# Substance Profile for The Challenge

# Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthracenyl]amino]-2,4,6-trimethyl-, disodium salt
# Acid Violet 48
# CAS RN 72243-90-4

**Environment Canada**
**Health Canada**

**August 2007**

# Introduction

The *Canadian Environmental Protection Act, 1999* [CEPA 1999] (Canada 1999) required the Minister of Health and Minister of the Environment to categorize the approximately 23 000 substances on the Domestic Substances List (DSL). Categorization involved identifying those substances on the DSL that are a) considered to be persistent (P) and/or bioaccumulative (B), based on criteria set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000), and "inherently toxic" (iT) to humans or other organisms, or b) that present, to individuals in Canada, the greatest potential for exposure (GPE).

Further to this activity, the Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that meet the categorization criteria. A screening assessment involves a scientific evaluation of available information for a substance to determine whether the substance meets the criteria set out in section 64 of CEPA 1999. Based on the results of a screening assessment, the Ministers can propose taking no further action with respect to the substance, adding the substance to the Priority Substances List (PSL) for further assessment or recommending the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999 and, where applicable, the implementation of virtual elimination of releases to the environment.

A number of substances have been identified by the Ministers as high priorities for action based on the information obtained through the categorization process. This includes substances:

- that were found to meet all of the ecological categorization criteria, including persistence, bioaccumulation potential and inherent toxicity to aquatic organisms (PBiT), and that are known to be in commerce or of commercial interest in Canada, and/or
- that were found either to meet the categorization criteria for GPE or to present an intermediate potential for exposure (IPE), and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, genotoxicity, developmental toxicity or reproductive toxicity.

Based on a consideration of the ecological and/or human health concerns associated with these substances, and the requirement under section 76.1 of CEPA 1999 for the Ministers to apply a weight of evidence approach and the precautionary principle when conducting and interpreting the results of an assessment, sufficient data are currently available to consider whether these substances meet the criteria under Section 64 of CEPA 1999.

As such, the Ministers have issued a Challenge to industry and other interested stakeholders through publication in Canada Gazette Part I December 9, 2006 (Environment Canada and Health Canada 2006) to submit, within the timelines stated in the Challenge section of this document, specific information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

The substance Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthracenyl]amino]-2,4,6-trimethyl-, disodium salt was identified as a high priority for action as it was found to be persistent, bioaccumulative and inherently toxic to aquatic organisms and is believed to be in commerce in Canada. The technical human health and ecological information, that formed the basis for concern associated with this substance, is presented in this document.

## The Challenge

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

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

Exceptionally, should no information be identified to indicate that this substance is in commerce in Canada, the Ministers will conclude, based on a screening assessment, that this substance does not satisfy the definition of toxic under section 64 of CEPA 1999. However, given the properties of this substance, there is concern that new activities for the substance that have not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore it would be recommended that this substance be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of this substance in quantities greater than 100 kg/year is notified, and that ecological and human health risk assessments are conducted as specified in section 83 of the Act prior to the substance being introduced into Canada.

## Section 71 Notice

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

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

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

## Opportunity to Submit Additional Information to Inform Screening Assessment

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

Data on the persistence, bioaccumulation, and potential for toxicity of the substance to organisms in different environmental media – Through the categorization exercise, available experimental data were collected up to December 2005. Where acceptable experimental data were not available, Quantitative Structure Activity Relationships (QSARs) or read-across data were used to fill the data gaps. Since experimental data are preferred, interested parties have an opportunity to provide new or additional relevant experimental study information on the persistence, bioaccumulation, and potential for toxicity of this substance to organisms in different environmental media (air, water, sediment, soil), or on the physical/chemical properties values that were used as input to the QSAR models. Efforts should focus on providing data for the endpoints for which good quality experimental data do not already exist, as demonstrated by the information summarized in the "Ecological Information" or "Physical/Chemical Properties" sections of this document. As submitted data will be evaluated for completeness and robustness, it is recommended that stakeholders follow the guidance for test protocols and alternative approaches for test data, as described in Section 8 of the "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers" (Government of Canada 2006).

