	Experimental	184-186		Thiel et al. 1986
	Analogue Disperse Blue 79	157		PhysProp 2006
	Analogue Disperse Blue 79:1	132 to 153		Sijm et al. 1999; Yen et al. 1989
	Analogue with CAS RN 68877-63-4	175 to 193		Anliker and Moser 1987; Yen et al. 1989
	Analogue Disperse Blue 165	252		Sijm et al. 1999
	Read-across for azo disperse dyes	117 to 175 74 to 236		Anliker and Moser 1987; Baughman and Perenich 1988
Boiling point[3] (ºC)	Not applicable			
Density (kg/m^3)	Not available			
Vapour pressure (Pa)	Analogue Disperse Blue 79	4.53×10^{-7}		Clariant 1996
	Read-across for azo disperse dyes	$5.33 \times (10^{-12}$ to $10^{-5})$ (4×10^{-14} to 4×10^{-7} mm Hg)	25	Baughman and Perenich 1988

Property	Type[1]	Value	Temperature (°C)	Reference
Henry's Law constant ($Pa \cdot m^3/mol$)	Read-across for azo disperse dyes[4]	10^{-8} to 10^{-1} (10^{-13} to 10^{-6} $atm \cdot m^3/mol$)		Baughman and Perenich 1988
Log K_{ow} (Octanol-water partition coefficient) (dimensionless)	Analogue Disperse Blue 79	4.1; 4.3		Clariant 1996; Brown 1992
	Analogue Disperse Blue 79:1	4.4; 4.8		Sijm et al. 1999; Yen et al. 1989
	Analogue with CAS RN 68877-63-4	2.5; 5.4		Anliker and Moser 1987; Yen et al. 1989
	Analogue Disperse Orange 30	4.2		Brown 1992
	Read-across for azo disperse dyes	1.79 to 5.1		Baughman and Perenich 1988
		>2 to 5.1		Anliker et al. 1981; Anliker and Moser 1987
Log K_{oc} (Organic carbon-water partition coefficient) (dimensionless)	Read-across, calculated[5]	3.4 to 4.2		Baughman and Perenich 1988
Water solubility (mg/L)	Analogue Diperse Blue 79	0.0054	25	Clariant 1996
		0.02		Brown 1992
	Analogue Disperse Blue 79:1	0.02		Sijm et al. 1999
		0.0052		Yen et al. 1989

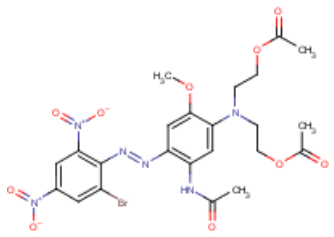
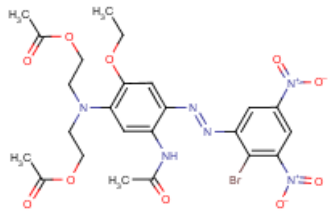
Property	Type[1]	Value	Temperature (°C)	Reference
		0.00063	100-125	Baughman and Perenich 1988
	Analogue with CAS RN 68877-63-4	0.00069		Yen et al. 1989
	Analogue Disperse Blue 165	0.0058 to 1.3		Sijm et al. 1999
	Read-across for azo disperse dyes	<0.01	20	Anliker and Moser 1987
		Substantially water insoluble		ETAD 1995
		1.2×10^{-5} to 35.5 (4×10^{-11} to 1.8×10^{-4} mol/L)		Baughman and Perenich 1988
n-octanol solubility (mg/L)	Analogue Disperse Blue 79:1	14		Sijm et al. 1999
	Analogue 68877-63-4	81	20	Anliker and Moser 1987
	Analogue Disperse Blue 165	225		Sijm et al. 1999
	Read-across for azo disperse dyes	81-2100	20	Anliker and Moser 1987
pK_a (Acid dissociation constant) (dimensionless)	Modelled	13.9 for acid form 1.85 for base form		ACD/pK_a DB 2005

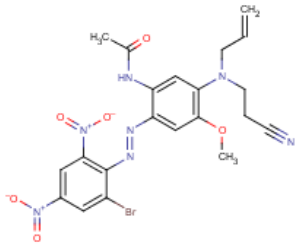
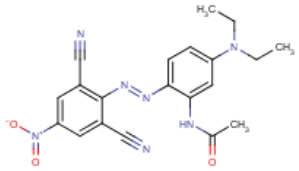
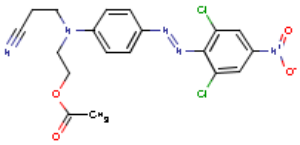
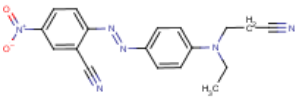
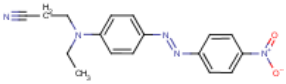
[1] These extrapolated values used for BDAP are based on evidence on disperse dyes submitted to Environment Canada under the New Substances Notification Regulations (ETAD 1995) and available evidence from other disperse dye analogues found in literature. Note CAS RN and molecular structures are provided for analogues in Table 3a.

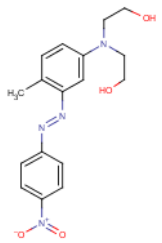
[2] The phrase melting point is used but this may be better referred to as a decomposition point because disperse dyes are known to char at high temperatures (greater than 200 °C) rather than melt.
[3] Boiling point is generally not applicable for disperse dyes. For powder dyes, charring or decomposition occurs at high temperatures instead of boiling. For liquids and pastes, boiling will only occur for the solvent component while the unevaporated solid will decompose or char (ETAD 1995).
[4] Solubilities of five azo disperse dyes (Disperse Orange 3, Disperse Red 1, Solvent Yellow 2, Dis. A. 5, Dis. A. 7) at 25 and 80°C were used by Baughman and Perenich (1988) to calculate Henry's Law constants for these dyes. These values are presented here as a range to illustrate the expected Henry's Law constant for BDAP.
[5] Log K_{oc} values are based on calculations by Baughman and Perenich (1988) using a range of measured solubilities for commercial dyes and an assumed melting point of 200°C.

Structural disperse azo analogues to BDAP are presented in Table 3a below. Certain empirical physical-chemical properties (Table 2), bioaccumulation data (Table 6) and toxicity data (Table 7b) of these analogues were used in support of the weight of evidence and proposed decisions in this screening assessment. Specifically, data were obtained for the structural analogues: Disperse Orange 30, Disperse Blue 79, Disperse Blue 79:1, 68877-63-4, Disperse Blue 165, Disperse Red 73, Disperse Orange 25 and Disperse Red 17.

Table 3a. Structural analogues for BDAP.

	CAS RN	Common Name	DSL name[1]	Structure of analogue	Available empirical data
i.	3618-72-2	Disperse Blue 79:1	Acetamide, N-[5-[bis[2-(acetyloxy)ethyl] amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-methoxyphenyl]-		Melting point, log K_{ow}, water solubility, aquatic toxicity
ii.	12239-34-8	Disperse Blue 79	Acetamide, *N*-[5-[bis[2-(acetyloxy)ethyl]amino]-2-[(2-bromo-4,6-dinitrophenyl)azo]-4-ethoxyphenyl]-		Melting point, vapour pressure, log K_{ow}, water solubility, aquatic toxicity

	CAS RN	Common Name	DSL name[1]	Structure of analogue	Available empirical data
iii.	68877-63-4	n/a	Acetamide, N-(2-(2-(2-bromo-4,6-dinitrophenyl)diazenyl)-5-((2-cyanoethyl)-2-propen-1-ylamino)-4-methoxyphenyl)-		Melting point, log Kow, water solubility, octanol solubility, bioaccumulation
iv.	41642-51-7	Disperse Blue 165	Acetamide, N-(2-(2-(2,6-dicyano-4-nitrophenyl) diazenyl)-5-(diethylamino) phenyl)-		Melting point, water solubility, octanol solubility
v.	5261-31-4	Disperse Orange 30	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2,6-dichloro-4-nitrophenyl) azo]phenyl]amino]-		Bioaccumulation, aquatic toxicity, log K_{ow}
vi.	16889-10-4	Disperse Red 73	2-((4-((2-Cyanoethyl) ethylamino)phenyl)azo)-5-nitro benzonitrile		Aquatic toxicity
vii.	31482-56-1	Disperse Orange 25	3-(Ethyl(4-((4-nitro phenyl)azo)phenyl) amino)propanenitrile		Aquatic toxicity

