Substance name: Lead chromate molybdate sulphate red (C.I. Pigment Red 104)
EC number: 235-759-9
CAS number: 12656-85-8

MEMBER STATE COMMITTEE SUPPORT DOCUMENT FOR IDENTIFICATION OF LEAD CHROMATE MOLYBDATE SULFATE RED (C.I. Pigment Red 104) AS A SUBSTANCE OF VERY HIGH CONCERN BECAUSE OF ITS CMR PROPERTIES

Adopted on 27 November 2009

CONTENTS

TABLES

Substance Name: Lead chromate molybdate sulphate red (C.I. Pigment Red 104)

EC Number: 235-759-9

CAS number: 12656-85-8

The substance is identified as a CMR according to Article 57 (a) and (c) of Regulation (EC) No 1907/2006 (REACH).

Summary of the evaluation:

Pursuant to the first ATP to Regulation (EC) No 1272/2008(Commission Regulation (EC) No 790/2009) as of 1 December 2010, Lead chromate molybdate sulfate red (C.I. pigment red 104) will be listed in Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Annex VI, part 3, of Regulation (EC) No 1272/2008[1] as carcinogen category 2[2], R 45 (May cause cancer).

Therefore, this classification of the substance in Commission Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as carcinogen in accordance with Article 57 (a) of REACH.

Lead chromate molybdate sulphate red (C.I. Pigment Red 104) is listed in Annex VI, part 3, Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Regulation (EC) No 1272/2008 as toxic to reproduction category 1, R61 (May cause harm to the unborn child)[3].

Therefore, this classification of the substance in Regulation (EC) No 1272/2008 shows that the substance meets the criteria for classification as toxic for reproduction in accordance with Article 57 (c) of REACH[4].

Registration number(s) of the substance or of substances containing the substance:

-

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

[2] This corresponds to a classification as carcinogen 1B, H350 in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) as amended by the 1st ATP to (EC) No 1272/2008.

[3] This corresponds to a classification Repr. 1A; H360Df (May damage the unborn child. Suspected of damaging fertility) in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances).

[4] This substance is also mentioned in the 1st ATP which does not change its classification for toxic for reproduction.

JUSTIFICATION

This report covers only the C.I. Pigment Red 104. However, results and information referring to "lead chromate pigments" are used in some sections. This is used for results and information covering both substances C.I. Pigment Yellow 34 and C.I. Pigment Red 104. Individual justification is used for the identification as SVHC, while grouping is proposed after their identifications as SVHC and their inclusion on the candidate list.

The yellow lead chromate pigments family is composed of the pure lead chromates, the mixed phase pigment of lead chromate and lead sulphate (lead sulfochromate pigment) and the mixed phase pigment of lead chromate, lead sulphate and lead molybdate (lead chromate molybdate sulphate pigment). The words "lead chromate" or "chrome yellow" are usually used in literature to describe this whole family and can thus mislead for the right substance identification according to their ESIS classification (three different substances).

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Names and other identifier of the substance

Chemical Name:	lead chromate molybdate sulfate red (C.I. pigment red 104)
EC Number:	235-759-9
CAS Number:	12656-85-8
Deleted CAS Numbers [5]:	12213-61-5, 8005-36-5, 64523-06-4
IUPAC Name:	lead chromate molybdate sulfate red

This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77605.

Inventory names[6]:

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[7]:

[5] These CAS numbers have been deleted from the CA index, but may still be in use by some companies.

[6] Sources (Environment Canada, 2008): National Chemical Inventories (NCI). 2007: AICS (Australian Inventory of Chemical Substances); ASIA-PAC (Combined Inventories from the Asia-Pacific Region); ECL (Korean Existing Chemicals List); EINECS (European Inventory of Existing Chemical Substances); ELINCS (European List of Notified 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 (Toxic Substances Control Act Chemical Substance Inventory)

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

1.2 Composition of the substance

C.I. pigment red 104 (formula $Pb(Cr,S,Mo)O_4$) is a variable solid mixed phase crystal which contains lead chromate, lead sulfate and lead molybdate in varying proportions. This substance is the result of a chemical co-precipitation reaction from other lead and chrome salts (see chapter on manufacturing).