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

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

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

## Opportunity to Submit Additional Information on Current Uses and Existing Control Measures to Inform the Risk Management Approach for this Substance

The Ministers of Health and Environment are inviting the submission of additional information that is deemed beneficial by interested stakeholders, relating to the extent and nature of the management/stewardship of substances listed under the Challenge.

Organizations that may be interested in submitting additional information in response to this invitation include those that manufacture, import, export or use this substance whether alone, in a mixture, in a product or in a manufactured item.

Additional information is being invited in the following areas:

- Import, manufacture and use quantities
- Substance and product use details
- Releases to the environment and spill management
- Current and potential risk management and product stewardship actions
- Existing legislative or regulatory programs controlling/managing the substance
- Information to support the development of a regulatory impact assessment.

A questionnaire is available which provides a detailed template as an example for the submission of this information. Guidance on how to respond to the Challenge questionnaire is also available. Interested stakeholders are invited to provide available additional information, recognizing that not all questions in the questionnaire may be relevant to a particular substance, use, or industrial sector.

Copies of the questionnaire and associated guidance are available from the Government of Canada Chemicals website (www.chemicalsubstanceschimiques.gc.ca)**,** or from the contact provided below.

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

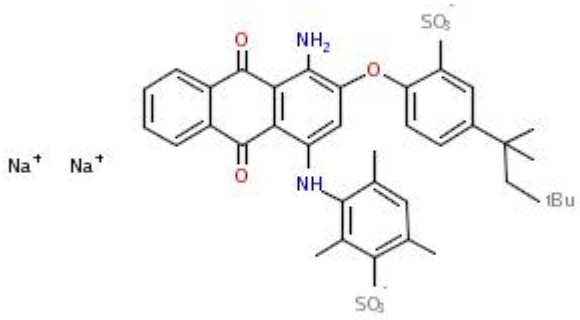
## Request for Documents and Submission of Information

Documents and instructions may be requested from the following contact. Information in response to the above Challenge must be submitted to this address:

DSL Surveys Coordinator
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530/819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: DSL.surveyco@ec.gc.ca

## Substance Identity

For the purposes of this document, this substance will be referred to as Acid Violet 48.

| | |
|---|---|
| Chemical Abstracts Service Registry Number (CAS RN) | 72243-90-4 |
| Inventory names | *Benzenesulfonic acid, 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulfo-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthracenyl]amino]-2,4,6-trimethyl-, disodium salt ; 3-[[4-Amino-9,10-dihydro-9,10-dioxo-3-[sulfonato-4-(1,1,3,3-tétramethylbutyl)phenoxy]-1-anthryl]amino]-2,4,6-triméthylbenzènesulfonate de disodium ; Disodium 3-[[4-amino-9,10-dihydro-9,10-dioxo-3-[sulphonato-4-(1,1,3,3-tetramethylbutyl)phenoxy]-1-anthryl]amino]-2,4,6-trimethylbenzenesulphonate* |
| Other names | *Sanolin violet FBL*<br>*C.I. Acid Violet 48* |
| Chemical group | Discrete organics |
| Chemical sub-group | Anthracenediones |
| Chemical formula | $C_{37}H_{40}N_2O_9S_2$. 2Na |
| Chemical structure |  |
| SMILES | CC(c3cc(c(cc3)Oc4c(c2c(c(c4)Nc5c(c(cc5C)C)S(=O)(=O)O[Na])C)C(=O)c1ccccc1C2=O)N)S(=O)(=O)O[Na])(C)CC(C)(C)C |
| Molecular mass | 720.86 g/mol |

## Physical/Chemical Properties

Table 1 contains modelled physical-chemical properties of Acid Violet 48 which are relevant to its environmental fate.

