

# **Draft Screening Assessment**

## **Stilbenes Group**

**Chemical Abstracts Service Registry Numbers  
4193-55-9, 16090-02-1**

**Environment and Climate Change Canada  
Health Canada**

**September 2017**

## Synopsis

Pursuant to sections 68 or 74 of the Canadian Environmental Protection Act, 1999 (CEPA), the Minister of the Environment and the Minister of Health have conducted a screening assessment of two of the four substances referred to collectively under the Chemicals Management Plan as the Stilbenes group. These two substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns. The other two substances were subsequently determined to be of low concern through other approaches, and proposed decisions for these substances are provided in a separate report.<sup>1</sup> Accordingly, this screening assessment addresses the two substances listed in the table below.

### Substances in the Stilbenes group

CAS RN <sup>2</sup>	Domestic Substances List name	Common name
4193-55-9 <sup>a</sup>	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl)amino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt	C.I. Fluorescent Brightener 28, disodium salt
16090-02-1	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-(4-morpholinyl)-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt	Fluorescent Brightener FWA-1

Abbreviations: C.I., colour index; FWA, fluorescent whitening agent

<sup>a</sup> This substance was not identified under subsection 73(1) of CEPA but was included in this assessment as it was considered a priority on the basis of other human health concerns.

According to information submitted under section 71 of CEPA, C.I. Fluorescent Brightener 28, disodium salt, was imported at quantities of between 10 000 and 100 000 kg and Fluorescent Brightener FWA-1 was imported at a quantity of 42 344 kg in 2011. These substances are intended to be used as dyes and bleaching agents in laundry detergents and dishwashing products. In Canada, consumer uses are limited to optical brighteners in liquid laundry detergents for C.I. Fluorescent Brightener 28, disodium salt, and in powdered laundry detergents for Fluorescent Brightener FWA-1.

The ecological risks of C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were characterized using the ecological risk classification of organic substances (ERC) approach. The ERC is a risk-based approach that employs multiple

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<sup>1</sup> Proposed conclusions for CAS RNs 1533-45-5 and 3426-43-5 are provided in the Rapid Screening of Substances with Limited General Population Exposure Draft Screening Assessment.

<sup>2</sup> The Chemical Abstracts Service Registry Number (CAS RN) is the property of the American Chemical Society and any use or redistribution, except as required in supporting regulatory requirements and/or for reports to the Government of Canada when the information and the reports are required by law or administrative policy, is not permitted without the prior, written permission of the American Chemical Society.

metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. Hazard profiles based principally on metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity are established. Metrics considered in the exposure profiles include potential emission rate, overall persistence, and long-range transport potential. A risk matrix is used to assign a low, moderate or high level of potential concern for substances on the basis of their hazard and exposure profiles. The ERC identified C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 as having low potential to cause ecological harm.

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1. It is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are 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.

The Organisation for Economic Co-operation and Development (OECD) determined that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 did not elicit effects of concern for human health and concluded that these substances have a “low hazard profile.” There were no findings of carcinogenicity, genotoxicity, or repeated-dose toxicity for the two substances considered in this assessment. Furthermore, the OECD found that these substances would not be expected to have reproductive or developmental effects on the basis of studies conducted with structurally similar chemicals. Considering the low hazard nature of these substances, risk to human health is considered to be low.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet any of the criteria set out in section 64 of CEPA.

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## 1. Introduction

Pursuant to sections 68 and 74 of the Canadian Environmental Protection Act, 1999 (CEPA) (Canada 1999), the Minister of the Environment and the Minister of Health have conducted a screening assessment of two of the four substances referred to collectively under the Chemicals Management Plan as the Stilbenes group, to determine whether these substances present or may present a risk to the environment or to human health. These two substances were identified as priorities for assessment as they met categorization criteria under subsection 73(1) of CEPA or were considered a priority on the basis of other human health concerns (ECCC, HC [modified 2007]).

The other two substances (CAS RNs<sup>3</sup> 1533-45-5, benzoxazole, 2,2'-(1,2-ethenediyl)di-4,1-phenylene)bis-; 3426-43-5, benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-methoxy-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt) were considered in the Ecological Risk Classification of Organic Substances (ERC) Science Approach Document (ECCC 2016a) and via the approach applied in the Rapid Screening of Substances with Limited General Population Exposure (ECCC, HC 2017) and were identified as being of low concern to both human health and the environment. As such, they are not further addressed in this report. Conclusions for these two substances are provided in the Rapid Screening of Substances with Limited General Population Exposure Screening Assessment Report (ECCC, HC 2017).