C.I. pigment red 104 can be considered borderline between a "well defined substance"[8] and an "UVCB substance"[9], with a variable concentration range of lead chromate, lead sulfate and lead molybdate. Literature mainly identifies it as an UVCB substance.

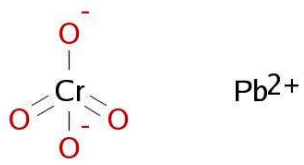
For this reason the composition indicated below is given as example but may vary considerably. Tables 2 and 3 display possible compositions of C.I. Pigment Red 104.

[7] Sources : Iuclid, 2000 ; Environment Canada, 2008

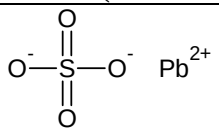
[8] According to the guidance for identification and naming of substances under Reach, a well defined substance is a "substance with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of Reach Annex IV item 2"

[9] According to the guidance for identification and naming of substances under Reach, an UVCB substance is a "substance of Unknown or Variable composition, Complex reaction products or Biological materials -UVCB that cannot be sufficiently identified by the parameters of Reach Annex IV item 2"

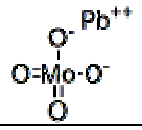
Main constituent 1: Lead chromate

Chemical Name:	Lead chromate
EC Number:	231-846-0
CAS Number:	7758-97-6
IUPAC Name:	lead(2+) chromate
Molecular Formula:	$PbCrO_4$ ($CrH_2O_4.Pb$)
Structural Formula:	
Molecular Weight:	323.2 g/mol
Typical proportion %	75% (Environment Canada, 2008)
Real proportion (range) in %	69-80% (Environment Canada, 2008)

Main constituent 2: Lead sulfate

Chemical Name:	Lead sulfate
EC Number:	231-198-9
CAS Number:	7446-14-2
IUPAC Name:	lead(2+) sulfate
Molecular Formula:	PbSO4 ($H_2O_4S.Pb$)
Structural Formula:	
Molecular Weight:	303.4 g/mol
Typical proportion %	12% (Environment Canada, 2008)
Real proportion (range) in %	9-15% (Environment Canada, 2008)

Main constituent 3: Lead molybdate

Chemical Name:	Lead molybdate
EC Number:	233-459-2
CAS Number:	10190-55-3
IUPAC Name:	lead(2+) molybdate
Molecular Formula:	PbMoO4 / Mo.O.Pb
Structural Formula:	
Molecular Weight:	367.1 g/mol
Typical proportion %	5% (Environment Canada, 2008)
Real proportion (range) in %	3-7% (Environment Canada, 2008)

A multi-constituent substance is a substance consisting of several main constituents present at concentrations generally ≥ 10% and < 80% (w/w). Lead molybdate, even if present in concentrations <10%, is presented as a main constituent because its presence distinguish C.I. Pigment Red 104 from C.I. Pigment Yellow 34.

1.3 Physico-Chemical properties

Table 1. Summary of available physico-chemical properties useful for this study

REACH ref Annex, §	Property	Value	References
VII, 7.1	Physical state at 20 C and 101.3 KPa	Solid Red orange powder (solid solution crystal)	Iuclid, 2000 Environment Canada, 2008
VII, 7.2	Melting / freezing point	> 800°C	Iuclid, 2000
VII, 7.3	Boiling point	unknown	
VII, 7.5	Vapour pressure	insignificant	
VII, 7.7	Water solubility of parent substance (lead sulfochromate yellow)	< 0.01 mg/L (at 20°C) Not soluble	Iuclid, 2000
	Water solubility of PbCrO4 (major component)	0.058 mg/L (at 25°C) 0.17 mg/L (at 20°C)	Weast, 1965 Lide, 2006
	Water solubility of PbSO4 (minor component)	42,5 mg/L (at 25°C)	Nicnas, 2007
	Experimental, total dissolved chromium[10]	0.012; 0.10; 0.179 mg/L	Environment Canada, 2008
	Experimental, total dissolved lead	0.02; 0.36; 0.223 mg/L	Environment Canada, 2008
	Calculated, parent substance[11]	0.062; 0.693; 0.764 mg/L	Environment Canada, 2008
VII, 7.8	Partition coefficient n-octanol/water (log value)	Not applicable	
IX, 7.16	Dissociation constant	unknown	

[10] Based upon dissolution of the parent substance C.I. Pigment Yellow 34 after 18 to 24 hours of stirring in dilution test water (pH 7.1 to 8.4, room temperature), 0.2 or 0.45 µm filtration and measurement of total dissolved metal in filtrate. The loading rate was 100 to 1000 mg of parent substance per liter.