	CAS RN	Common Name	DSL name[1]	Structure of analogue	Available empirical data
viii.	3179-89-3	Disperse Red 17	Ethanol, 2,2'-((3-methyl-4-(2-(4-nitrophenyl) diazenyl)phenyl) imino)bis-		Aquatic toxicity

It should be noted that there are several uncertainties associated with the use of physical-chemical, toxicological and bioaccumulation data available for the substances presented in Table 3a. All these substances belong to the same chemical class (disperse azo dyes with their characteristic azo bond) and are used for similar industrial purposes. However, there are differences between these substances associated with their unique functional groups (see Table 3b below) and for some of their molecular sizes. As a result, these analogues have empirical water solubilities that range over four orders of magnitude from 10^{-4} to 1 mg/L and empirical log K_{ow} values that vary over two orders of magnitude from 2.5 to 5.4 (Table 2). Due to this variability, caution should be exercised when applying analogue values as it would be preferable to use empirical data specific to the substance BDAP (Table 2).

Table 3b. Comparisons of structural analogues with BDAP.

	CAS RN	Common Name	Molecular mass (g/mol)	structure similarity[1] (%)	Minimum-maximum cross sectional diameter (nm)[2]
i.	3618-72-2	Disperse Blue 79:1	625.39	89.1	1.43-2.03
ii.	12239-34-8	Disperse Blue 79	639.4	86.7	1.69-2.045
iii	68877-63-4	n/a	546.3	84.2	1.48-1.97
iv.	41642-51-7	Disperse Blue 165	405.4	82.1	1.35-1.82
v.	5261-31-4	Disperse Orange 30	450.28	68.9	1.75-1.98
vi.	16889-10-4	Disperse Red 73	348.36	58.8	1.31-1.93
vii.	31482-56-1	Disperse Orange 25	323.35	NA	1.37-1.95
viii.	3179-89-3	Disperse Red 17	344.36	NA	1.41-1.86

[1] From ChemID Plus 2008 – an online chemical dictionary and structure database maintained by the National Library of Medicine. NA indicates no information available in the database.

[2] CPOP (2008)

Sources

BDAP is not naturally produced in the environment.

Recent information was collected through industry surveys conducted for the years 2005 and 2006 under a Canada Gazette Notice issued pursuant to section 71 of CEPA 1999 (Canada 2006b and 2008). These Notices required submission of data on the Canadian manufacture and import of the substance. For 2006, data were also required on use quantities of BDAP.

In 2006, no companies reported manufacturing BDAP above the prescribed reporting threshold of 100 kg/year in Canada. Fewer than four companies reported importing this substance in 2006, and collectively they imported between 10,000 and 100,000 kg of the substance (Canada 2008). In the Declaration of Stakeholder-Interest form associated with the section 71 survey for 2006, one company reported a stakeholder interest in this substance despite not meeting mandatory reporting requirements.

In 2005, fewer than four companies reported importing 100-1000 kg of BDAP and no companies identified themselves as having a stakeholder interest in the substance (Canada 2006b).

In the European Union (EU), BDAP is a low production volume chemical indicating that production within the EU is estimated to be between 10 and 1000 tonnes per year (ESIS 2008). The production volume of BDAP in the United States was 10,000 – 500,000 pounds in 1986, 1990, 1994 and 2002 and 500,000 – 1,000,000 pounds in 1998 (US EPA 2007). According to the Substances in Preparations in Nordic Countries (SPIN) database, BDAP was used in Sweden from 1999 – 2006 and in Finland and Denmark from 2000 – 2006 with reported use quantities ranging from 0.2 – 10 tonnes (SPIN 2008).

Uses

Information on uses for the 2005 and 2006 calendar years was gathered in response to the CEPA 1999 section 71 Notice (Canada 2008).

In 2006, some companies importing BDAP indicated that their business activities were synthetic dye and pigment manufacturing as well as other chemical product manufacturing. Together, those companies sold BDAP to 18 other companies (Canada 2008). The purchasing companies dye and finish fabrics for apparel and industrial uses (Industry Canada 2008a). Further research on tradenames given by an importing company (Canada 2008) indicates that BDAP is used as an ingredient in black textile dye suitable for application to polyester and polyester/cellulose blends. This dye has good fastness to perspiration and washing and is distinguished by its cost-effectiveness and

ability to dye textiles in strong dark shades. Methods of dye application include exhaust and continuous application and rapid and alkaline dyeing (All Business 2000).

In 2005, a company importing BDAP was engaged in chemical wholesale and distribution (Canada 2006b).

The following DSL use codes have been identified for the substance during the DSL nomination (1984-1986): "Colourant - pigment/stain/dye/ink", "Pigment, Dye and Printing Ink" and "Textile, Product".

In Nordic countries, BDAP is used as a colouring agent in the textile industry (SPIN 2008).

Releases to the Environment

Mass Flow Tool

To estimate potential releases of the substance to the environment at different stages of its life cycle, a Mass Flow Tool was developed (Environment Canada 2008a). Empirical data concerning releases of specific substances to the environment are seldom available. Therefore, for each identified type of use of the substance, the proportion and quantity of release to the different environmental media are estimated, as is the proportion of the substance chemically transformed or sent for waste disposal. Unless specific information on the rate or potential for release of the substance from landfills and incinerators is available, the Mass Flow Tool does not quantitatively account for releases to the environment from disposal.

Assumptions and input parameters used in making the release estimates are based on information obtained from a variety of sources including responses to regulatory surveys, Statistics Canada, manufacturers' websites and technical databases and documents. Of particular relevance are emission factors, which are generally expressed as the fraction of a substance released to the environment, particularly during its manufacture, processing, and use associated with industrial processes. Sources of such information include emission scenario documents, often developed under the auspices of the Organization for Economic Cooperation and Development (OECD), and default assumptions used by different international chemical regulatory agencies. It is noted that the level of uncertainty in the mass of substance and quantity released to the environment generally increases towards the end of the life-cycle.

Based on Statistics Canada information and an analysis by Industry Canada (2008b), it is proposed that BDAP may be imported in manufactured articles. A ratio of the amount of textiles manufactured in Canada relative to the amount imported textiles of 30/70 has been used to estimate the amount of dye imported in textiles (Environment Canada 2008b). This import quantity was included in the Mass Flow Tool calculations.

Table 4. Estimated releases and losses of BDAP to environmental media, chemical transformation and transfer to waste disposal sites, based on the Mass Flow Tool.

Fate	Proportion of the mass (%)[1]	Major life cycle stage involved[2]
Released to receiving media:		
To soil	0.0	n/a[3]
To air	0.0	n/a
To sewer[4]	14.8	Formulation, consumer use
Chemically transformed	0	n/a
Transferred to waste disposal sites (e.g., landfill, incineration)	85.2	Formulation, waste disposal

[1] For BDAP, information from the following OECD emission scenario documents was used to estimate releases to the environment and the distribution of the substance as summarized in this table: OECD 2004; OECD 2007. Values presented for release to environmental media do not account for possible mitigation measures that may be in place in some locations (e.g., partial removal by sewage treatment plants). Specific assumptions used in the derivation of these estimates are summarized in Environment Canada 2008b.
[2] Applicable stage(s): production-formulation-industrial use-consumer use-service life of article/product-waste disposal.
[3] Not applicable
[4] Wastewater before any form of treatment

Results indicate that, like other disperse azo dyes, BDAP can be expected to be found largely in solid waste disposal sites (85.2%), due to the eventual disposal of manufactured items containing it. The calculations assume that there is no release of the substance from these sites, although long-term releases may be possible. A small fraction of solid waste is incinerated which is expected to result in chemical transformation of the substance. Based largely on information contained in OECD emission scenario documents for processing and uses associated with this type of substance, it is estimated that 14.8% of BDAP may be released to sewers (5.4% from industrial processing and 9.4% from consumer uses).

