



Government
of Canada

Gouvernement
du Canada

Risk Management Approach
for
Certain Triarylmethanes, specifically:
Chemical Abstracts Service Registry Numbers
(CAS RN):
548-62-9
569-64-2
2390-59-2
2390-60-5

Environment and Climate Change Canada

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Summary of Proposed Risk Management

This document outlines the risk management options under consideration for Malachite Green (MG), Basic Violet 3 (BV3), Basic Violet 4 (BV4), and Basic Blue 7 (BB7), four non-sulfonated triarylmethane substances within the Triarylmethanes Group that have been found to be harmful to the environment and, in the case of MG, also harmful to human health.

In particular, to address environmental concerns, the Government of Canada is considering an environmental release guideline to limit releases of MG, BV3, BV4, and BB7 to water from pulp and paper facilities. An amendment to include the four substances in the *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* may be proposed.

To address human health concerns, the Government of Canada is considering:

- Communicating measures to reduce exposures to MG from certain cosmetics by describing it as a prohibited or restricted ingredient on Health Canada's Cosmetic Ingredient Hotlist. The Hotlist is an administrative tool that Health Canada uses to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* (F&DA), or provisions of the *Cosmetic Regulations*;
- Requiring that any proposed new manufacture, import or use of certain manufactured items containing MG (e.g. markers) be subject to further assessment and potential risk management, by applying Significant New Activity (SNAc) provisions under CEPA.

Moreover, because certain data gaps remain, the following information should be provided (ideally on or before December 16, 2020), to the contact details identified in section 8 of this document, to inform risk management decision-making:

- Identification of standard analytical methods for detecting MG, BV3, BV4, and BB7 in water media (wastewater and/or surface water);
- Potential alternatives to MG, BV3, BV4 and BB7 in paper dyes and in inks;
- Socio-economic impacts of reducing or substituting MG, BV3, BV4, and BB7 in paper dye and ink products;
- Socio-economic impacts associated with the risk management actions presented.

The risk management actions outlined in this Risk Management Approach document may evolve through consideration of assessments and risk management options or actions 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 actions proposed to manage these substances and to seek information on identified gaps. Refer to section 3 of this document for more complete details in this regard. It should be noted that the

proposed risk management actions may evolve through consideration of additional information obtained from the public comment period, literature and other sources.

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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, the Ministers plan to assess and manage, where appropriate, the potential health and ecological risks associated with approximately 1550 substances (Canada 2016a).

The four substances listed in Annex A and referred to throughout this document as Malachite Green (MG), Basic Violet 3 (BV3), Basic Violet 4 (BV4), and Basic Blue 7 (BB7), are non-sulfonated triarylmethane substances included in the Triarylmethanes Group of the Chemicals Management Plan (Canada 2020).

2. Issue

Health Canada and Environment and Climate Change Canada conducted a joint scientific assessment relevant to the evaluation of the Triarylmethanes Group in Canada. A notice summarizing the scientific considerations of the screening assessment for these substances was published in the *Canada Gazette*, Part I, on October 17, 2020 (Canada 2020). For further information, refer to the [Screening Assessment Report for the Triarylmethanes Group](#).

2.1 Screening Assessment Report Conclusion

On the basis of the information available, the screening assessment concludes that, of the substances in the Triarylmethanes Group, MG, BV3, BV4, and BB7 meet the criteria under section 64(a) of CEPA because they are entering the

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 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 used by consumers. A conclusion under CEPA is not relevant to, nor does it preclude, an assessment against the hazard criteria specified in the *Hazard Product Regulations*, which are a part of the regulatory framework for the Workplace Hazardous Materials Information System for products intended for workplace use. Similarly, a conclusion on the basis of the criteria contained in section 64 of CEPA does not preclude actions being taken under other sections of CEPA or other Acts.

environment in a quantity or concentration or under conditions that have an immediate or long-term harmful effect on the environment or its biological diversity (Canada 2020).

The screening assessment also concludes that MG meets the criteria 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 2020).

In addition, the screening assessment concludes that MG, BV3, BV4, and BB7 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).