[11] Solubility of the parent substance was back-calculated using the total dissolved concentrations of the metals (Cr, Pb) and information on the composition of that parent substance

Table 2. Composition range and weight fractions for C.I. Pigment Red 104 (Environment Canada, 2008)

Constituent	Composition range (%)	Average composition (%)	Molecular weight (g/mol)		Weight fraction (%)	
			Pb	Other	Pb	Other
$PbCrO_4$	69-80	75	207.2	116	48	27
$PbSO_4$	9-15	12	207.2	96	8	4
$PbMoO_4$	3-7	5	207.2	159	3	2
Other	3-13	8	--	--	--	--

Table 3. Weight fraction of specific moieties for C.I. Pigment Red 104 (Environment Canada, 2008)

Moiety	Composition (%)
Pb	59
CrO_4	27
SO_4	4
MoO_4	2

2 CLASSIFICATION AND LABELLING

2.1 Classification in Annex VI of Regulation (EC) No 1272/2008

According to Article 57 of the REACH Regulation, substances meeting the criteria for classification as carcinogenic (category 1 or 2) or as toxic for reproduction (category 1 or 2) in accordance with Directive 67/548/EEC may be included in Annex XIV.

Pursuant to the first ATP to Regulation (EC) No 1272/2008(Commission Regulation (EC) No 790/2009) as of 1 December 2010, the classification of lead chromate molybdate sulfate in Annex VI, part 3, Table 3.2 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) will be as follows:

Index Number: 082-010-00-5

Carc. Cat. 2; R45 (May cause cancer)

Repr. Cat. 1; R61 (May cause harm to the unborn child)

Repr. Cat. 3; R62 (Possible risk of impaired fertility)

R33 (Danger of cumulative effects)

N: R50-53 (Dangerous for the environment: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment).

According to the first ATP to Regulation (EC) No 1272/2008, the corresponding classification in Annex VI, part 3, Table 3.1 of this Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) will be as follows:

Index Number: 082-010-00-5
Carc. 1B; H350

Repr. 1A; H360Df

STOT RE 2; H373

Aquatic Acute 1; H400

Aquatic Chronic 1; H410

2.2 Self classification(s)

Not applicable.

3 ENVIRONMENTAL FATE PROPERTIES

This chapter is not relevant as C.I. Pigment Red 104 is identified as SVHC as a CMR substance and not as a PBT or vPvB substance. Although Pigment Red 104 contains additional molybdenum component ($PbMoO_4$), it contains the same two other major components as C.I. Pigment yellow 34 ($PbCrO_4$ and $PbSO_4$) in similar proportions. Both substances have similar types of applications that require durability (through low solubility) in order to resist weathering in harsh environments. These chemicals are therefore considered to be analogues for the purposes of the following health and environment assessment.

Since environmental fate properties may be useful to describe human exposure to C.I. Pigment Red 104, (Part II of Annex XV dossier on C.I. Pigment Red 104, Chapter 3: Information on exposure), the most relevant information is reported in annex 1 of Annex XV dossier for C.I. Pigment Yellow 34.

4 HUMAN HEALTH HAZARD ASSESSMENT

This chapter is not relevant as C.I. Pigment Red 104 has already been classified as a CMR substance. However, information is available in Annex 1.

5 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this type of dossier.

6 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

This chapter is not relevant as C.I. Pigment Red 104 is proposed to be identified as SVHC as a CMR substance and not as a PBT or vPvB substance.

REFERENCES

Boscolo P, Gioacchino MD, Bavazzano P, White M, Sabbioni E. (1997). Effects of chromium on lymphocyte subsets and immunoglobulins from normal population and exposed workers. Life Sci 60:1319-25.

Bragt PC, van Dura EA. (1983). Toxicokinetics of hexavalent chromium in the rat after intratracheal administration of chromates of different solubilities. Ann Occu Hyg 27:315-22.

