



Government
of Canada

Gouvernement
du Canada

PROPOSED RISK MANAGEMENT APPROACH

for

C.I. Pigment Red 104

Chemical Abstracts Service Registry Number (CAS RN):

12656-85-8

Environment Canada
Health Canada

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Canada

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This proposed risk management approach document builds on the previously released risk management scope document for C.I. Pigment Red 104, 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.

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 definition of “toxic” set out in section 64 of CEPA 1999.

In December 2006, the Challenge identified 193 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 15 to 30 high-priority substances.

In addition, the information-gathering provisions under section 71 of CEPA 1999 are 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 C.I. Pigment Red 104, Chemical Abstracts Service Registry Number (CAS RN)¹ 12656-85-8, was included in Batch 2 of the Challenge under the Chemicals Management Plan.

1.2 Final Screening Assessment Report Conclusion for C.I. Pigment Red 104

¹ 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 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.

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 C.I. Pigment Red 104 on January 31, 2009, under subsection 77(6) of CEPA 1999. The final screening assessment report concluded that C.I. Pigment Red 104 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 principally on the weight-of-evidence classification of C.I. Pigment Red 104 by the European Commission and the assessment of hexavalent chromium and inorganic lead compounds by several national and international agencies, a critical effect for the characterization of risk to human health is carcinogenicity. The substance C.I. Pigment Red 104, together with lead chromate and C.I. Pigment Yellow 34, was carcinogenic in rats after subcutaneous and intramuscular administration and these animal studies are supported by epidemiological studies that indicate an increased frequency of lung cancer in chromate pigment production workers. As well, C.I. Pigment Red 104 or its principal components were genotoxic in a limited number of *in vitro* and *in vivo* experimental systems. In the absence of a full evaluation of the mode of action for C.I. Pigment Red 104, a mode of action for induction of effects involving direct interaction with genetic material cannot be precluded.

On the basis of the carcinogenicity of C.I. Pigment Red 104, for which there may be a probability of harm at any level of exposure, it is concluded that C.I. Pigment Red 104 is a substance that may 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 2008).

It is therefore concluded that C.I. Pigment Red 104 does not meet the criteria in paragraph 64(a) and 64(b) of CEPA 1999, but it does meet the criteria in paragraph 64(c) of CEPA 1999.

The final screening assessment report also concluded that C.I. Pigment Red 104 meets the criteria for persistence as defined by the *Persistence and Bioaccumulation Regulations* made under CEPA 1999. The presence of C.I. Pigment Red 104 in the environment results primarily from human activity.

For further information on the final screening assessment report conclusion for C.I. Pigment Red 104, refer to the final screening assessment report, available at www.chemicalsubstanceschemiques.gc.ca/challenge-defi/batch-lot_2_e.html.

1.3 Proposed Measure

Following a screening assessment of a substance under section 74 of CEPA 1999, a substance may be found to meet 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 CEPA 1999. 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 Ministers

proposed to recommend the addition of C.I. Pigment Red 104 to the List of Toxic Substances in Schedule 1 of CEPA 1999. 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 C.I. Pigment Red 104 meets the conditions set out in subsection 77(4) of CEPA 1999. As a result, C.I. Pigment Red 104 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

C.I. Pigment Red 104 is part of the chemical grouping UVCBs (Unknown or Variable Composition, Complex Reaction Products, or Biological Materials) - Inorganics and the chemical sub-grouping group IVA and group VIB element compounds; chromium VI-containing; lead II-containing; molybdenum VI-containing; oxides; and sulfates

Table 1 presents other names, trade names, chemical groupings, the chemical formula, the chemical structure and the molecular mass for C.I. Pigment Red 104.

