Danish Ministry of the Environment
Environmental Protection Agency

Survey of C. I. Pigment Yellow 34

(lead sulfochromate yellow)

Part of the LOUS review

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Survey of C. I. Pigment Yellow 34

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011) includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic based on quantitative structure activity relationship (QSAR) modelling or due to other concerns. For inclusion in the list, substances must fulfil several specific criteria. Besides the risk of leading to serious and long-term adverse effects on health or the environment, only substances which are used in an industrial context in large quantities in Denmark, i.e. over 100 tonnes per year, are included in the list.

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives to the substances, on existing regulation, on monitoring and exposure, and information regarding ongoing activities under REACH, among others.

The main objective of this survey is to provide background for the Danish EPA's consideration regarding the need for further risk management measures. On the basis of the surveys, the Danish EPA will assess the need for any further information, regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns C. I. Pigment Yellow 34 (Lead sulfochromate yellow) (CAS: 1344-37-2). This substance has been included on the LOUS list since 2009 due to its classification as Carc. 1B, H350 (May cause cancer) and Repr.1A, H360Df (May damage fertility or the unborn child).

The process

The survey has been undertaken by DHI from September 2013 to February 2014.

The working group at DHI consisted of:

- Poul Bo Larsen, Project manager
- Tina Slothuus, contributor
- Anja Kamper, contributor
- Jens Tørsløv, quality supervisor

Further, the work has been followed by an advisory group consisting of:

- Trine Thorup Andersen, Danish EPA, Chair of advisory group
- Lone Schou, Danish EPA
- Nikolai Stubkjær Nilsen, Confederation of Danish Industry

Data collection

The survey and review is based on the available literature on the substances, information from databases and direct inquiries to trade organisations and key market actors.

The data search included (but was not limited to) the following:

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (incl. Registry of Intentions and Community Rolling Action Plan);
- Relevant documents regarding International agreements from HELCOM, OSPAR, the Stockholm Convention, the PIC Convention and the Basel Convention.
- Data on harmonised classification (CLP) and self-classification from the C&L inventory database on ECHAs website;
- Data on ecolabels from Ecolabelling Denmark (Nordic Swan and EU Flower) and the German Angel.
- Pre-registered and registered substances from ECHA's website;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Information from Circa on risk management options (confidential, for internal use only, not searched via the Internet)
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, the European Food Safety Authority (EFSA) and the INIRIS database.
- Reports, memorandums, etc. from the Danish EPA and other authorities in Denmark;
- Reports published at the websites of:
  - The Nordic Council of Ministers, ECHA, the EU Commission, OECD, IARC, IPCS, WHO, OSPAR, HELCOM, and the Basel Convention;
  - Environmental authorities in Norway (Klif), Sweden (KemI and Naturvårsverket), Germany (UBA), UK (DEFRA and Environment Agency), the Netherlands (VROM, RIVM), Austria (UBA). Information from other EU Member States was retrieved if quoted in identified literature.
  - US EPA, Agency for Toxic Substances and Disease Registry (USA) and Environment Canada.

This survey is mainly based on a compilation of existing reports and evaluations that has been made over time including data from the REACH system and from the common Nordic product register database, SPIN.

In addition the advisory group members have contributed with valuable information/ advice.

Summary and conclusions

The Danish EPA has included C.I. Pigment Yellow 34 (CAS 1344-37-2) on the LOUS list (2009) based on its classification as carcinogenic (Carc. 1B; H350) and as toxic to reproduction (Repr. 1A; H360Df). In addition the annual tonnage in Denmark is above 100 tonnes.

Regulation, risk management
C.I. Pigment Yellow 34 (lead sulfochromate yellow) is regulated through both national and EU legislation. The substance is subject to harmonized CLP classification as Carc. 1B, Repr. 1A, STOT RE 2, Aquatic Acute 1 and Aquatic Chronic 1, and thus covered by down-stream regulations due to this stringent classification, i.e. specific occupational regulation apply for working with carcinogens. At national level a general regulation on lead and lead substance was implemented in 2001 and the import and sale of products containing more than 100 ppm (mg/kg) of lead was banned (with some exemptions).

The exposure of consumers is prevented through various directives addressing and setting limits for the content of lead and/or chromium in for example cosmetics, toys and drinking water. In addition, numerous other legislations cover lead in general, e.g. with respect to emissions from industrial processes and with respect to impurities/ contamination of lead in food and feed.

C.I. Pigment Yellow 34 (CAS: 1344-37-2) is registered under REACH and has been included on the authorization list (Annex XIV) under REACH with a sunset date in May 2015. After this date the substances can only be used if authorization for a specific use is granted by the EU Commission.

The Eco labelling criteria (e.g. the criteria for the EU flower and the Nordic swan) generally exclude the use of C.I. Pigment Yellow 34 in eco-labelled products due to its classification as Carc 1B and Repro 1A.

Tonnage and use
C.I. Pigment Yellow 34 is registered under REACH at an annual tonnage level in the range of 1,000 10,000 tonnes. The volume of C.I. Pigment Yellow 34 produced in Europe in 2008 was approximately 19,500 tons (Association of European Manufacturers). In EU C.I. Pigment Yellow 34 is mainly used in plastics (~60%) and in paint and coatings (~40%) mainly for professional uses. The pigment is e.g. used for road signs and road painting; for coating of metallic and plastic surfaces for e.g. machinery, in aeronautics; for boats/ships and for military equipment.

Data from the Nordic SPIN database indicate that C.I. Pigment Yellow 34 in the Nordic countries is used in preparations such as a binding agent, as coloring agent as well as a component in paint and lacquers and for plastic-, rubber- and metal articles.

In Denmark the annual tonnage has in the last decade varied between approximately 100 and 500 tonnes with a declining trend. Recent data from the Danish Product Register from 2014 shows an annual consumption of 112 tonnes (about 50 preparations). The majority (about 106 tonnes) is used as raw materials and about 90-95% of this is used as coloring agent in plastics that is exported to other countries. Some of the remaining 6 tonnes not used for exported articles seems to be covered by old registrations that may not necessarily be active anymore .
However, lower volumes may still be used in Denmark for anticorrosion, antifouling and for restoration/ repair work (e.g. of historical buildings).

Thus, today the amount of C.I. Pigment Yellow 34 used in Denmark for products and articles for the Danish market may be considered very limited. An unknown amount of C.I. Pigment Yellow 34 may however, be imported in the form of surface treated articles or from colored plastics containing the pigment.

As Pigment Yellow 34 is subject to authorisation under REACH **all** uses of the substance will be banned after the sunset date of May 2015 unless an authorisation for its use is granted by the EU-Commission. This will limit or even totally restrict the future use of Pigment Yellow 34.

Waste
Waste containing C.I. Pigment Yellow 34 has to be treated as hazardous waste if the content of the substance in the waste is above 0.1% due to the carcinogenic properties of the substance.

For industrial enterprises where use or handling of C.I. Pigment Yellow 34 may occur (either as raw materials or in plastic, paint or lacquers) guidance has been elaborated by the Danish EPA concerning the correct treatment of waste containing lead or other heavy metals.

In waste from households C.I. Pigment yellow 34 may be anticipated to occur rather seldom as uses in general are in relation to professional uses. It cannot be ruled out that in rare cases the pigment may be contained in waste from households e.g. plastic articles, and articles with paint / lacquers containing the substance. These fractions may either be incinerated (various combustible articles with high energy content) or recycled (e.g. plastics or metallic parts).

Environmental aspects
Aquatic toxicity testing with C.I. Pigment Yellow 34 (parent substance) showed that there were no effects observed on aquatic organisms at a loading rate of 100 mg pigment/L water. The substance is considered as water insoluble, but may be dissolved in trace amounts.

The available data for the substance C.I. Pigment Yellow 34 do not alone trigger a classification as environmentally hazardous. However, C.I. Pigment Yellow 34 has a harmonized classification for aquatic toxicity (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) (ECHA C&L database, December, 2013). This classification is considered to be based on an overall environmental concern for substances containing lead and chromate, which may have a potential for release of lead- and chromate ions into the environment. It should be noted that lead and lead compounds are identified as priority substances in the field of water policy aiming at a progressive reduction of such substances (Water Framework Directive, Annex X). The hazard is reflected in the EU EQS for lead and its compounds set at 7.2 µg/L. The Danish EQS for lead and its compounds is 0.34 µg/L

Human health aspects
The main concern pertaining to the exposure to C.I. Pigment Yellow 34 is expressed in the classification of the substance as Carc. 1B, H350 (May cause cancer); Repr. 1A, H360Df (May damage the unborn child/ Suspected of damaging fertility); and STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure).

The concern of carcinogenicity is primarily related to inhalation of chromate dust that may cause cancer in the respiratory tract.

With respect to developmental effects and STOT RE2 classification this may especially be related to the lead content of the substance. Thus, no lower threshold level has been found for lead exposure to pregnant women and children and adverse effects towards development of the central nervous system in unborn and small child.

Furthermore, chromate (Cr(VI)) is a known cause of skin allergy in humans. However, as C.I. Pigment Yellow 34 is a water insoluble substance it is unclear whether there is concern for chromate skin sensitization and elicitation of symptoms in already chromium (VI) sensitized persons, as only very low level of free chromate ions may be available in relation to dermal exposure to the substance.

No measured data on exposure to C.I. Pigment Yellow 34 in the occupational environment has been found. However, adequate risk reduction measures should be taken to avoid especially inhalational exposure from working processes with generation of aerosols, (e.g. handling of C. I. Pigment Yellow 34 in powder form, spray painting or abrasion of materials or surfaces treated with lacquers containing C.I. Pigment Yellow 34.

In general there seems to be no exposure potential for consumers as the substance is used for professional use only, so it is difficult to specify further possible measures in that respect as it is not possible to point out any use of C.I. Pigment Yellow 34 that may be of specific concern.

Alternatives
A wide range of Pigments have been identified as suitable alternatives for C.I. Pigment Yellow 34. The decreasing and very limited use of C.I. Pigment Yellow 34 today indicates that substitution of this pigment is possible and to a great extent has taken place in Denmark.

Overall conclusion
The use of C.I. Pigment Yellow 34 in Denmark today is very limited except for the use in plastic production (about 100 tonnes) for export. Delivery to the Danish market is very limited (at the most few tonnes) and is mainly considered to be in relation to professional uses. Although no data exist, it cannot be excluded that the pigment is imported in surface treated articles or articles made of colored plastics. With respect to possible human exposure there may be an exposure potential for workers handling the substance or products containing the substance, whereas consumer exposure seems unlikely due to the use pattern of the substance. The decreasing trend in use of C.I. Pigment Yellow 34 and the availability of alternative pigments indicate that substitution to a great extent has taken place in Denmark. After May 2015 the use of Pigment Yellow 34 will be banned in the EU, unless a specific authorisation in relation to a current application for industrial and professional use is granted.

Sammenfatning og konklusion

Stoffet C.I. Pigment Yellow 34 (CAS 1344-37-2) indgår på Miljøstyrelsens Liste over Uønskede Stoffer (LOUS) fra 2009 på grund af stoffets klassificering som kræftfremkaldende (Carc. 1B; H350) og reproduktionsskadende (Repr. 1A; H360Df). Stoffet anvendes til erhvervsmæssig brug i Danmark i en mængde, der overstiger 100 tons/år.

