Substance Profile for The Challenge
C.I. Pigment Red 104
CAS No. 12656-85-8

Introduction

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) required the Minister of Health and Minister of the Environment to categorize the approximately 23 000 substances on the Domestic Substances List (DSL). Categorization involved identifying those substances on the DSL that are a) considered to be persistent (P) and/or bioaccumulative (B), based on criteria set out in the *Persistence and Bioaccumulation Regulations* (Government of Canada, 2000), and "inherently toxic" (iT) to humans or other organisms, or b) that present, to individuals in Canada, the greatest potential for exposure (GPE).

Further to this activity, the Act requires the Minister of the Environment and the Minister of Health to conduct screening assessments of substances that meet the categorization criteria. A screening assessment involves a scientific evaluation of available information for a substance to determine whether the substance meets the criteria set out in section 64 of CEPA 1999. Based on the results of a screening assessment, the Ministers can propose taking no further action with respect to the substance, adding the substance to the Priority Substances List (PSL) for further assessment or recommending the addition of the substance to the List of Toxic Substances in Schedule 1 of CEPA 1999 and, where applicable, the implementation of virtual elimination of releases to the environment.

A number of substances have been identified by the Ministers as high priorities for action based on the information obtained through the categorization process. This includes substances:

- that were found to meet all of the ecological categorization criteria, including persistence, bioaccumulation potential and inherent toxicity to aquatic organisms (PBiT), and that are known to be in commerce, or of commercial interest, in Canada, and/or
- that were found either to meet the categorization criteria for GPE or to present an intermediate potential for exposure (IPE), and were identified as posing a high hazard to human health based on available evidence on carcinogenicity, mutagenicity, developmental toxicity or reproductive toxicity.

Based on a consideration of the ecological and/or human health concerns associated with these substances, and the requirement under section 76.1 of CEPA 1999 for the Ministers to apply a weight of evidence approach and the precautionary principle when conducting and interpreting the results of an assessment, sufficient data are currently available to conclude whether these substances meet the criteria under section 64 of CEPA 1999.

As such, the Ministers have issued a Challenge to industry and other interested stakeholders through publication in Canada Gazette Part I December 9, 2006 to submit, within the timelines stated in the Challenge section of this document, specific information that may be used to inform risk assessment and to develop and benchmark best practices for risk management and product stewardship.

The substance C.I. Pigment Red 104 was identified as a high priority for action it was determined to have a high potential for exposure to individuals in Canada (GPE), and is considered to present a high hazard to human health. The technical human health and ecological information, that formed the basis for concern associated with this substance, is contained in Appendices I and II, respectively.

Substance Identity

CAS Registry Number	12656-85-8
Inventory names	C.I. Pigment Red 104; Rouge de chromate, de molybdate et de sulphate de plomb; Lead chromate molybdate sulfate red; Pigment Red 104; chromomolydate de plomb; Silica Encapsulated Pigment Red 204; Molybdate Orange; Lead Chromate Molybdate
Other names	C.I. 77605; Chrome Vermilion; Horna 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
Chemical group	UVCBs (Unknown or Variable Composition, Complex Reaction Products, or Biological Materials) - Inorganics
Chemical sub-group	Group IVA and group VIB element compounds; chromium containing; lead containing; molybdenum containing; oxides; sulfates
Representative Chemical formula (CII, 2007)	$PbCrO_4$, $PbMoO_4$
Chemical structure	N/A
SMILES	N/A
Molecular mass	N/A (variable)

Based on information submitted by the 21 companies that notified this substance to the Domestic Substances List, approximately 12,400,000 kg of C.I. Pigment Red 104 were in commerce in 1986 for a variety of uses, including (but not limited to) the categories of colorant- pigment/stain/dye/ink/printing ink and paint/coating. Other potential uses of the substance in Canada include two areas: formulation component; plastics and textile.

THE CHALLENGE

Respecting direction under section 76.1 of CEPA 1999, and in the absence of additional relevant information as a result of this Challenge, the Ministers are predisposed to conclude, based on a screening assessment, that this substance satisfies the definition of toxic under section 64 of CEPA 1999. As such, the Ministers are prepared to then recommend to the Governor in Council that this substance be added to the List of Toxic Substances in Schedule 1 of CEPA 1999, with the intent of initiating the development of risk management measures taking into account socio-economic considerations.

If it is determined that the substance meets the virtual elimination criteria in subsection 77(4) of CEPA 1999, then subsequent risk management activities will be based on the objective of eliminating the release of any measurable quantity of the substance to the environment. In the absence of further information on existing management practices for a substance, actions would be proposed based on the assumption of worst-case practices. The management actions being considered for such substances at this time include prohibition through regulations, of the manufacture, use, sale, offer for sale and import of this substance, except for those activities controlled under the *Pest Control Products Act* and/or the *Food and Drugs Act.*

Exceptionally, should no information be identified to indicate that this substance is in commerce in Canada, the Ministers will conclude, based on a screening assessment, that this substance does not satisfy the definition of toxic under section 64 of CEPA 1999. However, given the properties of this substance, there is concern that new activities for the substance that have not been identified or assessed under CEPA 1999 could lead to the substance meeting the criteria set out in section 64 of the Act. Therefore it would be recommended that this substance be subject to the Significant New Activity provisions specified under subsection 81(3) of the Act, to ensure that any new manufacture, import or use of this substance in quantities greater than 100 kg/year is notified, and that ecological and human health risk assessments are conducted as specified in section 83 of the Act prior to the substance being introduced into Canada.

