Screening Assessment for the Challenge

Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt (Acid Blue 80)

Chemical Abstracts Service Registry Number
4474-24-2

Environment Canada
Health Canada

November 2008

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 benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt (Acid Blue 80), Chemical Abstracts Service Registry Number 4474-24-2. This substance was identified as a high priority for screening assessment and included in the Ministerial Challenge because it was 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 Acid Blue 80 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.

Acid Blue 80 is a discrete organic substance that is used in Canada and elsewhere as a dark-blue colourant dye in cleaning products in consumer products and in several industrial and commercial sectors. In addition, Acid Blue 80 is used in Canada as a dye in one disinfectant registered under the *Pest Control Act*, and at low concentrations in cleaners and laundry detergents used in food plants. The substance is not naturally produced in the environment. Between 10 001 and 100 000 kg of Acid Blue 80, contained mainly in cleaning products, were imported into Canada in 2006. Such reported quantity and uses indicate that Acid Blue 80 could be released into the Canadian environment.

Based on certain assumptions and reported use patterns, most of the substance is expected to end up in surface water, with a relatively small faction being transferred to waste disposal sites. It is not expected to be present in significant quantities in other media.

Based on its physical and chemical properties, Acid Blue 80 does not have the potential to accumulate in aquatic organisms and it does not degrade quickly in the environment. Acid Blue 80 is expected to be persistent in water, soil and sediments based on criteria defined in the *Persistence and Bioaccumulation Regulations*. Empirical acute aquatic toxicity values for Acid Blue 80 and an analogue suggest that the substance is not highly hazardous to aquatic organisms (LC_{50} = 10-1 000 mg/L).

For this screening assessment, risk quotients were calculated based on two conservative exposure scenarios: one for industrial release, and one for consumer releases, both to the aquatic environment. The resulting predicted environmental concentration (PEC) were all below the predicted no-effect concentrations (PNECs) calculated for aquatic organisms, indicating that these releases are unlikely to cause ecological harm.

In addition and where relevant, research and monitoring will support verification of assumptions used during the screening assessment.

Based on the information available, Acid Blue 80 does not meet any of the criteria set out in section 64 of the *Canadian Environmental Protection Act, 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 2006), 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 benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt 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 May 12, 2007 (Canada 2007). 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 properties, hazard and uses of the substance were received.

Although benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt 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 February 2008for ecological sections of the document. Key studies were critically evaluated; modelling results may have been used to reach conclusions. When available and relevant, information presented in hazard assessment 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.

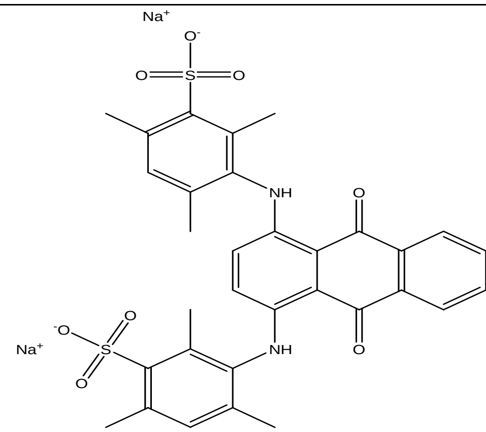
This screening assessment was prepared by staff in the Existing Substances Programs at Health Canada and Environment Canada and incorporates input from other programs within these departments. Additionally, the draft of this screening assessment was subject to a 60-day public comment period. The critical information and considerations upon which the assessment is based are summarized below.

Substance Identity

For the purposes of this report, this substance will be referred to as Acid Blue 80 based on its Color Index name.

Table 1: Substance identity

Chemical Abstracts Service Registry Number (CAS RN)	4474-24-2
Name on Domestic Substances List (DSL)	Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt
Inventory names[1]	*Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt (TSCA, PICCS, ASIA-PAC)* *Sodium 3,3'-(9,10-dioxoanthracene-1,4-diyldiimino)bis(2,4,6-trimethylbenzenesulphonate (EINECS)* *Acid Blue 80 (ENCS)* *Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt (AICS)* *C.I. acid blue 080 (ECL)* *ALIZARIN E (PICCS)*
Other names	*2-Mesitylenesulfonic acid, 4,4'-(1,4-anthraquinonylenediimino)di-, disodium salt; Acid Anthraquinone Brilliant Blue; Acid Brilliant Blue Anthraquinone; Acid Brilliant Blue RAWL; Alizarine Blue BL; Alizarine Fast Blue R; Alizarine Milling Blue R; Atlantic Alizarine; Milling Blue RB; Brilliant Alizarine Milling Blue BL; C-WR Blue 10; C.I. 61585; C.I. Acid Blue 80; Coomassie Blue B; Endanil Blue B; Nylosan Blue C-L; Nylosan Blue F-L; Nylosan Blue F-L 150; Polar Brilliant Blue RAW; Polar Brilliant Blue RAWL; Sandolan Milling Blue N-BL; Sandolan Milling N-BL; Stenolana Brilliant Blue BL; Weak Acid Brilliant Blue RAW; Lanasyn Blue F-L 150*
Chemical group (DSL stream)	Discrete organics
Chemical sub-group	Anthracenediones
Chemical formula	$C_{32}H_{28}N_2O_8S_2.2Na$

Chemical structure	
Simplified Molecular Input Line Entry System (SMILES)	O=C(C3=C2C=CC=C3)C1=C(NC5=C(C)C(S(=O)([O-])=O)=C(C)C=C5C)C=CC(NC4=C(C)C(S(=O)([O-])=O)=C(C)C=C4C)=C1C2=O.[Na+].[Na+]
Molecular mass	678.691 g/mol

[1] National Chemical Inventories (NCI). 2006: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); PICCS (Philippine Inventory of Chemicals and Chemical Substances); and TSCA (Toxic Substances Control Act Chemical Substance Inventory).

