

Annex XV dossier

**Proposal for identification of a substance as a CMR cat 1 or 2,
PBT, vPvB or a substance of an equivalent level of concern**

Substance: **Lead sulfochromate yellow (C.I. Pigment Yellow 34)**

EC Number: 215-693-7

CAS Number: 1344-37-2

Submitted by: **FRANCE**

Version: **PUBLIC version** - (August 2009)

PROPOSAL FOR IDENTIFICATION OF A SUBSTANCE AS A CMR CAT 1 OR 2, PBT, VPVB OR A SUBSTANCE OF AN EQUIVALENT LEVEL OF CONCERN

Substance name: LEAD SULFOCHROMATE YELLOW (C.I. Pigment Yellow 34)

EC number: 215-693-7

CAS number: 1344-37-2

- *It is proposed to identify the substance as a CMR according to Article 57 (a) and (c) according to the following argument.*

Summary of how the substance meets the CMR (Cat 1 or 2) criteria

According to Article 57 of Regulation 1907/2006 (the REACH Regulation), substances meeting the criteria for classification as carcinogen (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. Lead sulfochromate yellow has been classified as a carcinogen (Carc. Cat. 2) and as toxic to reproduction (Repr. Cat. 1) according to Directive 67/548/EEC by Commission Directive 2008/58/EC amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

Therefore, lead sulfochromate yellow met the criteria for classification as carcinogenic category 1 or 2 and as toxic for reproduction category 1 or 2 under Directive 67/548/EEC and accordingly may be included in Annex XIV.

This classification as Carc. Cat. 2 and as Repr. Cat. 1 will also be included 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 by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation 1272/2008. This Commission Regulation was adopted on 10 August 2009 (publication and entry into force of this Regulation is expected to be in September/October 2009).

The corresponding classification in Annex VI, part 3, Table 3.1 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) will be Carc. 1B and Repr. 1A.

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

Not relevant

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JUSTIFICATION

This report covers only the Pigment Yellow 34. However, results and information covering “lead chromate pigments” are used in some sections. This information refers to C.I. Pigment Yellow 34 and C.I. Pigment Red 104 and is used for results covering both substances. 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 (3 different substances).

1 IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1 Names and other identifier of the substance

Chemical Name: lead sulfochromate yellow (C.I Pigment yellow 34)
EC Number: 215-693-7
CAS Number: 1344-37-2
Deleted CAS numbers¹: 8012-76-8, 61513-05-1, 61513-06-2, 61513-07-3, 81209-53-2
IUPAC Name: lead sulfochromate yellow

This substance is identified in the Colour Index by Colour Index Constitution Number, C.I. 77600 and 77603².

Inventory names³:

Pigment Yellow 34 (TSCA, AICS, PICCS, ASIA-PAC, NZIoC); *Lead sulfochromate yellow*; (EINECS); *Pigment Yellow 34* (ENCS); *Pigment Yellow 034* (ECL); *Mix-Crystal Lead Sulfochromate-Molybdate* (PICCS); *Chrome Yellow* (PICCS); *Chrome Yellow Lead Sulfochromate* (PICCS)

¹ These CAS numbers have been deleted from the CA index, but may still be in use by some companies.

² 77603 C.I. Number refers to C.I. Pigment Yellow 34:1, which refers in turn to C.I. Pigment Yellow 34, with C.I. Constitution Number 77600, thus both colour index entries are covered by the proposal.

³ 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)

Other names⁴:

C 103; C 103 (pigment); 77600; 77603; C.P. Chrome Yellow Light 1066; Chrome Yellow Light 1074; Chrome Yellow Medium 1074; Chrome Yellow Medium 1085; Chrome Yellow Medium 1298; Chromastral Green Y; Chrome orange; Chrome Yellow 10G; Chrome Yellow 4G; Chrome Yellow 4GL Light; Chrome Yellow 500LSG; Chrome Yellow 5G; Chrome Yellow 5GF; Chrome Yellow 62E; Chrome Yellow 6GL Primrose; Chrome Yellow A 241; Chrome Yellow G; Chrome Yellow GL Medium; Chrome Yellow Lemon; Chrome Yellow LF AA; Chrome yellow light; Chrome Yellow Light Y 434D; Chrome yellow medium; Chrome Yellow Medium Y 469D; Chrome yellow middle; Chrome Yellow NEO 5GS; Chrome Yellow Pigment GMN 35; Chrome Yellow Primrose; Chromium yellow; Dainichi Chrome Yellow 10G; Dainichi Chrome Yellow 5G; Dark chrome yellow; Horna Chrome Yellow dark GL 35; Horna Chrome Yellow GUH 41; Horna Chrome Yellow medium GU 25; Krolor Yellow KY 787D; Krolor Yellow KY 788D; KZh 2; KZh 3; KZh 3 (pigment); Lead sulphochromate; Lemon Chrome A 3G; Lemon Chrome C 4G; Lemon Chrome Yellow 325; Light chrome yellow; Medium chrome yellow; Middle chrome; Middle Chrome BHG; Middle chrome yellow; Perma Yellow 1650S; Perma Yellow 5G; Primrose chrome; Primrose yellow; Pure Lemon Chrome 24882; Pure Lemon Chrome 3GN; Pure Lemon Chrome HL 3G; Pure Lemon Chrome L 3G; Pure Lemon Chrome L 3GS; Pure Middle Chrome 24883; Pure Middle Chrome LG; Pure Primrose Chrome 24880; Pure Primrose Chrome 24881; Pure Primrose Chrome L 10G; Pure Primrose Chrome L 6G; Renol Chrome Yellow Y 2G; Renol Chrome Yellow Y 2RS; Resino Yellow NSR 107; Sicomin Yellow L 1122; Sicomin Yellow L 1630S; Sicomin Yellow L 1635 ; Supra Lemon Chrome 4Gl; Supra Lemon Chrome H 4G; Supra Middle Chrome G; Supra Primrose Chrome 6G

1.2 Composition of the substance

C.I. Pigment Yellow 34 (formula $Pb(Cr,S)O_4$) is a variable solid mixed phase crystal that contains **lead chromate** and **lead sulphate**. This substance is the result of a chemical co-precipitation reaction from other lead and chrome salts (see chapter on manufacturing and uses).