Section 71 Notice

Under the Challenge, information deemed necessary for improved decision making may be gathered by the Minister of Environment using section 71 of CEPA 1999. This information may be used for the purpose of assessing whether a substance is toxic or is capable of becoming toxic as defined under section 64 of CEPA 1999, or for the purpose of assessing whether to control, or the manner in which to control a substance.

The information mandated through the notices may relate to, among other things; quantity of the substance imported, manufactured, used, or released, concentrations, suppliers, customers, as well as types of uses of the substance.

Copies of the section 71 notice and guidance on how to comply with it are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca), or from the contact provided below.

Opportunity to Submit Additional Information to Inform Screening Assessment

The Ministers of Health and Environment are inviting the submission of additional information for consideration during screening assessment of this substance. Data of the types described in the following paragraphs are considered most relevant, although other submitted information will be considered.

Data on the persistence, bioaccumulation, and potential for toxicity of the substance to organisms in different environmental media – Through the categorization exercise, available experimental data were collected up to December 2005. Where acceptable experimental data were not available, Quantitative Structure Activity Relationships (QSARs) or read across data were used to fill the data gaps. Since experimental data are preferred, interested parties have an opportunity to provide new or additional relevant experimental study information on the persistence, bioaccumulation, and potential for toxicity of this substance to organisms in different environmental media (air, water, sediment, soil). Efforts should focus on providing data for the endpoints for which quality experimental data does not already exist, as demonstrated by the information summarized in Appendix II of this document. As submitted data will be evaluated for completeness and robustness, it is recommended that stakeholders follow the guidance for test protocols and alternative approaches for test data, as described in Section 8 of the "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers".[1]

Data on the toxicity of the substance to human health - Through the categorization exercise, the high health priorities for action were those substances identified by various agencies as representing a high health hazard on the basis of potential to induce cancer, and/or adversely affect reproduction and development, two critical determinants of the health of Canadians of all ages. The hazard classifications used were those developed by national or international agencies in which large numbers of substances have been classified for endpoint-specific hazard based on original review and critical evaluation of data, assessments of weight of evidence and extensive peer review. Interested parties have an opportunity to provide new or additional relevant experimental study information on the toxicity of the substance to human health which could inform the screening assessment.

Responses to this part of the challenge for this substance should be received at the address provided below by November 13, 2007.

---

[1] "Guidelines for the Notification and Testing of New Substances: Chemicals & Polymers (version 2005)", Government of Canada, Available from http://www.ec.gc.ca/substances/nsb/eng/cp_guidance_e.shtml

Opportunity to Submit Additional Information on Current Uses and Existing Control Measures to Inform the Risk Management Approach for this Substance

The Ministers of Health and Environment are inviting the submission of additional information that is deemed beneficial by interested stakeholders, relating to the extent and nature of the management/stewardship of substances listed under the Challenge.

Organizations that may be interested in submitting additional information in response to this invitation include those that manufacture, import, export or use this substance whether alone, in a mixture, in a product or in a manufactured item.

Submission of additional information is being invited in the following areas:

- Import, manufacture and use quantities
- Substance and product use details
- Releases to the environment and spill management
- Current and potential risk management and product stewardship actions
- Existing legislative or regulatory programs controlling/managing the substance
- Information to support the development of a regulatory impact assessment.

A questionnaire is available which provides a detailed template as an example for the submission of this information. Guidance on how to respond to the challenge questionnaire is also available. Interested stakeholders are invited to provide available additional information, recognizing that not all questions in the questionnaire may be relevant to a particular substance, use, or industrial sector.

Copies of the questionnaire and associated guidance are available from the Government of Canada Chemicals Portal (www.chemicalsubstanceschimiques.gc.ca)**,** or from the contact provided below.

Responses to the questionnaire should be received at the address provided below by November 13, 2007.

Request for Documents and Submission of Information

Documents and instructions may be requested from the following contact. Information in response to the above Challenge must be submitted to this address.

DSL Surveys Coordinator
Place Vincent Massey, 20th Floor
351 Saint Joseph Boulevard
Gatineau QC K1A 0H3
Tel: 1-888-228-0530 / 819-956-9313

Fax: 1-800-410-4314 / 819-953-4936
Email: DSL.surveyco@ec.gc.ca

Appendix I
Human Health Information
to Support the Challenge for
C.I. Pigment Red 104
CAS No. 12656-85-8

Introduction

Under the *Canadian Environmental Protection Act, 1999* (CEPA, 1999), Health Canada undertook to categorize all substances on the Domestic Substances List (DSL) to identify those representing the greatest potential for human exposure (GPE) and those among a subset of substances considered persistent (P) and/or bioaccumulative (B) that are also considered to be "inherently toxic" to humans.