**Table 1. Physical and chemical properties for Acid Violet 48**

| Property | Type | Value | Temperature (°C) | Reference |
|---|---|---|---|---|
| Melting point (°C) | Modelled | 349.8 | | MPBPWIN v.1.41 |
| Boiling point (°C) | Modelled | 1143 | | MPBPWIN v.1.41 |
| Vapour pressure (Pa) | Modelled | $1.85 \times 10^{-27}$ ($1.39 \times 10^{-29}$ mm Hg) | 25 | MPBPWIN v.1.41 |
| Henry's Law constant ($Pa \cdot m^3/mol$) | Modelled | $1.15 \times 10^{-24}$ ($1.13 \times 10^{-29}$ $atm \cdot m^3/mol$) | 25 | HenryWin v.3.10 |
| Log Kow (Octanol-water partition coefficient) (dimensionless) | Modelled | 5.31 | | KOWWIN v.1.67 |
| Log Koc (Organic carbon partition coefficient) (dimensionless) | Modelled | 6.89 | | PCKOCWIN v.1.66 |
| Water solubility (mg/L) | Modelled | $2.91 \times 10^{-5}$ | 25 | WSKOWWIN v.1.41 |

## Sources and Uses

## Information from DSL Nomination (1984-1986)

### Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 1000 kg.

### Number of Notifiers

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

### Use Codes and Description

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

13 - Colourant- pigment/stain/dye/ink

### Recent Manufacture and Importation Information

Recent information was collected through an industry survey conducted for the year 2005 under a Canada Gazette Notice issued pursuant to section 71 of CEPA 1999 (Environment Canada 2006a). This Notice requested data on the Canadian manufacture and import of the substance. Acid Violet 48 was not manufactured in Canada in 2005 in a quantity meeting the 100kg reporting threshold (Environment Canada 2006a). Two Canadian companies reported import of Acid Violet 48 in the 100-1,000 kg/year range.

In the U.S., between 10,000 and 500,000 pounds (4.54 to 22.7 tonnes) of Acid Violet 48 was reported to be manufactured and/or imported in the years 1986, 1990, 1994, 1998 as part of the TSCA Inventory Update (US EPA 2007a). Acid Violet 48 was not reported to be manufactured or imported in 2002 (US EPA 2007a). Acid Violet 48 is an existing chemical in Europe, but is not on the low or high production volume chemicals lists (ESIS 2007).

Acid Violet 48 was in use in Denmark, Sweden, and Finland during 1999 to 2004 (SPIN 2007). Amounts used are confidential.

## Known Uses in Canada

According to DSL nomination data, Acid Violet 48 is used as a pigment/dyestuff. The Canadian companies importing Acid Violet 48 in 2005 identified their business activity as: Manufacture of Textile and Fabric Finishing and Fabric Coating Mills and the Wholesale

Trade/Distribution of Chemical (except Agricultural) and Allied Products (Environment Canada 2006a).

## Potential Uses in Canada

The additional information below on potential uses of Acid Violet 48 was identified through searches of the available scientific and technical literature.

Acid Violet 48 is registered as a pesticide formulant (inert) in the U.S. (US EPA 2007b), but not in Canada (PMRA 2005). It is on the US EPA List 3: Inerts of unknown toxicity (US EPA 2007b). It is used as a colouring agent in the manufacture of textiles in Finland (SPIN 2007).

According to the 1981-1983 U.S. National Occupational Exposure Survey, employees working in the following industry types would potentially be exposed to Acid Violet 48: textile mill products; museums, botanical, zoological gardens; food and kindred products; and printing and publishing (NIOSH 1983).

# Human Health Information

Under the *Canadian Environmental Protection Act, 1999* (CEPA 1999), Health Canada undertook to categorize all substances on the Domestic Substances List (DSL) to identify those representing the greatest potential for human exposure (GPE) and those among a subset of substances considered persistent (P) and/or bioaccumulative (B) that are also considered to be "inherently toxic" to humans.

In order to efficiently identify substances that represent the highest priorities for screening assessment from a human health perspective, Health Canada developed and applied a Simple Exposure Tool (SimET) to the DSL to identify those substances that meet the criteria for GPE, Intermediate Potential for Exposure (IPE) or Lowest Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

## Exposure Information from Health Related Components of DSL Categorization

SimET was developed and used to identify substances on the DSL considered to represent GPE. This approach was based on three lines of evidence: 1) the quantity in commerce in Canada, 2) the number of companies involved in commercial activities in Canada (i.e., number of notifiers), and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an IPE or LPE, based on criteria for quantity and nature of use (Health Canada 2003).