Regulering
C.I. Pigment Yellow 34 (bly sulfochromat gul) er reguleret gennem national lovgivning såvel som EU-lovgivning. Stoffet er underlagt harmoniseret CLP-klassificering som Carc. 1B, Repro. 1A, STOT RE 2, Aquatic Acute 1 og Aquatic Chronic 1, og er således omfattet af en række afledte bestemmelser på grund af denne strenge klassificering. Dette omfatter fx særlige forholdsregler for erhvervsmæssigt arbejde med kræftfremkaldende stoffer. Pga. indhold af bly er stoffets anvendelse også begrænset gennem det nationale blyforbud fra 2001 omfattende import og salg af produkter, der har et indhold på mere 100 mg bly/kg (med visse undtagelser)

En række direktiver beskytter endvidere forbrugerne mod potentiel udsættelse for stoffet, da der igennem disse er fastsat grænser for indhold af bly og/eller chrom i for eksempel kosmetik, legetøj og drikkevand. Derudover reguleres blyholdige forbindelser i almindelighed af mange andre lovgivninger, fx med hensyn til emissioner fra industrielle processer samt urenheder/forurening af bly i fødevarer og foder.

C.I. Pigment Yellow 34 er omfattet af godkendelsesordningen under REACH (bilag XIV) med en slutdato for anvendelse af stoffet i maj 2015. Herefter må det kun anvendes såfremt der er opnået særlig godkendelse af EU-Kommissionen.

Miljømærkningskriterierne (fx for EU-blomsten og det nordiske svanemærke) begrænser generelt brugen af C.I. Pigment Yellow 34, da miljømærkede produkter ikke må indeholde stoffet på grund af stoffets klassificering som Carc. 1B og Repr. 1A.

Anvendelse
I 2008 produceredes i Europa ca. 19.500 tons C.I. Pigment Yellow 34 (oplyst af sammenslutningen af europæiske producenter). I REACH-registreringen (2014) er det anført at stoffet produceres i/importeres til EU i en årlig tonnage på mellem 1.000-10.000 tons.
I EU anvendes C.I. Pigment Yellow 34 hovedsageligt i plast (~ 60 %) og i maling og belægninger (~ 40 %), hovedsageligt til professionel anvendelse. Stoffet anvendes fx som advarselsfarve til skiltning og vejbelægning, til coating af metal og plastdele fx til maskiner, i luftfarts- og skibsindustrien og til militære formål.

Data fra den nordiske SPIN-database viser, at C.I. Pigment Yellow 34 i de nordiske lande anvendes som farvestof i bindemidler, i malinger, samt til farvning og maling af plast-, gummi-og metalvarer.

I Danmark har den årlige tonnage i det sidste årti varieret mellem ca. 100 og 500 tons med en faldende tendens. De seneste data fra det danske produktregister fra 2014 viser et årligt forbrug på 112 tons (ca. 50 produkter). Størstedelen (ca. 106 tons) anvendes som råvarer, og omkring 90-95 % heraf anvendes som farvestof i plast, der eksporteres til andre lande. En del af de resterende 6 tons, der ikke anvendes i eksporterede artikler, ser ud til at være omfattet af gamle indrapporteringer, og det er derfor usikkert om der stadig ligger et reelt forbrug bag. En lavere og meget begrænset

mængde anvendes imidlertid stadig i Danmark til rustbeskyttelse, bundmaling og til restaurering/reparation af fx bevaringsværdige bygninger).

Mængden af C.I. Pigment Yellow 34, der i dag anvendes til produkter og artikler til det danske marked kan således betragtes som meget begrænset. En ukendt mængde C.I. Pigment Yellow 34 importeres muligvis via overfladebehandlede genstande eller i plast, der indeholder pigmentet.

På grund af stoffets kræftfremkaldende egenskaber, skal affald, der indeholder C. I. Pigment Yellow 34 behandles som farligt affald hvis indholdet af stoffet i affaldet er over 0,1 %. For virksomheder, der anvender eller håndterer C.I. Pigment Yellow 34 (fx som råvare eller i plast, maling eller lak), har Miljøstyrelsen udarbejdet en vejledning om korrekt behandling af affald, der indeholder bly eller andre tungmetaller.

I affald fra husholdninger forventes C.I. Pigment Yellow 34 kun at kunne forekomme meget sjældent, da anvendelsen generelt er tilknyttet professionel anvendelse. Det er dog uvist i hvilket omfang pigmentet være indeholdt i importerede artikler, fx plast og artikler malet med lak, der indeholder stoffet. Disse fraktioner fra private brugere vil typisk gå til forbrænding (forskellige brændbare artikler med højt energiindhold) eller genbruges (fx plast eller metaldele).

Miljømæssige aspekter
C. I. Pigment Yellow betragtes som uopløseligt i vand, og kun en begrænset fraktion af stoffet vil optræde i opløst form. I tests med vandorganismer blev der ikke observeret nogen skadelig effekt ved en tilførsel af 100 mg pigment/L vand. De konkrete testresultater giver således ikke anledning til at miljøklassificere stoffet. Imidlertid har C.I. Pigment Yellow 34 en harmoniseret klassificering for akvatisk toksicitet (Aquatic Acute 1, H400 og Aquatic Chronic 1, H410), hvilket kan anses at være knyttet til toksiciteten af bly- og chromat-indholdet, og ud fra en generel bekymring for frigivelse af disse metaller fra pigmentet. Bly og blyforbindelser er i Vandrammedirektivet identificeret som et prioriteret stof (Annex X) med sigte på at progressivt at reducere forureningen. Der er fastsat en EU kvalitetskrav for vandmiljøet for bly og blyforbindelser på 7,2 µg/L. Det tilsvarende danske Vandkvalitetskrav ligger på 0,34 µg/L.

Sundhedsmæssige aspekter
C.I. Pigment Yellow 34 er klassificeret som Carc. 1B, H350 (Kan fremkalde kræft); Repr. 1A, H360Df (Kan skade det ufødte barn/ Mistænkt for at skade forplantningsevnen); og STOT RE2, H373 (Kan forårsage organskader ved længerevarende eller gentagen eksponering).

Risikoen for kræftfremkaldende effekter anses primært at være knyttet til indånding af pigmentstøv og chromats (Cr(VI)) kræftfremkaldende effekt i luftvejene.
STOT RE2 klassificeringen kan især relateres til stoffets blyindhold, da bly i selv meget små mængder kan påvirke centralnervesystemet og dets udvikling hos fostre og børn. Der kendes således ikke nogen nedre træskelværdi for denne effekt.
Derudover er chromat (Cr(VI)) et velkendt allergifremkaldende stof, men da C.I. Pigment Yellow 34 er uopløseligt i vand er det uklart, om der kan afgives chromat i et omfang, der kan udgøre risiko for at fremkalde allergi eller evt. risiko for at fremkalde allergiske reaktioner hos personer der allerede lider af chrom (VI) – allergi.

Der er i forbindelse med udarbejdelsen af rapporten ikke fundet måledata for udsættelse med C.I. Pigment Yellow 34 i arbejdsmiljøet. For et stof som C.I. Pigment Yellow 34 bør der dog i forbindelse med reglerne i arbejdsmiljølovgivningen træffes særlige risikobegrænsende foranstaltninger. Det vil især være vigtigt at undgå indånding ved støvende arbejdsprocesser (fx håndtering af C.I. Pigment Yellow 34 i pulverform, ved sprøjtemaling/lakering eller ved slibning af materialer eller overflader behandlet med lak, indeholdende C.I. Pigment Yellow 34).

Der anses ikke umiddelbart at være risiko for udsættelse for C.I. Pigment Yellow 34 gennem forbrugerprodukter, da stoffet udelukkende anvendes i erhvervsmæssig sammenhæng. Der kan således ikke angives særlige forholdsregler for forbrugere.

Substitution og alternativer
En lang række pigmenter er identificeret som mulige alternativer for C.I. Pigment Yellow 34. Den faldende og meget begrænsede anvendelse af C.I. Pigment Yellow 34 i dag viser, at substitution af dette pigment er mulig og i vid udstrækning har fundet sted i Danmark.

Samlet konklusion
I Danmark anvendes C.I. Pigment Yellow 34 primært til brug i plastproduktion (ca. 100 tons) fremstillet til eksport. Levering til det danske marked er meget begrænset (højst et par tons) og anses primært for at være forbundet med professionel anvendelse. Selv om der ikke findes data, kan det ikke udelukkes, at pigmentet importeres i overfladebehandlede artikler eller artikler fremstillet af farvet plast.
Med hensyn til eventuel human eksponering, kan der være et potentiale for udsættelse for arbejdere, der håndterer stoffet eller produkter, der indeholder stoffet, mens eksponering af forbrugere forekommer usandsynlig som følge af stoffets anvendelsesmønster.

Den faldende tendens i anvendelsen af C.I. Pigment Yellow 34 og tilgængeligheden af alternative pigmenter indikerer, at substitution i stor udstrækning er mulig og har fundet sted i Danmark.

Godkendelsesordning under REACH har medført at pigmentet ikke længere kan forhandles og anvendes i EU efter maj 2015, medmindre der opnås særlig tilladelse til anvendelsen af EU-Kommissionen.

1. Introduction to the substance

1.1 Definition of the substance

C.I. Pigment Yellow 34 is identified in the Colour Index by Colour Index Constitution Number, C.I. 77600 and 77603. Other identifiers of C.I. Pigment Yellow 34 are listed in Table 1-1 below (ECHA, 2009).

TABLE 1-1
NAME AND IDENTIFIER OF C. I. PIGMENT YELLOW 34 (CAS: 1344-37-2) (ECHA, 2009)

C. I. Pigment Yellow 34	
Chemical Name	Lead sulfochromate yellow (C.I. Pigment yellow 34)
EC Number	215-693-7
CAS Number:	1344-37-2
Synonyms	DCC Yellow 1003; DCC Yellow 1012; DCC Yellow 1013; DCC Yellow 1014; DCC Yellow 1018; DCC Yellow 1019; DCC Yellow 1026; DCC Yellow 1032; DCC Yellow 1034; DCC Yellow 1036; DCC Yellow 1077; DCC Yellow 1080; DCC Yellow 1091; DCC Yellow 2603; DCC Yellow 4019; DCC Yellow 5003; DCC Yellow 5012; DCC Yellow 5020; DCC Yellow 5021; DCC Yellow 5026; DCC Yellow 5035; DCC Yellow 5036; DCC Yellow 9160; DCC Yellow 9259; DCC Yellow Y-933-LD; DCC Yellow Y-934-LD DCC Yellow Y-958-LD; DCC Yellow Y-969-LD DCC Yellow 1025; DCC Yellow 1016 DCC Yellow 1004; DCC Yellow 1009 DCC Krolor Yellow KY 895; DCC Krolor Yellow KY 788;

C. I. Pigment Yellow 34	
	DCC Krolor Yellow KY 781; DCC Krolor Yellow KY 787; DCC Krolor Yellow KY 795; RW38H; RW34S; RW37G; RW38D; RW38S RW38F; RW37D; RW37H; RW37C; RW37U HEUCOTRON T-Yellow 8064 HEUCOTRON T-Yellow 8070 HEUCOTRON T-Yellow 8064K DCC Yellow 1000; DCC Yellow 1002 DCC Yellow 1027; DCC Yellow 1028 DCC Yellow 1031; DCC Yellow 1037 DCC Yellow 4020; DCC Yellow Y 935 DCC Yellow Y 936; DCC Yellow 5022 DCC Yellow 5037; DCC Yellow 2603R

1.2 Purity and impurities

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

C.I. Pigment Yellow 34 can be considered borderline between a "well defined substance" and an "UVCB substance", with a variable concentration range of lead chromate and lead sulphate (Table 1-2 and Table 1-3). Literature mainly identifies it as an UVCB substance. Under the REACH regulation C. I. Pigment Yellow 34 is, however, registered as a mono-constituent substance.