In addition to MG, BV3, BV4, and BB7, two other substances were assessed as part of the Triarylmethanes Group: Brilliant Blue FCF (CAS RN 1324-76-1) and Pigment Blue 61 (CAS RN 3844-45-9). The following table is a summary of the assessment conclusions and proposed risk management for all substances in the Triarylmethanes Group:

Table 1. Summary of assessment conclusions and proposed risk management actions for all substances in the Triarylmethanes group

CAS RN	Common Name	CEPA Conclusion under s.64(a)	CEPA Conclusion under s.64(c)	Persistence and Bioaccumulation	Proposed Risk Management Actions
548-62-9	Basic Violet 3 (BV3)	Meets criteria of CEPA s. 64(a)	Does not meet s.64(c) criteria but has human health effects of concern ^a	Meets Persistence criteria; Does not meet Bioaccumulation criteria	See section 3.3
569-64-2	Malachite Green (MG)	Meets criteria of CEPA s. 64(a)	Meets criteria of CEPA s.64(c)	Meets Persistence criteria; Does not meet Bioaccumulation criteria	See section 3.3
2390-59-2	Basic Violet 4 (BV4)	Meets criteria of CEPA s. 64(a)	Does not meet s.64(c) criteria but has human health effects of concern ^a	Meets Persistence criteria; Does not meet Bioaccumulation criteria	See section 3.3
2390-60-5	Basic Blue (BB7)	Meets criteria of CEPA s. 64(a)	Does not meet s.64(c) criteria but has human health effects of concern ^a	Meets Persistence criteria; Does not meet Bioaccumulation criteria	See section 3.3
1324-76-1	Pigment Blue 61 (PB61)	Does not meet criteria of CEPA s.64 (a)	Does not meet criteria of s.64(c)	N/A	No proposed risk management or follow-up actions
3844-45-9	Brilliant Blue FCF (BBFCF)	Does not meet criteria of CEPA s.64 (a)	Does not meet criteria of s.64(c)	N/A	No proposed risk management or follow up actions

^aWhile exposures of the general population to the substance are not of concern at current levels, the substance is considered to have health effects of concern on the basis of classifications by other national or international agencies.

The exposure sources of ecological concern identified in the screening assessment for MG, BV3, BV4 and BB7 are effluent releases to the aquatic environment from pulp and paper facilities undertaking paper dyeing and paper de-inking activities. The human exposure source of concern for MG, identified in the screening assessment, is exposure from cosmetics (e.g. hair dye). Estimated oral and dermal exposures by children to MG from markers were listed as potential exposures of concern in the draft screening assessment; however, the presence of these markers on the Canadian market has not been confirmed and they are no longer available in Canada. Exposures to MG from drinking water was not considered to be a concern for human health. This document will focus on the risks, exposure sources of concern, and potential exposure sources of concern (refer to section 5).

2.2 Recommendation under CEPA

Based on the findings of the screening assessment, the Ministers recommend that MG, BV3, BV4, and BB7 be added to the List of Toxic Substances in Schedule 1 of the Act³.

The Ministers have taken into consideration comments made by stakeholders during the 60-day public comment period on the draft Screening Assessment Report for the Triarylmethanes Group and its associated Risk Management Scope document for Certain Triarylmethanes (Canada 2018).

As the Ministers finalize the recommendation to add MG, BV3, BV4, and BB7 to Schedule 1, risk management instruments will be proposed within 24 months from the date on which the Ministers recommended that MG, BV3, BV4, and BB7 be added to Schedule 1 of CEPA, and finalized within 18 months from the date on which the risk management instruments are proposed (refer to section 8 for publication timelines applicable to this group of substances).

2.3 Public Comment Period on the draft Screening Assessment Report and the Risk Management Scope

The draft screening assessment for the Triarylmethanes Group and its associated Risk Management Scope document for Certain Triarylmethanes summarizing the proposed risk management options under consideration at that time were published on December 8, 2018. Industry and other interested stakeholders were invited to submit comments on both documents during a 60-day comment period.

Comments received on the draft Screening Assessment Report and the Risk Management Scope document were taken into consideration in the development

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.

of this document. A [summary of responses to public comments received](#) is available.