Based on the above, sewer water is the medium potentially receiving the greatest proportion of BDAP emitted during product use. It is anticipated that the majority of the substance bound in the product will be sent to landfills for disposal.

Environmental Fate

As indicated by the results of the Mass Flow Tool (Table 4), the substance BDAP is expected to be released to waste water effluents during industrial processing and use. The moderate log K_{ow} values (2.5 to 5.4) and high log K_{oc} (read-across: 3.4 to 4.2) values (see Table 2) indicate that this substance may have affinity for solids. However, the log

K_{oc} is a calculated value (see footnote 3 below Table 2) and the adsorption potential of disperse particulate dye structures is generally not well understood, therefore the degree of adsorption of BDAP is uncertain.

BDAP is expected to be mostly found in sediment or soil. It is not expected to be subject to long-range atmospheric transport.

According to aerobic biodegradation models, BDAP is not expected to biodegrade quickly (see Table 5 below). It may inadvertently be applied to agricultural soils and pasture lands in Canada as a component of biosludge which is commonly used for soil enrichment. Moreover, it may also be released from coloured textiles deposited in landfills.

In solution BDAP behaves as a base with an estimated pKa that is low (1.85; see Table 2). Consequently, dissolved forms of BDAP are not expected to ionize in water at environmentally relevant pHs. Based on the water solubility of various analogues (Table 2), BDAP is however expected to be only sparingly soluble and behave as a colloidal dispersion (Yen et al. 1991).. Thus, when released into water, this substance is expected to be mostly present as a solid or adsorbed to suspended particles and to sink eventually to bed sediments where it is expected to remain in a relatively biologically unavailable form. It has been concluded by Yen at al. (1989) that disperse dyes tend to accumulate extensively in sediments and biota unless they are degraded at rates comparable to uptake. Razo-Flores et al. (1997) have stated that due to the recalcitrant nature of azo dyes in the aerobic environment, they eventually end up in anaerobic sediments due to sediment burial, shallow aquifers and in groundwater. Yen et al. (1991) observed that some azobenzene dye analogues were transformed under anaerobic conditions in sediment via hydrolysis and reduction, and concluded that most azo dyes would likely not persist in anaerobic sediment systems. In buried sediment BDAP may undergo anaerobic degradation, as described in the following section on Persistence.

The rate of volatilization from the surface of water is proportional to the Henry's law constant (Baughman and Perenich 1988). Baughman and Perenich (1988) also state that volatilization from aquatic systems will not be an important loss process for disperse dyes which agrees with the low to negligible Henry's Law constant value (10^{-8} to 10^{-1} $Pa \cdot m^3/mol$, read-across data inTable 2). Transfer to or transport in air due to the loss of this substance from moist and dry soil surfaces is not likely to be important for this substance as indicated by very low vapour pressure of BDAP (5.33 x (10^{-12} to 10^{-5}) Pa, read-across data in Table 2). This behaviour is consistent with the physical state (solid particle) of BDAP which does not make it a likely candidate for volatilization.

Persistence and Bioaccumulation Potential

Persistence

No experimental degradation data for BDAP have been identified. No environmental monitoring data relating to the presence of BDAP in the Canadian environment (air, water, soil, sediment) have been identified.

According to the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers, with some exceptions, dyes are considered essentially non-biodegradable under aerobic conditions (ETAD 1995). Repeated evaluation of ready and inherent biodegradability using accepted screening tests (see OECD Guidelines for Testing Chemicals) have generally confirmed this expectation (Pagga and Brown 1986; ETAD 1992). Based on the chemical structure of BDAP, there is no reason to suspect that biodegradation will be other than that described for dyes generally (ETAD 1995).

Some disperse azo dyes have been shown to undergo relatively rapid anaerobic degradation in sediment at depth where anoxic conditions persist (Yen et al. 1991, Baughman and Weber 1994, Weber and Adams 1995). Disperse dyes enter the aquatic system mostly as a dispersion of fine suspended particles, eventually settling to the aerobic layers of surface sediment where they will persist until sediment burial creates reducing conditions. The rate of sediment deposition and the extent of bioturbation varies from site to site and thus it is very difficult to ascertain the residence time of dyes in aerobic sediment layers. It is likely however, that in many cases this is greater than 365 days. Once under anaerobic or reducing conditions, azo dyes may undergo rapid degradation to substituted aromatic amine constituents as demonstrated by Yen *et al*. (1991) who measured reduction half-life values in compacted sediments at room temperature of 2.9 hours to 2.0 days for azobenze dyes.. However, in anoxic sediment, these biodegradation transformation products are not expected to present a high degree of exposure potential to most aquatic organisms, and therefore they are not likely to present an ecological concern.

Since no experimental biodegradation data are available for BDAP, a QSAR-based weight-of-evidence approach (Environment Canada 2007) was applied using the degradation models shown in Table 5 below. Although the expected release of BDAP will be to wastewater, its residence time in the water column may be short before finally sinking to the sediment bed due to its low solubility and behaviour as a colloidal dispersion. However, given the lack of data regarding this issue, persistence was primarily examined using predictive QSAR models for biodegradation in water. The following analysis applies primarily to the portion of this substance that is present in the environment in the dissolved form, recognizing that a significant proportion would also likely exist in dispersed form as solid particles. BDAP does not contain functional groups expected to undergo hydrolysis in aerobic environments (dyes are designed to be stable in aqueous conditions). Table 5 summarizes the results of available QSAR models for biodegradation in water.

Table 5. Modelled data for degradation of BDAP

Fate Process	Model and model basis	Result	Interpretation	Extrapolated half-life (days)	Extrapolation Reference and/or source

WATER					
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 1: Linear probability	-0.44	Dose not biodegrade fast in water	n/a	n/a
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 2: Non-linear probability	0.00	Does not biodegrade fast in water	n/a	n/a
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 3: Expert Survey (ultimate biodegradation)	1.05	Recalcitrant	≥ 182	US EPA 2002 Aronson et al. 2006
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 4: Expert Survey (primary biodegradation)	2.65	Primary biodegradation in weeks-months in water	37.5	US EPA 2002, Aronson et al. 2006
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 5: MITI linear probability	-0.79	Does not biodegrade fast in water	> 60	Aronson et al. 2006
Biodegradation (aerobic)	BIOWIN 2000 Sub-model 6: MITI non-linear probability	0.00	Does not biodegrade fast in water	> 60	Aronson et al. 2006
Biodegradation	BIOWIN 2000 Overall Conclusion	No	Not readily biodegradable in water	n/a	n/a
Biodegradation (aerobic)	CATABOL v. 5.10.2 % BOD (OECD 301C)	0	Persistent in water	> 182	calculated from BOD assuming first order rate kinetics

The results from Table 5 show that the majority of the biodegradation models (BIOWIN1, 2, 3, 5, 6 and 7) suggest this substance does not biodegrade fast. In fact all probability results are less than 0.3, the cut-off suggested by Aronson et al. (2006) to identify substances as having a half-life >60 days (based on the MITI probability models). The half-life result from the primary survey model (BIOWIN 4) of "weeks-months" is suggested to mean approximately 37.5 days (US EPA 2002; Aronson et al. 2006); however, the nature of degradation products is unknown. The ultimate survey model (BIOWIN 3) result of "recalcitrant" is suggested to mean > 182 days by the US EPA (2002). The overall conclusion from BIOWIN is not readily biodegradable.

Another ultimate degradation model, CATABOL, predicts that BDAP will be persistent in water.

When the results of the probability models, the overall BIOWIN conclusion and ultimate degradation models are considered, there is greater model consensus suggesting the ultimate biodegradation half-life in water is >182 days. This finding is consistent with what would be expected for this chemical structure (i.e., few degradable functional groups, solid sparingly soluble particle).

Using an extrapolation ratio of 1:1:4 for a water: soil: sediment biodegradation half-life (Boethling et al 1995), the ultimate degradation half-life in soil should be >182 days and the half-life in sediments should be >365 days. This suggests that BDAP is expected to be persistent in soil and sediment.