In order to efficiently identify substances that represent the highest priorities for screening assessment from a human health perspective, Health Canada developed and applied a Simple Exposure Tool (SimET) to the DSL to identify those substances that meet the criteria for GPE, Intermediate Potential for Exposure (IPE) or Low Potential for Exposure (LPE), and a Simple Hazard Tool (SimHaz) to identify those substances that pose a high or low hazard.

C.I. Pigment Red 104 is considered to meet the criteria for GPE under SimET and for high hazard under SimHaz. This document summarizes the currently available information used to support the inclusion of this substance in the Challenge.

Exposure Information from Health Related Components of DSL Categorization

SimET was developed and used to identify substances on the DSL considered to represent GPE. This approach was based on three lines of evidence: 1) the quantity in commerce in Canada, 2) the number of companies involved in commercial activities in Canada (i.e., number of notifiers), and 3) the consideration by experts of the potential for human exposure based on various use codes. The proposed approach was released for public comment in November 2003 and also enabled designation of substances as presenting an Intermediate (IPE) or Lowest Potential for Exposure (LPE), based on criteria for quantity and nature of use (Health Canada, 2003)

Results of the Application of SimET

C.I. Pigment Red 104 has been determined to be GPE based on a consideration of the DSL nomination information listed below.

Nomination Information for DSL

Quantity in Commerce

The quantity reported to be manufactured, imported or in commerce in Canada during the calendar year 1986 was 12,400,000 kg.

Number of Notifiers

The number of notifiers for the calendar years 1984-1986 was 21.

Use Codes and Description

The following DSL use codes have been identified for the substance:

Use codes

13 Colorant- pigment /stain/ dye/ ink (Functional use)
21 Formulation component (Functional use)
30 Paint / coating additives (Functional use)
80 Paint and coating (Industry sector)
85 Pigment, dye and printing ink (Industry sector)
86 Plastics (Industry sector)

Potential Uses in Canada

In an overview of major chromate pigments, Buxbaum and Pfaff (2005) state that C.I. Pigment Yellow 34, also known as lead chromate (chrome yellow), CAS No. 1344-37-2 and C.I. Pigment Red 104, also known as lead molybdate pigments (molybdate orange and molybdate red), CAS No. 12656-85-8, are the most important chromate pigments. The spectrum of colors for these pigments spans from light yellow to reds with a blue hue. Chrome yellow, molybdate orange and molybdate red are used in the production of paints, coatings, and plastics. They are characterized by brilliant hues, good tinting strength and good hiding power. Special treatment of the pigments improves their resistance to light, weathering, chemicals and temperature. Chromate pigments may be combined with blue pigments (e.g. iron blue or phthalocyanine blue) to make high-quality chrome green and fast chrome green pigments. Molybdate orange and molybdate red pigments are often combined with red organic pigments to increase and fine tune possible color range.

C.I. Pigment Red 104 (molybdate red and molybdate orange) are mixed-phase pigments. Applications in Canada may include; pigments in paints, alkyd resin enamels, lacquers, varnishes, anticorrosion coatings, motor vehicle paint mastics, rubber, plastics, artist's colors, cellulose acetate plastics, traffic paints, screen printing varnishes coating organic solvents, printing inks, leather cloth, linoleum, paper surfacing, textile printing, pigment in thermoplastics (general purpose polystyrene(GPPS), low density polyethylene (LDPE), high density polyethylene (HDPE), polypropylene(PP) flexible polyvinyl chloride(PVC), rigid polyvinyl chloride(PVC), cellulose, polyester), pigment in thermosetting plastics (epoxy's, polyesters, phenolics and polyurethanes) (NLM 2006, US EPA 2006, Kirk-Othmer 2001, SPIN database, BASF 1993, NTP 2004).

Hazard Information from Health Related Components of DSL Categorization

Simple Hazard Tool (SimHaz)

SimHaz is a tool that has been used to identify, among all of the approximately 23 000 substances on the DSL, those considered to present either high or low hazard to human health based on formalized weight of evidence criteria and/or peer review/consensus of experts. This tool has been developed through extensive compilation of hazard classifications of Health Canada and other agencies and consideration of their robustness based on availability of transparent documentation of both process and criteria (Health Canada, 2005).

Results of the Application of SimHaz

C.I. Pigment Red 104 is considered to be a potentially high hazard substance based on its classification for carcinogenicity, developmental toxicity, and reproductive toxicity by the European Commission.

The following classification for carcinogenicity of C.I. Pigment Red 104 is available:

The European Commission has classified C.I. Pigment Red 104 as Category 3 for carcinogenicity (Substance which causes concern for humans owing to possible carcinogenic effects) (European Commission, 2000, ESIS, 2006).

