Government of Canada / Gouvernement du Canada

Risk Management Scope

for

Solvent Violet 13

Chemical Abstracts Service Registry Numbers (CAS RN):

81-48-1

Environment and Climate Change Canada

Health Canada

November 2018

Canada

Summary of Proposed Risk Management

This document outlines the risk management options under consideration for one compound within the Anthraquinones Group, specifically:

- Solvent Violet 13 CAS RN 81-48-1

In particular, the Government of Canada is considering:

> Measures to prohibit or restrict consumer exposure to Solvent Violet 13 from the use of cosmetics.

Information on the following items should be provided (on or before January 2, 2019), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Possible alternative substances to replace Solvent Violet 13 in cosmetic products.
- The availability of children's face paint products containing Solvent Violet 13 in Canada.

The risk management options outlined in this Risk Management Scope document may evolve through consideration of assessments and risk management options published for other Chemicals Management Plan (CMP) substances as required to ensure effective, coordinated, and consistent risk management decision-making.

Note: The above summary is an abridged list of options under consideration to manage this substance and to seek information on identified information gaps and uncertainties. Refer to section 3 of this document for more complete details in this regard.

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1. Context

The *Canadian Environmental Protection Act, 1999* (CEPA) (Canada 1999) provides the authority for the Minister of Environment and the Minister of Health (the ministers) to conduct assessments to determine if substances are toxic to the environment and/or harmful to human health as set out in section 64 of CEPA[1,2], and if so to manage the associated risks.

The substances:

9,10-Anthracenedione, 1-hydroxy-4-[(4-methylphenyl)amino]- (CAS RN 81-48-1), referred to throughout this document as Solvent Violet 13;

5,9,14,18-Anthrazinetetrone, 6,15-dihydro- (CAS RN 81-77-6), referred to in this document as Pigment Blue 60;

9,10-Anthracenedione, 1,4-diamino-2,3-diphenoxy- (CAS RN 6408-72-6), referred to in this document as Solvent Violet 59;

9,10-Anthracenedione, 1,4-bis[(1-methylethyl)amino]- (CAS RN 14233-37-5), referred to throughout in this document as Solvent Blue 36;

9,10-Anthracenedione, 1-amino-4-hydroxy-2-phenoxy- (CAS RN 17418-58-5), referred to in this document as Disperse Red 60;

Benzenesulfonic acid, [[(chloroacetyl)amino]methyl][4-[[4-(cyclohexylamino)-9,10-dihydro-9,10-dioxo-1-anthracenyl]amino]phenoxy]methyl-, monosodium salt (CAS RN 72391-24-3) referred to in this document as Acid Blue 239; and,

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[1] Section 64 [of CEPA]: *For the purposes of* [Parts 5 and 6 of CEPA]*, except where the expression "inherently toxic" appears, 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.*

[2] 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.

9,10-Anthracenedione, 1,4-diamino-, N,N'-mixed 2-ethylhexyl and Me and pentyl derivs (CAS RN 74499-36-8), are included in the assessment of the Anthraquinones Group, as part of the Chemicals Management Plan (CMP) (Canada 2018a).

2. Issue

2.1 Draft Screening Assessment Conclusion

Health Canada and Environment and Climate Change Canada conducted a joint screening assessment of seven of fifteen substances referred to collectively as the Anthraquinones Group. Of the fifteen substances, seven 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 eight of the fifteen substances were subsequently determined to be of low concern through other approaches (Health Canada 2016; ECCC, HC 2017). Accordingly, the screening assessment specifically addressed Solvent Violet 13, Pigment Blue 60, Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36-8, to determine whether these substances present or may present a risk to the environment or to human health in Canada. A notice summarizing the scientific considerations for these substances was published in the *Canada Gazette*, Part I, on November 3, 2018 (Canada 2018b).

Based on the information available, the draft screening assessment proposes that Solvent Violet 13 meets the criteria under paragraph 64(*c*) of CEPA as it is 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. The exposures and sources of concern identified in the draft screening assessment are oral and dermal exposure to Solvent Violet 13 in cosmetics (body creams, lip balms, permanent hair dyes, perfumes and children's face paints) (refer to section 5) (Canada 2018a).

The draft screening assessment also proposes that Pigment Blue 60, Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36-8, do not meet the criteria under paragraph 64(*c*) of CEPA. It proposes that Solvent Violet 13, Pigment Blue 60, Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36-8, 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 under section 64(*a*) or 64(*b*) of CEPA, respectively (Canada 2018a).