Based on modelled ultimate degradation data (see Table 5 above) and expert judgment (ETAD 1995), BDAP meets the persistence criteria in water, soil and sediment (half-lives in soil and water ≥ 182 days and half-life in sediment ≥ 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential for Bioaccumulation

No experimental bioaccumulation data are available for BDAP. Since azo dyes fall outside the domains of applicability for available bioaccumulation models, predictions from such models are considered unreliable for this group of substances. As a result, in this assessment bioaccumulation modelling has not been used to evaluate the bioaccumulation status of BDAP.

In the absence of experimental and modelled data, bioconcentration (BCF) and bioaccumulation (BAF) factors for structural analogues were used to estimate BDAP's potential for bioaccumulation. To that end, bioaccumulation data for Disperse 79:1, substance 68877-63-4 and Disperse Orange 30 were reviewed for relevance to BDAP. A bioconcentration study submitted for a relatively close structural analogue, Disperse Orange 30, suggests that it is unlikely to accumulate in fish (Shen and Hu 2008). This test was performed according to OECD Guidelines for Testing of Chemicals, Test No. 305B-1996, Bioconcentration: Semi-Static Fish Test. The bioconcentration of Disperse Orange 30 in zebra fish (*Brachydanio rerio*) was determined in a 28-day semi-static test with test medium renewal every two days. An exposure test at a nominal concentration of 20 mg/L (mean measured concentration 0.028 - 0.28 mg/L) was performed in accordance with the result of the fish acute toxicity test to check the bioconcentration potential of the test substance. Samples from both test solutions and test organisms were taken daily from the 26th day to the last day during the 28-day exposure test period. Samples were prepared by extracting the lipid component from the test fish. The measured concentration of test substance, fish lipid content and BCF calculation are reported in Table 6.

Table 6. Measured concentrations, fish lipid content and BCF calculation for analogue Disperse Orange 30

Treatments (20 mg/L)	Sampling Time		
	The 26th day	The 27th day	The 28th day

Measured concentration of the test substance in extracted solutions (mg/L)	<0.028	<0.028	<0.028
Content of the test substance in the fish lipids (mg)	<1.68	<1.68	<1.68
Fish total weight (g)	2.07	2.13	2.53
Concentration of the test substance in the fish C_f (mg/kg)	<0.81	<0.79	<0.66
Measured concentration of the test substance in the water C_w (mg/L)	0.028 ~ 0.28	0.028 ~ 0.28	0.028 ~ 0.28
Fish lipid content (%)	0.81	0.57	1.25
BCF	<100	<100	<100
Average BCF	<100		

The Shen and Hu (2008) study has been reviewed and was considered acceptable (see Appendix 1). Lack of detection in fish extracts (<0.028 mg/L) suggests a limited solubility in lipids and/or limited potential to partition into fish tissue from aqueous systems. However, there is some uncertainty associated with limit bounded values in any study because the absolute value is not known. But given the structure and likely behavior of disperse dyes in aqueous systems, a low BCF result is expected. Most disperse dyes, as their name suggests, exist as fine dispersible particles with limited truly soluble fractions. Solubility, however, can be increased by adding polar functional groups to the molecule. While BDAP contains some of these solubilizing functional groups (amide and nitro groups), experimental solubility values for analogues containing many of the same groups are quite low.

While the above study serves as primary evidence to support BDAP's lack of bioaccumulation potential, other research corroborates this conclusion. Anliker et al. (1981) reported experimental fish bioaccumulation values for 18 disperse monoazo dyes, performed according to test methods specified by the Japanese Ministry of International Trade and Industry (MITI). Expressed on the basis of wet body weight of the fishes, these log bioaccumulation factors ranged from 0.00 to 1.76 (Anliker et al. 1981). A lack of reporting of chemical registry numbers and chemical structures limited the utility of this study for read-across purposes to BDAP. However, follow-up studies, which provided the chemical structures for the disperse dyes tested, confirmed low bioaccumulation potential for ten nitroazo dyes, with reported log bioaccumulation factors ranging from 0.3 to 1.76 (Anliker and Moser 1987; Anliker et al. 1988). Specifically, the bioaccumulation factor for one closely related analogue (CAS RN: 68877-63-4) to BDAP was 10. Studies available from MITI also support low bioaccumulation potential for disperse azo dyes. Reported BCFs for three disperse azo dyes (CAS Nos. 40690-89-9, 61968-52-3 and 71767-67-4) tested at a concentration of 0.01 mg/L were in the range of <0.3 to 47 (MITI 1992). An accumulation study by Brown (1987) also showed that none of the twelve disperse dyes tested accumulated during an eight week study with carp.

A high, median read-across log K_{ow} value of 4.3 for BDAP (Table 2) is the only line of evidence that suggests BDAP may have a high potential for bioaccumulation. In spite of the high K_{ow} values for BDAP's structural analogues and other disperse azo dyes,

evidence for bioaccumulation of such dyes is lacking (Anliker et al. 1981, Anliker and Moser 1987, Anliker et al. 1988, MITI 1992). Authors who have measured high log K_{ow}s and concomitant low bioaccumulation factors for disperse azo dyes suggest the low accumulation factors may be due to their low absolute fat solubility (Brown 1987) or relatively high molecular weight (typically 450-550 g/mol) which may make transport across fish membranes difficult (Anliker et al. 1981, Anliker and Moser 1987). It is also likely that the lack of bioavailability and limited capacity to partition under BCF test conditions limits accumulation in fish lipids.

It has been stated by ETAD (1995) that the molecular characteristics indicating the absence of bioaccumulation are a molecular weight of > 450 g/mol and a cross-sectional diameter of > 1.05 nm. Recent investigation by Dimitrov et al. (2002), Dimitrov et al. (2005) and the BBM (2008) suggests that the probability of a molecule crossing cell membranes as a result of passive diffusion declines significantly with increasing maximum cross-sectional diameter (D_{max}). The probability of passive diffusion lowers appreciably when cross-sectional diameter is > ~1.5 nm and more significantly for molecules having a cross-sectional diameter of >1.7 nm. Sakuratani et al. (2008) have also investigated the effect of cross-sectional diameter on passive diffusion from a test set of about 1200 new and existing chemicals, also observing that substances not having a very high bioconcentration potential often have a D_{max} >2.0 nm and an effective diameter (D_{eff}) >1.1 nm.

BDAP has a molecular weight of 479.3 g/mol (see Table 1) and its molecular structure is relatively uncomplicated; the latter characteristic in particular indicates a potential bioaccumulation capability. In addition, an Environment Canada (2007) report points out that there is no clear evidence for establishing strict molecular size cut-offs for assessing bioaccumulation potential. However, the report does not dispute the notion that a reduction in uptake rate can be associated with increasing cross-sectional diameter as demonstrated by Dimitrov et al. (2002, 2005). The maximum diameter of BDAP and its conformers ranges from 1.43 to 1.80 nm (BBM 2008) suggesting that a potential for a significantly reduced uptake rate from water and *in vivo* bioavailability exists with this dye.

Based on a lack of accumulation observed in bioconcentration tests of Disperse Orange 30 and other related disperse azo dyes, and BDAP's large molecular size, which likely limits its partitioning behavior, BDAP is expected to have a low potential for bioaccumulation. Therefore, considering analogue BCF evidence, and structural and bioavailability considerations, BDAP does not meet the bioaccumulation criteria (BCF or BAF $\geq$ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential to Cause Ecological Harm

Ecological Effects Assessment

A - In the Aquatic Compartment

Only one empirical study was submitted regarding BDAP's toxicity (SafePharm1990). According to the study, BDAP has a 96-hour LC_{50} of >100 mg/L in rainbow trout (*Salmo gairdneri*) (Table 7a). Due to lack of details, this study was deemed unreliable (See Appendix 1 for robust study summary). Moreover, the study's reported LC_{50} is 4 orders of magnitude larger than BDAP's predicted water solubility (i.e. ~ 0.005 mg/L, median water solubility of analogues in Table 2).

Table 7a. Empirical data for aquatic toxicity of BDAP

Test organism	Type of test	Duration (hours)	End point	Reliability of the study	Value (mg/L)	Reference
Salmo gairdneri	Acute	96	LC_{50}[1]	Unreliable	>100	SafePharm 1990

[1] LC_{50} – The median concentration of a substance that is estimated to be lethal to 50% of the test organisms.