The following classification for developmental toxicity of C.I. Pigment Red 104 is available:

The European Commission has classified C.I. Pigment Red 104 as Category 1 for developmental toxicity (Substance known to cause developmental toxicity in humans) (European Commission, 2000, ESIS, 2006).

The following classification for reproductive toxicity of C.I. Pigment Red 104 is available:

The European Commission has classified C.I. Pigment Red 104 as Category 3 for reproductive toxicity (Substance which causes concern for human fertility) (European Commission, 2000, ESIS, 2006).

Uncertainties

SimET and SimHaz have been developed as robust tools for effectively identifying substances from the DSL that are considered to be human health priorities for further consideration. It is recognized that they do not include a number of elements normally considered in a human health risk assessment such as a comprehensive characterization of exposure and hazard, a comparison of exposure metrics to hazard metrics and a detailed analysis of uncertainties: however, as a result of the combination of the severe hazard properties of these substances and their high potential for exposure to humans, evaluation of the need for preventative and protective actions is required.

References

BASF. 1993. Pigments for screen printing inks. Technical Information TI/P 3132e. [technical monograph on the internet]. BASF December 1993 [cited December 08, 2006]. Available from: http://www.basf.com/specialty_colorants/pdfs/pigments_for_screen_3132e.pdf

Buxbaum, G. and Pfaff, G. 2005. Industrial Inorganic Pigments, 3rd, Completely Revised and Extended Edition. WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim [book on the Internet]. ISBN. 3-527-30363-4

ESIS. 2006. CAS No. 12656-85-8. Lead chromate molybdate sulfate red. ESIS Version 4.50. European Chemical Substances Information System. http://ecb.jrc.it/esis/

European Commission. 2000. Lead chromate molybdate sulfate red C.I. Pigment red 104. Commission Directive 2000/32/EC of 19 May 2000. Annex 1C. Official Journal of the European Communities 8.6.2000. http://ecb.jrc.it/DOCUMENTS/Classification-Labelling/ATPS_OF_DIRECTIVE_67-548-EEC/26th_ATP.pdf

Health Canada. 2003. Proposal for Priority Setting for Existing Substances on the Domestic Substances List under the Canadian Environmental Protection Act, 1999: Greatest Potential for HumanExposure. http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/pubs/contaminants/existsub/exposure/greatest_potential_human_exposure-risque_exposition_humaine_e.pdf

Health Canada. 2005. Proposed Integrated Framework for the Health-Related Components of Categorization of the Domestic Substances List under CEPA 1999 http://www.hc-sc.gc.ca/ewh-semt/alt_formats/hecs-sesc/pdf/contaminants/existsub/framework-int-cadre_e.pdf

Kirk-Othmer Encyclopedia of Chemical Technology. 2001. John Wiley and Sons, Inc. [book on Internet, last updated November 17, 2006] [cited December 8, 2006] Available from: http://www.mrw.interscience.wiley.com/emrw/0471238961/home

NLM. NIH Hazardous Substances Data Bank. 2006. C.I. Pigment Red 104. National Library of Medicine, National Institutes of Health. http://toxnet.nlm.nih.gov/

NTP. 2004. 11th Report on Carcinogens. Substance Profile: Lead and Lead compounds. National Toxicology Program. http://ntp-server.niehs.nih.gov/ntp/roc/eleventh/profiles/s101lead.pdf

SPIN Database [homepage on the Internet]. [cited December 8, 2006] Available from: http://www.spin2000.net/FMPro?-db=spinstof.fp5&-format=spin%2fmaininfo.html&-lay=spinnavn&-findall=&-view

U.S. EPA (United States Environmental Protection Agency), 2006. SRD: Source Ranking Database. Last update: 03/10/2006. http://www.epa.gov/opptintr/exposure/pubs/srd.htm.

Appendix II
Ecological Information
to Support The Challenge for
C.I. Pigment Red 104
CAS No. 12656-85-8

Introduction

The information in this document will form the basis of a screening assessment under section 74 of CEPA, 1999. Data relevant to an ecological screening assessment were identified in original literature, review documents, commercial and government databases prior to December 2005.

Physical and Chemical Properties

Table 1 contains experimental physical-chemical properties of C.I. Pigment Red 104 which are relevant to its environmental fate.