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 certain manufactured consumer products (e.g. markers).

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 MG, BV3, BV4, and BB7, the proposed environmental objective is to prevent or minimize adverse effects from these dyes 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.

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

Proposed risk management objectives set quantitative or qualitative targets to be achieved by the implementation of risk management regulations, instruments and/or tools for a given substance or substances.

The proposed environmental risk management objective for MG, BV3, BV4, and BB7 is to limit their concentrations in the final effluent releases of pulp and paper facilities engaging in paper dyeing and deinking activities 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 limit the potential for exposure to MG from certain manufactured items (e.g. markers).

3.3 Proposed Risk Management Actions

To achieve the proposed risk management objectives and to work towards achieving the proposed environmental objective, the proposed risk management

action being considered for MG, BV3, BV4, and BB7 is an environmental release guideline (ERG) under CEPA section 54 to limit concentrations of these dyes in effluent releases to water from pulp and paper facilities using the substances or products containing them. Although effluent from pulp and paper facilities is already subject to the *Pulp and Paper Effluent Regulations* under the *Fisheries Act*, an ERG may assist facilities in predicting when their concentrations of MG, BV3, BV4, and BB7 in wastewater effluent may have an adverse effect on receiving waters and allow them to adjust their supplies and processes accordingly. An amendment to include MG, BV3, BV4, and BB7 in an existing ERG, the *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* (Canada 2013)⁴, may be proposed.

Stakeholders have commented that suppliers may not proactively disclose the presence or concentration of MG, BV3, BV4, and BB7 in their products to preserve trade secrets (ECCC, HC 2020). Consequently, consideration may be given to regulatory and non-regulatory options to encourage dye suppliers to disclose information related to MG, BV3, BV4, and BB7 and/or to limit or control the manufacture, importation, sale and/or purchase of MG, BV3, BV4, and BB7 or dye products containing these substances and facilitate the exploration of safer alternatives.

To achieve the proposed risk management objectives and to work towards achieving the proposed human health objective, the proposed risk management actions being considered for MG are:

- Communicating measures to reduce exposures to MG from certain cosmetics by describing it as a prohibited or restricted ingredient on Health Canada's Cosmetic Ingredient Hotlist. The Hotlist is an administrative tool that Health Canada uses to communicate that certain substances may not be compliant with requirements of the *Food and Drugs Act* (F&DA) or provisions of the *Cosmetic Regulations*⁵;
- Requiring that any proposed new manufacture, import or use of certain manufactured consumer items (e.g. markers) containing MG be subject to further assessment and potential risk management, by applying Significant New Activity (SNAC) provisions under CEPA.

Note that the proposed risk management actions described in this document are subject to change. Following the publication of this document, additional information obtained from the public comment period and from other sources will

⁴ The Minister of the Environment issued the *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* under subsection 54 (1) of the *Canadian Environmental Protection Act, 1999* to limit dye quantities released in the final effluent. See also sections 6.1 and 7.1.

⁵ Section 16 of the F&DA states that "No person shall sell any cosmetic that has in or on it any substance that may cause injury to the health of the user". In addition, the Cosmetic Ingredient Hotlist includes certain substances that may make it unlikely for a product to be classified as a cosmetic under the F&DA. Compliance with the provisions of section 16 are monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the F&DA, which requires that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.

be considered, along with the information presented in this document, in the instrument selection and development process⁶. The risk management actions outlined in this document may also evolve through consideration of assessments and risk management options or actions published for other CMP substances to ensure effective, coordinated, and consistent risk management decision-making.

3.4 Performance Measurement and Evaluation

Performance measurement evaluates the ongoing effectiveness and relevance of the actions taken to manage risks from toxic substances⁷. The aim is to determine whether human health and environmental objectives have been met and whether there is a need to revisit the risk management approach to ensure that risks are managed effectively over time. To achieve this, the Government of Canada will review, on a regular basis, the effectiveness of the risk management actions for MG, BV3, BV4, and BB7.

The Government of Canada plans to measure the effectiveness of the risk management actions to address ecological concerns by collecting and analyzing data such as declarations of adoption of the guidelines and compliance rates to measure progress towards meeting the risk management objectives.