TABLE 1-2
NAME AND IDENTIFIER OF LEAD (2+)CHROMATE (CAS: 7758-97-6) (ECHA, 2009)

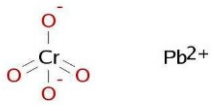
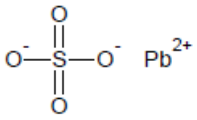
Property	Value
Formula	$PbCrO_4$ ($CrH_2O_4.Pb$)
Molecular Weight	323.2 g/mol
Typical proportion in C.I. Pigment Yellow 34	68%
Structure	 Pb^{2+}

TABLE 1-3
NAME AND IDENTIFIER OF LEAD SULPHATE (CAS: 7446-14-2) (ECHA, 2009)

Property	Value
Formula	$PbSO_4$ ($H_2O_4S.Pb$)
Molecular Weight	303.4 g/mol
Typical proportion in C.I. Pigment Yellow 34	29%
Structure	

Overall Pb^{2+}, CrO_3^{2-}, and SO_4^{2-} constitute 64%; 24%, and 9%, respectively.

The remaining constituents in C.I. Pigment Yellow 34 (up to 100%) are not further specified but only indicated as “other”.

(ECHA, 2009)

1.3 Physical and chemical properties

The physical and chemical properties of C. I. Pigment Yellow 34 (CAS: 1344-37-2) are listed in Table 1-4 below (ECHA, 2009).

TABLE 1-4
PHYSICAL AND CHEMICAL PROPERTIES OF C.I. PIGMENT YELLOW 34 (CAS: 1344-37-2) (ECHA, 2009; * ENVIRONMENT CANADA/ HEALTH CANADA, 2008)

Property	Value
Physical state at 20 C and 101.3 KPa	Solid Yellow powder (solid solution crystal)
Melting / freezing point	844°C
Boiling point	Unknown
Vapour pressure	Insignificant
Water solubility of parent substance (lead sulfochromate yellow)	< 0.01 mg/L (at 20°C) Not soluble
Water solubility of $PbCrO_4$ (major component)	0.058 mg/L (at 25°C) 0.17 mg/L (at 20°C)
Water solubility of $PbSO_4$ (minor component)	42.5 mg/L (at 25°C)
Experimental, total dissolved chromium*	0.012; 0.10; 0.179 mg/L (at 21-25; 19.5-20.4; 13-17°C
Experimental, total dissolved lead*	0.02; 0.36; 0.223 mg/L (at 21-25; 19.5-20.4; 13-17°C)
Calculated, parent substance*	0.062; 0.693; 0.764 mg/L (at 21-25; 19.5-20.4; 13-17°C)
Partition coefficient - octanol/water (log value)	Not applicable
Dissociation constant	Unknown

2. Regulatory framework

This chapter gives an overview of how C.I. Pigment yellow 34 (CAS: 1344-37-2) is addressed in existing and forthcoming EU and Danish legislation, international agreements and eco-label criteria.

For readers not used to dealing with legislative issues, Appendix 1 provides a brief overview of and connections between legislatives instruments in EU and Denmark. The appendix also gives a brief introduction to chemicals legislation, as well as a brief introduction to international agreements and the aforementioned eco-label schemes.

2.1 Existing legislation

Both the EU and Danish regulations specifically address the use of C.I. Pigment Yellow 34.
The current regulation of C.I. Pigment Yellow 34 (CAS: 344-37-2) listed in Table 2-1 below includes national and EU legislation, including i.e. the REACH Regulation, the CLP regulation and the regulation of the use of chemicals at the workspace.

Furthermore, the exposure of consumers is regulated through directives addressing and setting limits for the content of lead and/or chromium in for example cosmetics, toys and drinking water. In addition, numerous other legislations cover lead in general, e.g. with respect to emissions and lead in food and feed. For a thorough review of national and EU regulation for lead and lead compounds in general, reference is made to the Danish EPA survey for lead and lead compounds (Danish EPA 2014a).

TABLE 2-1
EU AND DANISH LEGISLATION ADRESSING C.I. PIGMENT YELLOW 34 (CAS: 1344-37-2)

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
Regulation addressing substances, mixtures and articles		
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	EU	REACH registered in the Tonnage band: 1000-10.000 tonnes per year. On the REACH Candidate list Included on Annex XIV for substances subject to authorisation. Sunset date: 21/5-2015.
COMMISSION REGULATION No 836/2012 of 18 September 2012 amending **Annex XVII** to regulation (EC) no. 1907/2006 of the European Parliament and of the Council	EU	Prohibits the placing on the market and use of lead and its compounds in metallic and non-metallic parts of jewellery articles, if the lead concentration is equal to or greater than 0.05 % by weight of the

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) as regards lead		individual part, unless it can be demonstrated that the rate of lead released does not exceed the limit of 0.05 µg/cm² /h (0.05 µg/g/h).
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.	EU	An EU harmonised classification applies to C. I. Pigment Yellow 34 (see section 2.1.1.1).
Danish Statutory Order: BEK nr. 856 af 05/09/2009	DK	This statutory order on lead bans all* import and sale of products that contain lead. Products are covered by this regulation when lead represents more than 100 ppm (mg/kg) of their homogeneous components (certain exemptions apply). *Raw materials and semi-finished goods are not part of the scope.
Directive 2009/48/EC relating to toy safety (with reference to Directive 88/378/EEC) Implemented in Denmark by the Danish Statutory Order: Bekendtgørelse om sikkerhedskrav til legetøjsprodukter BEK nr. 13 af 10/01/2011	EU/DK	Sets limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present. Limit values for lead in toys (Commission Directive 2012/7/EU of 2 March 2012): - In dry, brittle, power-like or pliable toy material: 13.5 mg/kg - In liquid or sticky toy material: 3.4 mg/kg - In scrapped-off toy material: 160 mg/kg

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste	EU	The sum of concentration levels of lead, cadmium, mercury and hexavalent chromium present in packaging or packaging components shall not exceed 100 ppm by weight. The concentration levels referred to in paragraph 1 shall not apply to packaging entirely made of lead crystal glass as defined in Directive 69/493/EEC (1).
Danish Statutory Order Bekendtgørelse om visse krav til emballager BEK nr. 1049 af 10/11/2011	DK	Danish Statutory Order stipulates in addition: Lead may not be added intentionally in the production of plastic boxes or pallets. By derogation of the general requirements, glass packaging may be used if the sum of the substances does not exceed 250 ppm in weight, in glass packaging based on recycled glass where the substances are not intentionally added. The order may only be relevant if C.I. Pigment Yellow 34 is applied in the production of packaging
REGULATION (EC) No 1223/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 30 November 2009 on cosmetic products.	EU	Lead as well as chrome and chrome-salts are included on Annex II on the list of substances prohibited in cosmetic products. Thus, C.I. Pigment Yellow 34 is implicitly covered by this list.
Environment and waste regulation		
DIRECTIVE 2000/60/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 23 October 2000 establishing a framework for Community action in the field of water policy.	EU	C. I. Pigment Yellow 34 is as a consequence of its classification as Carc. 1B included on Annex VIII (Indicative list of main pollutants). Lead and lead compounds are identified as a priority substance in the field of water policy (Annex X of the Directive)
DIRECTIVE 2008/105/EC on environmental quality standards in the field of water policy.	EU	Annex I: Environmental quality standards (EQS) for priority substances and certain pollutants. No quality standards are specified for

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
		CAS: 1344-37-2. However the EQS for lead and its compounds is: 7.2 µg/L.
Executive Order no. 1022 of 25/08/2010 (Order on environmental quality standards for water bodies and requirements for the discharge of pollutants into rivers, lakes or the sea).	DK	No quality standards are specified for C. I. Pigment Yellow 34. However the EQS for lead and its compounds is 0.34 µg/L (2.8 µg/L for short term releases) and for 3.4 µg/L chrome (III) (17 µg/L for short term releases).
DIECTIVE 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain directives.	EU	C.I. Pigment Yellow 34 is as a consequence of its classification as hazardous covered by the inclusion criteria in Annex III: Properties of waste which render it hazardous.
Danish regulation on waste "Affaldsbekendtgørelsen" 1309/18/12 (Danish regulation on waste).	DK	C.I. Pigment Yellow 34 is as a consequence of its classification as hazardous covered by the inclusion criteria in Annex 4: Properties and weight % for the classified substance which classifies waste as hazardous
Working environment		
COUNCIL DIRECTIVE 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work. Chemical Agents Directive Implemented by Danish Statutory order: Bekendtgørelse om arbejde med stoffer og materialer med senere ændringer	EU/DK	The requirements of this Directive apply where hazardous chemical agents are present or may be present at the workplace. Hazardous chemical agent means: any chemical agent which meets the criteria for classification as a dangerous substance according to the criteria in Annex VI to Directive 67/548/EEC. Annex I of the directive set an occupational exposure limits OEL for inorganics lead and its compounds of 0.15 mg/m^3 (8 hour average). Annex II further states binding biological limit values and health surveillance measures for inorganic lead and its compounds. This Executive Order applies to any work with substances and materials, including their manufacture, use and handling. The Order demands the employer to ensure that dangerous

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
BEK nr. 292 af 26/04/2001		substances and materials at the workplace are eliminated, replaced or reduced to a minimum. Annex 1 set specific requirements for work, where a risk of exposure to lead and its compounds, is expected.
Danish Statutory Order; Bekendtgørelse om ændring af bekendtgørelse om grænseværdier for stoffer og materialer (BEK nr. 1134 af 01/12/2011)	DK	The statutory order has a List of limits for gases, vapors and particulate pollution. For Lead the limit is: 0.05 mg/m^3 For chrome and chromate the limit is 0.5 mg/m^3 and 0.005 mg/m^3 respectively.
Executive Order No. 559 of 17 June 2004. Danish executive order: on the Performance of Work.	DK	Section 16. Any unnecessary effect of substances and materials shall be avoided. Therefore, the effect of substances and materials during work shall be reduced to the lowest level reasonably practicable taking account of technical progress, and any limit values fixed shall be complied with.
DIRECTIVE 2004/37/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work Carcinogens Directive Implemented by Danish Statutory Order: Bekendtgørelse om foranstaltninger til forebyggelse af kræftrisikoen ved arbejde med stoffer og materialer BEK nr. 908 af 27/09/2005	EU/DK	On the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC). Appendix 1. section A; determines the percentage of the substance, a material must contain in order to be covered by this notice. No percentage is stated for I. C. Pigment Yellow 34.
Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety	EU/DK	Sets out measures to protect pregnant workers and workers who have recently given birth or are breast-feeding, including requirement to

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
and health of pregnant workers and workers who have recently given birth or are breast-feeding Implemented by Executive order no. 559 of 17 June 2004 with later amendments on the performance of work		assess exposure to health risks, also specifically addressing lead and lead compounds. Annex II contains a list of agents, work processes and working conditions which may involve danger to the pregnant and breastfeeding worker.
Council Directive 94/33/EC on the protection of young people at work Implemented by Executive order no. 239 of 6 April 2005 with later amendments on young people's work	EU/DK	Prohibits the use of chemical agents, including lead compounds, by young workers.
Regulation addressing industry and emission/levels in the environment		
Commission Decision 2000/479/EC on the implementation of a European pollutant emission register (EPER)	EU	Sets out the requirements for reporting environmental releases of pollutants, including lead and lead compounds, from industrial facilities regulated under Council Directive 96/61/EC on integrated pollution prevention and control (IPPC).
Drinking water and food		
COUNCIL DIRECTIVE 98/83/EC of 3 November 1998 on the quality of water intended for human consumption.	EU	Member States shall take the measures necessary to ensure that the quality of water intended for human consumption complies with the Directive : Chromium: 50 µg/L Lead: 10 µg/L
Regulation 10/2011 on plastic materials and articles intended to come into contact with food	EU	Lead is only specifically mentioned in the purity specifications for one copolymer. Limit: 2 mg Pb/kg plastic. However, no lead or lead compounds are on the Union list of authorized monomers, other starting substances,

Legal instrument	EU/DK	Requirements as concerns C. I. Pigment Yellow 34
		macromolecules obtained from microbial fermentation, additives and polymer production aids.
Danish statutory order no. 822/2013 on food contact materials	DK	https://www.retsinformation.dk/Forms/R0710.aspx?id=152320 Sets a limit of migration from ceramics, enameled food contact materials, and glass. Note that metal grills and hot drink machines may contain lead, and this needs to be addressed in legislation, and enforced. May only be relevant if C.I. Pigment yellow 34 is applied in the production of food contact material/metal grills and hot drink machines

2.1.1 Classification and labelling

2.1.1.1 Harmonised classification in the EU

C.I. Pigment yellow 34 (CAS: 1344-37-2) has a harmonised classification according to (EC) No 1272/2008, see table 2-2.