Table 1. Physical and chemical properties for Pigment Red 104

Property	Type	Value	Temperature (C°)	Reference
Physical state	Experimental	Solid	~20	Expert judgment (chemist)[1]
Melting point (ºC)	Experimental	> 800	-	IUCLID, 2000
Boiling point (ºC)	-	Not available	-	-
Density (kg/m^3)	Experimental	3800-6000 (3.8-6 g/cm^3)	20	IUCLID, 2000
Vapour pressure (Pa)	Experimental	Negligible	Not indicated	IUCLID, 2000
Henry's Law constant ($Pa·m^3/mol$)	Calculated	Negligible	-	-
Log K_{ow} (Octanol-water partition coefficient, dimensionless)	-	Not applicable	-	-
Water solubility (mg/L)	Experimental	Insoluble	20	IUCLID, 2000
	Based on analogue[2]	8.60	~20	Expert judgment (chemist)[1]

Log K_{oc} (Organic carbon partition coefficient, dimensionless)	-	Not applicable	-	-
Log K_{sw} (Partition coeficient soil-water, dimensionless)	Experimental	Pb(3.444-5.212) Cr(2.812-4.764)	-	Thibault et al., 1990; Janssen et al., 1997; Sauve et al., 2000
Log K_{sdw} (Partition coefficient sediment-water, dimensionless)	Experimental	Pb(4.553-6.075) Cr(4.928-5.627)	-	Smock et al., 1983; Timmermans et al.,1989; Keenan and Alikhan, 1991; Van Hattum et al., 1991; Davis et al., 1996; Besser et al.,2001; Allison and Allison, 2005
Log K_{ssw} (Partition coefficient suspended sediment-water, dimensionless)	Experimental	Pb(5.391-6.879) Cr(4.376-5.759)	-	Chiffoleau et al., 1994; Lofts and Tipping, 2000; Roditi et al., 2000; Allison and Allison, 2005; Gobeil et al., 2005

[1] see Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List (Environment Canada, 2003)
[2] based on discrete inorganic substance, Lead chromate oxide ($Pb(H_2CrO4)$), CAS 7758-97-6

Manufacture, Importation, and Uses

Available information is presented in Appendix I.

Releases, Fate and Presence in the Environment

Additional information is also presented in Appendix 1.

Releases

As for all the elements of the Periodic Table, lead and chromium can be found under various forms in ambient air, groundwater, surface water, sediments and soils. Lead concentration in the upper continental crust has been determined to range between 17 and 20 ppm; chromium concentration has been determined to be 35 ppm (Reimann and de Caritat, 1998). The substance C.I. Pigment Red 104 is not naturally produced in the environment.

Fate

Solubility and dissociation

Inorganic metal containing compounds often dissolve, dissociate and release ions in the solution (Environment Canada, 2003). C.I. Pigment Red 104 is expected to dissolve, dissociate and release the lead (Pb^{2+}) and chromate (CrO_4^{2-}) ions in the aquatic media for which the pH is between 6 and 8 and conditions moderately oxic (~0.4–0.7 V, or dissolved oxygen > 4 mg/L). These moieties, released from the parent substance, are of greatest toxicological significance and are thus defined as moieties of concern (Environment Canada, 2003). The measured solubility in water is uncertain (Insoluble; IUCLID, 2000) and could not be validated because of the lack of experimental details. To further evaluate the solubility of Pigment Red 104, a substance (chemical analogue) with a similar structure was found on the discrete inorganics DSL list: lead chromate, $Pb(H_2CrO_4)$, CAS 7758-97-6. This substance has been estimated to have a solubility in water of 8.6 mg/L based on a chemist expert judgment. This estimate has a medium confidence.

Partitioning

As a metal containing inorganic substance, the fate analysis based on log K_{ow} and K_{oc} is not applicable to Pigment Red 104. Typical fugacity modelling is also not applicable to C.I. Pigment Red 104 because as for non-volatile chemicals this compound exerts zero partial pressure and fugacity in air (Diamond et al., 1992). As a result, the fate of metals is often best characterized by partition coefficients, namely soil, suspended particles and sediments to water partition coefficients (K_{sw}, K_{ssw} and K_{sdw}), which are presented in Table 1.

C.I. Pigment Red 104 likely has a negligible vapour pressure and is, therefore, not expected to partition to air. The partitioning of C.I. Pigment Red 104 may also depend on the compartment to which it is released. Once released to surface water and moist soils, the fate of C.I. Pigment Red 104 depends upon its solubility and dissociation in water (OECD, 2001) as mentioned above. The fate analysis of the dissociated Pb^{2+} and CrO_4^{2-} ions indicates that they can transform and form dissolved complexes with dissolved ligands present in the aquatic environment (Tipping, 2002; Schecher and MacAvoy, 1992). Information on metal binding to dissolved ligands is obtained from thermodynamic constant databases (Smith and Martell, 2004; IUPAC, 2001), assuming that the metal ion and ligand in the environment are at equilibrium (Stumm and Morgan, 1996). Because of the strong tendency of these metals to sorb to aquatic particles (Table 1; K_{ssw}), a significant proportion of dissolved forms of these metals will end up in sediments (Table 1; K_{sdw}), through the settling of suspended particles (Hamilton-Taylor et al., 1984). The remaining metal ions can then be taken up by aquatic organisms as assumed by models relating metal concentrations in aquatic organisms to those of their surroundings (e.g., the free ion activity model, Campbell, 1995; the biotic ligand model, DiToro et al., 2001; DiToro et al., 2005). Therefore, the moieties of concern issued from the dissolution and dissociation of C.I. Pigment Red 104, Pb^{2+} and CrO_4^{2-}, are expected to be found in water, sediments and soils but not in air (Table 1). Note that some non-dissolved C.I. Pigment Red 104 (as parent compound) is also expected to be found in sediments and moist soils. When released to dry soils, C.I. Pigment Red 104 will mainly remain there with some of the substance leaching local ground and/or surface water ecosystems when the soil gets soaked by rain or melting snow/ice. The parent substance is not expected to be found in water considering that its density is a few times greater than that of water.