Bragt PC, Zwennis, WCM, Franssen AC. (1990). Biological Monitoring of Exposure to Chromium (VI) Salts: The Role of Solubility. In: Dillon HK, Ho MH, editors. Biological monitoring of exposure to chemicals: Metals. New York (NY): Wiley, p. 119-126.

Chiazze Jr L, Ference LD, Wolf PH. (1980). Mortality among automobile assembly workers. 1. Spray painters. J Occupational Med 22:520-6.

Clapp TC, Umbreit TH, Meeker RJ, Kosson DS, Gray D, Gallo MA. (1991). Bioavailability of lead and chromium from encapsulated pigment materials. Bull Environ Contam Toxicol 46:271-5.

Cowley ACD. (1984). Controlling lead chromes in the work place. XVII. FATIPEC-Kongress, Lugano, Schweiz. Sept. 23-28, 1984. Swiss Colour and Paint Chemists' Association. p. 59-80.

Davies JM. (1979). Lung cancer mortality of workers in chromate pigment manufacture: An epidemiological survey. J Oil Colour Chem Assoc 62:157-63.

Davies JM. (1984). Lung cancer mortality among workers making lead chromate and zinc chromate pigments at three English factories. Br J Ind Med 41 :158-69.

DCC (2009). Dominion colour corporation (DCC) comments on the proposal to identify lead chromate pigments as substances of very high concern pursuant to EC 1907-2006 REACH, 29 May 2009.

Deschamps F, Nisse C, Haguenoer JM. (1995). Mortality study among workers producing pigments in France. Int Arch Occup Envion Health 67:147-52.

Eaton DL, Kalman D, Garvey D, Morgan M, Omenn GS. (1984). Biological availability of lead in a paint aerosol 2. Absorption, distribution and excretion of intra-tracheally instilled lead paint particles in the rat. Toxicol Lett 22:307-13.

ECB - European Chemical Bureau (2003). Proposal: Mutagen and carcinogen classification of Lead Chromate, C.I. Pigment Yellow 34, C.I. Pigment Red 104. ECBI/32/02 Add.15. Available from http://ecb.jrc.it/classlab/3202a15_N_lead_chromates.doc

EEH - Equitable Environmental Health (1976). An epidemiological study of lead chromate plants. Final report. Berkeley {CA): Equitable Environmental Health.

EEH - Equitable Environmental Health (1983). Mortality in employees of three plants which produced chromate pigments. Berkeley (CA): Equitable Environmental Health.

Environment Canada (2008). Screening assessment for the challenge C.I. pigment yellow 34, Environment Canada & Health Canada, November 2008. Available from http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_1344-37-2.cfm

Fentzel-Beyme R. (1983). Lung cancer mortality of workers employed in chromate pigment factories. A multicentric European epidemiological study. J Cancer Res Clin Oncol 105:183-88.

Gage JC and Litchfield MH. (1967). The migration of lead from polymers in the rat gastro-intestinal tract. Food Cosmet Toxicol 6:329-38.

Haguenoer JM, Dubois G, Frimat P, Cantineau A, Lefrancois H, Furon D. (1981). Mortality from bronchopulmonary cancer in a zinc- and lead-chromate producing factory (Fr.). In: Prevention of Occupational Cancer, International Symposium (Occupational Safety and Health Series No. 46). Geneva (CH): International Labour Office, p. 168-76.

Hayes RB, Sheffet A, Spirtas R. (1989). Cancer mortality among a cohort of chromium pigment workers. Am J Ind Med 16:127-33.

IUCLID(2000). International Uniform Chemical Information Database. IUCLID dataset for C.I. Pigment Yellow 34. Substance ID: 1344-37-2. European Commission. European Chemicals Bureau. Available from: http://ecb.jrc.it/esis/

Iyengar V, Woittiez J. (1988). Trace elements in human clinical specimens: Evaluation of literature data to identify reference values. Clin. Chem. 34:474-81.

Kano K, Horikawa M, Utsunomiya T, Tati M, Satoh K, Yamaguchi S. (1993). Lung cancer mortality among a cohort of male chromate pigment workers in Japan. Int J Epidemiol 22:16-22.

