



Government  
of Canada

Gouvernement  
du Canada

## PROPOSED RISK MANAGEMENT APPROACH

for

2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo]

Solvent Red 23

Chemical Abstracts Service Registry Number (CAS RN):  
85-86-9

Environment Canada  
Health Canada

September 2011

**Canada**

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This proposed risk management approach document builds on the previously released risk management scope document for Solvent Red 23, and outlines the proposed control actions for this substance. Stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Following this consultation period, the Government of Canada will initiate the development of the specific risk management instrument(s) where necessary. Comments received on the proposed risk management approach will be taken into consideration in developing the instrument(s). Consultation will also take place as instrument(s) are developed.

## SUMMARY OF RISK MANAGEMENT

1. The Government of Canada will regard Solvent Red 23 as a substance of concern when it is present in certain types of cosmetics and this will be communicated on Health Canada's Cosmetic Ingredient Hotlist.
2. The Government of Canada plans to implement Significant New Activity provisions under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) to this substance.

**Note:** This summary is an abridged list of the instruments and tools proposed to risk manage this substance. Please see section 9.1 of this document for a complete explanation of risk management.

## 1. ISSUE

### 1.1 Categorization and the Challenge to Industry and Other Interested Stakeholders

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) (Canada 1999) requires the Minister of the Environment and the Minister of Health (the Ministers) to categorize substances on the *Domestic Substances List* (DSL). Categorization involves identifying those substances on the DSL that a) are considered to be persistent (P) and/or bioaccumulative (B), based on the criteria set out in the *Persistence and Bioaccumulation Regulations*, and “inherently toxic” (iT) to humans or other organisms, or b) present, to individuals in Canada, the greatest potential for exposure (GPE). In addition, the Act requires the Ministers to conduct screening assessments of substances that meet the categorization criteria. The assessment further determines whether the substance meets the criteria set out in section 64 of the Act.<sup>1</sup>

<sup>1</sup> A determination of whether one or more of the criteria of section 64 are met and whether risk management may be required 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 exposures from ambient and indoor air, drinking water, foodstuffs and the use of consumer products. A conclusion under CEPA 1999 on the substances in the Chemicals Management Plan (CMP) Challenge Batches 1-12 is not relevant to nor does it preclude an assessment against the hazard criteria specified in the Workplace Hazardous Materials Information System [WHMIS] *Controlled Products Regulations* for products intended for workplace use. Similarly, a conclusion based on the criteria contained in section 64 of CEPA 1999 does not preclude actions being taken under other sections of CEPA or other Acts.

In December 2006, the Challenge identified 195 chemical substances through categorization which became high priorities for assessment due to their hazardous properties and their potential to pose risks to human health and the environment. In February 2007, the Ministers began publishing, for industry and stakeholder comment, profiles of batches containing 12 to 19 high-priority substances. New batches are released for comment every three months.

In addition, the information-gathering authority in section 71 of CEPA 1999 is being used under the Challenge to gather specific information where it is required. The information that is collected through the Challenge will be used to make informed decisions and appropriately manage any risks that may be associated with these substances.

The substance 2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo], Chemical Abstracts Service Registry Number (CAS RN)<sup>2</sup> 85-86-9, referred to throughout this document as “Solvent Red 23,” is included in Batch 6 of the Challenge under the Chemicals Management Plan.

## 1.2 Final Screening Assessment Report Conclusion for Solvent Red 23

A notice summarizing the scientific considerations of a final screening assessment report was published by Environment Canada and Health Canada in the *Canada Gazette*, Part I, for Solvent Red 23 on September 10, 2011, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that Solvent Red 23 is entering or may be entering the environment in a quantity or a concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

Based on the potential general population exposure, and evidence of genotoxicity and carcinogenicity for 4-aminoazobenzene (potential azo cleavage product) and Sudan I (analogue azo dye), for which there may be a probability of harm at any level of exposure, it is concluded that Solvent Red 23 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 final screening assessment report also concluded that Solvent Red 23 meets the criteria for persistence and does not meet the criteria for bioaccumulation, as defined in the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of Solvent Red 23 in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for Solvent Red 23, refer to the final screening assessment report, available at <http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-6/index-eng.php>

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<sup>2</sup> CAS RN: Chemical Abstracts Service Registry Number. 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.

