Government of Canada / Gouvernement du Canada

Risk Management Scope

for

Certain Triarylmethanes, specifically:

Basic Violet 3 (CAS 548-62-9)
Malachite Green (CAS 569-64-2)
Basic Violet 4 (CAS 2390-59-2)
Basic Blue 7 (CAS 2390-60-5)

Environment and Climate Change Canada

Health Canada

December 2018

Canada

Summary of proposed risk management

This document outlines the proposed risk management options for substances of concern for the environment (i.e., Basic Violet 3 (BV3), Malachite Green (MG), Basic Violet 4 (BV4), and Basic Blue 7 (BB7)) and health (i.e., MG) in the triarylmethanes grouping. These substances are non-sulfonated triarylmethanes.

Environment and Climate Change Canada is proposing to:

- Develop regulatory or non-regulatory initiatives that would limit releases of MG, BV3, BV4 and BB7 from the pulp and paper sector to levels that would prevent or minimize the effects on the aquatic environment.
- Work with stakeholders to further quantify sources of releases of non-sulfonated triarylmethanes to the environment throughout its lifecycle.

Health Canada is proposing to:

- Add MG to the List of Prohibited and Restricted Cosmetics Ingredients (commonly known as the Cosmetic Ingredient Hotlist); and
- Require that any proposed new manufacture, import or use of certain products containing MG be subject to further assessment and potential risk management, by applying Significant New Activity (SNAc) provisions under CEPA; and
- Further investigate the need for risk management of arts and crafts products containing MG, which may be used by children.

Moreover, because certain data gaps remain, information on the following items should be provided on or before February 6, 2019, to the contact details identified in section 7 of this document, to inform risk management decision-making:

- Current quantities and concentrations of MG used in arts and crafts products which may be used by children;
- Potential alternative substances to MG in children’s arts and crafts products;
- Use pattern and fate of triarylmethane dyes in pulp and paper and deinking facilities;
- Identification of standard analytical methods available for the testing of non-sulfonated triarylmethane dyes in water media (wastewater, surface water, etc.);
- Potential alternative substances to non-sulfonated triarylmethane dyes used in paper dyeing activities; and
- Identification of suppliers of non-sulfonated triarylmethane dyes or mixtures containing non-sulfonated triarylmethanes dyes to pulp and paper facilities. Useful sources include safety data sheets containing supplier information

as well as triarylmethane concentration in mixtures used at pulp and paper facilities.

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 these substances 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 the 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.

As part of the third phase of the Chemicals Management Plan (CMP), the ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada 2016a). The substances Malachite Green (MG), Chemical Abstract Service Registry Number (CAS RN)[3] 569-64-2, Basic Violet 3 (BV3), CAS RN 548-62-9, Basic Violet 4 (BV4), CAS RN 2390-60-5 and Basic Blue 7 (BB7), CAS RN 2390-60-5 are included in CMP under the triarylmethanes grouping.

2. Issue

2.1 Draft screening assessment conclusion

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of the triarylmethane substance grouping in Canada. A notice summarizing the scientific considerations of the draft screening assessment for these substances was published in the *Canada Gazette*, Part I, on December 8, 2018 (Canada 2018a).

Based on the information available, the draft screening assessment proposes that, of the substances within the triarylmethanes group, MG may be harmful to

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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, products used by 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.

[3] CAS RN: The Chemical Abstracts Service information 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.

human health under section 64(*c*) of CEPA because 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 (Canada 2018b).

The draft screening assessment also proposes that MG, BV3, BV4, and BB7 meet the criteria under paragraph 64(*a*) of CEPA because they are entering or may enter 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. These substances also meet the criteria for persistence, but do not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA (Canada 2000).

While exposure of the general population to BV3, BV4 and BB7 is not of concern for human health at current levels, these substances are associated with human health effects of concern. Therefore, there may be concern for human health if exposures were to increase. Follow-up activities to track changes in exposure or commercial use patterns are under consideration.

The human exposure sources of concern for MG, identified in the draft screening assessment, are exposures from cosmetics (e.g., hair dye) and potential exposures from the use of children's arts and crafts materials (e.g., dermal and oral exposures to paint markers). Exposures to MG from drinking water, food and food packaging were not considered to be a concern for human health.