Presence in the Environment

Data on environmental concentrations of C.I. Pigment Red 104 have not been gathered for this profile. However, lead and chromium has been measured in the Canadian environment (e.g., in surface waters: Borgmann et al., 2007).

Evaluation of P, B and iT Properties

Environmental Persistence

When a metal ion is the moiety of concern, it is considered infinitely persistent because it cannot degrade any further (Environment Canada, 2003). In turn, the persistence of the metal ion is attributed to the parent compound. This method is justified because even sparingly soluble compounds release a small quantity of metal ion into solution.

The moieties of concern for Pigment Red 104, the lead (Pb^{2+}) and chromate (CrO_4^{2-}) ions are both considered infinitely persistent. Therefore, C.I. Pigment Red 104 *meets the persistence criteria* as set out in the Persistence and Bioaccumulation Regulations (Government of Canada, 2000).

Long range atmospheric transport

In the context of The Challenge, further indication of long-range atmospheric transport is not deemed necessary to conclude on the persistence of C.I. Pigment Red 104.

Potential for Bioaccumulation

The current state of the science does not allow for the unambiguous interpretation of the bioaccumulation criterion for metal-containing inorganic substances. Therefore, such substances are evaluated only on the basis of their properties relating to toxicity and persistence (Environment Canada, 2003). It is anticipated that evolution of scientific understanding will eventually allow broader interpretation of the potential for bioaccumulation for such substances.

Ecological Effects

A - In the Aquatic Compartment

During DSL categorization of inorganic substances, the determination of inherent toxicity was based on the solubility of the parent compound in water, the stability of the dissolved ionic forms, and the toxicity of the parent compound and/or its constituent parts as interpreted from bioassay data (Environment Canada, 2003). Therefore, the inorganic substances that were identified as being of concern were: (i) those with a water solubility greater or equal to 1 mg/L and that released a metal moiety with an acute toxicity (e.g. LC50 or EC50) estimated to be lower or equal to 1 mg/L and, (ii) those with a water solubility lower than 1 mg/L and that released a metal moiety with an acute toxicity (e.g. LC50 or EC50) estimated to be equal or lower than the solubility value.

In the context of categorization and for all metal moieties, Environment Canada collected experimental acute toxicity data for pelagic organisms from reliable sources. The dataset included studies with the following endpoints and exposure duration:
· for algae and aquatic plants: 72-hour or 96-hour EC/LC_{50}
· for invertebrates: 48-hour EC/LC_{50}
· for vertebrates, including fish and amphibians: 96-hour LC_{50}

Other exposure durations for invertebrates and vertebrates included a duration of less than 10% of the life span of the organisms (Environment Canada, 2003). Species Sensitivity distributions (SSD) were then generated with the datasets. The initial intent was to use the 5^{th} percentile of the SSD as one estimate of the pivotal toxicity value for categorization. The 5^{th} percentile for lead and chromium were 131 and 35 µg/L respectively. However, it is well documented that the toxicity of metals depends on the pH and ionic strength of the external media (DiToro et al. 2001). As a result, toxicity data used as input in a SSD may be normalized for the effects of pH, ionic strength and dissolved organic carbon (EURAS, 2006) depending on assessment needs.

As a key line of evidence, Environment Canada, in partnership with the National Water Research Institute (NWRI) in Burlington, Ontario, performed a suite of toxicity tests on 63 metals using *Hyalella azteca* (Borgmann et al., 2005). The objective of this experiment was to compare the relative toxicity of the 63 metal ions in a worst-case water chemistry representative of the diluted waters of the Canadian Shield (10% Lake Ontario water with low ionic strength and low DOC). The tests were also conducted in undiluted Lake Ontario water. The chemistry of the undiluted water is as follows (69 samples): hardness 124 mg/L, carbonate alkalinity 84 mg/L, Ca 35 mg/L, Mg 8.7 mg/L, Na 13 mg/L, K 1.6 mg/L, SO_4 32 mg/L, Cl 25 mg/L and dissolved organic carbon (DOC) 1.1 mg/L. The pH range was 6.44-8.98. Culturing and toxicity tests were conducted in an incubator at 24 to 25ºC under a 16:8-h light:dark photoperiod (Borgmann et al., 2005). Table 2 shows the results of all of these tests with lead and chromium.