### Results of the Application of SimET

Acid Violet 48 has been determined to be LPE based on a consideration of the DSL nomination information listed in the section on Sources and Uses.

## Hazard Information from Health Related Components of DSL Categorization

### Simple Hazard Tool (SimHaz)

SimHaz is a tool that has been used to identify, among all of the approximately 23 000 substances on the DSL, those considered to present either high or low hazard to human health based on formalized weight of evidence criteria and/or peer review/consensus of experts. This tool has been developed through extensive compilation of hazard classifications of Health Canada and other agencies and consideration of their robustness based on availability of transparent documentation of both process and criteria. Those substances identified as a potential high health hazard were based on classifications for cancer, genotoxicity, reproductive toxicity or developmental toxicity (Health Canada 2005)

**Results of the Application of SimHaz**

Acid Violet 48 has not been classified for hazard by any of the agencies considered under the SimHaz tool and therefore does not meet the criteria for high hazard under SimHaz.

## Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL that are considered to be human health priorities for further consideration. It is recognized that they do not include a number of elements normally considered in a human health risk assessment such as a comprehensive characterization of exposure and hazard, a comparison of exposure metrics to hazard metrics and a detailed analysis of uncertainties.

# Ecological Information

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

## Releases, Fate and Presence in the Environment

### Releases

Acid Violet 48 is not naturally produced in the environment. No information on environmental releases of Acid Violet 48 is available.

### Fate

The moderate to high estimated log Kow and log Koc values (Table 1) indicate that Acid Violet 48 will likely partition to soil and sediments. Indeed, the results of the Level III Fugacity modelling indicates that if the chemical is released equally to the three major environmental compartments (air, water, and soil), it will partition almost entirely to soil and sediments (Table 2).

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

| | Fraction of Substance Partitioning to Each Medium (%) | | | |
|---|---|---|---|---|
| **Substance Released to:** | **Air** | **Water** | **Soil** | **Sediment** |
| - Air (100%) | 0.03 | 0.19 | 85.2 | 14.6 |
| - Water (100%) | 0.00 | 1.26 | 0.00 | 98.7 |
| - Soil (100%) | 0.00 | 0.00 | 99.8 | 0.19 |
| - Air, water, soil (33% each) | 0.00 | 0.69 | 44.9 | 54.4 |

Acid Violet 48 is predicted to partition negligibly to air, even when released entirely to air (see Table 2). The estimated vapour pressure of 1.8 $x10^{-27}$ Pa and Henry's Law constant of 1.15 x $10^{-24}$ $Pa \cdot m^3/mol$ (see Table 1) indicate that Acid Violet 48 is essentially non-volatile.

If released to soil, Acid Violet 48 is expected to remain essentially immobile in the soil (see Table 2), due to its very high log $K_{oc}$ of 6.9. Volatilization from moist soil surfaces is an unimportant fate process based on the estimated Henry's Law constant.

If released into water, 98.7% of Acid Violet 48 is expected to adsorb to suspended solids and sediment. Volatilization from water surfaces is expected to be an unimportant fate process based upon this compound's estimated Henry's Law constant.

### Presence in the Environment

No environmental monitoring data relating to the presence of Acid Violet 48 in the environment have been found.

## Evaluation of P, B and iT Properties

### Environmental Persistence

No experimental persistence data were available for this substance.

The Level III Fugacity model indicates negligible partitioning of the substance into air (Table 2). Accordingly, the long-range transport potential (LRTP) of Acid Violet 48 from its point of release in air is estimated to be low according to the model prediction presented in Table 3a. The Transport and Persistence Level III Model (TaPL3) (CEMC, 2000) was used to estimate Characteristic Travel Distance (CTD), defined as the maximum distance traveled by 63% of the substance; or in other words, the distance that 37% of the substance may travel beyond. Beyer et al (2000) have proposed CTD's of >2000 km as representing high LRTP, 700-2000 km as moderate LRTP, and <700 km as low LRTP. Based on its low LRTP in air, Acid Violet 48 is expected to remain primarily in the areas close to its emission sources.