TABLE 2-2
HARMONISED CLASSIFICATION AND LABELLING FOR C.I.PIGMENT YELLOW 34 (CAS: 1344-37-2) (FROM ECHA C&L DATABASE, DECEMBER, 2013)

Chemical identification (CAS No)	Classification	
	Hazard Class and Category Code(s)	Hazard statement Code(s)
1344-37-2	Carc. 1B	H350
	Repr. 1A	H360Df
	STOT RE 2	H373
	Aquatic Acute 1	H400
	Aquatic Chronic 1	H410

H350: May cause cancer; H360Df: May damage the unborn child. Suspected of damaging fertility; H373: May cause damage to organs through prolonged or repeated exposure; H400: Very toxic to aquatic life; H410: Very toxic to aquatic life with long lasting effects.

Furthermore the substance needs be labeled with the following hazard pictograms:

Environment

Health hazard

2.1.1.2 Notified classification in the EU

According to ECHA inventory for classification and labelling 513 notifiers have submitted a classification for C.I. Pigment Yellow 34. Only 10 of these notified classifications are not in accordance with the harmonized classification and 2 notifiers do not classify C. I. Pigment Yellow 34 at all.

2.2 REACH and risk assessments

C.I. Pigment Yellow 34 (CAS: 1344-37-2) is registered under REACH (1,000-10,000 tonnes). The registration dossier therefore has to comply with the information requirement in REACH Annex VI-XI.

C.I. Pigment Yellow 34 is not on the Community Rolling Action Plan (CoRAP) for substance prioritized for further evaluation.

C.I. Pigment Yellow 34 is included on the candidate list of Substances of Very High Concern (SVHC) due to its classification as carcinogenic and toxic to reproduction (ECHA, 2009). The notified uses of C.I. Pigment Yellow 34 in articles are presented in Table 3-1. The main identified use is pigments.

The substance is placed on the authorization list (Annex XIV) under REACH with a sunset date in May 2015. This implies that EU companies wishing to manufacture or import C.I. Pigment Yellow 34 will have to apply for authorization for use after May 2015. After the deadline for application (November 2013) one application for six different types of uses has been forwarded to ECHA from one applicant (see section 3.3.1).

There is no EU risk assessment for P. I. Pigment Yellow 34. EU Risk assessment Reports for chrome compounds (CAS: 1333-82-0; 7775-11-3; 10588-01-9; 7789-09-5 and 7778-50-5 (EU, 2005)) are available. A voluntary risk assessment report is available for lead and lead compounds (ECHA, data retrieved December 2013) but C.I. Pigment Yellow 34 and the CAS numbers referred to in Chapter 1 “Introduction to the substance” are not specifically included in this report.

2.2.1 International agreements

Lead is listed in Annex II of the Barcelona convention, the Annex regards Harmful or Noxious Substances and Materials for which the disposal in the Protocol Area is subject to a special permit.

The Basel convention sets out control measures of the movements of hazardous waste incl. waste containing lead between nations, and restricts transfer of hazardous waste from developed to less developed countries (non-adopted). The convention also intends to minimize the amount and toxicity of wastes generated to ensure their environmentally sound management as closely as possible to the source of generation, and to assist least developed countries (LDCs) in environmentally sound management of the hazardous and other wastes they generate.

2.2.2 Other legislation/initiatives

C. I. Pigment Yellow 34 is included as a substance in the SIN-list database developed by the Chemical Secretary (ChemSec.) (Data search December 19, 2013). The SIN-list includes substances which are identified by ChemSec as fulfilling the criteria for Substances of Very High Concern as defined in the REACH regulation.

C.I. Pigment Yellow 34 is also included on the PRIO-list developed by KEMI (the Swedish Chemical Agency) which is a web-based tool intended to be used to preventively reduce risks to human health and the environment from chemicals.

C.I. Pigment Yellow 34 is not included on the priority list developed by the Norwegian Environmental Authorities, who have a national objective of reducing the use and release of chemicals that pose a serious and continuous threat to health and the environment. However lead is listed (Klif, Data search October 21, 2013).

2.3 Eco-labels

Eco-labels are voluntary labeling schemes that can be applied to a range of products and services to document compliance with a specific set of criteria. This section will focus on the Nordic Swan, the EU flower and the German Blue Angel, which represent the eco-labels most often encountered on products on the Danish market. The Nordic Swan and the EU flower can largely be regarded as having the same criteria, and the EU flower is therefore considered as covered by the description of the Nordic Swan.

The use Pigment Yellow 34 – and other lead compounds - is generally prohibited or restricted in eco-labelled products due to the classification as a CMR substance. The Nordic eco-label, the Nordic Swan cover more than 60 different consumer product groups, ranging from alternatives to dry cleaning to dishwasher machines and vehicle tires. Thus, Pigment Yellow 34 is not specifically mentioned in the criteria but is covered by the general exclusion criteria for CMR substances.

2.4 Summary and conclusions

The Danish EPA has included C.I. Pigment Yellow 34 on the LOUS list (2009) based on its classification as carcinogenic (Carc. 1B; H350) and as toxic to reproduction (Repr. 1A; H360Df) In addition the annual tonnage level used in Denmark is above 100 tonnes.

C.I. Pigment Yellow 34 is regulated through both national and EU legislation. The substance is subject to harmonized CLP classification as Carc. 1B, Repro. 1A, STOT RE 2, Aquatic Acute 1 and Aquatic Chronic 1, and is thus covered by several down-stream regulations due to this classification, i.e. specific occupational regulation apply for working with carcinogens. At national level a general regulation on lead was implemented in 2001 the import and sale of products containing more than 100 ppm (mg/kg) of lead was banned (with some exemptions).

Furthermore the exposure of consumers is regulated through directives addressing and setting limits for the content of lead and/or chromium in for example cosmetics, toys and drinking water. In addition, numerous other legislations cover lead in general, e.g. with respect to emissions from industrial processes and with respect to impurities/ contamination of lead in food and feed.

C.I. Pigment Yellow 34 is registered under REACH (at a tonnage band of 1,000-10,000 tonnes), and is placed on the authorization list (Annex XIV) under REACH with a sunset date in May 2015

The Eco labelling criteria (e.g. the criteria for the EU flower and the Nordic swan) generally exclude the use of C.I. Pigment Yellow 34 in eco-labelled products due to its classification as Carc 1B and Repro 1A.

3. Manufacturing

3.1.1 Manufacturing processes

The substance C.I. Pigment Yellow 34 does not occur naturally in the environment. The principal metallic components of this substance, lead and chromium, are naturally occurring and are as such 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 (Environment Canada/ Health Canada 2008)

C.I. Pigment Yellow 34 is formed by co-precipitation 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). In order to be stable under environmental conditions, C.I. Pigment Yellow 34 is normally modified with small amounts oxides of Lanthanides, Al, Ce, Sb, Si, Sn, Ti, Zn, Zr, or Fluorine salts (ECHA, 2010).

3.1.2 Manufacturing sites and volumes

The HPV (High and low production volume) chemical program of OECD lists the following 9 manufacturers and importers in Europe: four in Germany and one in France, Spain, Belgium, Italy, and the Netherlands, respectively (ECHA, 2010). The SIN-list database (ChemSec.) further states the following producers: BASF, BASF Pigment GmbH, Germany Bruchsaler Farbenfabrik, Bruchsaler Farbenfabrik GmbH & Co. KG, Germany Habich, Habich GmbH, Austria Heubach Group, Heubach GmbH, Germany Nubiola Group, Nubiola Pigmentos, Spain Poliversal, Poliversal Av., Portugal Schilderwerken Thimister Maastricht, DCC Maastricht B.V., Netherlands.

C.I. Pigment Yellow 34 is registered under REACH with a total tonnage band of 1,000-10,000 tonnes/year. According to the association of European Manufacturers of Lead Chromate and Lead Molybdate Pigments (Annex XV dossier, 2009) the volume of lead chromate pigments (C.I. Pigment Yellow 34 plus C.I. Pigment Red 104) produced in Europe in 2008 was 30,000 tons, with 65% representing C.I. Pigment Yellow 34 i.e. 19,500 tons (ECHA, 2010).

3.2 Import and export

Data obtained from Danish Companies using Pigment Yellow 34 indicate that the substance is imported. More than 100 tonnes per year is used as raw materials in plastics manufactured for export to other countries (Danish EPA 2014b).

3.3 Uses

EU

The current uses in the EU include (ECHA 2010):

- Coloration of plastics covering ~60% of the EU market for the pigments. This use concerns each type of plastic material/composite (polyolefins, polyvinyl chloride and nylon) as well as each process of modelling (injection, extrusion, etc). Applications in this sector include industrial carpet fibers, automotive interiors, non-food packaging, rust resistant furniture and electronic housings. Examples of finished products include trash bags, industrial packaging, piping and tubing, PVC profiles, tarpaulins (Annex XV dossier, 2009).

- Coatings (e.g. paints, varnishes) covering ~40% of the EU market.
  These pigments are used in a variety of industrial coatings. Applications in this sector include:
  - Vehicles not covered by the end of live vehicles directive (trucks, buses, commercial vehicles, vintage cars)
  - Agricultural equipment
  - Civil engineering material
  - Boats / Ships
  - Road sign and road painting / Thermoplastic road marking / Airport horizontal painting
  - General industrial: skips, plant and machinery; industrial doors, pumps, machinery; large steel structures; gas cylinders; off shore steel structures (e.g. drilling rigs)
  - Camouflage / ammunition, interior coatings for military equipment
  - Aeronautics
  - Coil coating
  - Coating of plastic material (PVC, PP, ABS edge bands)
  - Glass reinforced plastic constructions (boats, auto parts, silos)
  - Coatings that can be applied to industrial surfaces by printing, such as decals (e.g. used for commercial identification)
  - Thermochromic paint

No new uses outside from the established ones in plastics and coatings are foreseen. Other uses mentioned in the literature, which could not be confirmed, include textile printing, leather finishing, printing inks (e.g. outer surface of food packaging), tattoo inks, artists' paints, mastics, paper, linoleum / flooring compounds, colouring of rubber, and wall covering (ECHA 2010).

The identified uses of C.I. Pigment Yellow 34 in EU is related to article categories which have been reported during the REACH registration are listed in Table 3-2 below (ECHA Notification Information, retrieved January 10 2014).