Table 2. Empirical aquatic toxicity data for lead and chromium

Test Organism	Type of Test	Type of water	Endpoint	Metal	Value* (µg/L)	Reference
Hyalella azteca (Invertebrate)	Acute	10% lake Ontario	7-day LC_{50}	Pb	1.01	Borgmann et al., 2005
		Lake Ontario			11	
		10% lake Ontario		Cr	3.1	
		Lake Ontario			137	

*Filtered (0.45 µm) total metal

Based on these results and associated weight of evidence, the moieties of concern, Pb^{2+} and CrO_4^{2-}, measured as total dissolved lead and chromium, are highly hazardous to aquatic organisms at very low concentrations (EC/LC_{50} << 1 mg/L) in conditions that are representative of Canadian surface waters. Since, the solubility of C.I. Pigment Red 104 in water may be higher than the acute aquatic toxicity values, it is concluded that the substance could cause harm to aquatic organisms (cf. Environment Canada, 2003).

B - In Other Media

Effects studies for non-aquatic non-human organisms were not considered at this time for these metal moieties (e.g. lead and chromium).

Potential to Cause Ecological Harm

Based on the available information relating to the metal moieties released on dissolution/dissociation, C.I. Pigment Red 104 does persist in the environment based on criteria defined in the Persistence and Bioaccumulation Regulations (Government of Canada, 2000). Information on concentrations of C.I. Pigment Red 104 in the environment (as parent substance form) has not been identified at this time. However, the experimental ecotoxicological aquatic data do indicate that C.I. Pigment Red 104 could cause harm to aquatic organisms at very low concentration in the water compartment. Information on potential impacts in other environmental compartments has not been included at this time.

References

Allison, J.D., Allison, T.L., 2005. Partition Coefficients for Metals in Surface Water, 564 Soil, and Waste. U.S. Environmental Protection Agency, Office of Research and 565 Development, Washington, DC.

Besser, J.M., Brumbaugh, W.G., May, T.W., Church, S.E., and Kimball, B.A. 2001. Bioavailability of metals in stream food webs and hazards to brook trout (*Salvelinus fontinalis*) in the upper Animas River Watershed, Colorado. Arch Environ Contam Toxicol 40:48-59.

Borgmann,U., Couillard, Y., Doyle, P., and Dixon, D.G. 2005. Toxicity of 63 metals and metalloids to Hyalella azteca at two water hardnesses. Environmental Toxicology and Chemistry 24 (3):641-652.

Borgmann, U., Couillard, Y., and Grapentine, L.C. 2007. Relative contribution of food and water to 27 metals and metalloids accumulated by caged *Hyalella azteca* in two rivers affected by metal mining. Environ. Pollut. 145: 753-765.

Campbell, P.G.C. 1995. Interactions between trace metals and aquatic organisms: A critique of the free-ion activity model. In: Metal speciation and bioavailability in aquatic systems, edited by Tessier A. and D.R.Turner, John Wiley and Sons Ltd., p. 45-102.

CEPA 1999. Canadian Environmental Protection Act, 1999. 1999, c. 33. C-15.31. [Assented to September 14th, 1999]. http://laws.justice.gc.ca/en/C-15.31/text.html

Chiffoleau, J.F., Cossa, D., Auger, D., and Truquet, I. 1994. Trace metal distribution in the Seine estuary (France) in low discharge regime. Marine Chemistry 47: 145-158.

CII (Colour Index International). 2007. http://www.colour-index.org/content/main.asp. Acessed May 8, 2007.

Davis, A., Sellstone, C., Clough, S., Barrick, R, Yare, B. 1996. Bioaccumulation of arsenic, chromium and lead by fish: constraints imposed by sediment geochemistry. Appl Geochem 11: 409-423.

Diamond, M.L., Mackay, D., and Welbourn, P.M. 1992. Models of multi-media partitioning of multi-species chemicals: the fugacity/aquivalence approach. Chemosphere 25 (12):1907-1921.

DiToro, D.M., Allen, H.E., Bergman, H. L., Meyer, J.S., Paquin, P. R., and Santore, R.C. 2001. Biotic ligand model of the acute toxicity of metals. 1.Technical basis. Environmental Toxicology and Chemistry 20 (10): 2383-2396.

DiToro, D.M., McGrath, J.A., Hansen, D.J., Berry, W.J., Paquin, P.R., Mathew, R., Wu, K.B., and Santore, R.C. 2005. Predicting Sediment Metal Toxicity Using a Sediment Biotic Ligand Model: Methodology and Initial Application. Env.Toxicol.Chem. 24(10): 2410-2427.

Dzombak, D.A., and Morel, F.M.M. 1990. Surface complexation modeling - Hydrous ferric oxide., NewYork:John Wiley, 393 p.

Environment Canada. 2003. Guidance Manual for the Categorization of Organic and Inorganic Substances on Canada's Domestic Substances List. Existing Substances Branch, Environment Canada, Gatineau, Canada, 124 p.