While exposure of the general population and the environment to Solvent Violet 59, Solvent Blue 36, Disperse Red 60, Acid Blue 239, and CAS RN 74499-36-8 is not of concern at current levels, these substances are considered to have health effects of concern. Therefore, there may be concern for human health if exposure levels were to increase. Follow-up activities to track changes in exposure or commercial use patterns are being considered for these substances.

The draft screening assessment report also proposes that Solvent Violet 13, meets the persistence criteria but not the bioaccumulation criteria as set out in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999 (Canada 2000).

Of note, the proposed risk management options described in this document and the proposed conclusion outlined in the draft screening assessment are preliminary and may be subject to change. For further information on the draft screening assessment refer to Draft Screening Assessment for the Anthraquinones Group .

2.2 Proposed Recommendation Under CEPA

Based on the findings of the draft screening assessment conducted as per CEPA, the ministers propose to recommend that Solvent Violet 13 be added to the List of Toxic Substances in Schedule 1 of the Act[3].

The ministers will take into consideration comments made by stakeholders during the 60-day public comment period on the draft screening assessment and Risk Management Scope document in the preparation of the final screening assessment and Risk Management Approach document, if required. If Solvent Violet 13 is concluded to meet one or more of the criteria under section 64 of CEPA at the time of the final screening assessment and the ministers finalize the recommendation to add these substances to Schedule 1, risk management instrument(s) will be proposed within 24 months from the date on which the final screening assessment is published, and finalized within 18 months from the date on which the risk management instrument(s) are proposed.

3. Proposed Risk Management

3.1 Proposed Human Health Objectives

[3] When a substance is found to meet one or more of the criteria under section 64 of CEPA, the ministers can propose to take no further action with respect to the substances, add the substance to the Priority Substances List for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act.

Proposed human health objectives are quantitative or qualitative statements of what should be achieved to address human health concerns.

For Solvent Violet 13, the proposed human health objective is focused on addressing the exposure sources of concern outlined in section 5 of this document. As such, the proposed human health objective is to reduce exposure of the general population to Solvent Violet 13 to levels that are protective of human health.

3.2 Proposed Risk Management Objectives and Options under Consideration

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instrument(s) and/or tool(s) for a given substance or substances. In this case, the proposed risk management objective for this substance for the protection of human health is:

- to reduce or eliminate dermal and oral exposure to Solvent Violet 13 from cosmetics.

To achieve the proposed risk management objective and to work towards achieving the proposed human health objective, the risk management options under consideration are:

(1) Measures to prohibit or restrict consumer exposure to Solvent Violet 13 in cosmetic products. This could include prohibition or restriction through addition to the List of Prohibited and Restricted Cosmetics Ingredients (commonly known as the Cosmetic Ingredient Hotlist) in accordance with the *Food and Drugs Act* and the *Cosmetic Regulations*. Voluntary actions by industry could also be considered.

Following the publication of this Risk Management Scope document, additional information obtained from the public comment period and from other sources will be considered, along with the information presented in this document, in the instrument selection and development process[4]. The risk management options outlined in this document may evolve through consideration of assessments and risk management options published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.3 Risk Management Information Gaps

[4] The proposed risk management regulation(s), instrument(s) or tool(s) will be selected using a thorough, consistent and efficient approach and take into consideration available information in line with the Government of Canada's Cabinet Directive on Regulatory Management (TBS 2012a), Red Tape Reduction Action Plan (TBS 2012b) and the *Red Tape Reduction Act* (Canada 2015).

In order to make informed decisions on proposed risk management, more information is needed on the following:

- Possible alternative substances to replace Solvent Violet 13 in cosmetic products.
- The availability of children's face paint products containing Solvent Violet 13 in Canada.

4. Background

4.1 General Information on Solvent Violet 13

Solvent Violet 13 is an organic substance which is part of the CMP Anthraquinones Group. The analogue Anthraquinone is the common structural backbone shared among substances in the CMP Anthraquinones Group. Substances within this group are structurally similar and/or functionally similar (e.g., based on physical-chemical properties, toxicokinetics).

4.2 Current Uses and Identified Sectors

Solvent Violet 13 was included in a survey for the CMP Anthraquinones Group under section 71 of CEPA (Canada 2012). Total reported imports of Solvent Violet 13 for 2011 ranged from 1000 to 10 000 kg and no manufacturing activities were reported above the reporting threshold of 100 kg. The major use reported in Canada for Solvent Violet 13 according to the above survey is for the manufacture of candles (Environment Canada 2013).