Ecotoxicological data has been located for several analogues of BDAP (Table 7b). A study submitted on behalf of ETAD provides acute ecotoxicity data in fish, invertebrates, algae and bacteria for 5 nitroazo disperse dyes, including the closely related analogue, Disperse Blue 79 (Brown 1992). Acute toxicity to zebra fish, *Daphnia magna* and *Scenedesmus subspicatus* for the 5 analogues ranged from 17 to 710 mg/L, 4.5 to 110 mg/L and 6.7 to 54 mg/L, respectively (Table 7b). In addition, all bacteria tests had an IC_{50} exceeding 100 mg/L. The experimental details for the dyes tested were not provided, which greatly limited evaluation of these studies (Brown 1992). However, these data were considered usable and are included in this screening assessment as weight of evidence.

Another acute fish toxicity study was submitted for Disperse Blue 79 (BASF 1990). According to the study, Disperse Blue 79 has a 96-hour LC_{50} in golden orfe (*Leuciscus idus*) between 100 and 220 mg/L. However, due to lack of details, this study was considered of uncertain reliability (Appendix 1).

Environment Canada received ecotoxicological data for another structurally similar disperse azo dye through the New Substances Notification Regulations (Environment Canada 1995). An acute fish toxicity study submitted to meet notification requirements revealed this substance has a 96-hour LC_{50} of 505 mg/L in rainbow trout (*Onchorhynchus mykiss*) (Table 7b). The test was conducted according to OECD Guideline No. 203. The Material Safety Data Sheet also contained information on bacterial toxic effects. The results indicate an activated sludge respiration inhibition EC_{50} > 100 mg/L. Based on the available ecotoxicity information, the notified substance is expected to be of low concern for toxic effects to aquatic organisms. Reliability of the study was assessed using a robust study summary and considered as satisfactory (Appendix 1).

Lastly, a chronic study submitted for Disperse Blue 79:1 revealed its no effect concentration (NOEC) in rainbow trout (*Onchorhynchus mykiss*) to be greater than 0.0048 mg/L (Table 7b). Reliability of this study was assessed as high (Appendix 1). However, this value was not used to calculate the predicted no effect concentration because the value is a hypothesis-based unbounded result. When considering all structural analogue toxicity information in concert with the lone experimental toxicity value for BDAP, these data suggest that BDAP is not highly hazardous to aquatic organisms (i.e. acute LC_{50} values are > 1 mg/L).

Table 7b. Empirical data for aquatic toxicity of BDAP analogues

Common Name or CAS#	Test Organism	End point	Value (mg/L)	Reference
Disperse Blue 79	Golden orfe	LC_{50}[1]	$100 < LC_{50} < 220$	BASF 1990
	Zebra fish	LC_{50}	340	Brown 1992
	Daphnia magna	EC_{50}[2]	4.5	
	Scenedesmus subspicatus	EC_{50}	9.5	
	Bacteria	IC_{50}[3]	>100	
Disperse Red 73	Zebra fish	LC_{50}	17	
	Daphnia magna	EC_{50}	23	
	Scenedesmus subspicatus	EC_{50}	>10	
	Bacteria	IC_{50}	>100	
Disperse Orange 30	Zebra fish	LC_{50}	710	
	Daphnia magna	EC_{50}	5.8	
	Scenedesmus subspicatus	EC_{50}	6.7	
	Bacteria	IC_{50}	>100	
Disperse Orange 25	Zebra fish	IC_{50}	268	
	Daphnia magna	LC_{50}	110	
	Scenedesmus subspicatus	EC_{50}	54	
	Bacteria	EC_{50}	>100	
Disperse Red 17	Zebra fish	LC_{50}	103	
	Daphnia magna	EC_{50}	98	
	Scenedesmus subspicatus	EC_{50}	7	
	Bacteria	IC_{50}	>100	
Analogue azo disperse dye	Rainbow trout	LC_{50}	505	Environment Canada 1995
Disperse Blue 79:1	Rainbow trout	NOEC[4] (122 days)	>0.0048	Cohle and Mihalik 1991

[1] LC_{50} – The median concentration of a substance that is estimated to be lethal to 50% of the test organisms.
[2] EC_{50} – The median concentration of a substance that is estimated to cause some toxic sublethal effect on 50% of the test organisms.
[3] IC_{50} – The median concentration of a substance that is estimated to cause inhibition to growth in 50% of the test organisms.
[4] The concentration at which no effects have been observed.

In general, due to their low solubility (<1 mg/L) disperse dyes are expected to have a low acute ecological impact (Hunger 2003). The results of empirical toxicity studies with both BDAP and several analogues of BDAP are consistent with this expectation, indicating fish LC_{50}s in the 17 to 505 mg/L range, with *Daphnia* being the most sensitive organisms tested (EC_{50}/LC_{50}s from 4.5 to 110 mg/L). Although interpretation of results from these tests is complicated by the fact that the reported effect values (*i.e.* EC_{50} and LC_{50}s) are likely to be much greater than the solubility of the substances tested as well as of BDAP, the analogue data available do indicate that the toxicity of BDAP is likely to be low.

A range of aquatic toxicity predictions for BDAP were also obtained from the various QSAR models. However, as with bioaccumulation, these QSAR ecotoxicity predictions for BDAP are not considered reliable because of the potential error associated with input parameters and the unique nature of disperse dyes – specifically structural and/or physical-chemical properties which fall outside of the models' domain of applicability.

The available empirical ecotoxicity information for BDAP and several analogues of BDAP thus indicates that BDAP is not likely to be highly hazardous to aquatic organisms.

B - In Other Environmental Compartments

Because BDAP could be released to soil from application of biosludge which is commonly used for soil enrichment as well as from the disposal of products that degrade and release BDAP, it would be desirable to obtain toxicity data for soil organisms. Although no suitable ecological effects studies were found for this compound in soil, considering the toxicity data for aquatic organisms as well as the lack of bioaccumulation potential and its low bioavailability, potential for toxicity to soil- dwelling organisms is likely to be low. For the same reasons, the toxicity potential is also likely to be low for sediment dwelling organisms, although this cannot be substantiated due to lack of whole organism sediment toxicity data for BDAP or suitable analogues.

Ecological Exposure Assessment

No data concerning concentrations of this substance in water in Canada have been identified. Environmental concentrations are, therefore, estimated from available information, including substance quantities in commerce, estimated release rates, and characteristics of receiving water bodies. Environment Canada's Industrial Generic Exposure Tool – Aquatic (IGETA) was employed to estimate the substance concentration (worst-case) in a generic water course receiving industrial effluents (Environment Canada 2008c). The generic scenario is designed to provide these estimates based on conservative assumptions regarding the amount of chemical processed and released, the number of processing days, sewage treatment plant (STP) removal rate, and the size of the receiving watercourse. The tool models an industrial-release scenario based on loading data from sources such as industrial surveys and knowledge of the distribution of

industrial discharges in the country, and calculates a predicted environmental concentration (PEC). The equation and inputs used to calculate the PEC in the receiving water course are described in Environment Canada (2008d). The maximum amount used by a single facility was used to calculate the PEC in the receiving environment. To make the exposure scenario more realistic, the average sewage treatment flow rate (0.282 m^3/s) and 10^{th} percentile flow rate of the receiving watercourse for the community in which the facility resides (5.6 m^3/s) were entered into the IGETA model in place of default values. To add a degree of conservatism to the assessment, the STP removal rate was assumed to be 0% even though it was confirmed that the STP in which the facility resides has secondary treatment. Based on these assumptions, the IGETA model yielded a site-specific conservative PEC of 0.014 mg/L in the receiving watercourse (Environment Canada 2008d).

Environment Canada's spreadsheet model to estimate down-the-drain releases from consumer uses (Mega Flush) was further employed to estimate the potential substance concentration in multiple water bodies receiving sewage treatment plant effluents to which consumer products containing the substance may have been released (Environment Canada 2008e). The spreadsheet model is designed to provide these estimates based on conservative assumptions regarding the amount of chemical used and released by consumers. By default, primary and secondary STP removal rates are assumed to be 0%, losses from use of 100% are assumed, consumer use of the substance is over 365 days/year, and the flow rate for receiving water bodies used at all sites is the 10^{th} percentile value. These estimates are made for approximately 1000 release sites across Canada, which account for most of the major STPs in Canada. These parameter values are considered to result in a very conservative scenario.