C.I. Pigment Yellow 34 can be considered borderline between a “well defined substance”⁵ and an “UVCB substance”⁶, with a variable concentration range of lead chromate and lead sulphate. Literature mainly identifies it as an UVCB substance.

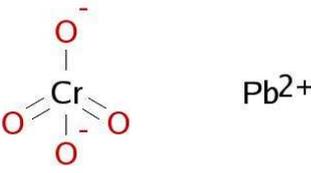
For this reason the composition indicated below is given as example but may vary considerably. Tables 2 and 3 display possible compositions of C.I. Pigment Yellow 34.

Main constituent 1: Lead chromate:

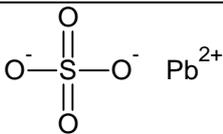
⁴ Sources : Iuclid 2000 ; Environment Canada 2008

⁵ 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”

⁶ 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”

Chemical Name:	Lead chromate
EC Number:	231-846-0
CAS Number:	7758-97-6
IUPAC Name:	lead(2+) chromate
Molecular Formula:	PbCrO ₄ (CrH ₂ O ₄ .Pb)
Structural Formula:	
Molecular Weight:	323.2 g/mol
Typical proportion %	68% (Environment Canada, 2008)
Real proportion (range) in %	61-76% (Environment Canada, 2008) 50-80% (HSBD) 40-90% (Producers and suppliers web sources)

Main constituent 2: Lead sulphate:

Chemical Name:	Lead sulphate
EC Number:	231-198-9
CAS Number:	7446-14-2
IUPAC Name:	lead(2+) sulfate
Molecular Formula:	PbSO ₄ (H ₂ O ₄ S.Pb)
Structural Formula:	
Molecular Weight:	303.4 g/mol
Typical proportion %	29% (Environment Canada, 2008)
Real proportion (range) in %	20-38% (Environment Canada, 2008) 20 - 50% (HSDB)

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 Yellow powder (solid solution crystal)	Iuclid, 2000 Environment Canada, 2008
VII, 7.2	Melting / freezing point	844°C	Lide, 2006
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 ⁷	0.012; 0.10; 0.179 mg/L	Environment Canada, 2008
	Experimental, total dissolved lead ⁸	0.02; 0.36; 0.223 mg/L	Environment Canada, 2008
	Calculated, parent substance ⁹	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	

⁷ 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.

⁸ This is original data taken from C.I. Pigment Red 104 (CAS RN 12656-85-8); the particle size range for C.I. Pigment Yellow 34 is assumed to be similar.

⁹ 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 Yellow 34 (Environment Canada, 2008)

Constituent	Composition range (%)	Average composition (%)	Molecular weight (g/mol)		Weight fraction	
			Pb	Other	Pb	Other
PbCrO ₄	61 - 76	68	207.2	116	44	24
PbSO ₄	20 - 38	29	207.2	96	20	9
Other	1 - 8	--	--	--	--	--

Table 3. Weight fraction of specific moieties for C.I. Pigment Yellow 34 (Environment Canada, 2008)

Moiety	Composition (%)
Pb	64
CrO ₄	24
SO ₄	9

2 MANUFACTURE AND USES

Not relevant for this type of dossier.

Information on uses may be useful for prioritisation for inclusion in Annex XIV but this should be summarised under Section 2 of the second part of this report.

3 CLASSIFICATION AND LABELLING

3.1 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. The classification of lead sulfochromate yellow according to Directive 67/548/EEC was updated by the 30th Adaptation to Technical Progress (30th ATP; Commission Directive 2008/58/EC¹⁰) as follows:

Index Number: 082-009-00-X

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

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

¹⁰ COMMISSION DIRECTIVE 2008/58/EC of 21 August 2008 amending, for the purpose of its adaptation to technical progress, for the 30th time, Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

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).

This classification will be included 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 1272/2008¹¹ by a Commission Regulation amending, for the purposes of its adaptation to technical progress, for the first time Regulation 1272/2008. This Commission Regulation has been adopted on 10 August 2009 (publication and entry into force of this first ATP is expected to be in September/October 2009¹²).

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: 082-009-00-X

Carc. 1B; H351

Repr. 1A; H360Df

STOT RE 2; H373

Aquatic Acute 1; H400

Aquatic Chronic 1; H410

3.2 Self classification(s)

Not applicable

4 ENVIRONMENTAL FATE PROPERTIES

This chapter is not relevant as C.I. Pigment Yellow 34 is identified as SVHC as a CMR substance and not as a PBT or vPvB substance. But since environmental fate properties may be useful to describe human exposure to C.I. pigment yellow 34 (Part II, Chapter 3: Information on exposure), the most relevant information is reported in annex 1.

¹¹ 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

¹² Pursuant to Article 53(1) of Regulation 1272/2008 this Commission Regulation was adopted in accordance with the regulatory procedure with scrutiny involving both the Council of the EU and the European Parliament.

5 HUMAN HEALTH HAZARD ASSESSMENT

This chapter is not relevant as C.I. Pigment Yellow 34 has already been classified as a CMR substance. However, some information are available in annex 2.

6 HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

Not relevant for this type of dossier.

7 ENVIRONMENTAL HAZARD ASSESSMENT

Not relevant for this type of dossier.

8 PBT, VPVB AND EQUIVALENT LEVEL OF CONCERN ASSESSMENT

This chapter is not relevant as C.I. Pigment Yellow 34 is proposed to be identified as SVHC as a CMR substance and not as a PBT or vPvB substance.

INFORMATION ON USE, EXPOSURE, ALTERNATIVES AND RISKS

Considering the general approach used by ECHA to develop the priority setting¹³, where the ‘regulatory effectiveness’ of including the substance into the authorisation process should also be taken into account, and the grouping approach proposed in section 1 of the “other information” part of this report, information on uses and exposure should be considered globally for the three “Lead chromates”: Lead chromate, C.I. pigment yellow 34 and C.I. pigment red 104.