Table 1. Identity of C.I. Pigment Red 104

Chemical Abstracts Service Registry Number (CAS RN)	12656-85-8
Name on Domestic Substances List (DSL)	C.I. Pigment Red 104
Inventory names²	C.I. Pigment Red 104 (TSCA, AICS, ECL, SWISS, PICCS, ASIA-PAC, NZIoC); Lead chromate molybdate sulfate red (EINECS); Pigment Red 104 (ENCS); Silica Encapsulated Pigment Red 204; Molybdate Orange; Lead Chromate Molybdate (PICCS)
Other names	C.I. 77605; Chrome Vermilion; Hona Molybdate Orange MLH 84SQ; Krolor Orange KO 906D; Krolor Orange RKO 786D; Mineral Fire Red 5DDS; Mineral Fire Red 5GGS; Mineral Fire Red 5GS; Molybdate Orange Y 786D; Molybdate Orange YE 421D; Molybdate Orange YE 698D; Molybdate Red; Molybdate Red AA 3; Molybden Red; Molybdenum orange; Molybdenum Red; Renol; Molybdate Red RGS; Vynamon Scarlet BY; Vynamon Scarlet Y

² National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories of Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ENCS (Japanese Existing and New Chemical Substances); NZIoC (New Zealand Inventory of Chemicals); PICCS (Philippine Inventory of Chemicals and Chemical Substances); SWISS (Inventory of Notified New Substances); TSCA (Toxic Substances Control Act Chemical Substance Inventory).

Chemical group (DSL stream)	UVCBs (Unknown or Variable Composition, Complex Reaction Products, or Biological Materials) - Inorganics
Chemical sub-group	Group IVA and group VIB element compounds; chromium VI-containing; lead II-containing; molybdenum VI-containing; oxides; sulfates
Chemical formula	PbCrO ₄ * PbSO ₄ * PbMoO ₄ (Solid solution crystal of PbCrO ₄ , PbSO ₄ , and PbMoO ₄ in varying proportions) (Environment Canada 2007)
Chemical structure	N/A
Simplified Molecular Input Line Entry System (SMILES)	N/A
Molecular mass	PbCrO ₄ = 323.2 g/mol (main constituent); PbSO ₄ = 303.3 g/mol; PbMoO ₄ = 367.1 g/mol

3. WHY WE NEED ACTION

3.1 Characterization of Risk

Based principally on the weight-of-evidence classification of C.I. Pigment Red 104 by the European Commission as a Category 3 carcinogen (ESIS 2007), and the assessments of hexavalent chromium and inorganic lead compounds by several national and international agencies (US EPA 1993, 1998; IARC 1990, 2006; Canada 1994; NTP 2005), a critical effect for characterization of risk to human health for C.I. Pigment Red 104 is carcinogenicity. Although most of these classifications were based on groups of hexavalent chromium compounds or inorganic lead compounds, they, along with the information on lead chromate, support the limited data available on C.I. Pigment Red 104. As well, C.I. Pigment Red 104 or its principal components were genotoxic in a limited number of *in vitro* and *in vivo* experimental systems. Therefore, a mode of action for carcinogenicity involving direct interaction with genetic material cannot be precluded.

With respect to non-cancer effects, margins of exposure comparison were not derived due to low potential for exposure to the general population of Canada and the uncertainties regarding non-cancer effect levels (reproductive toxicity, developmental toxicity and repeated-dose toxicity).

3.1.1 Uncertainties in Evaluation of Risk to Human Health

There is uncertainty regarding the bioavailability of this substance; however, limited data indicate that there is some level of absorption of lead and chromate after exposure to lead chromate and its derived pigments. In addition, although genotoxicity of the pigment or lead chromate is generally more pronounced after dissolution in acid or base, positive results were also obtained in aqueous media. However, encapsulation of the pigment has been shown to reduce bioavailability and genotoxicity in some studies. In-depth consideration of a mechanism of action for carcinogenicity for this substance is beyond the scope of this screening assessment. As well, the health effects database for the C.I. Pigment Red 104 as a discrete substance is limited.

The confidence in the characterization of exposure to C.I. Pigment Red 104 is low, as the concentrations of this substance in environmental media could not be quantified in Canada or elsewhere, leading to uncertainty in the exposure assessment. However, based on the properties and uses of the substance, there is confidence that actual environmental exposure levels are low. However, for a small population of Canadians, there is uncertainty regarding possible exposure to higher concentrations, but these could not be quantified (Canada 2008).