The Government of Canada plans to measure the effectiveness of the risk management actions to address health concerns by collecting and analyzing data, including data regarding the presence of MG in cosmetics in order to measure progress towards meeting the risk management objectives.

The Government of Canada also plans to explore options for monitoring MG, BV3, BV4, and BB7 in water media, such as addition to the CMP Monitoring and Surveillance Program, in order to establish analytical methods, a baseline and to determine presence following implementation of risk management actions to measure progress towards meeting the environmental objectives.

The results of performance measurement and evaluation will be used to inform whether further risk management action is warranted and will be made available to Canadians along with recommendations for further action, if applicable.

⁶ The proposed risk management regulations, instruments or tools 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), the Red Tape Reduction Action Plan (TBS 2012), and in the case of a regulation the *Red Tape Reduction Act* (Canada 2015).

⁷ Performance measurement can be performed at two levels:

- Instrument-based performance measurement evaluates the effectiveness of an individual instrument in meeting the specific risk management objectives that were set out when the risk management tool was designed. The results of performance measurement will help determine if additional risk management or assessment is needed (*i.e.* evaluate whether risk management objectives have been met); and
- Substance-based performance measurement considers performance of all final risk management instruments applied to a chemical substance and relevant data or indicators of exposure to the environment or human health (*i.e.* evaluate whether human health and/or environmental objectives have been met).

3.5 Risk Management Information Gaps

Interested stakeholders are invited to provide further information, such as information that may fill the gaps outlined below, to inform risk management decision-making regarding MG, BV3, BV4, and BB7:

- Identification of standard analytical methods for detecting MG, BV3, BV4, and BB7 in water media (wastewater and/or surface water);
- Potential alternatives to MG, BV3, BV4 and BB7 in paper dyeing activities;
- Socio-economic impacts of reducing or substituting MG, BV3, BV4, and BB7 in paper dye products;
- Socio-economic impacts associated with the risk management actions presented.

Should stakeholders have further information to help address these gaps, they should provide it ideally on or before December 16, 2020 to inform the risk management decision-making process, within the timelines (and to the contact) identified in section 8 of this document.

4. Background

4.1 General Information on Non-Sulfonated Triarylmethanes

The substances in the Triarylmethanes Group do not occur naturally. The four non-sulfonated triarylmethane dyes discussed here, namely MG, BV3, BV4 and BB7, are chloride salts. They were evaluated by Health Canada and Environment and Climate Change Canada under the Chemicals Management Plan.

4.2 Current Uses and Identified Sectors

MG, BV3, BV4, and BB7 have been included in surveys issued pursuant to section 71 of CEPA for the reporting years 2008 (MG and BV3) 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, Environment Canada 2013).

In Canada and globally, triarylmethanes 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.

Information received from stakeholders indicates that at least three pulp and paper facilities in Canada are using one or more of these substances. Information was

also received indicating that at least two formulators use MG, BV3, BV4 and/or BB7 to formulate printing ink and/or paper dye products supplied to pulp and paper facilities in Canada (ECCC, HC 2020).

Additional uses identified as occurring or having historically occurred 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.

Internationally, triarylmethane dyes and pigments are known to be used in the printing inks industry, particularly for use in packaging and the dyeing of paper and textiles, and are used in cosmetics, drugs, and food (Herbst and Hunger 2004; Hunger 2003). MG and BV3 are also well-known globally to have laboratory uses as pH indicators and biological stains (Hunger 2003).

5. Exposure Sources and Identified Risks

5.1 Ecological Exposure and Risks

The screening assessment identified risks associated with releases of non-sulfonated triarylmethane dyes to the aquatic environment through wastewater effluent from pulp and paper industrial facilities engaging in paper dyeing and paper deinking activities.

Both activities result in wastewater that contains leftover dye or ink that may contain MG, BV3, BV4, and/or BB7. The wastewater is then treated by on-site industrial wastewater treatment systems. MG, BV3, BV4, and BB7 are released to surface water through the wastewater effluent. Once reaching surface water, MG, BV3, BV4, BB7 may settle to bed sediment or be transported far from sources through the water column. Because these substances are expected to be persistent in the environment, there is higher potential for organisms to be exposed both spatially and temporally.