1 INFORMATION ON VOLUMES

1.1 Producers and importers in Europe

The HPV (High and low production volume) chemical program of OECD listed the following producers and importers in Europe:

Company	Country	Town
BASF AG	GERMANY	LUDWIGSHAFEN
BASF LACKE + FARBEN AG	GERMANY	MUENSTER
BASF PIGMENT GMBH	GERMANY	MUENSTER
DR.HANS HEUBACH GMBH & CO.KG	GERMANY	LANGELSHEIM
ETS. CAPPELLE FRERES	FRANCE	HALLUIN
INTERMEDIOS ORGANICOS S	SPAIN	MONTCADA
LAPORTE ITALIA DIVISIONE SILO SPA	ITALY	TORINO
N.V. CAPPELLE GEBROEDERS	BELGIUM	MENEN
WILL & CO. B.V	NETHERLANDS	BADHOEVEDORP

Seven other European importers have been identified by this study (confidential data).

¹³ http://echa.europa.eu/doc/consultations/recommendations/gen_approach_prioritisation.pdf

Data on manufactured and consumed volumes of lead chromates pigments have been asked to producers, importers and users through the consultation at the European level (see table 6). Very few data have been collected. Only global volumes have been shared by producers and no detailed volume per type of uses was available.

1.2 Production volumes

Lead chromate pigments are manufactured in Europe, Canada, USA, Korea, China, etc. China currently accounts for nearly 50% of the global chromium pigment production, with an increase in production of 23% in 2006 (Focus on pigments 2007).

In Europe, C.I pigment yellow 34 is referenced as High Production Volume Chemical (HPV) with a production or import volume in excess of 1000 tons/year in 1993.

1.3 Consumption volumes

- According to EMLC (EMLC 2009) the consumption of lead chromate pigments (C.I. pigment yellow 34 plus C.I. pigment red 104) in Europe and only from European production was much lower in 2008 than the volume produced in Europe (30,000 tons) (confidential data). This figure does not include import volumes from non-European manufacturers. Such volumes are known for only one of them (confidential data).

The total consumption of lead chromate pigments (C.I. pigment yellow 34 plus C.I. pigment red 104) in Europe seems to be around 7700 tons/year at the strict minimum. Other unknown import volumes should be added.

Assuming that the consumption of C.I. pigment yellow 34 is twice in comparison with C.I. pigment red 104 (regarding the detailed import volumes from one of the non-European producer), **the total European consumption of C.I. pigment yellow 34 seems to be around 5800 tons per year at the strict minimum.**

In France, the consumption of C.I. yellow 34 has been estimated in 2005 around 1500 tons including 1200 tons (88%) for paints and coatings, 60 tons (4,4%) for plastic manufacturing and coloration, 91 tons (6,7%) for paints and varnishes manufacturing, 0,06 ton for aircraft and spacecraft manufacturing and 0,05 ton for weapon manufacturing (paints for camouflage and weapon marking) (INRS, 2005). These 3 last uses have not been confirmed by EMLC.

The C.I. yellow 34 market trend is decreasing for the use of paints in France (FIPEC 2009). Less than 25% of the automotive companies still use these pigments. Paints tonnage containing lead chromate pigments is around 2250 tons and represents less than 3% of the total French paint tonnage (75 000 tonnes).

According to the SPIN database in the Nordic countries, the consumption of C.I. yellow 34 has been estimated in 2005 around 360 tons (570 tons in 2007), especially in Denmark for about 90%.

2 INFORMATION ON USES

The manufacturing of these 3 substances illustrates this nearness as it uses the same process of chemical precipitation of various lead and chromium salts. Lead chromate (see lead chromate annex XV report) is usually prepared by the addition of a sodium dichromate solution to a solution of lead salt or a suspension of a less soluble lead compound. The colour varies for green-yellow to yellow-red. Co-precipitation with lead sulphate gives primrose and lemon hues; precipitation in alkaline conditions gives rise to a basic salt PbO-PbCrO_4 with a redder shade. Co-precipitation with lead molybdate produces a scarlet pigment (see “lead chromate molybdate sulphate pigment” annex XV report).

Although Pigment Yellow 34 does not contain molybdenum component (PbMoO_4), it contains the same two other major components as C.I. Pigment Red 104 (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.

2.1 Process of manufacturing (see annex 3 and 4)

Although lead chromate occurs naturally as the mineral crocoite, the first synthetic lead chromate pigment appeared commercially in the XIXth century. These pigments exhibit numerous technical advantages and offer an efficient solution to pigmentation problems in the yellow, orange and red rangers (Levi, 1983). It has bright colour with outstanding and light fastness, good heat, acid and alkalis resistance, and it can be easily dispersed.

According to the Hazardous Substances Data Bank (HSDB)¹⁴ of the National Library of Medicine's - Toxicology Data Network (TOXNET[®]), C.I. Pigment Yellow 34 is formed by coprecipitation of lead chromate and lead sulphate in a reaction solution of sodium dichromate, sodium sulphate, lead salt (usually lead nitrate), aluminium sulphate and soda ash (sodium carbonate). The precipitation is washed with water to remove soluble compounds (Eurocolour, 2004).

To improve the required properties, the pigments can be stabilized (encapsulated) at a last step with fast protective coating of (Eurocolour, 2004):

- aluminium and titanium compounds and silicates up to 6%,
- or antimony compounds and silicates up to 10%,
- or resin.

These encapsulated pigments exhibit greatly improved properties, better resistance to harsh weather conditions and high temperatures and suitability for many industrial applications.

Concerning the derivatives, C.I pigment yellow 34 can be mixed with other constituents to extend the available range of colors: it can be mixed with pigment yellow 31 containing barium chromate, mixed with blue pigments (for example iron blue pigments or phtalocyanin blue) to obtain green chromate pigments (C.I. pigment green 15 or 48).

¹⁴ [http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+C.I. PIGMENT YELLOW 34](http://toxnet.nlm.nih.gov/cgi-bin/sis/search/r?dbs+hsdb:@term+@na+C.I.PIGMENT YELLOW 34)

2.2 Available grades of pigments

Several grades of pigments are available on the marketplace according to their way of manufacturing (encapsulation, special final treatment, etc.) that exhibits various properties and level of resistance to the environment conditions (confidential data).