TABLE 3-1
REGISTRATION INFORMATION ON IDENTIFIED USES OF C.I. PIGMENT YELLOW 34 IN ARTICLES (CAS: 1344-37-2) (ECHA NOTIFICATION INFORMATION, RETRIEVED JANUARY 2014)

Article category	Uses
Machinery, mechanical appliances, electrical/electronic articles	Pigment in articles
Metal articles	Pigment in articles
Plastic articles	Pigment in articles
Rubber articles	Pigment in articles
Stone, plaster, cement, glass and ceramic articles	Pigment in articles
Vehicles	Pigment in articles
Wood articles	Pigment in articles

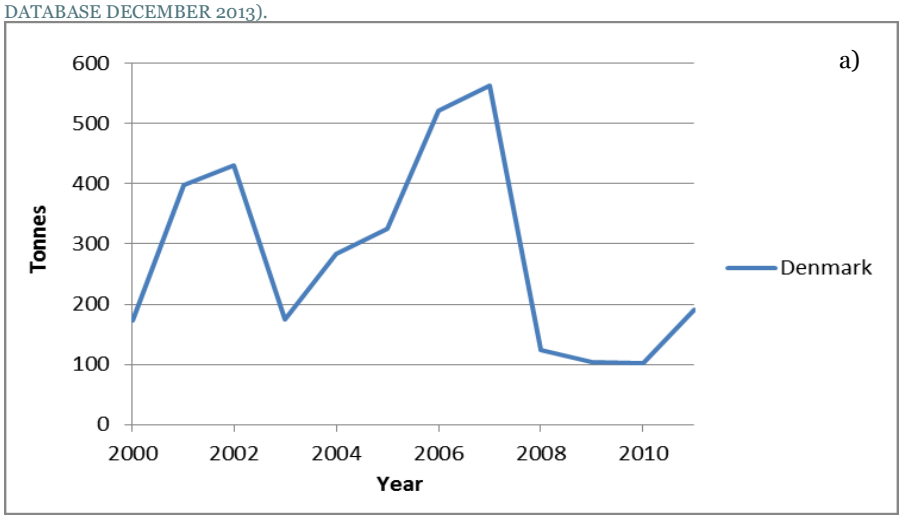
The Nordic countries

The Nordic SPIN database ("Substances in Preparations in the Nordic Countries") is the result of a common Nordic initiative to gather non-confidential data on the use of chemical substances in different types of preparations and industrial areas.

Data from the Nordic SPIN database is shown in Figure 3-1 and displays the total tonnage of C. I. Pigment yellow 34 (CAS: 1344-37-2) which is used in preparations in the Nordic countries. Figure 3-2 displays the corresponding numbers of preparations.

It can be seen that the use of C.I. Pigment Yellow 34 is especially high in Denmark (191 tonnes in 2011) compared to Norway, Sweden and Finland (less than 10 tonnes in each country. In Denmark the tonnage has almost doubled from 102 tonnes in 2010 to 191 tonnes 2011. In Sweden the tonnage is 0 tonnes (2011) and in Norway it has reached a steady state the last few years (about 10 tonnes). In Finland there is a slight increase from 2010 to 2011.

FIGURE 3-1
TOTAL TONNES OF C.I. PIGMENT YELLOW 34 (CAS. NO. 1344-37-2) INCLUDED IN PREPARATIONS ON A) THE DANISH MARKET AND B) FINLAND, NORWAY AND SWEDEN FROM 2000 TO 2011 (DATA RETRIEVEDFROM THE SPIN DATABASE DECEMBER 2013).



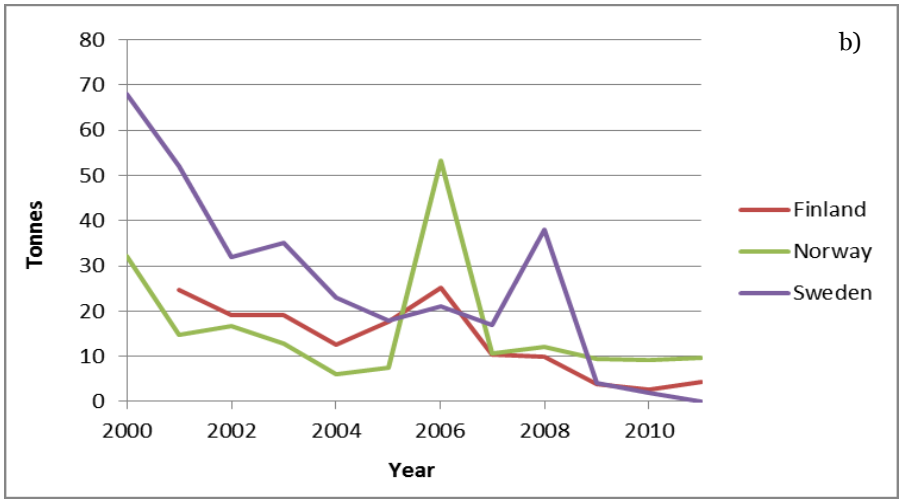
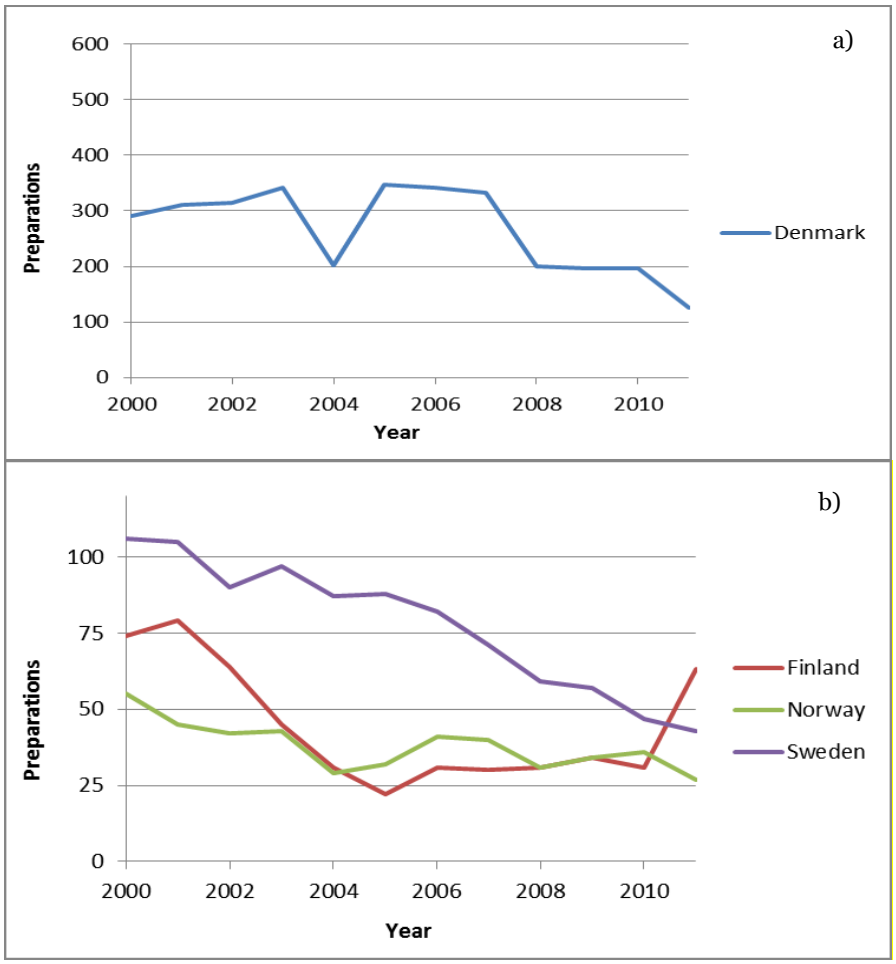


FIGURE 3-2
TOTAL NUMBERS OF PREPARATIONS CONTAINING C.I. PIGMENT YELLOW 34 (CAS. NO. 1344-37-2) ON A) THE DANISH MARKET AND B) FINLAND, NORWAY AND SWEDEN FROM 2000 TO 2011. (DATA RETRIEVEDFROM THE SPIN DATABASE DECEMBER 2013).



Recent data from the Danish Product Registry (2014) have shown an annual tonnage level of 112 tonnes of Pigment Yellow 34 of which 106 tonnes are used for raw materials (not covered by the Danish ban on lead). Data from specific companies indicate that at least 90-95% of this is used as couloring in plastics, which is exported to other countries. Some of the remaining 6 tonnes not used in exported articles seems to be covered by old registrations that may not necessarily be valid anymore . However, still a low volume may be used in Denmark for anti-corrsion, anitfouling and for restoration/ repair work (e.g. of historical buildings) (Danish EPA 2014b).

3.3.1 Uses applied for under the REACH authorisation

In the future (i.e. after the May 2015 sunset date) Pigment Yellow 34 can only be used by companies that have applied for and received an authorisation for the use. Currently one applicant has forwarded an application to ECHA for the six following uses of Pigment Yellow 34 (ECHA 2014):

1 Distribution and mixing pigment powder in an industrial environment into solvent-based paints for non-consumer use.
2 Industrial application of paints on metal surfaces (such as machines vehicles, structures, signs, road furniture, coil coating etc.).
3 Professional, non-consumer application of paints on metal surfaces (such as machines, vehicles, structures, signs, road furniture etc.) or as road marking.
4 Distribution and mixing pigment powder in an industrial environment into liquid or solid premix to colour plastic/plasticised articles for non consumer use.
5 Industrial use of solid or liquid colour premixes and pre-compounds containing pigment to colour plastic or plasticised articles for non-consumer use.

6 Professional use of solid or liquid colour premixes and pre-compounds containing pigment in the application of hotmelt road marking.

Thus all these uses are in relation to non-consumer uses. The decision whether the applicant will achieve authriosation for these uses will be taken by ECHA and the Commission in late 2014.

3.4 Historical trends in use

The overall historical trend in the use for the Nordic countries within the last 14 years can be seen from Figure 3-1 and 3-2 which show a gradually decrease in tonnage level.
According to the SPIN Database the use of C.I. Pigment Yellow 34 reported for Denmark (2003-2010) was stated as paint, lacquers and varnishes and coloring agents. In 2011 C. I. Pigment Yellow 34 was especially applied in pigments to paint and printing inks as well as other colouring agents. In Denmark the tonnage and the numbers of preparations which include Pigment Yellow 34 has declined in recent years (Figure 3-1 and 3-2). In Norway (2005-2011) and Sweden (2009-2011) the use was mainly stated as "Paint and varnish Volatile organic thinner Decorative/protection Industrial use". In Norway the tonnage applied is more or less steady and the numbers of preparations is declining. In Sweden and Finland both the numbers of preparations and the tonnage is declining. There is no specified use for Finland (SPIN database, 2013).

3.5 Summary and conclusions

C.I. Pigment Yellow 34 is registered under REACH (1,000-10,000 tonnes). The volume of lead chromate pigments (C.I. Pigment Yellow 34 plus C.I. Pigment Red 104) produced in Europe in 2008 was 30,000 tons, with 65% representing C.I. Pigment Yellow 34 i.e. 19,500 tons (Association of European Manufacturers). In EU C.I. Pigment Yellow 34 is mainly used in plastics (~60%) and in paint and coatings (~40%) mainly for professional uses.
Data from the Nordic SPIN database indicate that C.I. Pigment Yellow 34 in the Nordic countries is used in preparations such as a binding agent, as coloring agent as well as a component in paint and lacquers and for plastic-, rubber- and metal articles.
In Denmark the annual tonnage has in the last decade varied between approximately 100 and 500 tonnes with a declining trend. Recent data from the Danish Product Register from 2014 shows an annual consumption of 112 tonnes (about 50 preparations). The majority (about 106 tonnes) is used as raw materials and about 90-95% of this is used as coloring agent in plastics that is exported to other countries. Some of the remaining 6 tonnes not used as raw material seems to be covered by old registrations that may not necessarily be active anymore . However, still a low volume may be used for anticorrosion, antifouling and for restoration/ repair work (e.g. of historical buildings). Thus, today the amount of C.I. Pigment Yellow 34 used in Denmark for products and articles for the Danish market may be considered very limited. An unknown amount of C.I. Pigment Yellow 34 may be imported from surface treated articles or from plastics containing the pigment.