Physical and Chemical Properties

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 pigment and dyes as “difficult to model” using QSARs. The inherent 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, to determine the domain of applicability, Environment Canada reviews the applicability of QSAR models to dyes and pigments on a case-by-case basis. Environment Canada has considered it inappropriate to use QSAR models to predict the physical and chemical properties of Acid Blue 80 and has consequently used a "read-across" approach to determine the approximate physical and chemical properties in Table 2. These properties were subsequently used for further modelling in this assessment. Table 2 shows some experimental and extrapolated physical and chemical properties of Acid Blue 80.

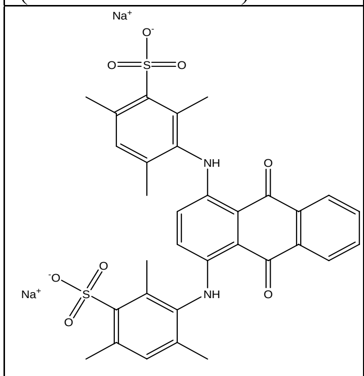
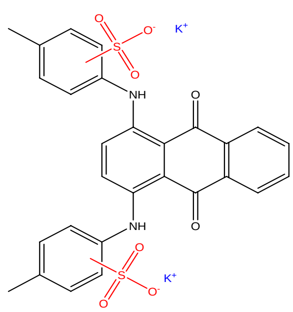
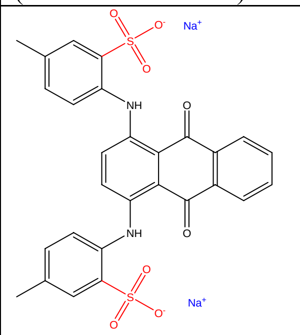
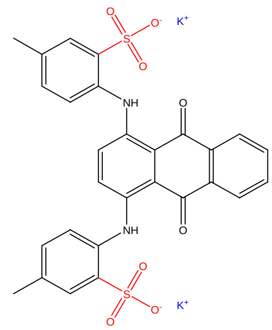
Table 2. Physical and chemical properties for Acid Blue 80

Property	Type	Value	Temperature (°C)	Reference
Physical state	Experimental	dark blue granules	-40 to 40	MSDS 2006
Boiling point (ºC)	Read-across[a]	> 150	n/a	ETAD 1995
Decomposition point (ºC)	Experimental	> 190	n/a	MSDS 2006
	Read-across[a]	> 300	n/a	ETAD 1995
Vapour pressure (Pa)	Read-across[a]	10^{-8} to 10^{-10}	25	ETAD 1995; Baughman 1988
Henry's Law constant (Pa·m^3/mol)		Information not available[b]		
Log K_{ow} (Octanol-water partition coefficient) (dimensionless)	Read-across[a]	< 3	25	Anliker et al. 1981; Anliker and Moser 1987
Log K_{oc} (Organic carbon-water partition coefficient) (dimensionless)		Information not available[b]		
Water solubility (mg/L)	Experimental	10 000	25	MSDS 2006
	Read-across[a]	> 10 000	25	ETAD 1995

[a] The extrapolated values used for substances in the disulfonic acid dyes group are based on empirical data on disulfonic acid dyes submitted to Environment Canada under the *New Substance Notification Regulations* (Canada 2005) and/or available evidence from other di-sulfonic acid dye analogues (e.g., ETAD 1995).
[b] For these properties, the modelled analogue data identified were deemed unreliable and not appropriate for use in this assessment.

In this screening assessment of Acid Blue 80, analogues from which empirical data, when available, were used as extrapolated values for Acid Blue 80 or as supporting values for the weight of evidence, are described in Table 3.

Table 3. Acid Blue 80 and its structural analogues

i. Benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt (CAS RN 4474-24-2)	ii. 9,10-Anthracenedione, 1,4-bis[(4-methylphenyl)amino]-, sulfonated, potassium salts (CAS RN 125351-99-7)	iii. Benzenesulfonic acid, 2,2'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[5-methyl-, disodium salt (CAS RN 4403-90-1)	iv. Benzenesulfonic acid, 2,2'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[5-methyl-, dipotassium salt (CAS RN 83044-88-6)
			

Comparative analysis:

As illustrated above, the substances with CAS RNs 125351-99-7 (ii), 4403-90-1 (iii) and 83044-88-6 (iv) are very good analogues for Acid Blue 80 (i) based on their structural similarities.

- The only differences between the chemical structures of Acid Blue 80 (i) and substance (ii) is the two additional methyl groups at the ortho position of the aromatic ring for (i) and the fact that (ii) does not define the position of the sulfonate groups.

- The only difference betweens the chemical structures of Acid Blue 80 (i) and substance (iii) is the presence of the sulfonate group at the meta position of the aromatic ring for (i) instead of the ortho position for (ii) and the two additional methyl groups at the ortho position of the aromatic ring for (i). Substance (iv) is the same as substance (iii) except that it is a dipotassium salt instead of a disodium salt.

Sources

Acid Blue 80 is not reported to be naturally produced in the environment.

Information gathered from the CEPA 1999 section 71 notices for the 2005 and 2006 calendar years indicates that Acid Blue 80 was not manufactured in Canada in a quantity meeting the 100 kg reporting threshold (Canada 2006a; Environment Canada 2007). For the 2006 calendar year, four Canadian companies reported importing Acid Blue 80 (either alone, or contained in a mixture, a product or a manufactured item) in a quantity equal to or greater than 100 kg, with three companies in the 100–1000 kg/year range and one company in the 1001–100 000 kg/year range. In addition, two Canadian companies reported importing this substance in a quantity below the prescribed threshold, and 10 Canadian companies identified a stakeholder interest (Environment Canada 2007).

For the 2005 calendar year, four Canadian companies reported importing this substance (either alone, or contained in a mixture, a product or a manufactured item), with three companies reporting amounts in the 100–1000 kg/year range and one company in the 1001–100 000 kg/year range. In addition, three Canadian companies identified themselves as having a stakeholder interest in the substance. Only one of the companies reported for both 2005 and 2006 (Environment Canada 2006).