2.3 Main uses listed by literature (not necessarily current)

For current uses, please refer to section 2 of the second part of the report. The main potential uses of C.I. Pigment Yellow 34 referenced by worldwide literature are the coloration (pigment) in and/or manufacturing of

- paints (HSDB 2009), non-consumer paints and coatings (Environment Canada 2008 ; Cetim 2008) in the areas of motor vehicle and farmer vehicle painters, ships building and repairing, civil engineering, treatment and coatings of metals, aircraft and spacecraft manufacturing, etc. (SPIN 2009).
- printing inks (HSDB 2009; Cetim 2008) (this use seems to be stopped now), a very limited number of commercial printing inks or coatings used for plastics and certain outdoor applications such as commercial identification decals (Environment Canada 2008 ;)
- vinyl and cellulose acetate plastics (HSDB 2009), rubber and plastic formulation for commercial applications and export (Environment Canada 2008)
- textile printing (HSDB 2009; Cetim 2008),
- leather finishing (HSDB 2009; Cetim 2008),
- linoleum (HSDB 2009),
- paper (HSDB 2009),
- artist's paints (HSDB 2009; Cetim 2008),
- varnishes (SPIN 2009, CETIM 2008),
- mastics (SPIN 2009).

For example, these pigments are used for applications that require safety attributes such as high visibility and so are used in traffic paint striping 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 2008; Cetim 2008). C.I. Pigment Yellow 34 is also used for military coatings applications (Cetim 2008).

Encapsulated pigments can be used in heat fusion road paint, which have special demand on weather, chemical resistance and light fastness and plastic manufacturing.

It should be noted that in the context of the DEFPI program and followings the conclusion of a screening assessment, the Canadian government has decided to ban progressively the use of C.I. Pigment Yellow 34 in road painting from the 31th of December 2010.

2.3.1 Uses in plastic industry

The plastic industry is the largest consumer of C.I. Pigment Yellow 34. Plastic manufacturers or transformers use concentrated liquid or viscous pigment preparations in the base plastic polymer. Each type of plastic material/composite (polyolefins, polyvinyl chloride and nylon) and each process of modelling (injection, extrusion, etc.) are concerned by the use of this pigment.

2.3.2 Uses in paints and coatings industry

The second largest user of C.I. Pigment Yellow 34 is the commercial - industrial paint and coatings industry, which uses these pigments in a variety of industrial coatings.

2.3.3 Miscellaneous uses

Lesser quantities of C.I. Pigment Yellow 34 are used in a variety of other industries, including the coloring of rubber and flooring compounds. These uses have declined in recent years. No data are available.

2.4 Current uses identified in Europe

Current uses have been identified by consultation of the European importers, manufacturers and users of C.I. Pigment Yellow 34. They are plastics colouring and painting/coatings due to “their excellent properties, brilliant colors and a cost benefit ratio not shown by any other pigment class”.

In general about 40% of the European market is paint production and 60% is plastics application with strong variations at each supplier (EMLC, 2009). Paint manufacturers usually produce a range of products for different applications, which makes it difficult for suppliers¹⁵ to know for which product a pigment is used.

For the Nordic market, more than 75% of C.I. Pigment Red 104 was used in 2007 for paint, varnishes, coatings manufacturing whereas 25% was used for plastic manufacturing (SPIN 2009). Around 200 preparations¹⁶ contained this substance in 2007 and around 20 preparations contained more than 95% of the total used tonnage (for paints and plastic manufacturing).

The following major uses of C.I. Pigment yellow 34 are referenced by EMLC for the European market (EMLC 2009) and by FIPEC for the French market (FIPEC 2009);

- paints manufacturing in the areas of vehicles not covered by the end-of-live-vehicles directive, civil engineering material (EMLC 2009 ; FIPEC 2009), aircraft manufacturing, agricultural equipment (FIPEC 2009),
- paints for coil coating (EMLC 2009; FIPEC 2009),
- paints for road and airport horizontal painting (EMLC 2009; FIPEC 2009),
- paints for plastic material (EMLC 2009; FIPEC 2009),

¹⁵ No comment nor data have been received during consultation period from federations of users.

¹⁶ A query of the “industrial uses (national)” reference indicated that 196 preparations contained the substance whereas, a query based on “Use cat. UC62” reference returned 282 preparations.

- coloration of plastic (EMLC 2009).

In France, the substitution for road horizontal marking is not complete. Some small companies still use paints containing C.I yellow 34. No data have been collected at the EU level.

Other uses have been identified as paints for camouflage and paints for ammunition marking in the Defense area (Cetim 2008).

Artists' paints manufactured in Europe do not contain C.I yellow 34 (EMLC, 2009). But no data are available for imported pigments for the same purpose and this use has been listed by non-European producers. According to Cetim (2008), this has been stopped because of the toxic properties of these substances and concerned a very negligible amount of the total used volume.

The encapsulated pigments have been brought to the market already some decades ago. Since that time only these (encapsulated) pigments are in use in the EU according to Eurocolour (2004) and EMLC (2009). This argument remains however questionable, since

- significant amounts of non encapsulated pigments are yearly imported into the EU market (see chapter 10.2),
- at least one European producer manufactures only non-encapsulated lead chromate pigments.

The lack of data from producers on the detailed uses of these non-encapsulated pigments and their becoming (exportation out of the EU market, encapsulation process carried out in Europe, etc.) did not allow to conclude on this issue.

2.5 Not reliable uses in Europe

C.I yellow 34 is no longer used in Europe in printing inks. The "Exclusion list for printing inks and related products" (5th revised edition, October 2007) of EuPIA (European Printing Ink Association - European Printing Ink Group of CEPE¹⁷) is a voluntary recommendation that excludes the use of CMR substances as raw materials (substances and preparations) for printing inks and related products. According to EuPIA, although it does not bring any legal obligation, this exclusion list has the full support of all printing ink manufacturer members in Europe. However according to Cetim (2008), lead chromate pigments are still used for printing ink manufacturing in Europe.