The exposure sources of ecological concern of MG, BV3, BV4 and BB7, identified in the draft screening assessment, are exposures based on the releases from pulp and paper facilities undertaking paper dyeing and paper de-inking activities.

As such, this document will focus on these risks, exposure sources of concern and potential exposures sources of concern.

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, see the draft screening assessment for the triarylmethanes grouping .

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 MG, BV3, BV4 and BB7 be added to the List of Toxic Substances in Schedule 1 of the Act[4].

[4] When a substance is found to meet one or more of the criteria under section 64 of CEPA 1999, the Ministers can propose to take no further action with respect to the substances, add the substance to the

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 MG, BV3, BV4, and BB7 are 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 recommend the addition of these substances to Schedule 1 of CEPA, risk management instrument(s) must 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

Section 3 presents the environmental and health objectives and risk management objectives, as well as the proposed actions to achieve them for each sector of concern, which are pulp and paper, cosmetics, and children's arts and crafts products.

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[5]. 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.

3.1 Proposed environmental and human health objectives

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

For these substances, the proposed environmental objective is to limit industrial releases from facilities processing or using products containing non-sulfonated triarylmethanes, to levels that would prevent or minimize the effects on the aquatic environment. The predicted no-effect concentration (PNEC) of 1 µg/L for the non-sulfonated triarylmethane substances (total) in surface water may be used as a goal to achieve this objective.

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.

[5] 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 Regulation (TBS 2018), Red Tape Reduction Action Plan (TBS 2012b) and the Red Tape Reduction Act (Canada, 2015).

The proposed human health objective is to decrease exposures to MG to levels which 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.

The proposed environmental risk management objective for MG, BV3, BV4, and BB7 is to limit concentrations of non-sulfonated triarylmethanes released in the final effluent of pulp and paper facilities using non-sulfonated triarylmethanes or products containing non-sulfonated triarylmethanes to levels that are protective of the aquatic environment taking into account technical and economic feasibility and consideration of socio-economic factors.

The proposed human health risk management objective for MG is to decrease exposures to MG from cosmetics and to further investigate the potential for exposures to MG from children's arts and crafts products.

The proposed risk management objective may next be revised in the Risk Management Approach document that will be published concurrently with the final screening assessment for these substances, or in subsequent risk management documents (e.g. consultation document on proposed instrument), as the case may be.

To achieve the proposed environmental risk management objective and to work towards achieving the proposed environmental objective, the risk management options under consideration for MG, BV3, BV4, and BB7 are:

- Working with stakeholders to further quantify sources of releases of non-sulfonated triarylmethanes to the environment throughout its lifecycle, including paper deinking activities, and developing risk management control actions under CEPA or other relevant acts, such as the *Fisheries Act* to address these releases as required.
- Regulatory or non-regulatory initiatives under CEPA or other relevant acts, such as the *Fisheries Act*, that would limit releases of non-sulfonated triarylmethanes from pulp and paper activities, in particular paper dyeing activities.

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

- Adding MG to the List of Prohibited and Restricted Cosmetics Ingredients (commonly known as the Cosmetic Ingredient Hotlist);
- Requiring that any proposed new manufacture, import or use of certain products containing MG be subject to further assessment and potential risk management, by applying Significant New Activity (SNAc) provisions under CEPA; and
- Further investigating the need for risk management of arts and crafts products containing MG, which may be used by children.

3.3 Risk management information gaps

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

- Current quantities and concentrations of MG used in children's arts and crafts products;
- Potential alternative substances to MG in children's arts and crafts products;
- Use pattern and fate of triarylmethane dyes in pulp and paper and deinking facilities;
- Identification of standard analytical methods available for the testing of non-sulfonated triarylmethane dyes in water media (wastewater, surface water, etc.);
- Potential alternative substances to non-sulfonated triarylmethane dyes used in paper dyeing activities; and Identification of suppliers of non-sulfonated triarylmethane dyes or mixtures containing non-sulfonated triarylmethanes dyes to pulp and paper facilities. Useful sources include safety data sheets containing supplier information as well as triarylmethane concentration in mixtures used at pulp and paper facilities.

Should stakeholders have further information to help address these gaps, they are encouraged to provide it on or before February 6, 2019 to the contact identified in section 7 of this document. Such information can help inform the risk management decision-making process.