### **1.3 Proposed Measure**

As a result of a screening assessment of a substance under section 74 of CEPA 1999, the substance may be 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 substance, add the substance to the Priority Substances List (PSL) for further assessment, or recommend the addition of the substance to the List of Toxic Substances in Schedule 1 of the Act. Under certain circumstances, the Ministers must make a specific proposal either to recommend addition to the List of Toxic Substances or to recommend the implementation of virtual elimination (or both). In this case, the Minister proposed to recommend the addition of Solvent Red 23 to the List of Toxic Substances in Schedule 1. As a result, the Ministers will develop a regulation or instrument respecting preventive or control actions to protect the health of Canadians and the environment from the potential effects of exposure to this substance.

The final screening assessment report did not conclude that Solvent Red 23 meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, Solvent Red 23 will not be subject to the virtual elimination provisions under CEPA 1999 and will be managed using a lifecycle approach, to prevent or minimize its release into the environment.

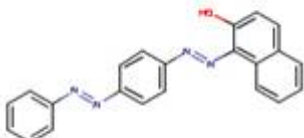
## **2. BACKGROUND**

### **2.1 Substance Information**

Solvent Red 23 is part of the chemical grouping Azo compounds and the chemical sub-grouping Disazo compounds.

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for Solvent Red 23.

**Table 1. Identity of Solvent Red 23**

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Chemical Abstracts Service Registry Number (CAS RN)</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | 85-86-9                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>DSL name</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | 2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo]-                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Inventory names</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 2-Naphthalenol, 1-[[4-(phenylazo)phenyl]azo]- (TSCA, AICS, PICCS, ASIA-PAC, NZIoC)<br>1-(4-(phenylazo)phenylazo)-2-naphthol (EINECS)<br>Solvent Red 23 (ENCS, PICCS)<br>C.I. solvent red 023 (ECL)<br>Sudan III (PICCS)<br>naphth-2-ol, 1-((4-phenylazo)phenyl)azo)- (PICCS)                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Other names</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | 1-(p-Phenylazophenylazo)-2-naphthol; 111440 Red;<br>2-Naphthol, 1-(p-phenylazophenylazo)-; Brasilazina Oil Scarlet; C.I. 26100; C.I. Solvent Red 23;<br>Certiquil Oil Red; D and C Red No. 17; Fast Oil Scarlet III; Fat Red Bluish; Fat Red HRR; Fat Red R;<br>Fat Red RS; Fat Scarlet LB; Fat Soluble Red Zh; FD and C Red No. 17; Grasal Brilliant Red G;<br>Grasan Brilliant Red G; Japan Red 225; Japan Red No. 225; NSC 65825; NSC 8995; Oil Red 3G; Oil<br>Red AS; Oil Red Extra; Oil Scarlet G; Organol Red BS; Organol Scarlet; Red No. 225; Red Zh; Silotras<br>Scarlet TB; Somalia Red III; Stearix Scarlet; Sudan 3; Sudan P III; Sudan Red III; Tetrazobenzene-b-<br>naphthol; Toney Red |
| <b>Chemical group</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Azo compounds                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Chemical subgroup</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Disazo compounds                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Chemical formula</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | C <sub>22</sub> H <sub>16</sub> N <sub>4</sub> O                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Chemical structure</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| <b>SMILES2</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Oc(ccc(c1ccc2)c2)c1N=Nc(ccc(N=Nc(cccc3)c3)c4)c4                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Molecular mass</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | 352.40 g/mol                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <sup>1</sup> National Chemical Inventories (NCI). 2006; AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Asia-Pacific Substances Lists); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Commercial Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); and TSCA (U.S. Toxic Substances Control Act Chemical Substance Inventory).<br><sup>2</sup> Simplified Molecular Line Input Entry System. |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |

### 3. WHY WE NEED ACTION

#### 3.1 Characterization of Risk

Exposure of the general population to Solvent Red 23 from environmental media is expected to be negligible. There is no expected exposure to Solvent Red 23 from food, as it is not listed as a permitted food additive as per Division 16 of the *Food and Drug Regulations*, nor has it been identified for use in food packaging applications. However, dermal and oral exposure from the use of cosmetics and personal care products may occur. Exposure by the inhalation route from these sources is expected to be minimal (Canada 2011).

As Solvent Red 23 may undergo azo cleavage, health effects data on the predicted azo cleavage products, particularly 4-aminoazobenzene, have been considered in the health effects characterization for Solvent Red 23. 4-aminoazobenzene has been shown to induce tumours in rats following oral and dermal exposure, and has been classified as a carcinogen by the International Agency for Research on Cancer (IARC 1987) and the European Commission (2010). In addition, the monoazo analogue dye Sudan I, a classified carcinogen and mutagen in Europe, has been shown to be metabolized to some of the same aromatic amines as Solvent Red 23 *in vitro* and *in vivo* (Canada 2011).

Based on evidence of genotoxicity and carcinogenicity for Sudan I, an analogue of Solvent Red 23, and based on aromatic amines expected to be released by azo reductive cleavage of Solvent Red 23 (i.e., 4-aminoazobenzene), genotoxicity and carcinogenicity are considered critical effects for risk characterization of Solvent Red 23. Given the consideration of exposure potential to the general population from the use of cosmetics and personal care products containing Solvent Red 23 and potential of genotoxicity and carcinogenicity for which there may be a probability of harm at any level of exposure, Solvent Red 23 is concluded to be 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 2011).

Evaluation of risk to human health involves consideration of data relevant to estimation of exposure (non-occupational) of the general population, as well as information on health hazards.

#### 3.2 Exposure of Children

An oral exposure estimate was developed for the general population and children aged 5-11 from the use of lip gloss/balm by applying a conservative assumption that 100% of the applied product is ingested with a frequency of 1460 applications per year or 4 per day (Canada 2011).

## 4. CURRENT USES AND INDUSTRIAL SECTORS

Information on uses for the 2005 and 2006 calendar years was gathered in response to the CEPA 1999 section 71 notices (Canada 2006, 2008). In 2005, companies importing Solvent Red 23 between 100 and 1000 kg indicated that they were engaged in retailing cosmetics, perfumes, toiletries and personal grooming products or providing hair care or aesthetic services (Environment Canada 2006). In 2006, Solvent Red 23 was not reported to be imported, used or manufactured in Canada above threshold.

In Canada, Solvent Red 23, also found as CI 26100 and D&C 17, is used primarily in cosmetics and personal care products (CNS 2009). The dye is also used as a formulant (non-active ingredient) in five registered commercial-class pesticide products (2009 email from the Pest Management Regulatory Agency [PMRA] to Existing Substances Risk Assessment Bureau, Health Canada; unreferenced). Solvent Red 23 is listed in the *Food and Drug Regulations* under section C.01.040.2(4) under the name Toney Red (D&C Red No. 17; C.I. No. 26100) (Canada 1978). As per the Regulations, it is permitted to be used as a colouring agent in drugs for external use only. However, no personal care products that are regulated as drugs have been identified as containing this substance as an ingredient. Solvent Red 23 is, however, listed in the Therapeutic Products Directorate's internal Non-Medicinal Ingredients Database as a colourant present in one liquid disinfectant used in hospitals and in premises in which food is manufactured, prepared or kept, but has not been identified as being present in pharmaceutical or veterinary drugs (2008 email from Therapeutic Products Directorate, Health Canada, to Risk Management Bureau; unreferenced). Solvent Red 23 is also listed in the Natural Health Products Ingredients Database as an acceptable non-medicinal ingredient where it may be used as a colouring agent in natural health products for external use only (NHPID 2010). Solvent Red 23 is listed in the Licensed Natural Health Products Database and therefore is present in licensed natural health products that are applied externally in topical applications, with no contact to mucous membranes (LNHPD 2010).