The equation and inputs used in Mega Flush to calculate the predicted environmental concentration (PEC) of BDAP in the receiving water bodies are described in Environment Canada (2008f). The Mass Flow Tool was used to predict releases to water (sewers) from formulation use and from consumer use of products containing this substance. A scenario was run assuming a total consumer use quantity of 30,184 kg/year (Environment Canada 2008b). This consumer use quantity was estimated conservatively using the total mass of substance reportedly imported into Canada by fewer than four companies based on information from the s. 71 survey, and the ratio of textiles manufactured in Canada / imported textiles of 30/70. A 10% loss of dye was then assumed for the total amount of the substance being used by consumers (Øllgaard et al. 1998). Thus, 3,018 kg of BDAP were predicted to be released to water, as a result of loss to sewers during the laundering of manufactured articles that contain this dye but are manufactured in another country, as well as of articles that contain this dye that were manufactured in Canada (Environment Canada 2008b).

Using this scenario, the tool estimates that the PEC in the receiving water bodies ranges from 0.00038 to 0.0046 mg/L.

Characterization of Ecological Risk

A predicted no-effect concentration (PNEC) was estimated based on the 48-hour EC_{50} of 4.5 mg/L in *Daphnia magna* for analogue Disperse Blue 79 (Table 7b). A factor of 100 was then applied to account for acute to chronic toxicity and lab to field extrapolations and use of a surrogate substance. The resulting PNEC is 0.045 mg/L.

When compared to the conservative PEC calculated above for industrial releases using IGETA, the resulting risk quotient (PEC/PNEC) is 0.014/0.045 = 0.3. Therefore, concentrations of BDAP in surface waters from industrial releases in Canada appear unlikely to cause adverse effects to aquatic organisms. Given that IGETA provides a conservative estimate of exposure, the results indicate a low potential for ecological harm to the aquatic environment resulting from local exposure to a point source industrial release.

For exposure resulting from down-the-drain releases through consumer uses (conservative scenario), MegaFlush results estimate that the PEC will not exceed the PNEC at any sites (i.e. all risk quotients < 1). This indicates that down-the-drain consumer releases of BDAP are not expected to harm aquatic organisms.

Based on the available information, BDAP is expected to be persistent in water, soil and sediment and it is expected to have a low bioaccumulation potential. The importation quantities of BDAP into Canada, along with information on physical and chemical properties and its uses, indicate a low to moderate potential for releases into the Canadian environment. If released into the environment, BDAP is expected to be discharged mainly to surface waters, although it is expected to ultimately be transferred to sediment. Through use of analogue data, BDAP has also been demonstrated to have only a low to moderate potential for acute toxicity to aquatic organisms. Risk quotients for aquatic exposures indicate that BDAP concentrations likely do not exceed concentrations associated with effects, even when using conservative scenarios and assumptions. Therefore, BDAP is unlikely to be causing harm to populations of aquatic organisms in Canada.

Uncertainties in Evaluation of Ecological Risk

An area of uncertainty for BDAP is associated with the use of read-across data for physical and chemical properties, as well as toxicity data from analogues. While the chemicals identified (Disperse Blue 79, Disperse Blue 79:1, Disperse Orange 30, Disperse Orange 25, Disperse Red 17 and Disperse Red 73), share many similarities with BDAP, including being azo dyes with high molecular weights and similar cross sectional diameters, having solid particulate structures that decompose at greater than 74 °C, and being “dispersible” in water (i.e., not truly soluble), they do have some differences in functional groups. These differences in chemical structure add uncertainty because the properties and toxicity of BDAP may be somewhat different. However, it was reasoned

that the similarities were sufficient to include the data from analogues to contribute to the weight of evidence in the assessment of BDAP.

The persistence assessment is limited by the absence of biodegradation data, which necessitated generation of model predictions. Although all model prediction has some degree of error, the aerobic biodegradation model outputs confirmed the expected persistence of BDAP given its uses and structural characteristics. In addition, the persistence assessment is limited by the uncertainty about the rate and extent to which degradation occurs in anaerobic sediments and whether the degradation products (e.g., amines) would be biologically available. Nevertheless it is clear that anaerobic degradation of the bioavailable portion of azo dyes in sediments to constitutive amines is much faster (half-lives in the order of days) than aerobic biodegradation. Although the degradation products are not expected to be biologically available because they form only in relatively deep anoxic sediment and can be irreversibly bound to sediment through nucleophilic addition and oxidative radical coupling (Colón *et al.* 2002, Weber *et al.* 2001), this issue is a source of uncertainty in the assessment of BDAP.

The bioaccumulation assessment for this substance was limited by the lack of empirical data and the inability of available models to reliably estimate bioaccumulation for azo dyes. Instead the assessment relied on the use of bioaccumulation data for a structural analogue.

Uncertainties are also present due to the lack of information on environmental concentrations in Canada for BDAP. However, the lack of reports of manufacturing in Canada, its high fixation rate to textiles and the anticipated high removal rate from sewage treatment plants suggests relatively low potential for releases of this chemical into the Canadian environment.

The experimental concentrations associated with inherent toxicity for aquatic organisms, may have an additional source of uncertainty when these concentrations exceed the solubility of the chemical in water (either experimental or predicted). Despite this, the available data indicate that BDAP is not highly hazardous to aquatic organisms.

Uncertainties are also associated with the fraction of the substance that is released, and with the fraction that is removed in sewage treatment plants. Those uncertainties were addressed through the use of fairly conservative assumptions in the exposure modelling.

Regarding ecotoxicity, based on the predicted partitioning behaviour of this chemical, the significance of soil and sediment 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.

Conclusion

Based on the information presented in this screening assessment, it is proposed that BDAP is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity or that constitute or may constitute a danger to the environment on which life depends.

It is therefore proposed that BDAP does not meet the definition of toxic as set out in section 64 of CEPA 1999. Additionally, BDAP meets the persistence criteria but does not meet the criteria for bioaccumulation potential as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

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Appendix I - Robust Study Summaries for Key Studies

Robust Study Summaries Form: Aquatic B				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	**Reference:** Shen, Genxiang and Hu, Shuangqing. 2008. Bioconcentration Test of C.I. Disperse Orange 30 in Fish. Prepared by Environmental Testing Laboratory, Shanghai Academy of Environmental Sciences, Shanghai, China for Dystar in the name of Ecological and Toxicological Association of the Dyes and Organic Pigments Manufacturers (ETAD) Basel, Switzerland. Report No. S-070-2007. Submitted to Environment Canada in April 2008. Challenge Submission ID#8351			
2	Substance identity: CAS RN	n/a	Y	5261-31-4
3	Substance identity: chemical name(s)	n/a	Y	Propanenitrile, 3-[[2-(acetyloxy)ethyl][4-[(2,6-dichloro-4-nitrophenyl)azo]phenyl]amino]-
4	Chemical composition of the substance	2	N	
5	Chemical purity	1	N	
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
7	If test material is radiolabelled, were precise position(s) of the labelled atom(s) and the percentage of radioactivity associated with impurities reported?	2	n/a	
	Method			
8	Reference	1	Y	OECD guidelines for the testing of chemicals No 305B-1996
9	OECD, EU, national, or other standard method?	3	Y	OECD
10	Justification of the method/protocol if not a standard method was used	2		
11	GLP (Good Laboratory Practice)	3	N	
Test organism	***Test organism***			
12	Organism identity: name	n/a	Y	*zebra fish, Brachydanio rerio*
13	Latin or both Latin & common names reported?	1	Y	both
14	Life cycle age / stage of test organism	1	N	
15	Length and/or weight	1	Y	Mean body length 3.91+/-0.18cm and mean body weight 0.32+/-0.06g
16	Sex	1	N	
17	Number of organisms per replicate	1	Y	7
18	Organism loading rate	1	Y	20mg/L
19	Food type and feeding periods during the acclimation period	1	Y	Fed a commercial fish diet until one day before start of test
	Test design / conditions			
20	Experiment type (laboratory or field)	n/a	Y	Laboratory
21	Exposure pathways (food, water, both)	n/a	Y	Water
22	Exposure duration	n/a	Y	28 days
23	Number of replicates (including controls)	1	Y	
24	Concentrations	1	Y	20 mg/L
25	Food type/composition and feeding periods during the test	1	Y	Fish were fed two hours before water renewal