Solvent Violet 13 is also identified as being used in cosmetics, based on notifications submitted under the *Cosmetic Regulations* to Health Canada, specifically for a variety of cosmetics, including body creams, bath products, lipsticks/lip balms, make-up, nail products, shampoos and conditioners, hair styling products and perfumes (personal communication, emails from the Consumer Product Safety Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated February 1, 2016; unreferenced). According to publicly available sources, Solvent Violet 13 may also be available in Canada in wax-based face make-up/face paint crayon products, which are regulated as cosmetics (MSDS 2009), but there are no face paint products notified with Solvent Violet 13. In addition, other Canadian uses include as a component in food packaging materials, and as a component in hand sanitizers, in cleaners, and in incidental additives used in food processing establishments. Exposure to Solvent Violet 13 from food packaging is expected

to be negligible (personal communication, e-mail from the Food Directorate, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated April 24, 2017; unreferenced).

Solvent Violet 13 is also listed in the Natural Health Products Ingredients Database with a non-medicinal role for external use only as colour additive, and listed in the Licensed Natural Health Products Database as being present as such, a non-medicinal ingredient, in a limited number of currently licensed topical natural health products, such as acne therapy products, anti-dandruff products, and antiseptic skin cleansers (LNHPD [modified 2016], NHPID [modified 2017]). Given it presence in a limited number of Natural Health Products combined with limited information regarding product concentrations, exposure from Natural Health Products has not been identified as a concern at this time.

Solvent Violet 13 is listed on Health Canada Pest Management Regulatory Agency (PMRA) Pesticide Formulants List with uses in insecticides, bird repellents and insect repellents and in rodenticides, respectively (personal communication, email from the PMRA, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, dated February 5, 2016; unreferenced).

Solvent Violet 13 is not on the List of Prohibited and Restricted Cosmetics Ingredients, nor is it a permitted food additive, nor is it listed on PMRA's List of Active Pesticide Ingredients (Canada 2017; Health Canada 2015; Health Canada [modified 2015]; personal communication, emails from the Risk Management Bureau, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada, 2016; unreferenced; Pesticide Label Search [modified 2016]).

Additional consumer uses for Solvent Violet 13 identified in Canada from publicly available sources include pet shampoos (MSDS 2007a,b; 2015a,b).

Globally, Solvent Violet 13 was also identified as a colourant in non-plastic toys (Danish EPA 2015).

No sources of exposure other than cosmetics were identified as a concern in the draft screening assessment (Canada 2018a).

5. Exposure Sources and Identified Risks

Direct exposures from use of products were evaluated. Product scenarios that result in the highest levels of potential exposure for each substance by the oral and dermal routes, or sentinel scenarios, were presented in the screening assessment. The critical health effects associated with Solvent Violet 13 identified in the draft screening assessment (Canada 2018a) are carcinogenicity (unlikely to be genotoxic) and developmental effects. In the assessment,

exposure of Canadians to Solvent Violet 13 in the following scenarios is identified as a potential concern:

Developmental:

- Oral and dermal exposure of toddlers through the use of face paint; and
- Dermal exposure of adults and/or teens through use of body cream, permanent hair dye and spray perfume.

Cancer:

- Oral exposure of all age groups through use of lip balm or lipstick;
- Dermal exposure of various age groups though the use of body cream, permanent hair dye, perfume, and face paint.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

It is not known whether there are safe alternatives available to replace Solvent Violet 13 in cosmetic applications. Consideration will be given to the likelihood that its presence in these products is for aesthetic rather than functional purposes.

6.2 Socio-economic and Technical Considerations

Socio-economic factors will be considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objectives(s). Socio-economic factors will also be considered in the development of regulations, instrument(s) and/or tool(s) as identified in the *Cabinet Directive on Regulatory Management* (TBS 2012a) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action* (TBS 2007).

7. Overview of Existing Risk Management

7.1 Related Canadian Risk Management Context

Domestically, the pertinent risk management actions are as follows:

- *Food and Drug Regulations*, *Food and Drugs Act* - listed as a colouring agent permitted in drugs for external use (Canada, 2017).

- *Natural Health Products Ingredients Database* – Listed with a non-medicinal role for external use only as a colour additive in natural health products (NHPID, 2017).

- Pest Management Regulatory Agency (PMRA) formulant list (personal communication, 2016 email from the PMRA, Health Canada, to the Existing Substances Risk Assessment Bureau, Health Canada; unreferenced).