4. CURRENT USES AND INDUSTRIAL SECTORS

According to the Color Pigments Manufacturers Association, the significant applications for these pigments in Canada are plastic formulation for commercial applications and export; commercial, non-consumer paints and coatings; and a very limited number of commercial printing inks or coatings used for plastics and certain outdoor applications such as commercial identification decals. For example, these pigments are used for applications that require safety attributes such as high visibility and so are used in traffic paint stripping for highways and airports, and safety identification paints on buses, ambulances and fire trucks. Industrial paints using lead chromate pigments include automotive finishes, industrial and agricultural equipment, industrial baking enamels and air-dried finishes (Environment Canada 2007).

Based on responses to a 2006 section 71 notice, C.I. Pigment Red 104 was reported to be manufactured in and imported into Canada in 2006. After exports, the amount remaining for use in this country ranged between 100 000 and 1 000 000 kg.

The substance C.I. Pigment Red 104 is not used in consumer paints as the *Hazardous Products Act* prohibits furniture and other articles for children that have a surface coating material applied to them containing lead compounds of which the total lead content is more than 600 mg/kg (Canada 2005a). The *Hazardous Products Act* also prohibits toys, equipment and other products for use by a child in learning or play and pencils and artists' brushes that have had a surface coating material applied to them that contains more than 600 mg/kg of total lead (Canada 2005a). A concentration greater than 600 mg/kg would be required technically to manufacture a paint coloured with this substance (Environment Canada 2007).

The *Surface Coating Materials Regulations* issued under the *Hazardous Products Act* (Canada 2005b) limits the total lead concentration in surface coating materials to not more than 600 mg/kg when a dry sample is tested. This limit does not apply to a surface coating material that is used

1. as an anti-corrosive or an anti-weathering coating applied to buildings or equipment used for agricultural or industrial purposes;
2. as an anti-corrosive or an anti-weathering coating applied to any structure, other than a building, used for agricultural, industrial or public purposes;
3. as a touch-up coating for metal surfaces;
4. on traffic signs;
5. for graphic art on billboards or similar displays;
6. for identification marks in industrial buildings; and
7. as material for the purposes of arts, crafts or hobbies, other than material for use by children.

These regulations do not apply in the case of a surface coating material that is used exclusively in an industrial setting, other than for a use described above, on surfaces where the finish is so durable and tightly adhered to the surface that it cannot be chewed or chipped under foreseeable use.

The substance C.I. Pigment Red 104 is not listed in the Food Additive Tables of Division 16 of the *Food and Drug Regulations*, and is therefore not permitted as a food colour in Canada. In addition, the Health Products and Food Branch of Health Canada confirmed that this substance is not currently being used in food packaging material (Health Canada 2008, personal communication).

5. PRESENCE IN THE CANADIAN ENVIRONMENT AND EXPOSURE SOURCES

5.1 Releases to the Environment

Submissions from a survey conducted under section 71 of CEPA 1999, in 2006, indicated that industrial releases of C.I. Pigment Red 104 to ambient air, water and soil were extremely low (i.e., less than 0.1% of total quantities manufactured in or imported into Canada) (Canada 2007).

Mass flow release estimates indicate that 87.8% of C.I. Pigment Red 104 would end up in waste management sites, 2.8% would be transformed (which in this case means destruction or modification of the chemical structure during incineration), and an estimated 7.9% of C.I. Pigment Red 104 may be released to water. Once released to water, a significant portion of the substance will end up in sediments. Negligible releases are expected to soil, groundwater and air. Results from a survey conducted in 2006 under section 71 of CEPA 1999 indicated that releases to all media from industrial manufacture and formulation processing were extremely low (i.e., less than 0.1% of total manufactured in or imported into Canada).

Based on the section 71 survey, water is expected to be the medium receiving the greatest proportion of C.I. Pigment Red 104 emitted during product manufacturing, formulation, industrial processing and use, and service life. It is anticipated that the majority of the substance bound in the product will be sent to landfills or incinerators for disposal.