During the 1986 calendar year, it was reported that approximately 2000 kg of Acid Blue 80 was manufactured, imported or in commerce in Canada (Environment Canada 1988). Fewer than four companies made notifications for the calendar years 1984–1986.

Elsewhere, Acid Blue 80 was reported to the United States Environmental Protection Agency under the Inventory Update Rule for use between 4.5 and 225 tonnes from 1986 to 2002. Acid Blue 80 has not been reported by European Union industry as a High Production Volume Chemical or a Low Production Volume Chemical (ESIS [cited 2007 Dec 12]). However, the Substances in Preparations in Nordic Countries database indicates that from 1999 to 2004, approximately 5 tonnes were in use in Sweden, 0.2 tonnes in Norway and 260 tonnes in Denmark (SPIN 2006). Acid Blue 80 was also used in Finland from 2001 to 2003; however, quantities were not specified.

Uses

Acid Blue 80 is used in Canada as a colourant in cleaners and laundry detergents at a low concentration (Environment Canada 2007).

Two of the four companies that reported importing Acid Blue 80 into Canada in response to a CEPA 1999 section 71 survey notice for the 2006 calendar year stated that they fell under the North American Industry Classification System (NAICS) codes with the following descriptions:

- 325130: “Synthetic Dye and Pigment Manufacturing. This Canadian industry comprises establishments primarily engaged in manufacturing synthetic organic and inorganic dyes, pigments, lakes and toners.”
- 418410: “Chemical (except Agricultural) and Allied Product Wholesaler–Distributors. This Canadian industry comprises establishments primarily engaged in wholesaling industrial and household chemicals, cleaning compounds and preparations, plastics resins, plastic basic forms and shapes, and industrial gases.”

The two other companies required that their NAICS codes be kept confidential.

Three of the four companies that reported importing Acid Blue 80 into Canada in response to a CEPA 1999 section 71 survey notice for the 2005 calendar year stated they fell under the same NAICS codes described above in addition to the following NAICS code:

- 325611: “Soap and Other Detergent Manufacturing. This U.S. industry comprises establishments primarily engaged in manufacturing and packaging soaps and other detergents, such as laundry detergents; dishwashing detergents; toothpaste gels, and tooth powders; and natural glycerin."

One company reporting for 2005 requested that its NAICS code be kept confidential.

These NAICS codes are consistent with the two DSL use codes that were identified for Acid Blue 80 in 1986: Colourant – pigment/stain/dye/ink and Textile, Primary Manufacture (Environment Canada 1988).

Additionally, Acid Blue 80 is used in Canada as a formulant in one disinfectant pest control products (PMRA 2007). Acid Blue 80 is a colourant in this product at a low concentration (0.005%). Pest control products are regulated by the Pest Management Regulatory Agency (PMRA) under the *Pest Control Products Act*.

In Europe, Acid Blue 80 has been used as a colouring agent allowed exclusively in cosmetic products intended to come into contact only briefly with the skin (EU 2006). In Australia, this chemical has been used as an ingredient in disinfectants and sterilants (TGA 2007). In the U.S., Acid Blue 80 is also used in detergent and textile applications (US ITC 2004). In Sweden, Norway and Denmark, Acid Blue 80 has been used in cleaning/washing agents; sanitation agents; colouring agents; non-agricultural pesticides and preservatives used in the following areas: general cleaning activities; industrial cleaning; specialized cleaning activities in the textile industry; construction; health and social work (SPIN 2006)

The above information suggests that Acid Blue 80 has dispersive uses.

Releases to the Environment

For the 2006 calendar year, four Canadian companies reported releases of Acid Blue 80 (whether alone, in a product, in a mixture or in a manufactured item) into the environment, and three Canadian companies reported transferring the substance to an off-site waste-management facility (including the substance contained in a mixture, in a product or in a manufactured item). The quantities and media cannot be specified as it was requested to be kept confidential (Environment Canada 2007).

Mass flow tool

To estimate release of the substance to the environment at different stages of its life cycle, a mass flow tool was used. The results of the tool include, for each identified type of use, the estimated proportion and quantity of release to the different environmental media and also the proportion of the substance chemically transformed or sent for waste disposal. Assumptions and input parameters used in making these estimates are based on information obtained from a variety of sources, including responses to regulatory surveys, Statistics Canada, manufacturers' websites and technical databases. Of particular relevance are emission factors, which are generally expressed as the fraction of a substance released to the environment, particularly during its manufacture, transformation 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), 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 later in the life cycle.

Results indicate that Acid Blue 80 is mostly released to water (96.5%) during the processing and use stages of the life cycle (see Table 4). Most of the products containing this colourant will be sent to landfill sites for disposal; the remainder will be sent for incineration. Note the tool assumes no releases from waste disposal sites.

Table 4. Estimated releases and losses of Acid Blue 80 to environmental media, transformation and distribution to management processes, based on the mass flow tool[1]

Medium or process	Proportion of the mass (%)	Major life cycle stage
Release to Soil	1.0	Use
Release to Air	0.0	Processing and use
Release to Water	96.5	Processing and use
Transformation	0.1	Use
Waste disposal	2.4	Waste management (e.g., landfill)
Hazardous waste management	n/a	Waste management (e.g., landfill)

[1]For Acid Blue 80, information from the following Organisation for Economic Co-operation and Development emission scenario documents was used to estimate releases to the environment and distribution of the substance, as summarized in this table: OECD 2004; OECD 2006. Values presented for releases 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 derivation of these estimates are summarized in Environment Canada 2007a.

Environmental Fate

According to the mass flow tool results presented in Table 4, most of Acid Blue 80 is released to water during the processing and use stages, so a release scenario to water seems to be the most relevant for Canada.

Due to its high water solubility value (10 000 mg/L), Acid Blue 80 will tend to stay in the water into which it is released.

Acid Blue 80 may enter soil with waste water treatment plant sludges, which may be used for soil enrichment, or through disposal of sludges, coloured textiles, papers and leather substrates in landfills. Volatilization from dry or moist soil surfaces seems to be an unimportant fate process based upon the low estimated vapour pressure. If released to soil (from products), Acid Blue 80 likely migrates to the water phase of the soil (e.g., groundwater) or undergoes surface runoff.