26	If BCF/BAF derived as a ratio of chemical concentration in the organism and in water, was experiment duration equal to or longer than the time required for the chemical concentrations to reach steady state?	3	Y	28 days
27	If BCF/BAF derived as a ratio of chemical concentration in the organism and in water, were measured concentrations in both water and organism reported?	3	Y	
28	Were concentrations in the test water measured periodically?	1	Y	On three separate days
29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	Y	Yes every second day
30	Photoperiod and light intensity	1	Y	12:12
31	Stock and test solution preparation	1	Y	
32	Analytical monitoring intervals	1	Y	Every second day for dissolved oxygen, pH and temperature
33	Statistical methods used	1	Y	
34	Was solubilizer/emulsifier used, if the chemical was unstable or poorly soluble?	n/a	N	
	Information relevant to the data quality			
35	Was the test organism relevant to the Canadian environment?	3	Y	
36	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	Y	
37	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and organism's nature/habits?	2	Y	Semi-static
38	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1	Y	7.22-7.84
39	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	Y	22-23
40	Was lipid content (or lipid-normalized BAF/BCF) reported?	2	Y	
41	Were measured concentrations of a chemical in the test water below the chemical's water solubility?	3	N	
42	If radiolabelled test substance was used, was BCF determination based on the parent compound (i.e. not on total radiolabelled residues)?	3	n/a	
	Results			
43	Endpoints (BAF, BCF) and values	n/a	n/a	BCF < 100
44	BAF or BCF determined as: 1) the ratio of chemical concentration in the organism and in water, or 2) the ratio of the chemical uptake and elimination rate constants	n/a	n/a	1
45	Whether BAF/BCF was derived from a 1) tissue sample or 2) whole organism?	n/a	n/a	2
46	Whether 1) average or 2) maximum BAF/BCF was used?	n/a	n/a	1
47	***Score*: ... %**	***75.0***		
48	***EC Reliability code*:**	***2***		
49	***Reliability category (high, satisfactory, low)*:**	***Satisfactory Confidence***		

50	***Comments***	*The present procedure is based on semi-static conditions (renewal of test solutions every 2 days). Therefore, test chemical with very low water solubility like AADM, can also be characterized as to their bioconcentration potential without adding solvents or other auxiliary substances which may affect the results.*

Robust Study Summary Form: Aquatic iT				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	Reference: SafePharm Laboratories Ltd. 1990. Acute toxicity to Rainbow Trout for FORVI (Cas No. 52697-38-8)			
2	Substance identity: CAS RN	n/a	Y	52697-38-8
3	Substance identity: chemical name(s)	n/a	Y	FORVI
4	Chemical composition of the substance	2	N	
5	Chemical purity	1	N	
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
Method				
7	Reference	1	N	
8	OECD, EU, national, or other standard method?	3	N	
9	Justification of the method/protocol if not a standard method was used	2	N	
10	GLP (Good Laboratory Practice)	3	N	
Test organism				
11	Organism identity: name	n/a	Y	*rainbow trout, Salmo gairdneri*
12	Latin or both Latin & common names reported?	1	Y	
13	Life cycle age / stage of test organism	1	N	
14	Length and/or weight	1	Y	4.8 +/- 0.2 cm; 1.55 +/- 0.13 g
15	Sex	1	N	
16	Number of organisms per replicate	1	Y	2
17	Organism loading rate	1	Y	0.78 g/L
18	Food type and feeding periods during the acclimation period	1	N	
Test design / conditions				
19	Test type (acute or chronic)	n/a	Y	acute
20	Experiment type (laboratory or field)	n/a	Y	lab
21	Exposure pathways (food, water, both)	n/a	Y	water
22	Exposure duration	n/a	Y	96 hours
23	Negative or positive controls (specify)	1	N	
24	Number of replicates (including controls)	1	Y	4
25	Nominal concentrations reported?	1	Y	4
26	Measured concentrations reported?	3	N	
27	Food type and feeding periods during the long-term tests	1		
28	Were concentrations measured periodically (especially in the chronic test)?	1	N	

29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	Y	limited exposure condtions reported (temperature, hardness, aeration)
30	Photoperiod and light intensity	1	N	
31	Stock and test solution preparation	1	Y	
32	Was solubilizer/emulsifier used, if the chemical was poorly soluble or unstable?	1	N	
33	If solubilizer/emulsifier was used, was its concentration reported?	1		
34	If solubilizer/emulsifier was used, was its ecotoxicity reported?	1		
35	Analytical monitoring intervals	1	N	
36	Statistical methods used	1	N	
Information relevant to the data quality				
37	Was the endpoint directly caused by the chemical's toxicity, not by organism's health (e.g. when mortality in the control >10%) or physical effects (e.g. 'shading effect')?	n/a	Y	
38	Was the test organism relevant to the Canadian environment?	3	Y	
39	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	Y	
40	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and organism's nature/habits?	2	Y	
41	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1		pH not specified
42	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	Y	14 +/- 1oC
43	Was toxicity value below the chemical's water solubility?	3	N	There is no available water solublitily for 52697-38-8 but based on its similarity to various azo disperse dyes for which water solubilities are available (0.00063 to 1.3), its solubility is expected to be less than 0.01 mg/L.
Results				
44	Toxicity values (specify endpoint and value)	n/a	n/a	96-hour LC50 > 100 mg/L
45	Other endpoints reported - e.g. BCF/BAF, LOEC/NOEC (specify)?	n/a	N	
46	Other adverse effects (e.g. carcinogenicity, mutagenicity) reported?	n/a	N	
47	***Score*: ... %**			***37.8***
48	***EC Reliability code*:**			***4***
49	***Reliability category (high, satisfactory, low)*:**			***Not Satisfactory***
50	***Comments***			

Robust Study Summaries Form: Aquatic iT				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	Reference: BASF. 1990. Bericht uber die Prufung der akuten Toxizitit an der Goldorfe (Leuciscus idus L.,. Goldvariante. Submitted by ETAD to Environment Canada, August 2008			
2	Substance identity: CAS RN	n/a		
3	Substance identity: chemical name(s)	n/a		
4	Chemical composition of the substance	2	N	
5	Chemical purity	1	N	
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
Method				
7	Reference	1	N	
8	OECD, EU, national, or other standard method?	3	N	
9	Justification of the method/protocol if not a standard method was used	2	N	
10	GLP (Good Laboratory Practice)	3		
Test organism				
11	Organism identity: name	n/a	Y	*Golden orfe*
12	Latin or both Latin & common names reported?	1	Y	
13	Life cycle age / stage of test organism	1	N	
14	Length and/or weight	1	N	
15	Sex	1	N	
16	Number of organisms per replicate	1	N	
17	Organism loading rate	1	N	
18	Food type and feeding periods during the acclimation period	1	N	

Test design / conditions				
19	Test type (acute or chronic)	n/a	Y	Acute
20	Experiment type (laboratory or field)	n/a	N	
21	Exposure pathways (food, water, both)	n/a	N	
22	Exposure duration	n/a	Y	96 hrs
23	Negative or positive controls (specify)	1	N	
24	Number of replicates (including controls)	1	N	
25	Nominal concentrations reported?	1	N	
26	Measured concentrations reported?	3	N	
27	Food type and feeding periods during the long-term tests	1		n/a
28	Were concentrations measured periodically (especially in the chronic test)?	1	N	
29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	N	
30	Photoperiod and light intensity	1	N	
31	Stock and test solution preparation	1	N	
32	Was solubilizer/emulsifier used, if the chemical was poorly soluble or unstable?	1	N	
33	If solubilizer/emulsifier was used, was its concentration reported?	1	N	
34	If solubilizer/emulsifier was used, was its ecotoxicity reported?	1	N	
35	Analytical monitoring intervals	1	N	
36	Statistical methods used	1	N	
Information relevant to the data quality				
37	Was the endpoint directly caused by the chemical's toxicity, not by organism's health (e.g. when mortality in the control >10%) or physical effects (e.g. 'shading effect')?	n/a	N	
38	Was the test organism relevant to the Canadian environment?	3	Y	
39	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	N	
40	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and organism's nature/habits?	2	N	
41	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1	N	
42	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	N	
43	Was toxicity value below the chemical's water solubility?	3		