Given some potentially dispersive uses of this chemical in specific coloured products, it is expected that C.I. Pigment Red 104 is being released into the Canadian environment mainly as a result of the industrial use and service life of these products (Canada 2008).

5.2 Exposure Sources

The substance C.I. Pigment Red 104 is not known to be naturally produced in the environment. The principal metallic components of this substance, lead and chromium, are naturally occurring elements and as such are considered infinitely persistent. Lead concentrations in the rock of the upper continental crust have been determined to range between 17 and 20 ppm; chromium concentrations have been determined to be approximately 35 ppm (Reimann and de Caritat 1998).

The general population of Canada is not expected to be exposed to C.I. Pigment Red 104 through inhalation of ambient air. C.I. Pigment Red 104 is not used for the manufacture of products for use by the general population and therefore there is no direct exposure to them via this route. This substance is used in commercial settings to manufacture items that consumers may come in contact with after application, such as road paint, pigmented polymers, and pigments used in wiring.

This substance is often directly incorporated into the matrix of the solid material (i.e., polymer) and generally, solid materials have the lowest potential for exposure by the dermal route as migration through the solid matrix and subsequent absorption through the skin would be very limited. Specifically, chromium and lead, particularly their salts, are not known to have a high potential for systemic exposure by the dermal route as they have low skin permeability coefficients relative to other chemicals (US EPA 1992), and the silica encapsulation (for special uses) of this pigment would further prevent migration.

There has been some concern regarding possible lead exposures resulting from the release of lead pigments (originating from C.I. Pigment Red 104) from aging artificial turf used in sports fields. The U.S. Consumer Product Safety Commission analysed various turf samples and concluded that in no case would the estimated exposure for children playing on the field exceed 15 µg lead/day (CPSC 2008).

There were no empirical data identified regarding measured concentrations of C.I. Pigment Red 104 in environmental media (i.e., air, water, soil and food) in Canada. Given the physical and chemical properties of this substance, exposure to C.I. Pigment Red 104 is expected to be negligible via drinking water, ambient air or consumer products. Exposure to the general population in Canada is expected to be predominantly from soils, although these exposures are expected to be low due to the primarily commercial use of the substance, very limited industrial releases, and the encapsulation and incorporation of the substance into a solid matrix. However, these exposures could not be quantified due to lack of measured concentrations (Canada 2008).

6. OVERVIEW OF EXISTING ACTIONS

6.1 Existing Canadian Risk Management

C.I. Pigment Red 104 is subject to

- the *Food and Drug Regulations* Cosmetic Ingredient Hotlist (restricted as lead and its compounds) (Canada 2004);
- the *Surface Coating Materials Regulations* established under the *Hazardous Products Act* (Canada 2005b);
- provincial and municipal regulations or bylaws regarding levels of acceptable releases of lead or chromium (such as the *Ontario Regulation 419/05 Air Pollution – Local Air Quality* (Ontario 2005) and the *Sewer Use By-Law* (Durham Region 2004));
- Schedule 1 (List of Toxic Substances) under the *Canadian Environmental Protection Act, 1999* (lead and hexavalent chromium compounds are listed under this schedule);
- the *Consumer Chemicals and Containers Regulations, 2001* established under the *Hazardous Products Act*, which require a consumer chemical product to be classified against criteria based

on short-term exposure situations, with the results determining the appropriate product labelling and packaging requirements (Canada 2001); and

- the *Controlled Products Regulations* established under the *Hazardous Products Act*, which requires any chemical ingredient on the Ingredient Disclosure List to be disclosed on the Material Safety Data Sheet that must accompany workplace chemicals if present above a certain prescribed concentration (Canada 1988).

6.2 Existing International Risk Management

- C.I. Pigment Red 104 is listed in the United States *Toxic Substances Control Act* (TSCA) Chemical Substances Inventory;
- The United States Consumer Product Safety Commission (CPSC) banned the sale of residential paint containing greater than 600 ppm lead;
- New United States consumer safety legislation signed on August 14, 2008, bans all lead to specified limits in toys intended for children 12 years and under and further reduces the total lead limit in surface coatings (paints).