Data collection initiatives (including voluntary initiatives or s.71 surveys) may be undertaken to collect additional information on non-sulfonated triarylmethane dyes to inform risk management decision-making.

4. Background

4.1 General information on substances

The substances in the triarylmethanes group do not occur naturally. The four dyes BV3, MG, BV4 and BB7 are chloride salts. They were evaluated by Health Canada and Environment and Climate Change Canada as part of CMP.

4.2 Current uses and identified sectors

These substances have been included in surveys issued pursuant to section 71 of CEPA for the reporting years 2008 (BV3 and MG) or 2011 (BV4 and BB7) (Canada 2009, 2012). All four substances were reported to be imported into Canada in quantities ranging from 1000 to 100 000 kg (Canada 2009, 2013).

In Canada and globally, these substances are primarily used as colourants. Based on information obtained from section 71 surveys, Canadian uses of MG, BV3, BV4, and BB7 are in inks, toners and colourants, and in paper products, mixtures or manufactured items. Additional uses identified as occurring or likely occurring in Canada for MG include in arts, crafts and hobby materials, in cosmetics (specifically semi-permanent hair dyes and previously used in a body oil) and as a treatment for aquarium fish which are not intended for human consumption. MG is potentially used in food packaging materials in Canada.

BV3 and MG are also well-known globally to have laboratory uses as pH indicators and biological stains (Hunger 2003).

Internationally, triarylmethane dyes and pigments are known to be used in the printing inks industry, particularly for use in packaging (Herbst and Hunger 2004), for the dyeing of paper and textiles, and for their use in cosmetics, drugs, and food (Hunger 2003).

4.3 Exposure sources and identified risks

The draft screening assessment identified releases of non-sulfonated triarylmethane dyes through wastewater from pulp and paper industrial plants with paper dyeing or paper deinking activities.

Triarylmethanes are not likely to bioaccumulate in aquatic organisms, but are expected to be persistent in water.

The draft screening assessment estimated exposures to MG from drinking water and food packaging. However these exposures were low and not considered to be a concern for Canadians. Estimated dermal exposures from the use of hair dye containing MG were considered to be a concern. Additionally, estimated dermal and oral exposures from children putting paint markers containing MG in their mouth or writing on their skin were considered to be a concern. However the

presence of these markers on the Canadian market has not been confirmed. The critical health effect for MG was developmental, based on data for a similar substance (i.e., MG oxalate). (Canada 2018b).

5. Risk management considerations

5.1 Alternatives and alternate technologies

No information on alternatives to MG in hair dyes or in arts and crafts materials which may be used by children was identified. No information specific to alternatives to MG, BV3, BV4, and BB7 in paper dye products or alternative processes for paper dyeing or paper deinking activities was identified. We ask that stakeholders please submit this information, if known.

5.2 Socio-economic and technical considerations

No information on socio-economic and technical considerations for MG in hair dyes or in arts and crafts materials which may be used by children was identified. No information specific to socio-economic or technical considerations for use of MG, BV3, BV4, and BB7 in paper dye products or alternative processes for paper dyeing or paper deinking activities was identified. We ask that stakeholders please submit this information, if known.

6. Overview of existing risk management

6.1 Related Canadian risk management context

MG is not a permitted food additive in Canada. It is prohibited to sell a food in Canada that has been coloured with MG or any other non-permitted colouring agent (personal communication, emails from Food Directorate Health Canada to Risk Management Bureau, Health Canada, dated August 15, 2017; unreferenced).

In Canada, the safety of chemicals used in food packaging materials is subject to the provisions of Division 23 of the *Food and Drug Regulations* and paragraph 4(1)(a) of the *Food and Drugs Act* (personal communication, email from Food Directorate, Health Canada to Risk Management Bureau, Health Canada, dated Oct 31, 2017; unreferenced).

MG is not approved for use in food-producing animals or fish in Canada. Domestic and imported fish containing MG at concentrations above 1 µg/kg are not permitted for sale in Canada (Canada, 2017a).

MG is neither listed in the Natural Health Products Ingredients Database (NHPID), nor in the Licensed Natural Health Products Database as being present in currently licensed natural health products in Canada.