In addition, the "EuPIA Guideline on printing inks applied to the non-food contact surface of food packaging materials and articles" (April 2008 edition) does not allow the use of CMR classified substances for ink manufacturing for food packaging. This guideline has been developed to support ink manufacturers on how to formulate inks which comply with Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food, as this regulation does not specifically concern printing inks for food packaging.

Lead chromates pigments, even encapsulated, are not suitable for enamels and ceramics due to high application temperatures (EMLC, 2009).

¹⁷ European Council of producers and importers of paints, printing inks and artists' colours -CEPE

2.6 Regulation

As for all CMR substances, lead chromates pigments and preparation containing them can not be supplied to private end-users. Preparations with more than 0,15% total lead content must, in accordance with Regulation (EC) 1272/2008 on “classification, packaging and labelling of dangerous substances” be labelled “Contains lead. Should not be used on surfaces liable to be chewed or sucked by children”.

C.I. Pigment Yellow 34 is not permitted for use in toys or children’s products according to the Council directive 88/378/EEC of 3 May 1988 concerning the safety of toys (on the approximation of the laws of the Member States concerning the safety of toys).

Directive 2000/53/EC of the European Parliament and of the Council of 18 September 2000 on end-of-life vehicles does not allow the use in vehicles put on the market of material and components (as paints) containing lead, mercury, cadmium and hexavalent chromium after 1 July 2003, other than in cases listed in Annex II (exemption for coating inside petrol tanks). But this Directive does not cover the use of paints or coatings containing lead in the bodywork area where remaining preparations can still be used and old vehicles be repaired.

Regulation (EC) 1935/2004 of 27 October 2004 on materials and articles intended to come into contact with food requires in article 3 that materials and articles in contact with food, whether printed or not, shall be manufactured in accordance with good manufacturing practices, so that under normal conditions of use, they do not transfer their constituent to food in quantities which could endanger human health.

Lead sulphates placing on the market or use, in substances or mixtures, is restricted where they are intended for use as paint, as referred in the entry 17 of Annex XVII of REACH, amended by Regulation (EC) No 552/2009. Restoration and maintenance of works of art and historic buildings may though be permitted by the Member States.

3 INFORMATION ON EXPOSURE

Main results and conclusions reported hereafter come from the Canadian screening assessment (Environment Canada 2008) (where “lead chromate pigments” is mentioned, it refers to both C.I. pigment yellow 34 and C.I. pigment red 104).

3.1 Exposure of the environment

Lead chromate pigments are 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).

Lead chromate pigments are used in many specific coloured products, in a dispersive way. They can be released into the environment mainly as a result of industrial use and service life of these coloured products.

Table 4¹. Estimated releases and losses of C.I. Pigment Yellow 34 to environmental media, transformation and distribution to management processes, based on the mass flow tool (Environment Canada 2008)

Medium or process	Proportion of the mass (%)	Major life cycle stage involved ²
Soil	0	Industrial use
Air	0	Manufacture, waste disposal
Water	35.3	Manufacture, formulation, industrial use and service life
Transformation	1.9	Waste disposal
Waste disposal	62.7	Waste disposal

¹For C.I. Pigment Yellow 34, information from the following OECD emission scenario documents was used to estimate releases to the environment and distribution of the substance, as summarized in this table: OECD 2004; Brooke and Crookes 2007. Values presented for releases to environmental media do not account for possible mitigation measures that may be in place in some locations (e.g., partial removal by sewage treatment plants). Specific assumptions used in derivation of these estimates are summarized in Environment Canada 2007c.

²Applicable stage(s): production-formulation-industrial use-consumer use-service life of article/product-waste disposal.

These results suggest that C.I. Pigment Yellow 34 mainly ends up in waste management sites (62.7%), due to the eventual disposal of manufactured items containing it. Of the substance, 1.9% is transformed, which in this case means destruction or modification of the structure of the substance during its incineration. It is estimated that 35.3% of C.I. Pigment Yellow 34 may be released to water. Negligible releases are expected to soil, groundwater and air. Although results from a Canadian survey (Environment Canada 2007b) indicate that releases to all media from industrial manufacture and formulation were extremely low (i.e. less than 0.1% of total manufactured or imported into Canada), the study indicates that specific applications and/or post-application releases (e.g. from commercial use) are expected to make the greatest contribution to environmental levels.

Based on the above, water is expected to be the medium receiving the greatest proportion of lead chromate pigments emitted during product manufacturing, formulation, industrial 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.

3.2 Exposure of the general population

3.2.1 Exposure of the general population via consumer products

According to the CLP Regulation (EC Regulation No 1272/2008), use of C.I. Pigment Yellow 34 is banned for the manufacture of preparations for use by the general population. Nevertheless its presence in few consumer preparations is reported by Sweden and Norway (SPIN 2009). Lead chromate pigments are however used in commercial settings to manufacture a wide range of articles and preparations that are sold throughout the European market and that each consumer (the whole general population including children) may come in contact with and be potentially exposed to (paints, pigmented polymers, plastics, rubbers and pigments used in wiring, but not toys covered by Directive 88/378/EEC). Pigments concentration in industrial final paints can range from 5% to 40% by weight (see Part II chapter 2.1.2).

As the substance is not volatile, there would be no relevant exposure through the inhalation pathway. It is possible that a consumer may have dermal contact with the pigments following

application; however, the resulting dermal exposure is expected to be low for several reasons. 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, and 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 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 Yellow 34) 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).

Given the above and the physical and chemical properties of this substance and its commercial use and applications, the Canadian screening assessment concluded that exposure of the general population is negligible.

3.2.2 Exposure of the general population via the environment

Based on the properties and uses previously described of the substance, the actual environmental exposure levels are expected to be low. There are no empirical data identified regarding measured concentrations of C.I. Pigment Yellow 34 in environmental media (i.e., air, water, soil and food).

Given the physical and chemical properties and sources of this substance, the Canadian screening assessment concluded that exposure to C.I. Pigment Yellow 34 is expected to be negligible via drinking water and ambient air. Main exposure of general population from the environment is supposed predominantly from soils, even if it is 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.

This conclusion is argued hereafter for each environmental media (drinking water, ambient air, soil and the food chain) (Environment Canada 2008).