As Pigment Yellow 34 is subject to authorisation under REACH **all** uses of the substance will be banned after the sunset date of May 2015 unless an authorsiation for its use has been granted by the EU-Commission. This will limit or even totally restrict the future use of Pigment Yellow 34. At present only one company has submitted an application for six types of industrial and professional uses. The application is currently being evaluated by ECHA before a final decision will be taken by the Commission in late 2014.

4. Waste management

4.1 Waste from manufacture and use of C.I. Pigment Yellow 34

Industrial waste should to be treated as hazardous waste if the waste contains substances in an amount that according to classification rules for chemical substances and preparations would result in classification for either physico-chemical, toxicological or environmental properties (Danish Ministry of Environment, 2012; DIRECTIVE 2008/98/EC).

Waste is considered as hazardous if it exhibits one or more of the characteristics listed in Table 1 in Annex IV of the Danish statutory order on waste (Bek. 1309 of 18/12/2012). The limits indicated in table 2 of the order, are the limits in relation to the old chemical classification system. Below is indicated the concentration limits for the various classifications that are applied for C.I. Pigment Yellow 34

Carc. Cat 2; R45	≥ 0.1%
Repr. Cat. 1; R61	≥ 0.5%
Xn; R48	≥ 10%

Thus, the limit for classification as hazardous waste would be a content of 0.1% (1000 mg/kg) in the waste.

4.2 Waste treatment

About 65% of the industrial use of C.I. Pigment Yellow 34 in EU has been estimated to end up in waste whereas approximately 35% may be released to the aquatic environment in connection with manufacture and industrial use (see chapter 5).

In 2003 the Danish EPA analyzed various industrial activities where lead may be a part of the waste and guides were elaborated in order to provide instructions on how to identify heavy metals in waste and ideas on how to achieve a higher degree of sorting and recycling of heavy metals (Danish EPA 2003). The guide comprises instructions for 16 types of enterprises:

> *metal-processing enterprises, plastics-processing enterprises, carpenters/joiners, plumbing and heating firms, plumbers and locksmiths' shops, electricians, bricklayers , damage services, demolition enterprises, scrap dealers, electronics scrap dealers, cable-processing enterprises, sorting plants, garages, fishery, hospitals and dental clinics*

Thus industries where C.I. Pigment yellow 34 may be handled or used are covered e.g. *metal-processing enterprises, plastics-processing enterprises, electricians, damage services, demolition enterprises, scrap dealers, electronics scrap dealers, cable-processing enterprises, sorting plants, garages.*

For waste from households C.I. Pigment yellow 34 may primarily be contained in articles e.g. plastics, and articles with paint / lacquers containing the substance. These fractions may either be incinerated (various combustible articles with high energy content) or recycled (e.g. various types of plastics or metallic parts). Due to the limited use of C.I. Pigment yellow 34 in consumer products

the substance may only rarely occur in household waste. It may, however, be very difficult to identify the relevant items in this waste fraction.

4.3 Recycling of waste containing C.I. Pigment Yellow 34

No data on recycling of C.I. Pigment Yellow 34 has been found. It seems very difficult to imagine a targeted recycling of waste containing the substance as it would very difficult and resource-demanding to identify waste where C.I. Pigment Yellow 34 has been used either as surface coloring of different articles or as a pigment in PVC plastics.

4.4 Summary and conclusions

Waste containing C.I. Pigment Yellow 34 has to be treated as hazardous waste if the content of the substance in the waste is above 0.1% due to the carcinogenic properties of the substance.

For industrial enterprises where use or handling of C.I. Pigment Yellow 34 may occur (either as raw materials or in plastic, paint or lacquers) guidance has been elaborated by the Danish EPA concerning the correct treatment of waste containing lead or other heavy metals.

In waste from households C.I. Pigment yellow 34 may be anticipated to occur only rarely due to the limited use in consumer products. Household waste may either be incinerated (various combustible articles with high energy content) or recycled (e.g. plastics or metallic parts).

5. Environmental effects and exposure

5.1 Environmental hazard

As mentioned in chapter 2 C.I. Pigment Yellow 34 has a harmonized classification as hazardous to the aquatic environment (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410). The toxicity is considered to be associated to the liberation of lead and chromate ions from C.I. Pigment Yellow 34.

5.1.1 Toxicity to aquatic organisms

The results of aquatic toxicity testing of C. I. Pigment Yellow 34 are shown in table 5.1. The measured concentrations of dissolved lead and chromium in these tests are shown in table 5.2.

TABLE 5-1
EMPIRICAL DATA FOR AQUATIC TOXICITY OF C.I. PIGMENT YELLOW 34 (ENVIRONMENT CANADA/ HEALTH CANADA 2008)

Test organism	Type of test	Endpoint	Duration (hours)	Value (mg/L)
Scenedesmus subspicatus (Algae)	Acute	EC_{50}[1]	72	> 100[2]
Daphnia magna (Invertebrate)	Acute	EC_{50}[3]	48	> 100[2]
Oncorhynchus mykiss (Rainbow Trout – Fish)	Acute	LC_{50}	96	> 100[2]

[1] Effect on growth rate or development of biomass.
[2] No effect at 100 mg/L loading rate, the highest nominal concentration tested.
[3] Immobilization.

TABLE 5-2
SOLUBILITY DATA IN AQUATIC TOXICITY STUDIES OF C.I. PIGMENT YELLOW 34 (ENVIRONMENT CANADA/ HEALTH CANADA 2008)

Parameter	Algae study	Invertebrate study	Fish study
Experimental, total dissolved chromium[1]	0.012 mg/L	0.10 mg/L	0.179 mg/L
Experimental, total dissolved lead[1]	0.02 mg/L	0.36 mg/L	0.223 mg/L
Temperature	21–25 °C	19.5–20.4 °C	13–17 °C

[1] 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 litre.

Green algae, *Scenedesmus subspicatus* cultures, were exposed to C.I. Pigment Yellow 34 (Study Submission 2006a, Environment Canada/ Health Canada, 2008)). The tests were run at a water temperature of 23 °C and a pH of 7.1 on average. The water hardness level was not mentioned. The

substance C.I. Pigment Yellow 34 was added to deionized water, stirred during 20 hours and the undissolved test substance was removed by filtration (0.2 µm). Total dissolved metals (Cr, Pb) were measured in the filtrate (table 5.2). Organisms were exposed to the full strength filtrate (nominal 100 mg/L) and subsequent dilutions of the filtrate. There were no significant effects on the reduction in biomass or on the growth rate of algae in any of the concentrations tested after 72 hours (Health Canada, 2008).

C.I. Pigment Yellow 34 was also tested on *Daphnia magna* (Study Submission 2006b, Environment Canada/ Health Canada, 2008). The water temperature during the test varied between 19.5 and 20.4°C, pH oscillated between 7.4 and 8.1 and the hardness was in between 220 and 241 mg/L as $CaCO_3$. The test substance was added to test medium, stirred during 24 hours and the undissolved test substance was removed by filtration (0.2 µm). Total dissolved metals (Cr, Pb) were measured in the filtrate (table 5.2). Organisms were exposed to the full-strength filtrate (nominal 100 mg/L) and subsequent dilutions of the filtrate. No effects were observed: all daphnids were mobile after 48 hours in each of the concentrations tested.

Finally, the pigment was tested on fish. Juvenile Rainbow Trout, *Oncorhynchus mykiss* were exposed during 96 hours to a moderately hard groundwater containing the test substance (Study Submission 2006c, Environment Canada/ Health Canada, 2008). Average hardness and pH of the test water were 230 mg/L as CaCO3 and 8.3, respectively. The water temperature ranged from 13 to 17°C. Each of the test concentrations (1000; 100; 10 and 1 mg/L) were prepared as follows. All test solutions containing the various amounts of test substance were stirred overnight, followed by 2 filtrations (1 and 0.45 µm) to remove the undissolved test substance. Total dissolved metals (Cr, Pb) were measured in the filtrate (table 5.2). Fish were exposed to the filtrates and no mortality was observed in any of the concentrations tested after 96 hours.

No acute toxicity was thus observed at the three trophic levels at a loading rate corresponding to 100 mg/L. Chronic toxicity studies were not available. The available acute toxicity data do not trigger a classification as environmentally hazardous. The harmonized classification of C.I. Pigment Yellow 34 for aquatic toxicity is most likely based on the general environmental concern for substances that contain and may be a potential for release of lead-ions and chromates-ions. Most lead and chromate compounds thus have a harmonized classification as hazardous to the environment (Aquatic acute 1 and Acuatic chronic 1).

5.1.2 Predicted No Effect Concentration (PNEC) – Aquatic organisms

All laboratory studies showed that there were no effects observed on aquatic organisms at measured concentrations resulting from a 100 mg/L loading rate of the parent substance. It should be noted that the proportion that dissolves could be higher under different environmental conditions. For calculating a PNEC an assessment factor of 1000 is applied resulting in a PNEC (freshwater) of 0.1 mg/L.

5.1.3 Toxicity to microorganisms

No data

5.1.4 Toxicity to sediment living organisms

No data

5.1.5 Toxicity to terrestrial organisms

No data

5.1.6 PBT

A metal ion is considered infinitely persistent.

The substance C.I. Pigment Yellow 34 is considered persistent because both of its moieties of concern, the lead (Pb^{2+}) and the chromate (CrO_4^{2-}) ions are considered infinitely persistent and C.I. Pigment Yellow 34 thus meets the persistence criteria.

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, although reports are available that documents uptake and bioaccumulation of lead by organisms in aquatic ecosystems. Therefore, such substances are evaluated only on the basis of their properties relating to toxicity and persistence (Environment Canada/ Health Canada, 2008). It is anticipated that evolution of scientific understanding will eventually allow broader interpretation of the potential for bioaccumulation for such substances.

5.2 Environmental fate

5.2.1 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 ($CrO4^{2-}$) ions in typical aquatic media with a pH between 6 and 8 under conditions that are moderately oxic (~ 0.4-0.7 V, or dissolved oxygen > 4 mg/L) (Annex XV dossier, 2009). 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 (ECHA, 2009).

5.2.2 Environmental degradation

As a metal-containing inorganic substance, a fate analysis based on log Kow and Koc 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 (ECHA, 2009). 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 (ECHA, 2009).

Due to the lack of hydrolysable groups in the substances hydrolysation is not expected. Because the substance is inorganic and has a very low solubility in water biotic degradability studies are not relevant and hence not available.

Secondary poisoning

No available data.

5.3 Environmental exposure

5.3.1 Sources of release

Lead chromate pigments do not occur naturally 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 (ECHA, 2009).
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 (ECHA, 2009).

5.3.2 Estimated releases

To estimate the potential release of the substance to the environment at all stages of its life cycle, a mass flow tool was used (Table 5.3). Empirical data concerning releases of this substance to the environment are not available. Therefore, for each identified type of use of the substance, the proportion and quantity of release to the different environmental media are estimated, as is the proportion of the substance chemically transformed or sent for waste disposal. Assumptions and input parameters used in making these estimates are based on information obtained from a variety of sources including responses to regulatory surveys, Statistics Canada, manufacturers' websites and technical databases. Of particular relevance are emission factors, which are generally expressed as the fraction of a substance released to the environment, particularly during its manufacture, formulation and use associated with industrial processes. Sources of such information include emission scenario documents, often developed under the auspices of the Organisation for Economic Cooperation and Development (OECD), and default assumptions used by different international chemical regulatory agencies. It is noted that the level of uncertainty in the mass of substance in circulation and quantity released to the environment generally increase towards the end of the life cycle (Environment Canada/ Health Canada, 2008).

TABLE 5-3
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[1]

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

[1]For 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).
[2]Applicable 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 the substance. 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 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 (Environment Canada/ Health Canada 2008).