7. CONSIDERATIONS

7.1 Alternative Chemicals or Substitutes

Research by Health Canada showed that the use of lead-free pavement markings is already becoming the norm in some Canadian provinces, and several parts of the United States and Europe have already converted to a lead-free pavement marking system. The current legislative exemption for pavement markings is no longer valid, since suppliers can already meet standards for lead-free pavement markings. It was also determined that the burden on industry and other affected parties that are not already meeting the requirements would be substantially reduced, given a sufficient lead time. Subsequent consultation showed little objection to restricting the maximum lead content requirement for pavement markings after December 31, 2010 (Canada 2005b).

It is important to note that these substitutes may not have undergone an assessment to determine whether they meet the section 64 criteria under CEPA 1999.

For specialized industrial and military applications, there do not appear as yet to be suitable replacements for C.I. Pigment Red 104 with regard to colour-fastness and corrosion resistance.

7.2 Alternative Technologies and/or Techniques

There are various grades of C.I. Pigment Red 104, including those in which the pigment is encapsulated in a dense amorphous silica coating, which significantly reduces its solubility and bioavailability.

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*.

C.I. Pigment Red 104 was manufactured in and imported into Canada. After exports, the remaining quantity for use in Canada ranged between 100 000 and 1 000 000 kg in 2006. C.I. Pigment Red 104 is primarily used for plastic formulation, for commercial applications and export; commercial, non-consumer paints and coatings; and commercial printing inks or coatings used for plastics and certain outdoor applications such as commercial identification decals. Exposure to the general population in Canada is expected to be low, due to the primarily industrial use of the substance, very limited industrial releases, and the encapsulation and incorporation of the substance into a solid matrix.

The socio-economic impacts of an instrument/tool that focuses on potential changes in the use-pattern for C.I. Pigment Red 104 are limited, and depend on future uses. Potential chemical and product alternatives that are identified for C.I. Pigment Red 104 will be examined as part of the socio-economic analysis of the proposed instrument(s)/tool(s).

An analysis of benefits and costs will be conducted as part of instrument development for C.I. Pigment Red 104. This analysis will identify economic factors as they relate to the use and production of C.I. Pigment Red 104 in Canada where data are available, and may include employment and regional dispersion of industries that use C.I. Pigment Red 104. The benefits of pursuing instruments and/or tools will be identified, with a valuation of benefits conducted where possible.

7.4 Children's Exposure

The Government of Canada considered, where available, risk assessment information relevant to children's exposure to this substance. As part of the Challenge, 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 through a questionnaire if any of the products containing the substance were intended for use by children.

Given the information received, and other data considered, it is proposed that no additional risk management actions to specifically protect children are required for this substance at this time.

8. PROPOSED OBJECTIVES

8.1 Human Health Objective

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

The proposed human health objective for C.I. Pigment Red 104 is to minimize exposure to, and hence risk to human health associated with, exposure to C.I. Pigment Red 104 to the extent practicable.

8.2 Risk Management Objective

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 C.I. Pigment Red 104 is to prevent increases in exposure to this substance.

9. PROPOSED RISK MANAGEMENT

9.1 Proposed Risk Management Instrument

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

In order to achieve the risk management objective and to work towards achieving the human health objective, the risk management being considered for C.I. Pigment Red 104 will be a requirement for notification of the federal government under CEPA 1999 regarding any proposed future uses.

9.1.1 Future Uses

It is proposed to create a provision whereby any proposed future uses of C.I. Pigment Red 104 would be subject to notification of the federal government under CEPA 1999.

9.1.2 Pigment and Plastics Sectors

C.I. Pigment Red 104 is used in Canada for plastic formulation for commercial applications and export; commercial, non-consumer paints and coatings; and a very limited number of

³ 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."

commercial printing inks or coatings used for plastics and certain outdoor applications such as commercial identification decals. These uses lock the pigment into the paint or plastic matrix and minimize its availability to the general public.