Exposure via drinking water

Given its physical and chemical properties, estimations of the concentration of C.I. Pigment Yellow 34 in drinking water were not considered to be relevant. Its low solubility in water indicates that the majority of releases to this medium, from industrial or post-application commercial sources (e.g., deterioration of traffic striping paint and migration from landfills after waste disposal), would be in the form of suspended particulates. These particulates are highly likely to be removed via settling or filtration during wastewater and/or subsequent drinking water treatment processes, and therefore the concentrations remaining in drinking water would be negligible.

Exposure via ambient air

Due to its negligible vapour pressure, any industrial releases of C.I. Pigment Yellow 34 to ambient air would be in the form of particulates. The majority of these particulates would be captured prior to release from the facility and any remaining particulates would be expected to settle before significant transport had occurred. The maximum concentration of C.I. Pigment Yellow 34 predicted to be present in ambient air was $0.66 \mu\text{g}/\text{m}^3$. This concentration is expected to be extremely conservative and would only be relevant for those living next to the facility. The general population is not expected to be exposed to C.I. Pigment Yellow 34 through inhalation of ambient air.

Exposure via soils, sediments and food chain

Given the physical chemical properties of C.I. Pigment Yellow 34 it is expected to be found primarily in soils and/or sediments. Reported industrial releases of this substance to the environment via manufacturing or formulation were extremely low and so are not expected to contribute to the overall concentrations found in soil. However, given that the substance is often directly incorporated into the matrix of the solid material and the dispersive use of these products, the availability of this substance for human exposure is expected to be minimal. The low solubility of this substance also indicates that bioavailable exposures through soils, suspended solids and sediment are not likely to be significant and would be further reduced by the substance being incorporated into a solid matrix or encapsulated in silica. Therefore significant quantities of C.I. Pigment Yellow 34 are not expected to be found in the food chain.

3.2.3 Conclusion on exposure of the general population

Despite the concluded low exposure of the general population via consumer products and via the environment, and on the basis of the carcinogenicity of C.I. Pigment Yellow 34 for which there may be a probability of harm at any level of exposure, the Canadian government has concluded that C.I. Pigment Yellow 34 is a substance that may be entering the environment in a quantity or concentration or under conditions that constitute or may constitute a danger to human life or health.

3.3 Exposure of workers in Europe

Exposure of workers has been shown in Canada by several epidemiological investigations conducted in occupational settings in various geographic locations that have shown an increased risk of lung cancer among the workers in the plants where both lead and zinc chromate pigments were produced (exposure to pigments and to lead and chrome compounds used for their manufacturing) (Environment Canada, 2008) (see chapter 5). Pigment concentrations in concentrates and mill base can range from 30% to 70% by weight, which can lead to a high level of potential exposure (see chapter 9.1.1 and 9.1.2).

Worker exposure to C.I. pigment yellow 34 has been referenced by the SPIN database (SPIN 2009).

In France, the number of workers potentially exposed to C.I. yellow 34 is estimated around 3,000 (1000-1500 for paints and coatings, less than 100 for plastic manufacturing, 500 to 1000 for paints and varnishes manufacturing, 150 to 500 for aeronautic and spacecraft construction and 150 to 500 for weapon manufacturing) (INRS 2005). This includes only workers related to pigments manufacturing and to the primary use of pigments (paints

manufacturing, plastics colouring, etc). It excludes workers potentially exposed to secondary uses such as painters, coating applicator, etc. This estimation of potential exposed workers in France is thus underestimated.

No data is available at the European community level.

The producers of C.I. pigment yellow 34 underline that exposure of workers to lead chromates pigments is closely monitored and restricted by concentration limits (Eurocolour, 2004).

4 INFORMATION ON ALTERNATIVES

Data collected on available alternatives of C.I. pigment yellow 34 are not very corroborating and may be opposite depending of the type of uses.

4.1 Alternative substances

According to EMLC and FIPEC (2009), there are no economic alternatives to lead chromate pigments with the same application properties. Substituted colour shades similar to lead chromate pigments are available but the application requirements, such as weather resistance, light fastness, opaqueness capacity and others are not met. Moreover, the technical implementation of substitutes is difficult and often inefficient (lack of stability, etc.). At least, costs for such alternatives are four to ten times the price and present an economic burden for end users and consumers alike.

No achieved and complete substitution has been identified¹⁸ in France for the use of C.I. pigment yellow 34, in contrary to C.I. pigment red 104. According to producers, main reasons are the lack of permanent efficiency, the economic cost and the lower specific color and brightness properties (FIPEC 2009). But even so, in the specific area of road marking, the use of C.I. yellow 34 has been totally substituted by the two main companies. Therefore, substitution may be applied for some specific uses but not for all.

According to Kemi (2007), a large selection of organic pigments or metal compounds are now used in Sweden as alternatives in decorative paints. The composition is confidential information. However, some use of lead chromates pigments remains in car touch-up paints such as yellow pigment where it is not been possible to develop alternatives with the same shade of colour and coverage. The problem is that if a thicker coat is applied to compensate for coverage, the coat of paint becomes brittle. The lead chromate pigment is principally present in solvent-based paints, and with the change-over to water-thinnable products this use of lead would probably disappear. However, some pigments containing lead chromates will remain in certain “high solid” paints.

According to Goodman (2006), in the context of RoHS¹⁹ Directive, lead chromate pigments used in electrical and electronic equipments can be substituted by yellow pigments based on bismuth vanadate or organic pigments.

¹⁸ <http://www.substitution-cmr.fr/>

¹⁹ Directive ECC/2002/95 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

4.2 Alternative techniques

Not known.

5 RISK-RELATED INFORMATION

Not known

OTHER INFORMATION

1 GROUPING APPROACH

Grouping makes sense in the authorisation process at the time of a potential prioritisation of candidate substances for inclusion in annex XIV.

Moreover, the three substances “lead chromate” (CAS n°7758-97-6), “lead sulfochromate pigment” (CAS n°1344-37-2) and “lead chromate molybdate sulphate pigment – C.I. pigment red 104” (CAS n°12656-85-8) are proposed for SVHC candidate identification in a grouping approach since they chemically belong to the same family and they share chemical similarities (similar hazard profile, same classification and labelling), similar technical performances and similar uses.