5.4 Environmental impact

Due to the very low solubility of C.I. Pigment Yellow 34 in water the bioavailability of the substance is expected to be low. However, a small proportion of the parent substance might dissolve and release chromate ions ($CrO4^{2-}$) and lead ions (Pb^{2+}). Both substances may have chronic effects on aquatic and sediment living organisms. Pb^{2+} and CrO_4^{2-}, are expected to be found in water, sediments and soils but not in air. The bioavailability of the ions depends on factor like pH and the amount of organic matter present. The availability of the ions is assumed to be low. Some non-dissolved C.I. Pigment Yellow 34 (as the parent substance) is also expected to be found in sediments and moist soils. No acute aquatic toxicity of C.I. Pigment Yellow 34 has been shown at the solubility limit and no chronic studies are available.

5.5 Summary and conclusions

All laboratory studies with C.I. Pigment Yellow 34 (parent substance) showed that there were no effects observed on aquatic organisms at measured concentrations resulting from a 100-mg/L loading rate of the parent substance, which is far higher than the solubility of the substance at < 0.01 mg/L. It should be noted that the proportion that dissolves depends on the environmental conditions.. Based on the available test data the substance C.I. Pigment Yellow 34 is not as such considered to be hazardous to aquatic organisms. Nevertheless C.I. Pigment Yellow 34 has a harmonized classification as environmentally hazardous (Aquatic Acute 1; H400 and Aquatic Chronic 1; H410) (ECHA C&L database, December, 2013), due to the toxicity and potential release of lead and chromate ions. It should be noted that lead and lead compounds are identified as priority substances in the field of water policy aiming at a progressive reduction of the pollution with such substances (Water Framework Directive, Annex X) and that the EU EQS for lead and its compounds is 7.2 µg/L. The Danish EQS for lead and its compounds is 0.34 µg/L.

6. Human health hazard.

6.1 Hazardous effects

The human health effects of lead and chromate has been intensively covered e.g. in the recent Danish EPA (2014a) report on 'Survey of Lead and Lead Compounds' and in the EU-RAR (2005) on chromium trioxide and chromates. Further assessment of the human health hazards and risks has been made by Environment Canada/ Health Canada (2008).

6.1.1 Classification

As mentioned in chapter 2.1.1, C.I. Pigment Yellow 34 has a harmonized classification as Carc. 1B, H350 (May cause cancer); Repr. 1A, H360Df (May damage the unborn child/ Suspected of damaging fertility); and STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure).
The toxicity of C.I. Pigment Yellow 34 to humans is considered to be associated to the potential for release of lead-ions and chromate ions from the substance. Since C.I. Pigment Yellow 34 is a non-soluble substance only minute amounts of these ions are liberated.

6.1.2 Absorption, Distribution, Metabolism and Excretion

The bioavailability of lead chromate and lead-chromate-derived pigments has been investigated in experimental animals. Due to the insoluble nature of C.I. Pigment Yellow 34 and no reported effects from acute toxicity studies very low absorption may be assumed after oral exposure.

Thus, the low solubility of C.I. Pigment Yellow 34 is indicative of limited bioavailability. Administration of non-encapsulated or silica-encapsulated Chrome Yellow/lead chromate to rats by gavage (150 mg/kg-bw d, five days per week, for four weeks) resulted, however, in an increased level of lead in the blood and kidneys. 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 (Environment Canada/ Health Canada 2008).

Overall, 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 (Environment Canada/ Health Canada 2008).

6.1.3 Acute toxicity

In acute oral studies no lethality occurred and the LD50 values was indicated to be above 5000 mg/kg bw and 10000 mg/kg bw. No data is available from acute dermal or inhalational exposure. IUCLID (2000).

6.1.4 Irritation and sensitization

According to OECD irritation tests for skin and eye irritation C.I. Pigment Yellow 34 does not cause irritation (IUCLID 2000).
No data on skin sensitization is available, however, it is well-known that low levels of dermal exposure to chromate-ions may cause skin sensitization (EU-RAR 2005; ECHA 2012).

Thus low level of chromate (Cr VI) release may pose a potential for sensitisation or elicitation of allergic symptoms among persons already suffering from chromate allergy.

Skin sensitisation is generally regarded as a threshold effect with dose-response relationships for both the induction and elicitation phase, although these are not absolute values that can be applicable to the whole population. Setting a DNEL (derived no effect level) in relation to risk assessment may therefore be difficult since individual susceptibility and other factors influence the induction and elicitation thresholds. As a general rule the dose required to induce sensitisation in a non-sensitised individual is greater than the dose required to elicit an allergic response in a previously exposed individual. Keeping exposures below the elicitation threshold should therefore protect against the induction of sensitization (ECHA 2012).

The elicitation thresholds for humans identified in the literature and presented in the table 6-1 below:

TABLE 6-1
ESTIMATED ELICITATION THRESHOLDS FOR CHROMIUM (VI), (ECHA 2012)

Elicitation threshold	Value	Unit	Number of test subjects
*MET10%	0.09	µg Cr(VI)/cm² (2 days)	54
MET10%	0.35	µg Cr(VI)/cm² (2 days)	14
MET10%	0.90	µg Cr(VI)/cm² (2 days)	17
MET10%	0.02	µg Cr(VI)/cm² (2 days)	5
MET10%	0.03	µg Cr(VI)/cm² (2 days)	18
MET10%	1.04	µg Cr(VI)/cm² (2 days)	17

*MET10%: Minimum elicitation threshold inducing a response in 10% of the subjects tested

The table shows that the database is fairly consistent. It is not possible however, to define a NOAEL from which to derive a DNEL. Instead a LOAEL of 0.02 µg/cm² (lowest MET10%) is used as a dose metric for the risk characterization. This level of exposure is expected to protect the vast majority towards induction as well as elicitation from chromium (VI) (ECHA 2012).

6.1.5 Repeated dose toxicity

In a study where rats were dosed with C.I. Pigment Yellow 34 mixed in the diet for 90 days a no observed adverse effect level (NOAEL) of 288 mg (C.I. Pigment Yellow 34)/ kg bw /d was found. The lead content in the blood increased with increased exposure and haematological effects were observed (decreased levels of leucoytes). At the dose level of 1600 mg/kg bw /d and higher impaired kidney and liver weights were observed. The levels of lead were increased in bones and in the kidneys and increased level of chromium were found in brain, liver and kidneys (IUCLID 2000).

In dogs dosed with C.I. Pigment Yellow 34 at 71, 178 and 713 mg (C.I. Pigment Yellow 34)/kg bw d no NOAEL was found as dose-response related adverse effects occurred at all dose levels in kidney, liver and bone marrow. Increased levels of lead were fund in blood and increased levels of chromium were found in liver, kidney, bones and brain (IUCLID 2000).

The data on specific organ toxicity warrants a classification as STOT RE 2, H373.

As mentioned in the Danish EPA (2013) survey on lead and lead compounds especially low level exposure to lead may be of concern as no lower threshold for the adverse effects of lead has been identified. The most critical effects of lead (i.e. effects that occur at the lowest exposure levels) are the neurodevelopmental effects which causes impaired brain function in children, and in adults the critical effects are haematological effects (increased blood pressure) and adverse effects on the kidneys .

For neurodevelopmental effect a daily dose of 0.50 µg Pb/kg bw d to children is considered to affects a child with an IQ loss of 1 point. Based on this the Risk Assessment Committee at ECHA has used a dose of 0.05 µg Pb/kg bw d (corresponding to a loss in IQ in children of 0.1 point) as a DMEL-value (derived minimum effect level) of the exposure to lead.

6.1.6 Mutagenicity

The Technical Working Group for Classification and Labelling in 2003 assessed the mutagenic potential of C.I. Pigment Yellow 34.

Reduction of insoluble lead chromate by glutathione reductase/NADPH generates $^{\cdot}OH$ radicals that may cause DNA strand breakage. Lead chromate did not induce DNA damage in prokaryotes. It induced gene mutations in prokaryotes and mitotic recombination in lower eukaryotes when solubilised in acids or alkali. Aqueous suspensions of fine lead chromate particles produced DNA single-strand breaks, Cr-DNA adducts, and DNA-protein crosslinks in animal and human cells *in vitro*. Apoptosis is a major mode of death in cultured cells exposed to particulate lead chromate and sodium chromate. It induced mutations in hamster cells after being dissolved in sodium hydroxide. Lead chromate induced sister chromatid exchange and chromosomal aberrations in animal and human cells *in vitro*. Lead chromate increased the frequency of micronuclei in erythrocytes in bone-marrow cells of intraperitoneally treated mice. Lead chromate has induced transformations of mouse cells, Syrian hamster embryo cells, and of a human osteosarcoma cell line (ECB 2003).

Thus, the substance showed pronounced response in several *in vitro* asssays and was further positive in one in vivo bone marrow test, indicating concern for mutagenicity.

This may warrant classification as Muta. 2, H341 (Suspected of causing genetic defects).

6.1.7 Carcinogenicity

Although classified as a carcinogenic substance (Carc 1B; H350) the carcinogenicity of C.I. Pigment Yellow 34 has not explicitly been examined in experimental animals via oral, dermal or inhalation administrations.

However, C.I. Pigment Yellow 34, together with lead chromate and C.I. Pigment Red 104 (lead chromate molybdate sulphate red), show(s) evidence for carcinogenicity in several studies with rats after subcutaneous and intramuscular administration. Lead chromate induced both benign and malignant tumors 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 genotoxicity studies as well as cell transformation studies. The substances show resemblance to known mutagens/carcinogens (ECB 2003).

Furthermore, bronchial squamous cell carcinomas were observed in male rats in a two-year implantation study, in which various C.I. Pigment Yellow 34 preparations were implanted in the left lung. Although these results were not statistically significant, the rarity of this lesion in the control animals indicates a certain level of relevance. Additionally, local benign and malignant tumours

were significantly induced in male and female rats following subcutaneous or intramuscular injection of lead chromate, the principal component of C.I. Pigment Yellow 34. In one study 3 of 23 male rats developed renal tumors, which were not observed in control animals (0 of 22). A number of additional studies by intratracheal, intrapleural, intrabronchial and intramuscular administration of lead chromate or its derived pigments did not significantly induce tumor incidence in various animal species (Environment Canada/ Health Canada 2008).

Chromium trioxide and various water soluble chromates are classified as Carc. 1A, H350 or Carc 1B, H350 and with Muta 1B, H340. The carcinogenic responses in humans and in experimental animals has been demonstrated only in relation to *inhalational* exposure and development of tumors in the respiratory tract (EU-RAR 2005).

In the REACH registration dossier a DMEL (Dervied Minimal Effect Level) value for the carcinogenic effect of 2.96 µg/m^3 was given for inhalational exposure to workers. This value was based on an OEL value for hexavalent chromium compounds and adjusting for the very low solubility of C.I. Pigment Yellow.

In connection with the evaluation of applications for EU-authorization the Risk Assessment Committee at ECHA recently concluded risks estimates for inhalation exposure to workers and the general population (ECHA 2014) for Cr (VI) containing substances (including Pigment Yellow 34). RAC concluded on an excess lifetime lung cancer mortality risk for *workers* of 4 x 10^{-3} per µg Cr(VI)/m^3 in relation to inhalation exposure during 40 years of working life (8h/day, 5 days/week). Thus, exposure to 1 µg/m^3 during a full working life would results in an increased risk comparable to 4 extra cancer cases among 1000 exposed workers.

For the general population an excess lifetime lung cancer mortality risk of 2.9 x 10^{-2} per µg Cr(VI)/m3 was concluded in relation to inhalation exposure during 70 years (24h/day, every day). Thus, exposure to 1 µg/m^3 during 70 years would result in an increased risk comparable to 29 extra cancer cases among 1000 exposed people.