Results				
44	Toxicity values (specify endpoint and value)	n/a		LC50=>100<220mg/L
45	Other endpoints reported - e.g. BCF/BAF, LOEC/NOEC (specify)?	n/a		NOEC=100mg/L
46	Other adverse effects (e.g. carcinogenicity, mutagenicity) reported?	n/a		
47	***Score*: ... %**			***9.5***
48	***EC Reliability code*:**			***4***
49	***Reliability category (high, satisfactory, low)*:**			***Not Satisfactory***
50	***Comments***			***Not enough data submitted to properly assess the reliability of this study.***

Robust Study Summaries Form: Aquatic iT				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	Reference: Environment Canada. 1995. Acute fish toxicity test submission in fulfillment of new substances notification regulations to New Substances Branch, Environment Canada under New Substance Notification Program.			
2	Substance identity: CAS RN	n/a	N	
3	Substance identity: chemical name(s)	n/a	Y	
4	Chemical composition of the substance	2	N	
5	Chemical purity	1	N	
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
	Method			
7	Reference	1	Y	OECD 203
8	OECD, EU, national, or other standard method?	3	Y	
9	Justification of the method/protocol if not a standard method was used	2		not applicable
10	GLP (Good Laboratory Practice)	3	Y	
	Test organism			
11	Organism identity: name	n/a	Y	*Rainbow trout*
12	Latin or both Latin & common names reported?	1	Y	
13	Life cycle age / stage of test organism	1	Y	mean length 51mm and mean weight 1.54
14	Length and/or weight	1	Y	see above
15	Sex	1		not applicable
16	Number of organisms per replicate	1	Y	10
17	Organism loading rate	1	Y	

18	Food type and feeding periods during the acclimation period	1	Y	
Test design / conditions				
19	Test type (acute or chronic)	n/a	Y	acute
20	Experiment type (laboratory or field)	n/a	y	lab
21	Exposure pathways (food, water, both)	n/a	y	water
22	Exposure duration	n/a	y	96hrs
23	Negative or positive controls (specify)	1	Y	3
24	Number of replicates (including controls)	1	Y	2
25	Nominal concentrations reported?	1	Y	320 to 3200 mg/L
26	Measured concentrations reported?	3	N	
27	Food type and feeding periods during the long-term tests	1		not applicable
28	Were concentrations measured periodically (especially in the chronic test)?	1	N	
29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	Y	
30	Photoperiod and light intensity	1	Y	
31	Stock and test solution preparation	1	Y	
32	Was solubilizer/emulsifier used, if the chemical was poorly soluble or unstable?	1	N	
33	If solubilizer/emulsifier was used, was its concentration reported?	1		
34	If solubilizer/emulsifier was used, was its ecotoxicity reported?	1		
35	Analytical monitoring intervals	1	Y	
36	Statistical methods used	1	Y	
Information relevant to the data quality				
37	Was the endpoint directly caused by the chemical's toxicity, not by organism's health (e.g. when mortality in the control >10%) or physical effects (e.g. 'shading effect')?	n/a	Y	
38	Was the test organism relevant to the Canadian environment?	3	Y	
39	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	Y	
40	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and organism's nature/habits?	2	Y	
41	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1	Y	
42	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	Y	

43	Was toxicity value below the chemical's water solubility?	3		unknown water solubility
Results				
44	Toxicity values (specify endpoint and value)	n/a	n/a	96hr LC50=505 mg/L
45	Other endpoints reported - e.g. BCF/BAF, LOEC/NOEC (specify)?	n/a	N	
46	Other adverse effects (e.g. carcinogenicity, mutagenicity) reported?	n/a	N	
47	***Score*: ... %**	***77.5***		
48	***EC Reliability code*:**	***2***		
49	***Reliability category (high, satisfactory, low)*:**	***Satisfactory Confidence***		
50	***Comments***			

Robust Study Summaries Form and Instructions: Aquatic iT				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	Reference: Cohle P, R Mihalik R. 1991. Early life stage toxicity of C.I. Disperse Blue 79:1 purified preecake to rainbow trout (*Oncorhynchus mykiss*) in a flow-through system. Final report. ABC Laboratories Inc. Columbia MO.			
2	Substance identity: CAS RN	n/a		
3	Substance identity: chemical name(s)	n/a		Disperse Blue 79:1
4	Chemical composition of the substance	2		n/a
5	Chemical purity	1	Y	96.61
6	Persistence/stability of test substance in aquatic solution reported?	1	N	
Method				
7	Reference	1	Y	
8	OECD, EU, national, or other standard method?	3	Y	
9	Justification of the method/protocol if not a standard method was used	2		n/a
10	GLP (Good Laboratory Practice)	3	Y	
Test organism				
11	Organism identity: name	n/a		*Rainbow trout*
12	Latin or both Latin & common names reported?	1	Y	
13	Life cycle age / stage of test organism	1	Y	
14	Length and/or weight	1	Y	
15	Sex	1		n/a
16	Number of organisms per replicate	1	Y	20
17	Organism loading rate	1	Y	0.36 to 4.8ug/L

18	Food type and feeding periods during the acclimation period	1	Y	
Test design / conditions				
19	Test type (acute or chronic)	n/a	Y	chronic
20	Experiment type (laboratory or field)	n/a	Y	lab
21	Exposure pathways (food, water, both)	n/a	Y	water
22	Exposure duration	n/a	Y	122 days
23	Negative or positive controls (specify)	1	Y	control and carrier blank
24	Number of replicates (including controls)	1	Y	2
25	Nominal concentrations reported?	1	Y	5
26	Measured concentrations reported?	3	Y	
27	Food type and feeding periods during the long-term tests	1	Y	
28	Were concentrations measured periodically (especially in the chronic test)?	1	Y	
29	Were the exposure media conditions relevant to the particular chemical reported? (e.g., for the metal toxicity - pH, DOC/TOC, water hardness, temperature)	3	Y	
30	Photoperiod and light intensity	1	Y	
31	Stock and test solution preparation	1	Y	
32	Was solubilizer/emulsifier used, if the chemical was poorly soluble or unstable?	1	Y	
33	If solubilizer/emulsifier was used, was its concentration reported?	1	Y	
34	If solubilizer/emulsifier was used, was its ecotoxicity reported?	1	Y	no tox value but however solubilizer was used as a control
35	Analytical monitoring intervals	1	Y	
36	Statistical methods used	1	Y	
Information relevant to the data quality				
37	Was the endpoint directly caused by the chemical's toxicity, not by organism's health (e.g. when mortality in the control >10%) or physical effects (e.g. 'shading effect')?	n/a	Y	
38	Was the test organism relevant to the Canadian environment?	3	Y	
39	Were the test conditions (pH, temperature, DO, etc.) typical for the test organism?	1	Y	
40	Does system type and design (static, semi-static, flow-through; sealed or open; etc.) correspond to the substance's properties and organism's nature/habits?	2	Y	flow through
41	Was pH of the test water within the range typical for the Canadian environment (6 to 9)?	1	Y	
42	Was temperature of the test water within the range typical for the Canadian environment (5 to 27°C)?	1	Y	

43	Was toxicity value below the chemical's water solubility?	3		n/a
Results				
44	Toxicity values (specify endpoint and value)	n/a	n/a	NOEC>0.005mg/L
45	Other endpoints reported - e.g. BCF/BAF, LOEC/NOEC (specify)?	n/a		
46	Other adverse effects (e.g. carcinogenicity, mutagenicity) reported?	n/a		
47	***Score*: ... %**	***97.6***		
48	***EC Reliability code*:**	***1***		
49	***Reliability category (high, satisfactory, low)*:**	***High Confidence***		
50	***Comments***			