EURAS, 2006. Metal Risk Assessment Guidance Document http://www.euras.be/eng/project.asp?ProjectId=67

Gallon, C., Tessier, A., Gobeil, C., and Carignan, R. 2006. Historical Perspective of Industrial Lead Emissions to the Atmosphere from a Canadian Smelter. Environmental Science & Technology, 40(3):741-747.

Gobeil, C., Rondeau, B., and Beaudin, L. 2005. Contribution of Municipal Effluents to Metal Fluxes in the St. Lawrence River. Environ Sci Technol 39: 456-464.

Government of Canada. 2000. Persistence and Bioaccumulation Regulations (SOR/2000-107). Canada Gazette, v. 134. http://www.ec.gc.ca/CEPARegistry/regulations/detailReg.cfm?intReg=35.

Hamilton-Taylor, J. M., Willis, C. S. 1984. Reynolds Depositional fluxes of metals and phytoplankton in Windemere as measured by sediment traps. Limnology and Oceanography 29 (4):695-710.

IUCLID dataset. 2000 Existing chemical CAS 12656-85-8, C.I. Pigment Red 104. European Commission, European Chemicals Bureau, 46 p.

IUPAC. 2001. Stability constants database.

Janssen, R.P.T, Peijnenburg, W.J.G.M, Posthuma, L., and Van Den Hoop, M.A.G.T. 1997. Equilibrium Partitioning of Heavy Metals in Dutch Field Soils. I. Relationship Between Metal Partition Coefficients and Soil Characteristics. Environ Toxicol Chem 16: 2470-2478.

Keenan, S., Alikhan, M.A.. 1991. Comparative study of cadmium and lead accumulations in *Cambarus bartoni* (Fab.) (Decapoda, Crustacea) from an acidic and a neutral lake. Bull Environ Contam Toxicol 47:91-96.

Loft, S., and Tipping, E. 1998. An assemblage model for cation binding by particulate matter. Geochimica et cosmochimica acta 62 (15):2609-2625.

Lofts S, and Tipping, E. 2000. Solid-solution metal partitioning in the Humber Rivers: application of WHAM and SCAMP. Sci Total Environ 251/252: 381-399.

OECD, 2001. OECD Environment, Health and Safety Publications. Series on Testing and Assessment, No. 29. Guidance Document on Transformation/Dissolution of Metals and Metal Compounds in Aqueous Media.

Rai, D., Eary, L.E., and Zachara, J.M. 1989. Environmental Chemistry of Chromium. Sci Tot Environ 86: 15-23.

Reimann, C., and de Caritat, P. 1998. Chemical elements in the environment – factsheets for the geochemist and environmental scientist. Springer, Berlin, Heidelberg. 398 p.

Roditi, H.A., Fisher, N.S. and Sañudo-Wilhelmy, S.A. 2000. Field Testing a Metal Bioaccumulation Model for Zebra Mussels. Environ Sci Technol 34: 2817-2825.

Sauvé, S., Hendershot, W., and Allen, H.E. 2000. Solid-Solution Partitioning of Metals in Contaminated Soils: Dependence on pH, Total Metal Burden and Organic Matter. Environ Sci Technol 34: 1125-1131

Schecher, W.D., and McAvoy, D.C. 1992. MINEQL+: a software environment for chemical equilibrium modeling. Comput., Environ., and urban Systems 16:65-76.

Shotyk, W., Zheng, J., Krachler, M., Zdanowicz, C., Koerner, R. and Fisher, D. 2005. Predominance of industrial Pb in recent snow (1994-2004) and ice (1842-1996) from Devon Island, Arctic Canada. Geophys.Res.Lett. 32:L21814

Smith, R.M., and Martell, A.E. 2004. Critical constants for metal complexes. NIST Standard Reference database 46, U.S.Department of Commerce, National Institute of Standards and Technology, Gaithersburgh, MD.

Smock LA. 1983. The influence of feeding habits on whole-body metal concentrations in aquatic insects. Freshwater Biol. 13: 301-311.

Stumm, W., and Morgan, J.J. 1996. Aquatic Chemistry, Chemical Equilibria and Rates in Natural Waters, 3rd ed. John Wiley & Sons, Inc., New York, 1022p.

Thibault, D.H., Sheppard, M.I., Smith, P.A. 1990. A Critical Compilation and Review of Default Soil Solid/Liquid Partition Coefficients, Kd, for use in Environmental Assessments: Report Number 10125. Atomic Energy of Canada Limited, Pinawa, Manitoba, Canada.

Timmermans, K.R., van Hattum, B., Kraak, M.H.S., Davids C. 1989. Trace metals in a littoral foodweb: concentrations in organisms, sediment and water. Sci Total Environ 87/88: 477-494.

Tipping, E. 2002. Cation binding by humic substances, Cambridge UK:Cambridge University Press.

Van Hattum, B., Timmermans, K.R., and Govers, H.A. 1991. Abiotic and biotic factors influencing trace metal levels in macroinvertebrates in freshwater systems. Environ Toxicol Chem 10: 275-292.