Acid Blue 80 is not released to air, likely because of its low predicted vapour pressure.

Persistence and Bioaccumulation Potential

Environmental Persistence

No environmental monitoring data relating to the presence of Acid Blue 80 in the Canadian environment (air, water, soil, sediment) have been identified. Furthermore, no experimental biological degradation data for Acid Blue 80 have been identified. Given that the majority of Acid Blue 80 is expected to be released into wastewater, persistence was primarily examined using predictive QSAR models for biodegradation in water. Acid Blue 80 does not contain functional groups expected to undergo hydrolysis (dyes are designed to be stable in aqueous conditions).

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 the *OECD Guidelines for the Testing of Chemicals* website) have confirmed this assumption (Pagga and Brown 1986; ETAD 1992). Based on the chemical structure of Acid Blue 80, there is no reason to suspect that biodegradation will be other than that described for dyes (ETAD 1995). As described below, modelled data in Table 5 support this assumption of non-degradability.

Additionally, a QSAR weight-of-evidence approach (Environment Canada, 2006a) was applied for estimating degradation in water using the models shown in Table 5. The modelled results in Table 5 support the above assumption of non-degradability. Acid Blue 80 is therefore considered persistent in water (half-life $\geq$ 182 days).

Table 5. Modelled data for persistence of Acid Blue 80

Medium	Fate process	Degradation value	Degradation endpoint	Reference
Air	Atm-oxidation	0.09	Half-life (days)	AOPWIN 2000
Air	Ozone reaction	Non-reactive	Half-life (days)	AOPWIN 2000
Water	Biodegradation	> 182 (recalcitrant)	Half-life (days)	BIOWIN 2000 (Ultimate Survey Model)
Water	Biodegradation	0 (does not biodegrade fast)	Probability	BIOWIN 2000 (MITI Non-linear Probability Model)
Water	Biodegradation	Not Ready Biodegradable	Weighted 6 Model Assessment	BIOWIN 2000
Water	Biodegradation	Out of acceptable domain of model	Probability	TOPKAT 2004
Water	Biodegradation	1.2%	BOD (MITI 301C)	CATABOL c2004–2008
Water	Anaerobic Biodegradation	0 (does not biodegrade fast)	Probability	BIOWIN 2000

To estimate a half-life in soils and sediments, an approach has been developed using Boethling's extrapolation factors (Boethling et al. 1995), which involves estimating the half-life in these media from that estimated for water ($t_{1/2\ water}$: $t_{1/2\ soil}$:$t_{1/2\ sediment}$ = 1: 1: 4). Therefore, in soils and sediments, the half-lives for Acid Blue 80 are expected to exceed 182 days and 365 days, respectively.

Acid Blue 80 is not expected to be released to air and an oxidation half-life of 0.09 days (Table 5) demonstrates that any Acid Blue 80 in air could be rapidly oxidized. Acid Blue 80 is not expected to react, or react appreciably, with other photo oxidative species in the atmosphere, such as O_3 and NO_3, nor is it likely to degrade via direct photolysis. Therefore, it is expected that reactions with hydroxyl radicals will be the most important fate process in the atmosphere for this chemical. With a half-life of 0.09 days via reactions with hydroxyl radical, Acid Blue 80 is not persistent in air.

The weight of evidence based on the above-described data indicates that Acid Blue 80 meets the persistence criteria for water and soil (half life ≥ 182 days) and sediment (half life ≥ 365 days) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential for Bioaccumulation

There are no empirical bioaccumulation data available for this substance.

The log K_{ow} data in Table 2 from read-across suggest that this substance does not have the potential to bioaccumulate in the environment.

A reliable log K_{ow} for Acid Blue 80 could not be estimated using predictive models. A range of QSAR bioaccumulation predictions were obtained from the various QSAR models considered for Acid Blue 80. However, these QSAR predictions for Acid Blue 80 are not considered reliable. The main reason for the lack of reliability of these QSAR bioaccumulation predictions is the high water solubility potential of anionic dyes like Acid Blue 80, which is not accounted for in these predictions.

Anionic dyes, in general, will have low log K_{ow} values (< 3.0) and high water solubility values (> 2000 mg/L). This pattern has been observed based on data from previous bioconcentration and partition studies with dyes (ETAD 1995). The high water solubility of Acid Blue 80 (Table 2) provides an indication that Acid Blue 80 has a low potential to bioaccumulate/bioconcentrate in aquatic biota.

Another reason for the low bioaccumulation potential of Acid Blue 80 is its high degree of dissociation under typical environmental conditions. Perrin et al. (1981) and Lee et al. (1990) suggest a decrease of only 0.11 unit in the pKa for organic acids and bases with a change in ionic strength (μ) from 0 to 0.1. Ionic strength for aqueous phases in the environment typically range from 0.001 to 0.14. Therefore, overall effects from pH and pKa changes due to ionic strength upon speciation are likely to be minimal. This suggests that "salt" form is likely to behave as either the ionized or the neutral species depending on the pH and the pKa of the chemical. The degree of dissociation is dependent on the pKa (estimated to be ~< 1), therefore Acid Blue 80 is expected to be highly dissociated under typical environmental conditions. This high degree of dissociation is a likely reason for the low bioaccumulation potential for this substance.

The weight of evidence indicates that Acid Blue 80 does not meet the bioaccumulation criterion (BCF, BAF ≥ 5000) as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

Potential to Cause Ecological Harm

Ecological Effects Assessment

In the Aquatic Compartment

There are few empirical ecotoxicity data available for Acid Blue 80 and therefore data from a close chemical analogue (CAS RN 125351-99-7) was also considered. Based on the available experimental evidence (Table 6) and analysis of functional groups, Acid Blue 80 is not expected to cause harm to aquatic organisms at relatively low concentrations (i.e., acute LC_{50}s are not < 1 mg/L).