The key sector involved is cosmetics; the sectors involved to a relatively minor degree include pest control products, drugs, and natural health products.

## 5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

### 5.1 Releases to the Environment

Solvent Red 23 is not listed in the National Pollutant Release Inventory and is unlikely to be causing harm to populations of aquatic organisms in Canada. Based on its use pattern in personal care products, it is anticipated that 100% of products containing Solvent Red 23 could be released to sewer water, surface water or land during their use. Once released to surface or sewer water, due to its physical and chemical properties Solvent Red 23 is expected to bind to sediment in aquatic environments and to sludge in wastewater treatment systems (Canada 2011).

Sewer water is the medium potentially receiving the greatest proportion of Solvent Red 23 during product use. It is anticipated that the majority of the substance, bound to sewage sludge from down-the-drain releases of personal care products to sewage treatment plants, will be sent

entrained in sludge to landfills. In addition to being landfilled, some of the biosolids from wastewater treatment facilities may be applied to forested or agricultural land and a small percentage may be incinerated (Canada 2011).

## 5.2 Exposure Sources

The general population's potential exposure to Solvent Red 23 through the use of cosmetic and some personal care products was estimated using ConsExpo 4.1 (ConsExpo 2006; RIVM 2006). Estimates of dermal exposures from representative cosmetic and personal care products containing Solvent Red 23, such as bath preparations, massage oil, hair conditioner, hair dye, body lotion, facial cleanser and nail polish, were derived. Oral exposure was estimated for the use of lip gloss/balm containing Solvent Red 23.

Dermal exposure from the use of personal care products was estimated to range from 0.002 mg/kg-body weight (bw) per day (massage oil) to 0.18 mg/kg-bw per day (body lotion), with a conservative assumption that 26% of the applied product is absorbed. Oral exposures of 0.01 mg/kg-bw per day for children aged 5-11 and 0.006 mg/kg-bw per day for the general population were estimated from the use of lip gloss/balm by applying a conservative assumption that 100% of the applied product was ingested. Given the conservative nature of the modelling assumptions, and conservatively assuming 26% and 100% absorption via dermal and oral routes, respectively, these values are considered to be upper-bounding estimates of exposure. Exposure to consumer products via the inhalation route was considered to be minimal based on the low volatility of this substance (Canada 2011).

As Solvent Red 23 is a member of the family of azo colourants, relevant information on its potential azo cleavage products is also considered. Collectively, the data for Solvent Red 23 and its analogues support the potential for reductive cleavage of the azo bonds, particularly when administered by the oral route, and therefore the potential for exposure to aromatic amines (Canada 2011).

There is a higher degree of confidence that Solvent Red 23 (or its predicted cleavage products) is absorbed via the oral route than via the dermal route. There is also a high degree of confidence that Solvent Red 23 can be cleaved to release aromatic amines after oral exposure, as evidenced by azo cleavage by isolated gastrointestinal bacteria. Therefore, there is greater relative concern for the oral route of exposure (i.e., lip gloss/balm), for which a potential hazard is supported by the available data. Although a lack of supporting data does not preclude possible risks from the dermal route of exposure, based on the available information it is reasonable to assume that although some dermal absorption of Solvent Red 23 (or its metabolites) may potentially occur, the potential risks of health effects from dermal exposure is likely lower than that for the oral route (Canada 2011).

## 6. OVERVIEW OF EXISTING ACTIONS

### 6.1 Existing Canadian Risk Management

Solvent Red 23 is not listed in Table III of Division 16 of the *Food and Drug Regulations*, and therefore it is not permitted for use as a colouring agent in foods offered for sale in Canada (i.e., this substance has no approved food additive uses in Canada).