Non-sulfonated triarylmethanes are acutely toxic to a variety of aquatic organisms at low concentrations. Adverse effects have been documented for several species and taxonomic groups including invertebrates and algae, but the most sensitive organisms appear to be freshwater fish.

Although MG, BV3, BV4, and BB7 are not likely to bioaccumulate in the lipids of aquatic organisms, they may accumulate in other types of tissues.

Non-sulfonated triarylmethanes may cause mitochondrial disturbance and free radical damage. These substances can interact and bind with proteins and DNA, as evidenced by the use of MG and BV3 as laboratory and biological stains (Mani and Bharagava 2016 in Canada 2020). They can also cause physical adverse

effects such as clogged fish gills, increased mucus production, and epithelial damage leading to increased ventilation and respiration rates in fish (Ross et al. 1985 in Canada 2020). In addition, the substances may physically bind to the surface of algae, skin, or other tissues.

5.2 Human Health Exposure and Risks

The screening assessment estimated exposures to MG from drinking water; however, this exposure was 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. The critical health effect for MG was developmental, based on data for a similar substance (*i.e.* MG oxalate) (Canada 2020).

Additionally, oral and dermal exposures by children to MG from markers were considered as a potential exposure of concern in the draft screening assessment; however, these markers are no longer available in Canada.

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Chemicals Management Plan, the Government asked industry and interested stakeholders to submit any information on the substance that may be used to inform risk assessment, risk management and product stewardship. In particular, stakeholders were asked if any of the products or manufactured items containing the substance were intended for use by children.

6. Risk Management Considerations

6.1 Alternatives and Alternate Technologies

Information received from stakeholders suggests that there may be alternative classes of colourants, such as direct dyes and pigments, to non-sulfonated triarylmethanes in paper dyes, however substituting MG, BV3, BV4, or BB7 for these alternatives may not be economically viable (ECCC, HC 2020, personal communication, letters from stakeholder dated August 28, 2019 and October 7, 2019; unreferenced).

Information was also received indicating that at least one company in the pulp and paper industry has replaced its use of the dye MAPBAP acetate with BV4. The company indicated that it is not aware of other alternatives for MAPBAP acetate and BV4 (ECCC, HC 2020). A previous [screening assessment](#) concluded that MAPBAP acetate meets the criteria for toxic under CEPA (Canada 2010a). The

use of that substance for paper dyeing is subject to the *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* (Canada 2013)⁸.

No information on alternatives to MG in hair dyes was identified.

Stakeholders are asked to please submit information on alternative substances or alternate technologies, if known.

6.2 Socio-economic and Technical Considerations

Based on information obtained from section 71 surveys, MG, BV3, BV4, and BB7 are not manufactured in Canada (all are imported).

Stakeholders indicated that substituting MG, BV3, BV4 and BB7 in paper dye products could take several months or years (ECCC, HC 2020, personal communication, letter from stakeholder dated August 28, 2019; unreferenced). In addition, a stakeholder indicated that the cost of alternative substances may be similar or much higher than the cost of using dyes containing MG, BV3, BV4, and BB7 (personal communication, letter from stakeholder dated August 28, 2019; unreferenced).

Information received from stakeholders identified three pulp and paper facilities in Canada using MG, BV3, BV4, and BB7 (refer to Section 4.2).

Pulp and paper dyeing only occurs at mechanical mills, which includes newsprint mills. Dyes containing MG, BV3, BV4, and BB7 are predominantly used by newsprint mills and therefore can potentially be used by the following pulp and paper manufacturing subsectors:

- Mechanical pulp mills (NAICS 322111); and
- Newsprint mills (NAICS 322122).

There are a total of 32 pulp and paper mills currently in operation that can potentially use dyes containing MG, BV3, BV4, and BB7, of which approximately 17 produce newsprint. The mills are distributed across Canada in British Columbia, Alberta, Saskatchewan, Ontario, Quebec, Newfoundland, New Brunswick and Nova Scotia with almost 50% located in Quebec (Fisher International 2019).