Experience with new dyes at Environment Canada and the U.S. EPA Office of Pollution Prevention and Toxics (OPPT) has shown that, in general, the number of sulphonic acid groups determines potential for toxicity. Dyes with one or two sulphonic acid groups have shown moderate to high acute toxicity (< 1–10 mg/L) to some aquatic biota, while dyes with more than two sulphonic acid groups have shown very low acute (> 100 mg/L) and chronic (> 10 mg/L) toxicity to most aquatic biota. Furthermore, Environment Canada has generally found anionic dyes to be of low toxicity regardless of the number of acid groups, but some exceptions have been found (e.g., when a reactive functional group is not hindered). Therefore, Acid Blue 80, as an anionic dye with two sulphonic acid groups and no reactive functional group, is expected to have a low to moderate toxicity to aquatic organisms.

Table 6. Empirical data for aquatic toxicity of Acid Blue 80

CAS RN	Test organism	Type of test	Duration (hours)	End point	Value (mg/L)	Reference
4474-24-2 (Acid Blue 80)	*Oncorhynchus mykiss (Salmo gairdneri)* [rainbow trout]	Acute	48	LC_{50}[1]	75	Sandoz 1977
	Bacteria (activated sludge)	Respiration Inhibition	3	IC_{50}[2]	> 1.000	Clariant 1989
125351-99-7 (analogue)	*Poecilia reticulata* (guppy)	Acute	96	LC_{50}[1]	14.3	BMG 1996

[1] LC_{50} – The median or nominal Lethal Concentration (LC_{50}) is the concentration of a substance that is estimated to be lethal to 50% of the test organisms.
[2] IC_{50} – The concentration of a substance that is estimated to cause inhibition of 50% of the test organisms.

An empirical acute toxicity study on *Salmo gairdneri, oncorhynchus mykiss* (Table 6) found a 48-hour LC_{50} of 75 mg/L, indicating that Acid Blue 80 is not hazardous to aquatic organisms at relatively low concentrations (i.e., LC/EC_{50}s > 1 mg/L). The result of this study was deemed to be of low reliability, as detailed test methods were not provided. However, this conclusion is also supported by another empirical acute toxicity study for a structural analogue of Acid Blue 80 (CAS RN 125351-99-7) on *Poecilia reticulata* (Table 6) which found a 96-hour LC_{50} of 14.3 mg/L (Appendix I).

A range of aquatic toxicity predictions were obtained from the various QSAR models considered for Acid Blue 80 and its analogues. However, as with bioaccumulation, these QSAR ecotoxicity predictions for Acid Blue 80 are not considered reliable.

The available empirical ecotoxicity information indicates that Acid Blue 80 is moderately toxic to aquatic organisms (i.e., acute toxicity 10–100 mg/L).

In Other Environmental Compartments

Because Acid Blue 80 could be released to soil from the disposal of products that degrade and release Acid Blue 80, it would be desirable to obtain toxicity data for soil organisms. However, no suitable ecological effects studies were found for this compound in media other than water.

Ecological Exposure Assessment

No data concerning concentrations of this substance in environmental media (air, water, soil, sediment) in Canada have been identified. Environmental concentrations have, therefore, been estimated from available information, including estimated substance quantities, release rates and receiving water bodies.

Quantitative evaluations of exposure have been conducted for two different release scenarios. For both scenarios, it is conservatively assumed that 100% of the Acid Blue 80 in commerce in Canada is used in cleaning products. This assumption is based on information gathered from the CEPA 1999 section 71 notices for the 2005 and 2006 calendar years which indicated that one company imported Acid Blue 80 in the 1001–100 000 kg/year range for use in cleaning products. The quantities provided by other importing companies are small compared to this amount. Firstly, since a single facility reported importing large quantities of Acid Blue 80, an exposure scenario considering potential industrial releases (through such activities as processing and cleaning) was developed. Additionally, as the substance is mainly used in cleaning products which are distributed to the Canadian market, an exposure scenario considering down-the-drain releases from consumer use was also developed. These are described further below.

Industrial release scenario

According to available information, the importer rinses all containers for Acid Blue 80 and treats the residues together with other production waste streams containing Acid Blue 80 by sending them to water treatment facilities that use an activated sludge process. The industrial facility in question has both primary and secondary treatment, either industry-operated or in association with municipal waste water treatment plants.

Environment Canada's Industrial Generic Exposure Tool – Aquatic (IGETA) (Environment Canada 2007b) was used to estimate the substance concentration in a generic watercourse receiving industrial effluents. 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 removal rate, and the size of the receiving watercourse. This scenario yielded a predicted environmental concentration of 0.56 mg/L, which is above the identified effects threshold (see Characterization of Ecological Risk below) and therefore, the industrial release scenario was further refined to develop a more realistic exposure characterization. In doing so, the actual location of the importing company was identified, and the actual receiving water body was used to determine the resulting predicted environmental concentration instead of the generic river used above. The receiving body of water is in fact a lake and when considering that the removal rate from the sewage treatment plant was 78.7% instead of the default value of 0 the resulting concentration in the receiving water body is estimated (based on instantaneous dilution using a factor of 10) to be 0.119 mg/L (ASTreat 2006, Environment Canada 2008a). This value can be considered to be the predicted environmental concentration (PEC) for this scenario.