In accordance with the *Surface Coatings Materials Regulations* of the *Hazardous Products Act*, pavement marking paints containing C.I. Pigment Red 104 are being phased out in Canada. After December 31, 2010, the concentration of total lead present in this class of paints must not be more than 600 mg/kg when a dried sample is tested as stipulated in subsection 4(1) of the *Surface Coating Materials Regulations* under the *Hazardous Products Act*. The 600 mg/kg total lead limit represents the acceptable background level or unintentional level of lead that cannot be completely eliminated from the paint. As residential paint must already meet this requirement, as specified in subsection 4(1) of the *Surface Coating Materials Regulations* under the *Hazardous Products Act*, this sector will not be a candidate for risk management of C.I. Pigment Red 104 under CEPA 1999.

9.1.3 Industrial Use Sector

All industrial chemical uses are governed under federal, provincial or territorial health and safety regulations and all workplace chemicals must comply with the *Controlled Products Regulations*, which includes Workplace Hazardous Materials Information System (WHMIS) labelling, supply of Material Safety Data Sheets (MSDS) and worker training. This regulation also extends to workplace facilities that are under federal jurisdiction.

9.1.4 Cosmetics Sector

Issues pertaining to lead in cosmetics fall under the regulatory area of the *Food and Drugs Act*. Section 16 of the Act states that no person shall sell a cosmetic product that has in it any substance that may injure the health of the user when the cosmetic is used according to its customary method. To help cosmetic manufacturers satisfy this requirement, Health Canada has developed the Cosmetic Ingredient Hotlist—the government places on this administrative list substances in cosmetics that may injure users (Health Canada 2007). Since lead and its compounds are on the Hotlist as prohibited ingredients, C.I. Pigment Red 104 is not to be used in cosmetics sold in Canada. As Health Canada already prohibits the use of lead in cosmetics, this sector will not be a candidate for risk management of C.I. Pigment Red 104 under CEPA 1999.

9.1.5 Foods and Beverages

C.I. Pigment Red 104 is not listed in the Food Additive Tables of Division 16 of the Food and Drug Regulations, and is therefore not permitted as a food colour in Canada. It is not currently used in food packaging material. Therefore, this sector will not be a candidate for risk management of C.I. Pigment Red 104 under CEPA 1999.

9.2 Implementation Plan

The proposed regulation or instrument respecting preventative or control actions in relation to C.I. Pigment Red 104 will be published in the *Canada Gazette*, Part I, no later than January 2011, as per the timelines legislated in CEPA 1999.

10. CONSULTATION APPROACH

The risk management scope for C.I. Pigment Red 104, which summarized the proposed risk management under consideration at that time, was published on May 17, 2008, and is available at www.ec.gc.ca/TOXICS/EN/detail.cfm?par_substanceID=236&par_actn=s1. 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.

Consultation for the risk management approach will involve publication on January 31, 2009, and a 60-day public comment period.

The primary stakeholders include

- pigment manufacturers; and
- the paint and plastics manufacturing industry.

11. NEXT STEPS / PROPOSED TIMELINE

Actions	Date
Electronic consultation on proposed risk management approach	January 31, 2009 to April 1, 2009
Response to comments on the Risk Management Approach	At time of publication of proposed instrument
Consultation on the draft instrument	Spring-Summer 2009
Publication of the proposed instrument	No later than January 2011
Formal public comment period on the proposed instrument	No later than Spring 2011
Publication of the final instrument	No later than July 2012.

Industry and other interested stakeholders are invited to submit comments on the content of this proposed risk management approach or to provide other information that would help to inform decision making. Please submit comments prior to April 1, 2009, since the Government of Canada will be moving forward with the risk management of C.I. Pigment Red 104 after this date. Pursuant to section 313 of CEPA 1999, any person who provides information to the Minister of the Environment under CEPA 1999 may submit with the information a request that it be treated as confidential. During the development of the risk management regulations, instrument(s) and/or tool(s), there will be opportunity for consultation on the proposed risk management. Comments and information submissions on the proposed risk management approach should be submitted to the address provided below:

Existing Substances Division
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313
Fax: 1-800-410-4314 / 819-953-4936
Email: Existing.Substances.Existantes@ec.gc.ca

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