The ecological risks of C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were characterized using the Ecological Risk Classification of Organic Substances (ERC) approach (ECCC 2016a). The ERC describes the hazard of a substance using key metrics including mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity and considers the possible exposure of organisms in the aquatic and terrestrial environments on the basis of such factors as potential emission rates, overall persistence and long-range transport potential in air. The various lines of evidence are combined to identify substances as warranting further evaluation of their potential to cause harm to the environment or as having a low likelihood of causing harm to the environment.

The substances currently being evaluated were reviewed internationally through the OECD Cooperative Chemicals Assessment Programme, and there are OECD SIDS initial assessment reports (SIARs) available (OECD 2005a; OECD 2005b). These assessments undergo rigorous review (including peer review) and endorsement by international governmental authorities. Health Canada and Environment and Climate Change Canada are active participants in this process and consider these assessments

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reliable. The OECD SIARs will be used to inform this assessment. This draft screening assessment also includes consideration of information on chemical properties, environmental fate, hazards, uses, and exposure, including additional information submitted by stakeholders.

This draft screening assessment was prepared by staff in the CEPA Risk Assessment Program at Health Canada and Environment and Climate Change Canada and incorporates input from other programs within these departments. The ERC document was subject to an external peer review and a 60-day public comment period. While external comments were taken into consideration, the final content and outcome of the screening assessment remain the responsibility of Health Canada and Environment and Climate Change Canada.

This draft screening assessment focuses on information critical to determining whether substances meet the criteria as set out in section 64 of CEPA, by examining scientific information and incorporating a weight of evidence approach and precaution.<sup>4</sup> The draft screening assessment presents the critical information and considerations upon which the proposed conclusions are based.

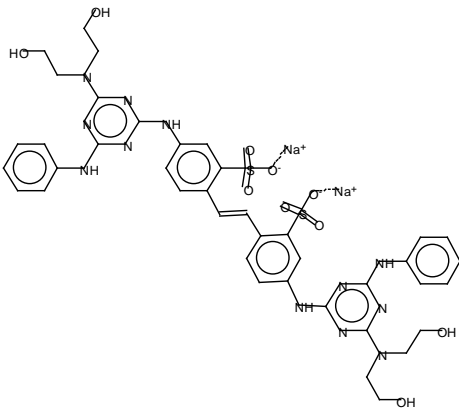
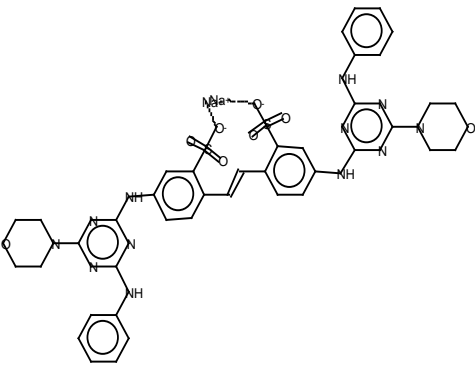
## 2. Identity of substances

The Chemical Abstracts Service Registry Numbers (CAS RN), Domestic Substances List (DSL) names and common names and/or acronyms for the individual substances in the Stilbenes group that are being evaluated in this assessment are presented in Table 2-1.

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<sup>4</sup>A determination of whether one or more of the criteria of section 64 of CEPA are met is based upon an assessment of potential risks to the environment and/or to human health associated with exposures in the general environment. For humans, this includes, but is not limited to, exposures from ambient and indoor air, drinking water, foodstuffs, and products available to consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazardous Products Regulations*, which are part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

**Table 2-1. Substance identities**

CAS RN	DSL name (common name)	Chemical structure and molecular formula	Molecular weight (g/mol)
4193-55-9	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-[bis(2-hydroxyethyl)amino]-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt  (C.I. Fluorescent Brightener 28, disodium salt)	 $C_{40}H_{42}N_{12}O_{10}S_2 \cdot 2Na$	960.95
16090-02-1	Benzenesulfonic acid, 2,2'-(1,2-ethenediyl)bis[5-[[4-(4-morpholinyl)-6-(phenylamino)-1,3,5-triazin-2-yl]amino]-, disodium salt  (Fluorescent Brightener FWA-1)	 $C_{40}H_{38}N_{12}O_8S_2 \cdot 2Na$	924.93

Abbreviations: C.I., Colour Index; FWA, Fluorescent Whitening Agent

### 3. Sources and uses

C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 are not naturally-occurring substances and are currently manufactured in closed systems in Europe (OECD 2005a, OECD 2005b).