Consumer use release scenario

Environment Canada's tool to estimate down-the-drain releases from consumer uses (MegaFlush) was used to estimate the substance concentration in multiple watercourses receiving sewage treatment plant effluents resulting from uses of products containing Acid Blue 80 (Environment Canada 2007c). MegaFlush then presented the percentage of watercourses in which the concentration exceeds a selected predicted no-effect concentration (PNEC), which provides an indication of the extent of possible risks on a national basis (see Characterization of Ecological Risk below). The tool is designed to provide these estimates based on conservative assumptions regarding the amount of chemical used and released by consumers and sewage treatment plant removal rate. For this scenario, some parameters were modified to be more appropriate for this substance, making them more true to reality. The equation and inputs used to calculate the predicted environmental concentration (PEC) in the receiving watercourses as well as the final output of the model are described below:

$$\text{PEC (mg/L)} = \frac{I \times L \times (1-R) \times P}{D \times C \times F \times H} \times \frac{1000}{86\,400}$$

Where

PEC	=	Predicted environmental concentration (mg/L)
I	=	Total quantity of substance used in Canada (100 000 kg/year; this is the high end of the reporting range, as the actual quantity reported was confidential)
L	=	Losses from use (100%; this value is assumed to represent releases from the use of the cleaning product)
R	=	Removal rate of the sewage treatment plant (78.7%; this assumes a conservative value estimated by ASTreat 1.0)
P	=	Population of representative community (100 000 people; default value)
1000	=	Conversion of units (kg/m^3 to mg/L)
D	=	Days of release of the substance from site (365 days/year; this value assumes constant use of the substance)
C	=	Canadian population (32 501 147 people; default value)
F	=	Flow of the receiving watercourse (variable for each water body; calculated at the 10th and 50th percentile of annual distribution of the flow)
H	=	Spatial homogeneity of the use (50%; default value used to represent a potential different use pattern for a product)
86 400	=	Conversion of units (days to seconds)

The PEC calculated using the MegaFlush tool ranged from 0 to 0.064mg/L, depending on the flow of the receiving water course (Environment Canada 2008b).

Characterization of Ecological Risk

The approach taken in this ecological screening assessment was to examine various supporting information and develop conclusions based on a weight-of-evidence approach and using precaution as required under section 76.1 of CEPA 1999. Particular consideration is given to fate in the environment, bioaccumulation, inherent toxicity, and risk quotient analysis.

Although Acid Blue 80 is expected to be persistent in water, soil and sediment, it is also expected to have a low bioaccumulation potential. The importation volumes of Acid Blue 80 into Canada, along with information on its uses, indicate potential for releases into the Canadian environment. Once released into the environment, it will be found mainly in water. It has also been demonstrated to have a moderate potential for toxicity to aquatic organisms.

A risk quotient analysis, integrating conservative and more realistic estimates of exposure with toxicity information, was performed for the aquatic medium to determine whether there are ecological risks in Canada.

The industrial scenario presented above yielded a predicted concentration of 0.119 mg/L in the receiving water body. A PNEC was derived from the acute toxicity value of 14 mg/L for the guppy, by dividing this value by an assessment factor of 100 (10 to account for interspecies and intraspecies variability in sensitivity and 10 to estimate a long-term no-effects concentration from a short-term LC_{50}) to give a PNEC of 0.14 mg/L. The resulting risk quotient (PEC/PNEC) is 0.85. Given that IGETA provides a conservative estimate of exposure and in view of the large assessment factor used to estimate chronic effect thresholds (PNECs), the results indicate a low potential for ecological harm resulting from local exposure to a point source industrial release of Acid Blue 80 to the aquatic environment, especially where the location has a large dilution capacity.

For exposure resulting from down-the-drain releases using a moderately conservative consumer release scenario, risk quotients of 0 to 0.1 were obtained based on the PEC of 0 to 0.064 mg/L calculated with the MegaFlush tool, and the PNEC of 0.75 mg/L. This means the PNEC will not be exceeded at any sites (i.e., all risk quotients < 1) (Environment Canada 2008b). This indicates that down-the-drain consumer releases of Acid Blue 80 are also not expected to harm aquatic organisms in water bodies receiving wastewater across Canada.

Uncertainties in Evaluation of Ecological Risk

The lack of supporting evidence from empirical studies is a source of uncertainty in the bioaccumulation assessment.

The persistence assessment is limited by the lack of experimental biodegradation data, which necessitated generation of model predictions.

The uncertainties also exist because of the lack of information on environmental concentrations (e.g., monitoring data) in Canada for Acid Blue 80.

Uncertainties are also associated with the fraction of substance in commerce that is released, and with the fraction that is removed in sewage treatment plants.

Regarding toxicity, based on the anticipated release pattern for the substance, the significance of soil as a medium of exposure is not well addressed by the effects data available. Indeed, the only effects data identified apply primarily to pelagic aquatic exposures.

For the exposure assessment, the PEC accounts for concentrations in water only, so exposure through soils, suspended solids, and sediments is not considered.

Conclusion

Based on the information presented in this screening assessment, it is concluded that Acid Blue 80 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 concluded that Acid Blue 80 does not meet the definition of toxic as set out in section 64 of CEPA 1999. Additionally, Acid Blue 80 does not meet criteria for bioaccumulation potential but meets criteria for persistence as set out in the *Persistence and Bioaccumulation Regulations* (Canada 2000).

References

Anliker R, Clarke EA, Moser P. 1981. Use of the partition coefficient as an indicator of bioaccumulation tendency of dyestuffs in fish. Chemosphere. 10: 263-274.

Anliker R and Moser P. 1987. The limits of bioaccumulation of organic pigments in fish: their relation to the partition coefficient and the solubility in water and octanol. Journal of Ecotoxicology and Environmental Safety. 6: 43-52.

[AOPWIN] Atmospheric Oxidation Program for Windows [Estimation Model]. 2000. Version 1.91. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. [cited 2007 Sept 12]. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

[ASTreat] Activated Sludge Treatment. Computer model for sewage treatment plant removal predictions [CD-ROM]. 2006. Version 1.0. Cincinnati (OH): Procter & Gamble. Available from: P&G, P.O. Box 538707, Cincinnati, OH, 45253-8707, USA.

Baughman G and Perenich T. 1988. Fate of dyes in aquatic systems: I. Solubility and partitioning of some hydrophobic dyes and related compounds. Environmental Toxicology and Chemistry. 7: 183-199.