MG is the only non-sulfonated triarylmethane dye that is listed on the *National Pollutant Release Inventory (NPRI)* with a threshold category of 1A, which means

a report is required if the substance was manufactured, processed or otherwise used at a concentration ≥ 1% by weight and in quantity of 10 tonnes or more, and employees worked 20 000 hours or more at a facility (Canada, 2017b). Low MG releases (i.e., ≤ 0.004 tonnes per year) were reported between 2003 and 2007 and no releases were reported between 2008 and 2015.

BV3 is described on the Cosmetic Ingredient Hotlist as an ingredient that is prohibited for use in cosmetic products (Canada, 2017c). BV3 is listed in the NHPID with a non-natural health product role as it is not a naturally occurring substance included in Schedule 1 to the *Natural Health Products Regulations* (NHPID, 2017). It is used in drug products for human and veterinary use in Canada. It has been identified in one product for human use (to treat thrush) (DPD, 2017). It is on the Canadian Food Inspection Agency (CFIA) Aquaculture Therapeutant Residue Monitoring List where it is not permitted to be used in Canada during any part of the aquaculture fish production life-cycle. Canada has an action level of ≥ 0.50 µg/kg for residues of BV3 in internationally traded aquatic food consignments (Canada, 2016b). BV3 was used previously in poultry feeds to inhibit the growth of mold and fungus; however, the registration of this use was withdrawn in 1992 (Canada, 1992). Currently, BV3 is approved as a topical preparation for use in food producing animals for ringworms, treatment of pink eye and topical treatment of skin wounds (FAO, 2014).

No existing risk management was identified for BV4, or BB7 in Canada.

Effluents from pulp and paper mills are regulated by the *Pulp and Paper Effluent Regulations* (PPER) of the *Fisheries Act*. These regulations establish effluent release limits for biochemical oxygen demand (BOD) and total suspended solids (TSS), and prohibit the discharge of acutely lethal effluent to fish. Although non-sulfonated triarylmethane dyes are not within the prescribed list of deleterious substances of the PPER, the level of wastewater treatment required to meet the PPER requirements may also remove substances such as the non-sulfonated triarylmethane dyes (Canada, 2012a).

The Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills were published under CEPA in 2012 and set-out baseline standards for the levels of dyes released from pulp and paper mills. The dye MAPBAP Acetate (CAS RN 72102-55-7) is the only dye for which a limit has been specified in the guideline (Canada, 2012b).

6.2 Pertinent international risk management context

Similar to Canada, MG is not permitted as a food additive (US FDA, 2017a) or as a veterinary drug for food animals, aquaculture or fish for human consumption (FFDCA, 2015) in the United States (US). The US also requires reporting of releases of MG (US Code of Federal Regulations, 2017). Additionally, MG is not permitted in food packaging in the US (US FDA, 2017a,b).

Europe also does not allow MG in food including fish for human consumption (FAO, 2014). The European Commission has listed MG as a banned substance in cosmetics (EC Regulation, 2017).

MG has also been prohibited in cosmetics in New Zealand (EPANZ, 2017) and by the Association of Southeast Asian Nations (ASEAN, 2016). Several other countries were identified as prohibiting MG from being in food (Government of Hong Kong, 2016) including fish (FSANZ, 2005).

7. Next steps

7.1 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 section 3.3). Please submit additional information and comments prior to February 6, 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
Gatineau, Quebec K1A 0H3
Telephone: 1-800-567-1999 (in Canada) or 819-938-3232
Fax: 819-938-5212

Email: eccc.substances.eccc@canada.ca

Companies who have a business interest in MG, BV3, BV4, BB7 or other triarylmethanes and paper dyeing/ paper deinking activities or cosmetics or children's arts and crafts products are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding the substances in the Triarylmethanes group and may be contacted for further information.

7.2 Timing of actions

Electronic consultation on the Risk Management Scope:December 8, 2018 to February 6, 2019

Publication of responses to public comments on the draft screening assessment and Risk Management Scope: on or before Winter, 2020

Publication of the final screening assessment and, if required, the Risk Management Approach document: on or before Winter, 2020

Publication of responses to public comments on the Risk Management Approach, if applicable and if required, the proposed instrument(s): at the latest, 24-month 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(s)

Publication of the final instrument(s), if required: at the latest, 18-month from the publication of each proposed instrument(s)

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