According to surveys issued pursuant to section 71 of CEPA (Environment Canada 2013), C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were not manufactured in Canada, but were imported into Canada for the 2011 reporting year. Table 3-1 presents a summary of the total import quantities for these two substances.

Table 3-1. Summary of information on Canadian imports of Stilbenes submitted pursuant to a section 71 survey under CEPA (Environment Canada 2013)

Common name	Total imports <sup>a</sup> (kg)
C.I. Fluorescent Brightener 28, disodium salt	10 000 - 100 000 kg <sup>b</sup>
Fluorescent Brightener FWA-1	42 344 kg

<sup>a</sup> Values reflect quantities reported in response to the surveys conducted under section 71 of CEPA (Environment Canada 2013). See surveys for specific inclusions and exclusions (schedules 2 and 3).

<sup>b</sup> Recent changes in commercial status were identified for this substance, which resulted in import quantities being reduced to 1000–10 000 kg.

Globally, C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were reported to be used as whitening agents (optical brighteners) in the paper/textile industry and in household cleaning products (OECD 2005a; OECD 2005b).

In Canada, these substances are used as dyes and bleaching agents in laundry and dishwashing products. With respect to products available to consumers, C.I. Fluorescent Brightener 28, disodium salt, is used as an optical brightener in liquid laundry detergents (concentrations less than 0.80%), and Fluorescent Brightener FWA-1 is used as an optical brightener in powdered laundry detergents (concentrations between 0.067 and 0.54%) (Environment Canada 2013).

C.I. Fluorescent Brightener 28, disodium salt, is currently permitted as an indirect food additive in the United States (US FDA 2016). However, no information was identified on the existing concentrations in food. In Canada, C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 are not used as food additives and are not present in food packaging. However, Fluorescent Brightener FWA-1 could be a component of an incidental additive used in food processing plants (personal communications, emails from Food Directorate, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated Oct 28, 2016; unreferenced).

C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 are not present in drugs, natural health products, cosmetics, or pesticides in Canada (personal communications, emails from Natural and Non-Prescription Health Products Directorate, Consumer Product Safety Directorate, Pest Management Regulatory Agency, Health Canada, to Existing Substances Risk Assessment Bureau, Health Canada, dated November 2016; unreferenced).



## 4. Potential to cause ecological harm

### 4.1 Characterization of ecological risk

The ecological risks of C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were characterized using the ecological risk classification of organic substances (ERC) (ECCC 2016a). The ERC is a risk-based approach that considers multiple metrics for both hazard and exposure, with weighted consideration of multiple lines of evidence for determining risk classification. The various lines of evidence are combined to discriminate between substances of lower or higher potency and lower or higher potential for exposure in various media. This approach reduces the overall uncertainty with risk characterization compared to an approach that relies on a single metric in a single medium (e.g., LC<sub>50</sub>) for characterization. The following summarizes the approach, which is described in detail in ECCC (2016a).

Data on physical-chemical properties, fate (chemical half-lives in various media and biota, partition coefficients, fish bioconcentration), acute fish ecotoxicity, and chemical import or manufacture volume in Canada were collected from scientific literature, from available empirical databases (e.g., OECD QSAR Toolbox), and from responses to surveys under section 71 of CEPA or were generated using selected quantitative structure-activity relationship (QSAR) or mass-balance fate and bioaccumulation models. These data were used either as inputs to other mass-balance models or to complete the substance hazard and exposure profiles.

Hazard profiles were established principally on the basis of metrics regarding mode of toxic action, chemical reactivity, food web-derived internal toxicity thresholds, bioavailability, and chemical and biological activity. Exposure profiles were also established using multiple metrics, including potential emission rate, overall persistence and long-range transport potential. Hazard and exposure profiles were compared to decision criteria in order to classify the hazard and exposure potentials for each organic substance as low, moderate or high. Additional rules were applied (e.g., classification consistency, margin of exposure) to refine the preliminary classifications of hazard or exposure.