Grouping in prioritisation promotes effective substitution toward safer alternatives by avoiding or limiting possibility to use another hazardous substance as a substitute. Substitution between these 3 substances (especially between lead chromate and lead sulfochromate pigment) can be envisaged for some limited uses such as yellow shade paints or colouring. However, significant difference of colour (especially between yellow and red pigments) doesn't allow a systematic substitution for all uses. No more available substitutes with same hazard profile have been identified than the 3 grouped lead chromate substances.

2 CONSULTATION OF INDUSTRY

A closed consultation has been conducted by e-mailing during the development of the dossier (from the 7th to the 26th of July 2009) at both the French and the European levels. A first pre-consultation had previously been conducted in May and June 2009 on a list of 24 substances identified as potential SVHC.

The organisations and companies contacted for this purpose are in the sectors of:

- lead chromate pigments manufacturing (Eurocolour, European manufacturers of lead Chromate and lead molybdate pigments - EMLC, Lead chromate pigments Reach consortium, non-European producers, etc.),
- lead chromate pigments import and distribution in Europe,
- primary uses of lead chromate pigments: paints, coatings and plastic manufacturing (European Council of Producers and importers of paints, printing inks and artists' colours - CEPE, French trade union of paints, inks, colors, pastes and adhesives – FIPEC, Plastics Europe, European plastic converters EuPC, etc),
- secondary uses of lead chromate pigments: textile manufacturing, bodywork, etc.

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ANNEX 1: ENVIRONMENTAL FATE PROPERTIES

The most relevant information reported hereafter come from the environmental assessment²⁰ conducted in 2008 by the Canadian government under section 74 of the Canadian Environmental Protection Act, 1999 (Environment Canada, 2008). Please refer to the full study²¹ for more available information

As this substance was not listed in a priority list under Regulation (EEC) 793/93, no risk assessment report (for environment and human health) is available for this substance.

According to the Canadian screening assessment, C.I. Pigment Yellow 34 meets the persistence criteria as set out in the *Persistence and Bioaccumulation Regulations* as it contains metal ions, lead (Pb^{2+}) and the chromate (CrO_4^{2-}) ions, which are themselves considered to be infinitely persistent. The current state of the science does not allow for the unambiguous interpretation of the bioaccumulation potential of metal containing inorganic substances such as C.I. Pigment Yellow 34. Experimental toxicity studies suggest that the substance is not hazardous to aquatic organisms at a loading rate (100 mg/L) that is considered to represent a reasonable environmental worst-case scenario. Additionally, considering its low solubility, it is unlikely that organisms associated with other compartments would be harmed by exposure to this substance.

On the basis of ecological hazard and reported releases of C.I. Pigment Yellow 34, it was concluded that this substance is not entering the environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity, or that constitute or may constitute a danger to the environment on which life depends.

Solubility and dissociation

The measured and estimated solubility in water of C.I. Pigment Yellow 34 is quite low ranging from < 0.01 to 0.764 mg/L with geometric and arithmetic means of 0.135 and 0.382 mg/L respectively. A relatively low proportion of the parent substance is thus expected to dissolve, dissociate and release the lead (Pb^{2+}) and chromate (CrO_4^{2-}) ions in typical aquatic media with a pH between 6 and 8 under conditions that are moderately oxidic (~ 0.4 - 0.7 V, or dissolved oxygen > 4 mg/L). In addition to the low solubility of the parent substance itself, its encapsulation of the substance in paints, plastics and coatings that are made to last for long periods of time and resist harsh environments further restrains the dissolution of the parent substance and therefore further limits the bioavailability of the metals contained in the substance (Environment Canada 2007a; Lewis 1988). According to Pier (1991) silica encapsulated forms of C.I. Pigment Yellow 34 are leached to a substantially smaller extent than the identical pigment lacking silica encapsulation. However, recent literature showed that

²⁰ 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.

²¹ (http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot_2_e.html)

the particulate forms of Cr(VI) rather than the water soluble ones could be toxic (Xie et al., 2005).

Partitioning

As a metal-containing inorganic substance, a fate analysis based on $\log K_{ow}$ and K_{oc} is not applicable to C.I. Pigment Yellow 34. Since C.I. Pigment Yellow 34 is a solid and has a negligible vapour pressure, it is not expected to partition to air. Because of the strong tendency of these metals to sorb solid particles in aquatic media, a significant proportion of dissolved forms of these metals will end up in sediments, through the settling of suspended particles (Hamilton-Taylor et Willis 1984).

Therefore, the moieties of concern issued from the dissolution and dissociation of C.I. Pigment Yellow 34, Pb^{2+} and CrO_4^{2-} , are expected to be found in water, sediments and soils but not in air. Note that some non-dissolved C.I. Pigment Yellow 34 (as the parent substance) is also expected to be found in sediments and moist soils. When released to dry soils, C.I. Pigment Yellow 34 will mainly remain there with some of the substance leaching locally into ground and/or surface water ecosystems when the soil gets soaked by rain or melting snow/ice. The solid parent substance is not expected to be found in significant amounts in water, considering that its density is a few times greater than that of water.

Persistence and Bioaccumulation Potential

Environmental Persistence

The substance C.I. Pigment Yellow 34 is considered persistent according to criteria as set out in the Canadian *Persistence and Bioaccumulation Regulations* as both of its moieties of concern, the lead (Pb^{2+}) and the chromate (CrO_4^{2-}) ions are considered infinitely persistent.

Potential for Bioaccumulation

The current state of the science does not allow for the unambiguous interpretation of the significance of various measures of bioaccumulation (e.g., BCFs, BAFs) 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.

The PBT and vPvB criteria of Annex XIII to the REACH Regulation do not apply to inorganic substances, although they shall apply to organo-metals,

ANNEX 2: HUMAN HEALTH HAZARD ASSESMENT

The European Commission has concluded that C.I. Pigment Yellow 34, together with lead chromate and C.I. Pigment Red 104, "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 chapter 11, main conclusions from the screening assessment conducted by the Canadian government under section 74 of the Canadian Environmental Protection Act, 1999 are reported hereafter for information (Environment Canada 2008). See the full study for more available information.