Canada is the world's largest producer of newsprint (14% of global production) and the world's largest exporter of newsprint (33.5% of world value), with the majority of exports going to the United States. Quebec leads Canada's newsprint production and exports (65% of total value of exports) followed by Ontario (11% of total value of exports). The rise in digital media has led to a structural decline in Canada's newsprint (10% decline of newsprint product from 2016 to 2017). The

⁸ The Minister of the Environment issued the *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* under subsection 54 (1) of the *Canadian Environmental Protection Act, 1999* to limit dye quantities released in the final effluent. The guidelines apply to pulp and paper mills using MAPBAP acetate for paper dyeing. See also section 7.1.

market for newsprint is expected to continue to decline as consumers shift away from paper toward electronic media (NRCan 2019).

No further 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.

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.

7. Overview of Existing Risk Management

7.1 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).

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 is manufactured, processed or otherwise used at a concentration $\geq 1\%$ by weight and in quantity of 10 tonnes or more, and employees work 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). All BV3 drugs (human and veterinary) have been withdrawn from sale in Canada as of June, 2019 and a warning has been issued by HC regarding their use. BV3 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).

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 2012).

The *Guidelines for the Reduction of Dyes Released from Pulp and Paper Mills* were published under CEPA in 2013 and set out standards and good practices to observe in order to limit dye quantities released in the final effluent from pulp and paper mills. Currently, the dye MAPBAP Acetate is the only dye for which standards have been specified in the ERG (Canada 2013).

7.2 Pertinent International Risk Management Context

7.2.1 United States

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). Additionally, MG is not permitted in food packaging in the US (US FDA 2017a,b). The US also requires reporting of releases of MG, which is included in the Toxics Release Inventory (TRI) Program (US Code of Federal Regulations 2017).

7.2.2 European Union

The European Union (EU) 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).

In addition, BV3 substances that contain Michler's ketone or Michler's base⁹ equal to or above 0.1% are identified as carcinogenic and substances of very high concern (SVHC) and are included on the Candidate List, which entails certain reporting obligations (ECHA 2019).

7.2.3 Other Jurisdictions

MG has also been prohibited in cosmetics in New Zealand (EPANZ 2017) and by the Association of Southeast Asian Nations (ASEAN 2016). Several other

⁹ In the EU, the BV3 substance must include Michler's ketone (CAS RN 90-94-8) or Michler's base (101-61-1) in a concentration equal to or above 0.1% in order for the risk management actions to apply. A BV3 substance that does not meet the above condition is exempt.

countries were identified as prohibiting MG from being in food (Government of Hong Kong 2016) including fish (FSANZ 2005).

7.3 Risk Management Alignment

From an environmental perspective, Canada does not appear to align with international risk management activities as international risk management actions are mainly focused on uses related to human exposures. No information was found on the risk management of MG, BV3, BV4, or BB7 specifically in regards to protection of the environment or with respect to paper dyeing or uses in inks.

From a human health perspective, Canada is mostly aligned with the international community regarding MG and its use as a food additive or as a veterinary drug for food animals, aquaculture or fish for human consumption. The EU also lists MG as banned from cosmetics. With respect to alignment on BV3, it is banned from use in cosmetics in Canada, the EU and South Asian Countries, but does not appear on the prohibited or restricted cosmetic ingredients list in the US. BV3 human and veterinary drugs have been withdrawn from the Canadian market and BV3 is not recognized as safe for veterinary drugs in the US, though OTC human BV3 drugs appear to be still approved in the US and at least some EU countries. As well, BV3 is not permitted as a colourant in drugs in Canada. BV3 is also not recognized as safe for use in animal feed in the US and was withdrawn from use in poultry feed in Canada in 1992. Canada is not aligned with the international community on BV4 and BB7 where the EU and South Asian Countries prohibit their use in cosmetics (hair dye); they are not listed on Health Canada's Cosmetic Ingredient Hotlist.

In addition, both Canada and the EU recognise the risk posed by Michler's ketone as an intermediate in certain dyes, including BV3. A previous [screening assessment](#) for Michler's ketone concluded that Michler's ketone meets one or more of the criteria set out in section 64 of CEPA 1999 in Canada. Canada has applied a [Significant New Activity \(SNAC\) order](#) to Michler's Ketone (Canada 2010b).