A risk matrix was used to assign a low, moderate or high classification of potential risk for each substance on the basis of its hazard and exposure classifications. ERC classifications of potential risk were verified using a two-step approach. The first step adjusted the risk classification outcomes from moderate or high to low for substances that had a low estimated rate of emission to water after wastewater treatment, representing a low potential for exposure. The second step reviewed low risk potential classification outcomes using relatively conservative, local-scale (i.e., in the area immediately surrounding a point-source of discharge) risk scenarios, designed to be protective of the environment, to determine whether the classification of potential risk should be increased.

ERC uses a weighted approach to minimize the potential for both over- and under-classification of hazard, exposure and subsequent risk. The balanced approaches for dealing with uncertainties are described in greater detail in ECCC 2016a. The following describes two of the more substantial areas of uncertainty. Error in empirical or modeled acute toxicity values could result in changes in classification of hazard, particularly metrics relying on tissue residue values (i.e., mode of toxic action), many of which are predicted values from QSAR models. The impact of this error is mitigated, however, by the fact that overestimation of median lethality will result in a conservative (protective) tissue residue value used for critical body residue (CBR) analysis. Error in underestimation of acute toxicity will be mitigated through the use of other hazard metrics, such as structural profiling of mode of action, reactivity and/or estrogen binding affinity. Changes or errors in chemical quantity could result in differences in classification of exposure as the exposure and risk classifications are highly sensitive to emission rate and use quantity. The ERC classifications thus reflect exposure and risk in Canada based on what is believed to be the current use quantity and may not reflect future trends.

Critical data and considerations used to develop the substance-specific profiles for C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 and the hazard, exposure and risk classification results are presented in ECCC (2016b).

The hazard and exposure classifications for C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 are summarized in Table 4-1.

Table 4-1. Ecological risk classification results for C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1

<b>CAS RN</b>	<b>ERC hazard classification</b>	<b>ERC exposure classification</b>	<b>ERC risk classification</b>
C.I. Fluorescent Brightener 28, disodium salt	moderate	moderate	moderate
Fluorescent Brightener FWA-1	moderate	low	Low

C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were classified as having moderate hazard potential based on mode of toxic action (above baseline toxicity (i.e., above narcosis)). Both substances were found to have a long overall persistence in the environment. C.I. Fluorescent Brightener 28, disodium salt, had a moderate emission rate, which resulted in moderate exposure potential. Fluorescent Brightener FWA-1 had a low emission rate and corresponding low exposure potential. On the basis of hazard and exposure classifications, C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were classified as having a low and moderate potential for ecological risk, respectively. It is

therefore unlikely that these substances result in concerns for organisms or the broader integrity of the environment in Canada.

## **5. Potential to cause harm to human health**

OECD 2005a and OECD 2005b summarized the health effects literature for C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1, respectively. These assessments were used to inform the health effects characterization in this screening assessment.

A literature search for each substance was conducted from the year prior to their respective OECD SIARs (April 2005 and October 2005) to April 2017. No additional health effects studies were identified.

On the basis of the available datasets, C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 were both considered by the OECD to have a “low hazard profile.” There were no treatment-related adverse effects observed in repeated-dose toxicity, genotoxicity, or carcinogenicity studies. Although no data was available for reproductive and developmental toxicity, studies conducted with a structurally similar chemical (C.I. Fluorescent Brightener 220, CAS RN 16470-24-9) indicate that the substances in this assessment would not be expected to have effects on fertility or development, as determined by the OECD (OECD 2005a; OECD 2005b).

The OECD did not identify effects of concern for human health and classified these substances as low priority for further work. Considering the low hazard nature of these substances, the potential risk to human health is considered to be low.

### **5.1 Uncertainties in evaluation of risk to human health**

The OECD addressed data gaps, namely reproductive and developmental toxicity, through the use of read-across from structurally similar substances. However, there is inherent uncertainty in the use of a read-across approach relative to use of results from studies conducted on the substances being assessed.

## **6. Conclusion**

Considering all available lines of evidence presented in this draft screening assessment, there is low risk of harm to organisms and the broader integrity of the environment from C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1. It is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet the criteria under paragraphs 64(a) or (b) of CEPA as they are 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.

On the basis of the information presented in this draft screening assessment, it is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet the criteria under paragraph 64(c) of CEPA as they are not entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Therefore, it is proposed to conclude that C.I. Fluorescent Brightener 28, disodium salt, and Fluorescent Brightener FWA-1 do not meet any of the criteria set out in section 64 of CEPA.

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