[BIOWIN] Biodegradation Probability Program for Windows [Estimation Model]. 2000. Version 4.02. Washington (DC): US Environmental Protection Agency, Office of Pollution Prevention and Toxics; Syracuse (NY): Syracuse Research Corporation. [cited 2007 Sept 12]. Available from: www.epa.gov/oppt/exposure/pubs/episuite.htm

BMG Engineering AG.1996. Study Title: *Sandlan Green MF-BL: 96-hour Acute Toxicity to Poecilia reticulate (Guppy)*. Report Number 512-96. Performed by BMG Engineering AG in December 1996, Zurich, Switzerland.

Boethling, RS, Howard, PH, Beauman, JA, Larosche, ME 1995. Factors for intermedia extrapolations in biodegradability assessment. Chemosphere. 30(4): 741-752.

Canada. 1999. *Canadian Environmental Protection Act, 1999 = Loi canadienne sur la protection de l'environnement, 1999*. Statutes of Canada = Statuts du Canada, Chapter 33. Act assented to September 14, 1999. Ottawa: Queen's Printer. Available at Canada Gazette (Part III) 22(3): chapter 33 http://canadagazette.gc.ca/partIII/1999/g3-02203.pdf (accessed August 3, 2007).

Canada. 2000. *Canadian Environmental Protection Act: Persistence and Bioaccumulation Regulations,* P.C. 2000-348, 23 March, 2000, SOR/2000-107, Canada Gazette. Part II, vol. 134, no. 7, p. 607–612. Available from: http://canadagazette.gc.ca/partII/2000/20000329/pdf/g2-13407.pdf

Canada. 2005. *Canadian Environmental Protection Act: New Substances Notification Regulations (Chemicals and Polymers).* P.C. 2005-1484, 31 August, 2005, SOR/2005-247, Canada Gazette. Part II, vol. 139, no. 19, p.1864-1903.
Available from: http://www.ec.gc.ca/ceparegistry/documents/regs/g2-13919_r2.pdf

Canada, Dept. of the Environment, Dept. of Health. 2006. *Canadian Environmental Protection Act, 1999*: *Notice of intent to develop and implement measures to assess and manage the risks posed by certain substances to the health of Canadians and their environment*. Canada Gazette, Part I, vol. 140, no. 49, p. 4109–4117. Available from: http://canadagazette.gc.ca/partI/2006/20061209/pdf/g1-14049.pdf.

Canada, Dept. of the Environment, Dept. of Health. 2006a. *Canadian Environmental Protection Act, 1999*: *Notice with respect to selected substances identified as priority for action*. Canada Gazette, Part I, vol. 140, no. 9, p. 435–459. Available from: http://canadagazette.gc.ca/partI/2006/20060304/pdf/g1-14009.pdf

Canada, Dept. of the Environment, Dept. of Health. 2007. *Canadian Environmental Protection Act, 1999: Notice of second release of technical information relevant to substances identified in the Challenge.* Canada Gazette, Part I, vol. 141. no. 19, p. 1182–1186. Available from: http://canadagazette.gc.ca/partI/2007/20070512/pdf/g1-14119.pdf

[CATABOL] Probabilistic assessment of biodegradability and metabolic pathways [Computer Model]. c2004−2008. Version 5.10.2. Bourgas (BG): Laboratory of Mathematical Chemistry. [2008 February 4]. Available from: http://oasis-lmc.org/?section=software&swid=1

Clariant in-house Activated Sludge Respiration Inhibition Test. Project Number 47/673. 8 September 1989.

Environment Canada. 1988. Data relating to the Domestic Substance List (DSL) 1984-1986, collected under CEPA, 1988, s. 25(1). Collected according to: Reporting for the Domestic Substance List [reporting guide], Minister of Supply and Services Canada, DSS cat. no. En40−364/1998E. Prepared by: Environment Canada, New Substances Division.

Environment Canada. 2000. Chemicals Evaluation Division. *Environmental Categorization for Persistence, Bioaccumulation and Inherent Toxicity of Substances on the Domestic Substances List Using QSARs. Final Report.* Environment Canada. July.

Environment Canada. 2006. Data for selected substances collected under the Canadian Environmental Protection Act, 1999, Section 71: *Notice with respect to selected substances identified as priority for action.*. Prepared by: Environment Canada, Health Canada, Existing Substances Program.

Environment Canada. 2007. Data for Batch 2 substances collected under the Canadian Environmental Protection Act, 1999, Section 71: *Notice with respect to certain Batch 2 Challenge substances.* Data prepared by: Environment Canada, Existing Substances Program.

Environment Canada. 2007a. Assumptions, limitations and uncertainties of the mass flow tool for benzenesulfonic acid, 3,3'-[(9,10-dihydro-9,10-dioxo-1,4-anthracenediyl)diimino]bis[2,4,6-trimethyl-, disodium salt, CAS RN 4474-24-2. Existing Substances Division, Environment Canada, Gatineau (QC). Internal draft document available on request.

Environment Canada. 2007b. Guidance for conducting ecological assessments under CEPA 1999, Science resource technical series, Technical guidance module: The Industrial Generic Exposure Tool - Aquatic (IGETA). Gatineau (QC): Environment Canada, Existing Substances Division. Preliminary draft working document available on request.

Environment Canada. 2007c. Guidance for conducting ecological assessments under CEPA 1999, Science resource technical series, Technical guidance module: Mega Flush consumer release scenario. Gatineau (QC): Environment Canada, Existing Substances Division. Preliminary draft working document available on request.

Environment Canada. 2008a. IGETA report: CAS RN 4474-24-2, 2008-09-04. Unpublished report. Gatineau (QC): Environment Canada, Existing Substances Division.

Environment Canada. 2008b. Mega Flush report: CAS RN 4474-24-2, 2008-08-22. Unpublished report. Gatineau (QC): Environment Canada, Existing Substances Division.

[ESIS] European Substances Information System [database on the Internet]. [date unknown]. Version 5. European Chemical Bureau (ECB). [2007 December 12]. Available from: http://ecb.jrc.it/esis

ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers). 1992. Draft Guidelines for the Assessment of Environmental Exposure to Dyestuffs.