Solvent Red 23 is listed in the *Food and Drug Regulations* under section C.01.040.2(4), under the name Toney Red (D&C Red No. 17, C.I. No. 26100)—which indicates that this colourant may be used in drugs for external use only.

Solvent Red 23 is listed in the Natural Health Products Ingredients Database (NHPID) as an acceptable non-medicinal ingredient to be used as a colouring agent for external-use-only (topical) natural health products.

Solvent Red 23 is on the list of formulants that are found in pest control products currently registered in Canada (PMRA 2007). It is included on List 2, which contains formulants that are considered potentially toxic.

### 6.2 Existing International Risk Management

#### *United States*

Solvent Red 23 is not an approved colour additive for use in foods under Code of Federal Regulations Title 21 Part 73 Subpart A (21 CFR 73 Subpart A) or 21 CFR 74 Subpart A.

Solvent Red 23 is currently approved in the United States as D&C Red No. 17 for use as a colourant in:

- Externally applied drugs under 21 CFR Part 74.1317
- Externally applied cosmetics but not around eyes or lips under 21 CFR Part 74.2317
- Contact lenses under 21 CFR Part 74.3230

Solvent Red 23 is on the list of inert ingredients permitted for use in pesticide products applied in non-food-use applications, such as ornamental plants and highway rights-of-way, in the United States (US EPA 2008).

#### *Europe*

Solvent Red 23 is currently prohibited in Europe for use in hair dyes (Cosmetics Directive Annex II) (European Commission 2010).

It is approved for use as a colourant in cosmetics that are not intended to come into contact with mucous membranes (Cosmetics Directive Annex IV).

This substance is not listed in the Colours in Food Directive 94/36/EEC (of June 1994), and thus is not permitted to be present at any level in foodstuffs.

Europe prohibits the import of chili, chili products, curcuma and palm oil unless an original analytical report accompanying the consignment demonstrates that the product does not contain Solvent Red 23.

The European Spice Association designed a document to provide guidance for the spice industry to minimize the risk of contaminated spices entering the food supply chain, as this substance is not a permitted food colourant in the European Union.

#### **4-Aminoazobenzene, CAS 60-09-3 (potential azo cleavage product):**

The European Commission REACH (Registration, Evaluation, Authorization and Restriction of Chemical Substances), regulation EC 1907/2006, specifically Point 43 of Annex XVII, restricts certain “Azocolourants and Azodyes” in certain textiles that may release one of 22 aromatic amines by cleavage of the azo bonds (European Commission 2006). Although Solvent Red 23 would theoretically be subject to this regulation by virtue of possibly releasing one of the 22 restricted aromatic amines (i.e., 4-aminoazobenzene CAS RN 60-09-3), the current use pattern of this substance does not at this time indicate its presence in textiles and leather products.

## **7. CONSIDERATIONS**

### **7.1 Alternative Chemicals or Substitutes**

Solvent Red 23 belongs to a group of azo substances that may metabolize to aromatic amines, which as a chemical class are known to exhibit hazardous properties, including carcinogenicity. Therefore, additional activity (e.g., research, assessment, monitoring and surveillance) to characterize the risk to human health in Canada posed by this broader group of azo substances may be undertaken. A Notice of Intent outlining how Health Canada and Environment Canada will address this group of substances is available at the following Internet address:  
[http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/azo\\_benzidine-eng.php](http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/azo_benzidine-eng.php).

### **7.2 Alternative Technologies and/or Techniques**

No alternative technologies or techniques have been identified.

### 7.3 Socio-economic Considerations

Socio-economic factors have been considered in the selection process for a regulation and/or instrument respecting preventive or control actions, and in the development of the risk management objective(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 Streamlining Regulation* (Treasury Board of Canada Secretariat 2007) and the guidance provided in the Treasury Board document *Assessing, Selecting, and Implementing Instruments for Government Action*.

## 8. PROPOSED OBJECTIVES

### 8.1 Environmental or Human Health Objective

An environmental or human health objective is a quantitative or qualitative statement of what should be achieved to address environmental or human health concerns identified during a risk assessment.