Korallus U, Ulm K, Steinmann-Steiner-Haldenstaett W. (1993). Bronchial carcinoma mortality in the German chromate-producing industry: the effects of process modification. Int Arch Occup Environ Health 65F:F171-8.

Lide DR (2006). CRC Handbook of Chemistry and Physics. 87th ed. New York (NY): Taylor & Francis Group.

McAughey JJ, Samuel AM, Baxter PJ, Smith NJ. (1988). Biological monitoring of occupational exposure in the chromate pigment production industry. Sci Total Environ 71:317-22.

NICNAS - National Industrial Chemicals Notification and Assessment Scheme. (2007).Lead compounds in industrial surface coatings & inks. (Priority Existing Chemical Assessment Report No. 29). Australian Government. Dept of Health and Ageing.

Perrault G, Dufresne A, Strati G, McNeil M, Michaud D, Begin M, Labbe J, Lariviere P, Eeckhaoudt S, Van Grieken R. (1995). Physico-chemical fate of chromium compounds in the sheep lung model. J Toxicol Environ Health 44:247-62.

Pier SM, Gallo MA, Umbreit TH, Connor TH, Gray D, Cappelleri FA. (1991). Silica encapsulation reduces bioavailability. Environ Tox Chem 10:1247-53.

Sheffet A, Thind I, Miller AM, Louria DB. (1982). Cancer mortality in a pigment plant utilizing lead and zinc chromates. Arch Environ Health 37: 44-52.

Weast RC, editor. (1965). CRC Handbook of Chemistry and Physics. 46th edition. Cleveland (OH): Chemical Rubber Co.

Wiegand HJ, Ottenwälder H, Bolt HM. (1988). Recent advance in biological monitoring of hexavalent chromium compounds. Sci Total Environ 71:309-15.

Xie H, Wise SS, Holmes AL, Xu B, Wakeman TP, Pelsue SC, Singh NP, Wise JP Sr. (2005). Carcinogenic lead chromate induces DNA double-strand breaks in human lung cells. Mutat. Res. 2005 Oct 3;586(2):160-72.

ANNEX I: HUMAN HEALTH HAZARD ASSESMENT

The European Commission has concluded that C.I. Pigment Red 104, together with C.I. Pigment Yellow 34 and lead chromate "show(s) evidence for carcinogenicity in several studies with rats after subcutaneous and intramuscular administration. Lead chromate induced both benign and malignant tumours at the site of injection and, in one study, renal carcinomas. The animal studies are supported by epidemiological studies demonstrating an increased frequency of lung cancer among workers involved in production of chromate pigments. The animal studies are also supported by genotoxic(ity) studies as well as cell transformation studies. The substances show resemblance to known mutagens/carcinogens" (ECB 2003).

Whereas the toxicologic profile and properties of the substance may be useful to evaluate the human exposure in Part II of Annex XV dossier on Pigment Red 104, Chapter 3: Information on exposure, main conclusions from the screening assessment[12] conducted by the Canadian government under section 74 of the Canadian Environmental Protection Act, 1999 (Environment Canada 2008) can be found in Annex 2 of the Support Document for C.I. Pigment Yellow 34.

Bioavailibility and absorption

The low solubility of C.I. Pigment Red 104 is indicative of limited bioavailability. The bioavailability of lead chromate and lead-chromate-derived pigments has been investigated in experimental animals. Administration of non-encapsulated or silica-encapsulated chrome yellow/lead chromate to rats by gavage (150 mg/kg-bw/day, five days per week, for four weeks) resulted in an increased level of lead in the blood and kidneys. No chromium could be detected in blood from exposed rats (detection limit = 10 µg/L). The kidney levels of chromium were increased significantly only in rats treated with non-encapsulated pigment. These results indicate that silica encapsulation reduces the gastrointestinal bioavailability of chromium from lead chromate pigments (Clapp et al. 1991; Pier et al. 1991). Administration of lead chromate to rats via whole body inhalation (5.3 ± 0.8 mg CrVI /m^3, 4 hours per day for 1 to 4 days) led to the accumulation of both chromium and lead chromate in the lungs. The chromium concentration in urine and feces were significantly increased following administration, whereas both chromium and lead concentrations in blood were only slightly elevated (above 5 µg/L for chromium) (Bragt et al. 1990). In addition, a short-term study in male rats showed that lead did not migrate from polypropylene plastic coloured with lead chromate-molybdate following oral administration (Gage and Litchfield 1967). Investigations employing other routes of administration, including intratracheal injection, instillation and infusion to the tracheal lobe bronchus, of lead chromate or lead paint resulted in increased lead and chromium levels in various tissues and retention in the lungs (Bragt and van Dura 1983; Perrault et al. 1995; Eaton et al. 1984). Finally, it was recently shown that the particulate forms of Cr(VI), rather than the water soluble ones, were the potent carcinogens (Xie et al, 2005).