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 Approach or other information that would help to inform decision-making (such as outlined in section 3.5). Please submit additional information and comments prior to December 16, 2020.

Comments and information submissions on the Risk Management Approach 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 or paper deinking, cosmetics, or children's arts and crafts products are encouraged to identify themselves as stakeholders. Stakeholders will be informed of future decisions regarding these substances and may be contacted for further information.

Following the public comment period on the Risk Management Approach document, the Government of Canada will initiate the development of the specific risk management instruments, where necessary. Comments received on the Risk Management Approach document will be taken into consideration in the selection or development of these instruments. Consultation will also take place as instruments are developed.

8.2 Timing of Actions

Electronic consultation on the Risk Management Approach: October 17, 2020 to December 16, 2020.

Publication of responses to public comments on the Risk Management Approach document: Concurrent to the publication of the proposed instruments.

Publication of the proposed instruments: At the latest, 24-months from the date on which the Ministers recommended that the substances be added to Schedule 1 of CEPA.

Consultation on the proposed instruments: 60-day public comment period starting upon publication of each proposed instrument.

Publication of the final instruments: At the latest, 18-months from the publication of each proposed instrument.

These are planned timelines and are subject to change. Please consult the [schedule of risk management activities and consultations](#) for updated information on timelines.

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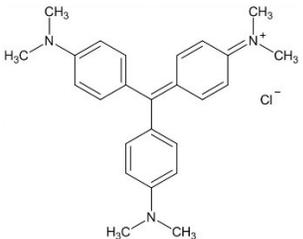
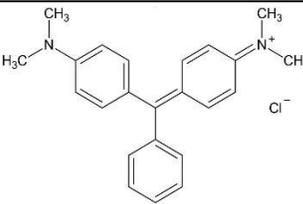
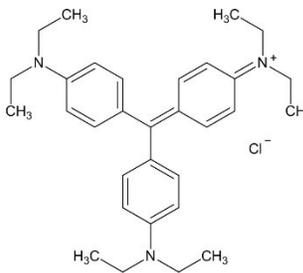
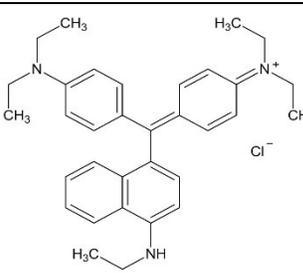
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ANNEX A. List of Targeted Substances

CAS RN ^a	DSL Name (English)	Other Names and Identifiers	Acronym	Chemical Structure and Formula	Molecular Weight (g/mol)
548-62-9	Methanaminium, N-[4-[bis(4-(dimethylamino)phenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride	Basic Violet 3, Crystal Violet, Gentian Violet ^b , Aniline Violet, Hexamethyl Violet, Methylrosanilinium Chloride, Hexamethyl Pararosaniline Chloride, Color Index 42555	BV3	 <p style="text-align: center;">C₂₅H₃₀N₃ Cl</p>	407.99
569-64-2	Methanaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, chloride	Malachite Green, Basic Green 4, China Green, Aniline Green, Color Index 42000	MG	 <p style="text-align: center;">C₂₃H₂₅N₂ Cl</p>	364.92
2390-59-2	Ethanaminium, N-[4-[bis(4-(diethylamino)phenyl)methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, chloride	Basic Violet 4, Ethyl Violet, Color Index 42600	BV4	 <p style="text-align: center;">C₃₁H₄₂N₃ Cl</p>	492.15
2390-60-5	Ethanaminium, N-[4-[[4-(diethylamino)phenyl][4-(ethylamino)-1-naphthalenyl]methylene]-2,5-cyclohexadien-1-ylidene]-N-ethyl-, chloride	Basic Blue 7, Victoria Blue, Color Index 42595	BB7	 <p style="text-align: center;">C₃₃H₄₀N₃ Cl</p>	514.15

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^bThe term "gentian violet" was originally used to describe a mixture of methyl pararosaniline dyes (methyl violet), but is now commonly used to refer to the single component Basic Violet 3.