7.2 Pertinent International Risk Management Context

Internationally, the pertinent risk management actions are as follows:

US

- Food and Drug Act, Title 21 of the Code of Federal Regulation (CFR):
    - Part 74 – Listing of Color Additives Subject to Certification. Solvent Violet 13 is listed as a color additive that is subject to certification and permitted for use in cosmetics for external use only, and not allowed for eye area or generally (including lipsticks). It is also allowed for use in externally applied drugs and in medical devices not to exceed (NTE) 0.1-0.3% by weight in various absorbable sutures; in amounts NTE the minimum reasonably required to accomplish the intended coloring effect in contact lenses; NTE 0.2% of intraocular lens haptics, NTE 0.15% by weight of meniscal tracks (US eCFR, 2017a).
    - Part 82, Listings of Certified Provisionally Listed Colors and Specifications (drugs and cosmetics) (US eCFR, 2017b); and
    - Part 81, General Specification and General Restrictions for Provisional Color Additives for Use in Foods, Drugs and Cosmetics where it is restricted from use in the manufacture of ingested drugs or cosmetics subject to ingestion (US eCFR, 2017c).

- *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA), Environmental Protection Agency (EPA) Regulations. Solvent Violet 13 is classified as List 4B -- an inert ingredient in pesticides based upon the

‘reasonable certainty of no harm’ safety finding. It is cleared for use in food and non-food as a dye. This inert ingredient is used pre-harvest with exemptions from the requirement of a tolerance when used in accordance with good agricultural practice. To be exempt from the requirement of a tolerance, it must be limited to not more than 0.005% of the pesticide formulation. It is also an inert ingredient applied to animals (with exemption from the requirement of a tolerance) (US EPA, 2005; US eCFR 2017d).

- Inventory of Effective Food Contact Substance (FCS) Notifications - The database lists effective premarket notification for food contact substances that have been demonstrated to be safe for their intended use. Solvent Violet 13 is listed as a colourant in food-contact polystyrene, at levels not to exceed 0.70 ppm, for all food types except for use in contact with infant formula and breast milk. It is also listed as a component in epoxy resin coatings for repeat use in contact with beer, at a maximum level of 1 percent by weight of the cured epoxy coating (US FDA, 2017).

EU

- While Solvent Violet 13 is included in Annex IV, List of Colorants Allowed in Cosmetic Products, of European Commission Regulation No 1223/2009 (EC, 2009), it is also listed in Annex II of the List of Substances Prohibited in Cosmetic Products, as per Commission Implementing Regulation No 344/2013 (EC, 2013), specifically when used as a substance in hair dye products.

Other

- New Zealand - Cosmetic Products Group Standard Solvent Violet - listed in schedule 4, components cosmetic product must not contain when used as a substance in hair dye products (New Zealand, 2006).

- Australia - Australian Government Regulation of Cosmetics (website) - listed as a colouring for use as excipients in medicines for topical use only and does not require evaluation of toxicology data (Australia, 2016).

7.3 Regulatory Alignment

Canada is largely aligned with the international community on regulation of Solvent Violet 13 in drugs and pesticides, although not for cosmetics.

8. Next Steps

8.1 Public Comment Period

Industry and other interested stakeholders are invited to submit comments on the content of this Risk Management Scope or other information that would help to inform decision-making (such as outlined in sections 3.2). Please submit additional information and comments prior to January 2, 2019. The Risk Management Approach document, which will outline and seek input on the proposed risk management instrument(s), will be published at the same time as the final screening assessment. At that time, there will be further opportunity for consultation.

Comments and information submissions on the Risk Management Scope should be submitted to the address provided below:

Environment and Climate Change Canada
Chemicals Management Division
Gatineau Quebec K1A 0H3

Tel: 1-800-567-1999 | 819- 938-3232
Fax: 819-938-3231
Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in Solvent Violet 13 are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding Solvent Violet 13 and may be contacted for further information.

8.2 Timing of Actions

Action	Date
Electronic consultation on the Risk Management Scope	November 3, 2018 to January 2, 2019
Submission of additional studies or information on Solvent Violet 13	On or before January 2, 2019
Publication of responses to public comments on the draft screening assessment and Risk Management Scope	No later than the time of publication of the final screening assessment

Publication of the final screening assessment and, if required, the Risk Management Approach document	Expected to be Fall 2019
Publication of responses to public comments on the Risk Management Approach, if applicable, and publication if required, of the proposed instrument(s)	At the latest, 24-months from the publication of the final screening assessment
Consultation on the proposed instrument(s), if required	60-day public comment period starting upon publication of each proposed instrument
Publication of the final instrument(s), if required	At the latest, 18 months from the publication of each proposed instrument

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