ETAD (Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers). 1995. Health & Environmental Information on Dyes Used in Canada. An overview to assist in the implementation of the New Substances Notification Regulation under the Canadian Environmental Protection Act. Prepared by the ETAD Canadian Affiliates. July 1995. Report 7/21/95

EU (European Union) Commission Decision of 9 February 2006. Available at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_097/l_09720060405en00010528.pdf

Lee LS, Suresh P, Rao C, Nkedi-Kizza P, Delfino J. 1990. Influence of solvent and sorbent characteristics on distribution of pentachlorophenol in octanol-water and soil-water systems. Environmental Science and Technology. 24: 654-661.

[MSDS] Material Safety Data Sheet [Internet]. 2003.European Union: Clariant. Safety data sheet in accordance with 2001/58/EC Nylosan Green N-GL.

[MSDS] Material Safety Data Sheet [Internet]. 2006.European Union: Clariant. Safety data sheet in accordance with 2001/58/EC Lanasyn Blue F-L 150, CAS RN 4474-24-2.

[NCI] National Chemical Inventories [database on a CD-ROM]. 2006. Issue 1. Columbus (OH). American Chemical Society, Chemical Abstracts Service Columbus, Ohio. Available from: http://www.cas.org/products/cd/nci/require.html

[OECD] Organisation for Economic Co-operation and Development. 2004. Emission Scenario Document on Plastics Additives [Internet]. Paris (FR): OECD Environmental Directorate, Environmental Health and Safety Division. [2007 December 15]. Available from: http://oecd.org/ehs/

[OECD] Organisation for Economic Co-operation and Development. 2006. Draft Emission Scenario Document on Transport and Storage of Chemicals. Prepared by the Environment Agency (UK). Available on request from: Environment Canada, Existing Substances Division, Ottawa, K1A 0H3.

Pagga U and Brown D. 1986. The degradation of dyestuffs: Part II behaviour of dyestuffs in aerobic biodegradation tests. Chemosphere. 15(4): 478-491.

Perrin DD, Dempsey B, Serjeant EP. 1981. pKa prediction for organic acids and bases. 1981, Chapman and Hall: London, Great Britain.

[PMRA] Pest Management Regulatory Agency. 2007. Regulatory Note REG 2007-04: PMRA list of formulants [Internet]. Ottawa (ON): Health Canada, Pest Management Regulatory Agency. Available from: http://www.pmra-arla.gc.ca/english/pdf/reg/reg2007-04-e.pdf

Sandoz Chemicals LTD. Muttenz, Switzerland. 1977. Study provided by Clariant Canada and available in [MSDS] Material Safety Data Sheet [Internet]. 2006.European Union: Clariant. Safety data sheet in accordance with 2001/58/EC Lanasyn Blue F-L 150, CAS RN 4474-24-2.

[SPIN] Substances in Preparations in Nordic Countries [database on the Internet]. 2006. Copenhagen (DK): Nordic Council of Ministers. [cited 2006 Mar] Available from: http://195.215.251.229/Dotnetnuke/Home/tabid/58/Default.aspx

[TGA] Therapeutic Goods Administration. 2007. Australian Approved Chemical Substance Names (AANs). Available from: http://www.tga.gov.au/docs/pdf/aan/aanchem.pdf

[TOPKAT] Toxicity Prediction Program [Internet]. 2004. Version 6.2. San Diego (CA): Accelrys Software Inc. [2008 January 23]. Available from: http://www.accelrys.com/products/topkat/index.html

[US ITC] United States International Trade Commission. 2004. Washington, DC 20436 (USA). MEMORANDUM ON PROPOSED TARIFF LEGISLATION of the 108th Congress. August 27, 2004. Available at http://hotdocs.usitc.gov/tata/hts/other/rel_doc/bill_reports/hr-4540.pdf

Appendix I - Robust Study Summary

Robust Study Summaries Form and Instructions: Aquatic iT				
No	**Item**	**Weight**	**Yes/No**	**Specify**
1	Reference: BMG Engineering AG.1996. Study Title: Sandlan Green MF-BL: 96-hour Acute Toxicity to Poecilia reticulate (Guppy). Report Number 512-96. Performed by BMG Engineering AG in December 1996, Zurich, Switzerland.			
2	Substance identity: CAS RN	n/a		125351-99-7
3	Substance identity: chemical name(s)	n/a		Sandolan Gruen MF-BL
4	Chemical composition of the substance	2		
5	Chemical purity	1	Y	
6	Persistence/stability of test substance in aquatic solution reported?	1	Y	
Method				
7	Reference	1	Y	
8	OECD, EU, national, or other standard method?	3	Y	OECD 203
9	Justification of the method/protocol if not a standard method was used	2		
10	GLP (Good Laboratory Practice)	3	N	Good Scientific Practice
Test organism				
11	Organism identity: name	n/a		*poecilia reticulata*
12	Latin or both Latin & common names reported?	1	Y	
13	Life cycle age / stage of test organis	1	Y	
14	Length and/or weight	1	Y	
15	Sex	1		
16	Number of organisms per replicate	1	Y	7
17	Organism loading rate	1	N	
18	Food type and feeding periods during the acclimation period	1	Y	
Test design / conditions				
19	Test type (acute or chronic	n/a		acute
20	Experiment type (laboratory or field	n/a		laboratory
21	Exposure pathways (food, water, both)	n/a		water
22	Exposure duration	n/a		96 hour
23	Negative or positive controls (specify)	1	Y	negative
24	Number of replicates (including controls)	1	N	
25	Nominal concentrations reported?	1	Y	5
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	
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		
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	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	static
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	Y	
Results				
44	Toxicity values (specify endpoint and value)	n/a	n/a	LC50=14.3mg/L
45	Other endpoints reported - e.g. BCF/BAF, LOEC/NOEC (specify)?	n/a		NOEC=8mg/L
46	Other adverse effects (e.g. carcinogenicity, mutagenicity) reported?	n/a		
47	***Score: ... %***	***75.0***		
48	***EC Reliability code:***	***2***		
49	***Reliability category (high, satisfactory, low):***	***Satisfactory Confidence***		
50	***Comments***			