**Table 3b – Model Predicted Characteristic Travel Distance (CTD) for Acid Violet 48**

| Characteristic Travel Distance | Model (Reference) |
|---|---|
| 477 km | TaPL3 (CEMC, 2000) |

Once released into the environment, Acid Violet 48 appears to be persistent in water, soil and sediments. Since no experimental data on biological degradation of Acid Violet 48 are available, a QSAR-based weight-of-evidence approach (Environment Canada 2007) was applied using the biodegradation models shown in Table 3b. Based on these results, the estimated timeframe and probability for biodegradation indicates that Acid Violet 48 can be considered as persistent in water.

**Table 3b. Modelled data for persistence**

| Medium | Fate Process | Degradation Value | Endpoint/Units | Reference |
|---|---|---|---|---|
| Water | Biodegradation | 182 | Half-life, days | BIOWIN v4.02, Ultimate survey |
| Water | Biodegradation | 0 | Probability | BIOWIN v4.02, MITI Non-Linear |
| Water | Biodegradation | 0 | Probability | TOPKAT v.6.2 |

To extrapolate half-life in water to half-lives in soils and sediments, Boethling's extrapolation factors $t_{1/2\ water} : t_{1/2\ soil} : t_{1/2\ sediment} = 1: 1: 4$ (Boethling *et al.*, 1995) can be used. Using these factors and the biodegradation model results, it may be concluded that Acid Violet 48 is expected to be persistent in soil and sediments.

Based on the above data, Acid Violet 48 is considered to be persistent in water, soil and sediment (half-lives in soil and water ≥ 182 days; half-life in sediment ≥ 365 days) as defined in the *Persistence and Bioaccumulation Regulations* (Government of Canada 2000).

## Potential for Bioaccumulation

There is no experimental bioaccumulation data for Acid Violet 48. The modeled log Kow value of 5.13, as well as modeled bioaccumulation data (Table 4) indicates that it has the potential to bioaccumulate in the environment.

The Modified GOBAS bioaccumulation factor (BAF) middle trophic level model produced a BAF of approximately 51 286 L/kg, indicating that Acid Violet 48 has the potential to bioaccumulate and biomagnify in the environment. The OASIS bioconcentration factor (BCF) model also supports the high bioconcentration and bioaccumulation potential of this substance.

**Table 4. Modelled data for bioaccumulation and bioconcentration**

| Test Organism | Endpoint | Value wet wt | Reference |
|---|---|---|---|
| Fish | BAF | 51 286 | GOBAS BAF T2MTL (Arnot & Gobas 2003) |
| Fish | BCF | 9 120 | Gobas BCF 5% T2LTL (Arnot & Gobas 2003) |
| Fish | BCF | 28 576 | OASIS Forecast v1.20, BCF Max |
| Fish | BCF | 10* | BCFWIN v2.15 |

* - default value due to ionizable groups

Metabolism information for this substance was not available, nor was it considered in the BCF/BAF models.

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

## Ecological Effects

### A - In the Aquatic Compartment

No experimental toxicity data were found for Acid Violet 48. A range of aquatic toxicity predictions were obtained from the various QSAR models considered (as discussed in Environment Canada 2003). However, only one of these predicted values was considered to be reliable. This value is given in Table 5, and was used as the "pivotal toxicity value"

for the Categorization of Acid Violet 48. This toxicity prediction is higher than the predicted water solubility of Acid Violet 48 (Table 1). Nevertheless, this prediction is still considered to be acceptable since it is within two orders of magnitude of the predicted water solubility (Environment Canada 2007). This predicted toxicity value indicates that Acid Violet 48 is highly hazardous to aquatic organisms (i.e. acute $LC/EC_{50} \leq 1.0$ mg/L**).**

**Table 5. Modelled data for aquatic toxicity**

| Test Organism | Type of Test | Endpoint | Value (mg/L) | Reference |
|---|---|---|---|---|
| Fish | Acute (14 d) | $LC_{50}$ | 0.007 | ECOSAR v.0.99h |

$LC_{50}$ – Lethal concentration affecting 50% of the test population

This prediction of high aquatic toxicity for Acid Violet 48 is supported by new substance notification data from the U.S. and Canada for dyes containing sulphonic acid groups. 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 been shown to exhibit moderate to high acute toxicity (<1–10 mg/L) to some aquatic biota (Environment Canada 2003). Acid Violet 48 contains one sulphonic acid group.