Workers in a plastic production plant exposed to dust containing various chemicals, including lead and lead chromate, had significantly increased chromium levels in their urine samples. Their blood lead levels were also significantly increased, but not their serum chromium levels (Boscolo et al. 1997). Other occupational studies (McAughey et al. 1988; Wiegand et al. 1988) also showed that

[12] This substance was identified in the categorization of the domestic substances list as a high priority for action because it was considered to pose greatest potential for exposure to individuals, because it had been classified of carcinogenicity, reproductive toxicity and developmental toxicity and because the substance also met the Canadian ecological categorization criteria for persistence and inherent toxicity to aquatic organisms.

the urine and blood chromium levels in lead chromate pigment production workers were higher than those typically observed in non-occupationally exposed persons (Iyengar and Woittiez 1988). In two lead chromate-based paint factories in the UK, blood lead levels were detected in a range of 9-25 µg/L for warehouse men, a range of 10-36 µg/L for ball mill loaders, and a range of 9-15 µg/L for spray painters. The author stated that these levels were commonly found in non-lead workers (Cowley 1984).

In conclusion, there is uncertainty regarding the bioavailability of this substance; however, limited data from the bioavailability studies in experimental animals and observations in occupationally exposed humans suggest that lead chromate and its derived pigments have some level of bioavailability and absorption after exposure. 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.

Epidemiological surveys

Human epidemiological investigations have been conducted in occupational settings in various geographic locations with an attempt to identify the relationship between occupational engagement in lead chromate pigment production and cancer risk. Workers in this industry were exposed not only to the pigments themselves but also to the soluble hexavalent chromium compounds used as raw materials in the pigment production. The majority of the results showed an increased risk of lung cancer among the workers in the plants where both lead and zinc chromate pigments were produced (Sheffet et al. 1982; Hayes et al. 1989; EEH 1976; EEH 1983; Davies 1979; Davies 1984; Haguenoer et al. 1981; Deschamps et al. 1995; Fentzel-Beyme 1983; Korallus et al. 1993). The only exception is the study conducted in five chromate pigment production plants in Japan where no significantly increased mortality due to lung cancer was observed (Kano et al. 1993). The authors stated this might be because the amount of hexavalent chromium compounds in the work environment has been lowered as a result of engineering hygiene considerations such as improved ventilation, the wearing of masks, attention to work clothes and bathing after work. Two epidemiological studies conduced in the plants where only lead chromate pigments were produced reported a slightly elevated risk in respiratory tract tumour, but no statistical significance has been reached (Davies 1979; EEH 1983). The authors speculated that the numbers of observed and expected deaths were too small in these studies for definitive conclusions. With respect to lead chromate pigment use, the only available epidemiological investigation did not indicate a statistically significant association between spray painting and respiratory-cancer-caused mortality (Chiazze et al. 1980).

Based on the above, the Canadian screening assessment concluded that several epidemiological investigations conducted in occupational settings in various geographic locations have shown an increased risk of lung cancer among the workers in the plants where both lead and zinc chromate pigments were produced. But it is underlined that there is uncertainty concerning the actual exposure levels of the workers in some of the epidemiological investigations as workplace exposure monitoring data were not available and protective measures were sometimes implemented during the time period of studies (Environment Canada 2008).

According to producers (DCC, 2009), any lung cancer that has been attributed over 60 years to exposure to C.I. Pigment Red 104 and the observed excess of cancer deaths is more linked to a mixed exposure to soluble zinc, strontium or calcium chromate, which are known carcinogens, than to C.I. Pigment Red 104.