The proposed human health objective for Solvent Red 23 is to minimize human exposure to the greatest extent practicable.

### 8.2 Risk Management Objectives

A risk management objective is a target expected to be achieved for a given substance by the implementation of risk management regulations, instrument(s) and/or tool(s). The proposed risk management objective for Solvent Red 23 is to reduce human exposure to sources of greatest concern, i.e., cosmetics, personal care products and drugs containing Solvent Red 23.

## 9. PROPOSED RISK MANAGEMENT

### 9.1 Proposed Risk Management Instruments

As required by the Government of Canada's *Cabinet Directive on Streamlining Regulation*<sup>3</sup> and criteria identified in the Treasury Board document entitled *Assessing, Selecting, and Implementing Instruments for Government Action*, the three proposed risk management measures were selected using a consistent approach, and took into consideration the information that was received through the Challenge and other information available at the time.

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<sup>3</sup> Section 4.4 of the *Cabinet Directive on Streamlining Regulation* states that "Departments and agencies are to: identify the appropriate instrument or mix of instruments, including regulatory and non-regulatory measures, and justify their application before submitting a regulatory proposal".

In order to achieve the risk management objective and to work towards achieving the environmental or human health objective, the Government of Canada is proposing the following actions for Solvent Red 23:

- 1. The Government of Canada will regard Solvent Red 23 as a substance of concern when it is present in certain types of cosmetics and this will be communicated on Health Canada's Cosmetic Ingredient Hotlist**, which is an administrative tool to communicate to manufacturers and others that certain substances, when used in a cosmetic, may cause injury to the health of the user in contravention of section 16 of the *Food and Drugs Act*. Compliance with the provisions of section 16 is monitored, in part, through the mandatory notification provisions of section 30 of the *Cosmetic Regulations* of the *Food and Drugs Act*, which require that all manufacturers and importers provide a list of the cosmetic's ingredients to Health Canada.
- 2. The Government of Canada also plans to implement Significant New Activity provisions under CEPA 1999 for this substance.** This would require that any proposed new manufacture, import or use be subject to further assessment, and would determine if the new activity requires further risk management consideration.

## 9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to Solvent Red 23 will be published in the *Canada Gazette*, Part I, no later than September 2013.

## 10. CONSULTATION APPROACH

The risk management scope for Solvent Red 23, which summarized the proposed risk management under consideration at that time, was published on October 2, 2010. Industry and other interested stakeholders were invited to submit comments on the risk management scope during a 60-day comment period. Comments received on the risk management scope document were taken into consideration in the development of this proposed risk management approach document.

The primary stakeholders include the following sectors:

- Cosmetics and personal care products
- Drug products
- Natural health products
- Pest control products

## 11. NEXT STEPS / PROPOSED TIMELINE

| Actions                                                      | Date                                                                |
|--------------------------------------------------------------|---------------------------------------------------------------------|
| Electronic consultation on proposed risk management approach | September 10, 2011 to November 9, 2011                              |
| Response to comments on the risk management approach         | No later than at the time of publication of the proposed instrument |
| Consultation on the draft instrument                         | Spring/Summer 2012                                                  |
| Publication of the proposed instrument                       | No later than September 2013                                        |
| Formal public comment period on the proposed instrument      | No later than Fall 2013                                             |
| Publication of the final instrument                          | No later than March 2015                                            |

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or provide other information that would help to inform decision making. Please submit comments prior to November 9, 2011, as the risk management of Solvent Red 23 will be moving forward after this date. During the development of regulations, instrument(s) and/or tool(s), there will be opportunity for consultation. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Chemicals Management Division  
 Gatineau Québec K1A 0H3  
 Tel: 1-888-228-0530 / 819-956-9313  
 Fax: 819-953-7155  
 Email: [Substances@ec.gc.ca](mailto:Substances@ec.gc.ca)

## 12. REFERENCES

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