**B - In Other Media**

No effects studies for non-aquatic non-human organisms were found for this compound.

## Potential to Cause Ecological Harm

Evidence that a substance is highly persistent and bioaccumulative as defined in the *Persistence and Bioaccumulation Regulations* of CEPA 1999 (Government of Canada 2000), when taken together with potential for environmental release or formation and potential for toxicity to organisms, provides a significant indication that it may be entering the environment under conditions that may have harmful long-term ecological effects (Environment Canada 2006b). Substances that are persistent remain in the environment for a long time after being released, increasing the potential magnitude and duration of exposure. Substances that have long half-lives in mobile media (air and water) and partition into these media in significant proportions have the potential to cause widespread contamination. Releases of small amounts of bioaccumulative substances may lead to high internal concentrations in exposed organisms. Highly bioaccumulative and persistent substances are of special concern, since they may biomagnify in food webs, resulting in very high internal exposures, especially for top predators. Evidence that a substance is both highly persistent and bioaccumulative, when taken together with other information such as evidence of toxicity at relatively low concentrations, and evidence of uses and releases may, therefore, be sufficient to indicate that the substance has the potential to cause ecological harm.

Acid Violet 48 was imported into Canada in the year 2005 for use in manufacturing, so it may be released to the environment during the manufacturing process or during subsequent usage and disposal of consumer items containing Acid Violet 48. It is also in commerce in the U.S. and Europe, and appears to be used as a pigment/dyestuff in textile products, and so may be entering into Canada in manufactured items. Information about environmental releases from the manufacturing process, and releases through consumer use of manufactured items has not been identified. As well, no information on concentrations of Acid Violet 48 in the environment have been found.

Based on the available information, Acid Violet 48 is persistent and bioaccumulative, based on criteria defined in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000). Once released in the environment, because of its resistance to degradation, it will remain in sediment and soil for long times. As it persists in the environment, and because of its lipophilic character, it will likely bioaccumulate and may be biomagnified in food chains. It also is predicted to have relatively high toxicity to aquatic organisms. This information suggests that Acid Violet 48 has the potential to cause ecological harm in Canada.

## Uncertainties

Information about environmental releases of Acid Violet 48 from manufacturing and through consumer use of manufactured items has not been identified. As well, no information on concentrations of Acid Violet 48 in the environment have been found.

Experimental data for ecotoxicity, degradation and bioaccumulation were not identified during categorization activities, and QSARs were used to estimate them. There are uncertainties associated with the use of QSAR models to estimate these characteristics. Additionally, physical/chemical properties, which are used as input to the QSAR models, have also had to be estimated.

The predicted concentration associated with inherent toxicity for aquatic organisms has an additional source of uncertainty since this concentration exceeds the predicted water solubility of Acid Violet 48. However, this predicted toxicity concentration is still considered acceptable since it is within two orders of magnitude of the predicted water solubility.

Regarding toxicity, the significance of sediments or soil as significant media of exposure based on the predicted partitioning behaviour of this chemical is not well addressed by the effects data available. Indeed, the only effects data identified apply to pelagic aquatic exposures, although soil and sediments are the main media of concern based on partitioning estimates.

There is also uncertainty associated with the overall conclusion that Acid Violet 48 may be causing ecological harm, based solely on information relating to its persistence, bioaccumulation, relative toxicity and use pattern. Typically quantitative risk estimates

(i.e., risk quotients or probabilistic analyses) are important lines of evidence when evaluating a substance's potential to cause environmental harm. However when risks for persistent and bioaccumulative substances such as Acid Violet 48 are estimated using such quantitative methods, they are highly uncertain and are likely to be underestimated (Environment Canada 2006b). Given that long term risks associated with persistent and bioaccumulative substances cannot at present be reliably predicted, quantitative risk estimates have limited relevance. Furthermore since accumulations of such substances may be widespread and are difficult to reverse, a conservative response to uncertainty (that avoids underestimation of risks) is justified.

# References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