Bioavailability and absorption

The low solubility of C.I. Pigment Yellow 34 was longer seen as 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 /m³, 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 (McAughy et al. 1988; Wiegand et al. 1988) also showed that 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 conducted 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 has been attributed over 60 years to exposure to C.I. Pigment Yellow 34 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 Yellow 34.

ANNEX 3: PIGMENT SYNTHESIS AND PROCESSING

European Commission, 2007

The wet chemical process is based on a precipitation reaction of dissolved raw material substances followed by product isolation. After a sometimes necessary purification step (e.g. for the production of zinc sulphide pigments), the raw materials are individually dissolved in water, acid, alkaline or salt solutions. The solutions are then mixed together and led into a precipitation tank for reaction. The solubility of the reaction product is much lower than the solubility of the starting materials. After the reaction step, the product is dehydrated in chamber filter presses. The dehydration step causes a leachate containing some residues of the starting raw materials, by-products of the reaction (mainly salts) and, in some cases, also a dissolved share of the desired pigment product. The wet chemical process is used when the raw materials are soluble, which is the case for metal sulphates, chlorides or hydroxides. In the case of oxides, which are sparingly soluble or insoluble, the dry calcination process is used instead. In most technologies dissolving and/or precipitation of (pre)pigments need a given acidity/alkalinity of solution (optimal pH range). Consequently, the pH value of the waste water resulting from the production of inorganic pigments using a wet chemical process may have environmental importance.

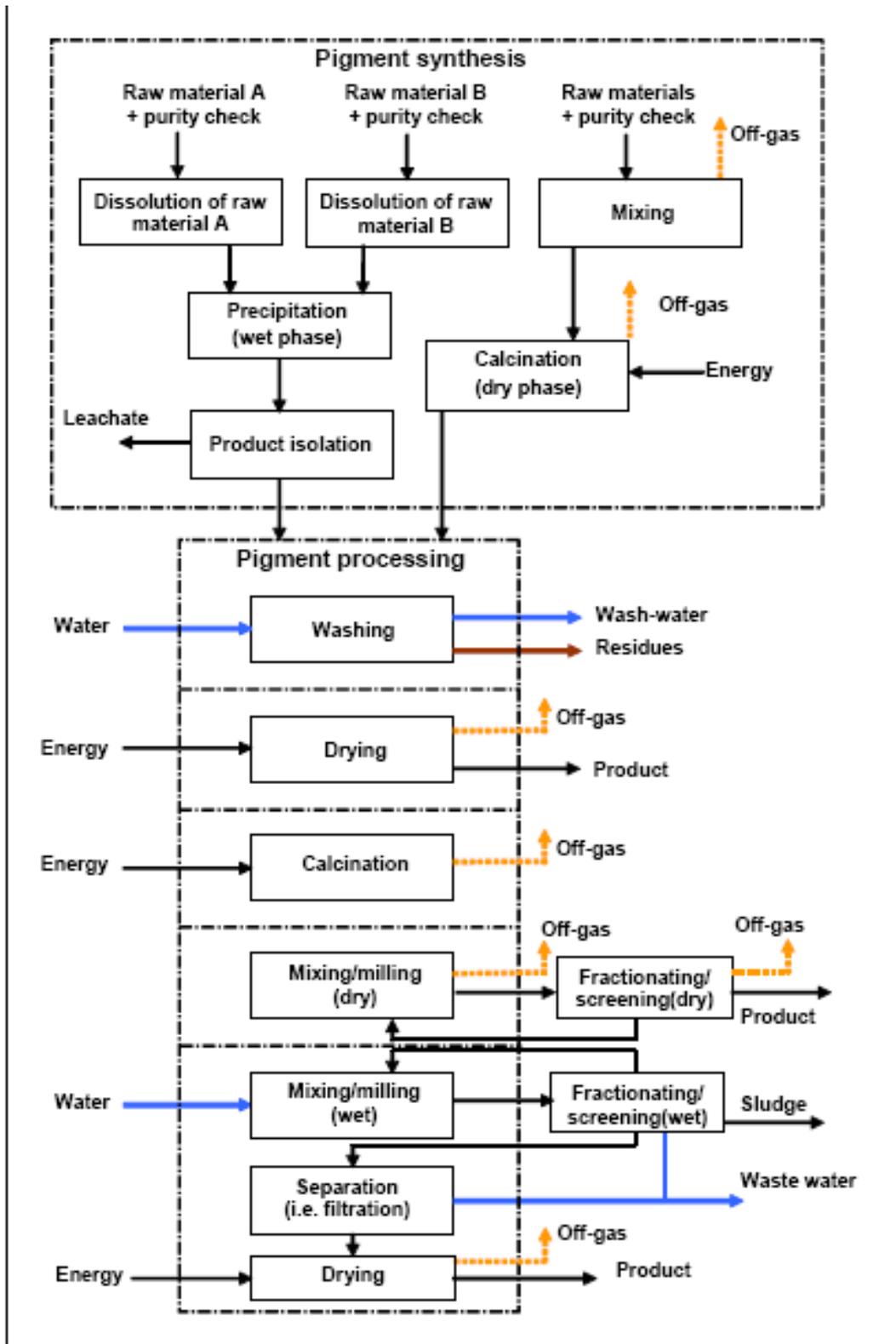


Figure 1. Pigment synthesis and processing (European Commission, 2007)

ANNEX 4: EXAMPLES OF C.I. PIGMENT YELLOW 34 AVAILABLE ON THE MARKET AND RELATED YELLOW TINT RANGE

Name	Chemischer Charakter	Colour Index, Name	Colour Index, Nummer	Farbton
Sicomin® Yellow L 1425	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1522	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1622	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1622 Type U	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1625	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1630 S	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1635 S	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1835 S	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1922	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1922 Type U	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 1925	lead chromate	Pigment Yellow 34	77603	
Sicomin® Yellow L 2135 S	lead chromate	Pigment Yellow 34	77603	

Source :

http://worldaccount.basf.com/wa/NAFTA~en_US/Catalog/Pigments/pi/BASF/range/co_auto_pig_sicomin