Further, RAC concluded on an excess risk for intestinal cancer of 8 x 10^{-4} per µg Cr(VI)/kg bw/day for oral exposure for the general population exposed daily during 70 years. Thus, exposure to 1 µg Cr(VI)/kg bw/day during a lifetime would result in an increased risk comparable to 8 extra cancer cases among 10 000 exposed people.

It was noted by RAC that these risk estimates may be overestimate the risk from nonsoluble Cr(VI)-containing substances (e.g. Pigment Yellow 34), however it was not possible to evaluate the extent of this overestimation (ECHA 2014b).

6.1.8 Reproduction and Developmental toxicity

Only few data are available with regard to developmental toxicity and fertility on C.I. Pigment Yellow 34.

The substance has been classified as Repr. 1A, H360Df (May damage the unborn child/ Suspected of damaging fertility). The classification as Repr. 1A is consistent with the classification of inorganic lead compounds in general, and further the Risk Assessment Committee at ECHA has recently agreed also to recommend a classification with Repr. 1A for metallic lead.

A limited epidemiological investigation of a lead chromate production plant in China showed that the rates of threatened abortions were significantly higher among female workers and the wives of male workers who had been exposed to lead chromate. Effects of Pigment Yellow 34 on the reproductive system were also observed in oral subchronic studies in dogs, described above, where

impaired gonadal development was noted in the treated animals but not in the controls, although the authors considered it as an indirect effect of the treatment (Environment Canada/ Health Canada 2008).

In the REACH registration dossier a DMEL (Derived Minimal Effect Level) value of 5 mg/kg bw d is indicated for the dermal exposure to workers. This value was based on the non-threshold effects of lead with regard to the adverse effects on the development of the CNS. A level of 0.5 µg/kg bw d of lead was adjusted by a factor for the low dermal absorption of C.I. Pigment Yellow by a factor of 0.0001.

No DMEL value was given for inhalation exposure with respect to reproductive toxicity (see DMEL for cancer)

6.1.9 Overall conclusions

The main concern pertaining to the exposure to C.I. Pigment Yellow 34 is expressed in the classification of the substance as Carc. 1B, H350 (May cause cancer); Repr. 1A, H360Df (May damage the unborn child/ Suspected of damaging fertility); and STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure).
Concern of carcinogenicity is primarily in relation to inhalation exposure.
With respect to developmental effects and STOT RE2 classification this may especially be related to the effects of the lead content of the substance as no lower threshold level has been found for the development of the CNS in children as well as in the unborn child.
It is unclear whether there is concern for skin sensitization and elicitation of symptoms in already chromium(VI) sensitized persons, as only very low level of free chromate may be available in connection with dermal exposure due to the very low solubility of the substance.

6.2 Human exposure

6.2.1 Direct exposure

6.2.1.1 Consumers

Environment Canada/ Health Canada (2008) made a qualitative assessment of the potential for exposure to consumers. In this assessment it is stated that C.I. Pigment Yellow 34 is used for professional use and not used for the manufacture of products for use by the general population and therefore there is no (or very low) direct exposure to them via this route.

Environment Canada/ Health Canada (2008) assessed however, that consumers may come in contact with C.I. Pigment Yellow 34 after use of the substance in certain applications, such as road paint, pigmented polymers and pigments used in wiring.
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. Silica encapsulation of the pigment would further prevent migration.

(Further, there may be a potential for inhalational consumer exposure in relation to spray painting and abrasion of surfaces treated with paint/ lacquers containing the pigment).

The REACH registration does not contain any safety evaluation of C.I. Pigment Yellow 34 in relation to consumer exposure, which implicitly indicates that consumers are not considered to be exposed to the substance. Also the background document from ECHA (2012) indicates low/no concern for consumer exposure.

It is also noted that in relation to the authorization procedure under REACH applications for use of Pigment Yellow 34 have only been forwarded in relation to industrial and professional use and not in relation to products/ articles not intended for consumer use.

6.2.1.2 Occupational exposure

Occupational exposure to C.I. Pigment Yellow 34 may occur in the pigment industry as well in in the plastic industry using C.I. Pigment 34 as a colouring agent and in the car and car repair industry where C.I. Pigment 34 may be contained in the lacquer. Occupational exposure to C.I. Pigment 34 may also occur when the pigment is used in warning paints in signage and traffic striping.
However, no specific data on occupational exposure to C.I. Pigment Yellow 34 is available.

6.2.2 Indirect exposure

Hot spot industrial soil pollution with C.I. Pigment Yellow 34 could possibly occur if the substance is not be handled properly at industrial sites, however, the substance is not considered as a general concern for soil pollution.
Due to the low solubility of C.I. Pigment Yellow 34 and due to the substance occurring primarily embedded in a matrix of plastic or surface coating, leaching into the water is not expected to occur. Thus, the substance is not expected to occur in drinking water.
In air the substance may occur in isolated cases where e.g. abrasion take place of surfaces coated with the pigment. However, this exposure potential seems to be extremely low and rather theoretical in relation to the general public.

6.3 Bio-monitoring data

No bio-monitoring data are available concerning the contribution to the lead- and chromate levels in humans that can be related to C.I. Pigment Yellow 34 exposure.

6.4 Human health impact

6.4.1 Workers

Based on lack of exposure data it is not possible to make a quantitative risk assessment for workers. However, due to the potential for severe hazardous effects, risk reduction measures should be taken to avoid especially inhalational exposure from working processes with generation of aerosols, (e.g. handling of C.I. Pigment Yellow 34 in powder form, spray painting or abrasion of materials or surfaces treated with lacquers containing C.I. Pigment Yellow 34. For both lead and chromate specific occupational limit value apply and furthermore specific instructions are given for the working with carcinogenic substances as well as with lead substances in the occupational environment (see table 2-1).

6.4.2 Consumers

Environment Canada/ Health Canada (2008) found that a quantitative risk assessment could not be made due to the negligible potential for exposure to C.I. Pigment Yellow 34 for the general population. Also the background document from ECHA (2012) indicates low/no concern for consumer exposure.

6.5 Summary and conclusions

The main concern pertaining to the exposure to C.I. Pigment Yellow 34 is expressed in the classification of the substance as Carc. 1B, H350 (May cause cancer); Repr. 1A, H360Df (May damage the unborn child/ Suspected of damaging fertility); and STOT RE2, H373 (May cause damage to organs through prolonged or repeated exposure). Concern of carcinogenicity is primarily related to the effects of chromate upon inhalation exposure.

With respect to developmental effects and the STOT RE2 classification this may especially be related to the effects of the lead content of the substance as no lower threshold level has been found for the development of the central nervous system in children as well as in the unborn child.
It is unclear whether there is concern for skin sensitization and elicitation of symptoms in already chromium(VI) sensitized persons, as only very low level of free chromate may be available in relation to dermal exposure to the substance.

No specific cases of concern for the working environment have been identified in connection to the use or handling of C.I. Pigment Yellow 34. However, adequate risk reduction measures should be taken to avoid especially inhalational exposure from working processes with generation of aerosols, (e.g. handling of C. I. Pigment Yellow 34 in powder form, spray painting or abrasion of materials or surfaces treated with lacquers containing C.I. Pigment Yellow 34.

Due to very low exposure potential for the consumer it is not possible to point out any use of C.I. Pigment Yellow 34 that may be of specific concern.

7. Information on alternatives

7.1 Identification of possible alternatives

In connection with a Swedish EU Restriction proposal for the use of lead and lead compounds in articles a survey was made regarding candidates for lead-free alternatives for the Pigments containing lead today (Swedish Chemical Agency 2012).

Possible alternatives to lead containing pigments have been searched for in the Swedish Product Register. The register contains information on chemical products (mixtures) manufactured, imported or brought in to Sweden in quantities ≥ 100 kg/year.
The screening in the register was done by first sorting out yellow pigments by their name, i.e. substances having a synonym containing the ”fragment “ pigment yellow”, from the register’s database of substance names. From these the lead-, cadmium-, mercury- and arsenic containing names were removed. The remaining substance names were then screened for in the registered chemical compositions of products (mixtures) reported to have a function as coloring agent (including pigments to glazing materials, enamels and glass, pigments to paint and printing inks, pigment pastes, regenerator to colours and colouring agents, other), raw materials for production of rubber products, raw materials for production of plastics, printing inks and “paints and varnishes”. The quantities of the substances were monitored in order to select high volume substances (2010) for the assessment.

The list of 110 identified Pigment Yellows presented in appendix 2 is not meant to be a complete list of possible lead free pigments, but shows that several lead free yellow pigments are being used. There could thus be more lead free pigments available than the ones found in the Swedish Product Register. Substances not having a synonym fragment “pigment”, or substances that the Swedish chemicals agency not yet have registered in their database are for example not included. (Swedish Chemical Agency, 2012).

In relation to the authorization process in REACH, the current application for authorisation forwarded to ECHA has been sent to public consultation. After the dead-line of the commenting period ECHA has received between 20 and 60 comments on alternatives for each of the six uses applied for (mostly suggesting other types of pigments).
Overall, it seems to be possible to substitute Pigment Yellow 34 with other pigments.

The decreasing trend in use and today´s very limited use of C.I. Pigment Yellow 34 for the Danish market also indicates that substitution of this pigment is possible and has taken place in Denmark.

7.2 Summary and conclusions

Based on a survey by the Swedish Chemical Agency in 2012 there seems to be a wide range of Pigments that may be candidates for suitable alternative for C.I. Pigment Yellow 34.

The decreasing trend in use and today´s very limited use of C.I. Pigment Yellow 34 for the Danish market indicate that substitution of this pigment is possible and has taken place in Denmark.

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Appendix 1

Background information to chapter 2 on regulatory framework

The following annex provides some background information on subjects addressed in chapter 2. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 2.

EU and Danish legislation

Chemicals are regulated via EU and national legislations, the latter often being a national transposition of EU directives.

There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvering as to the form and means of implementation. However, there are great differences in the space for manoeuvering between directives. For example, several directives regulating chemicals previously were rather specific and often transposed more or less word-by-word into national legislation. Consequently and to further strengthen a level playing field within the internal market, the new chemicals policy (REACH) and the new legislation for classification and labelling (CLP) were implemented as Regulations. In Denmark, Directives are most frequently transposed as laws (DK: love) and statutory orders (DK: bekendtgørelser).

The European Commission has the right and the duty to suggest new legislation in the form of regulations and directives. New or recast directives and regulations often have transitional periods for the various provisions set-out in the legal text. In the following, we will generally list the latest piece of EU legal text, even if the provisions identified are not yet fully implemented. On the other hand, we will include currently valid Danish legislation, e.g. the implementation of the cosmetics directive) even if this will be replaced with the new Cosmetic Regulation.

- Decisions are fully binding on those to whom they are addressed. Decisions are EU laws relating to specific cases. They can come from the EU Council (sometimes jointly with the European Parliament) or the European Commission. In relation to EU chemicals policy, decisions are e.g. used in relation to inclusion of substances in REACH Annex XVII (restrictions). This takes place via a so-called comitology procedure involving Member State representatives. Decisions are also used under the EU ecolabelling Regulation in relation to establishing ecolabel criteria for specific product groups.
- Recommendations and opinions are non-binding, declaratory instruments.

In conformity with the transposed EU directives, Danish legislation regulate to some extent chemicals via various general or sector specific legislation, most frequently via statutory orders (DK: bekendtgørelser).

Chemicals legislation

REACH and CLP

The REACH Regulation[1] and the CLP Regulation[2] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

(Pre-)Registration

All manufacturers and importers of chemical substance > 1 tonne/year have to register their chemicals with the European Chemicals Agency (ECHA). Pre-registered chemicals benefit from tonnage and property dependent staggered dead-lines:

- 30 November 2010: Registration of substances manufactured or imported at 1000 tonnes or more per year, carcinogenic, mutagenic or toxic to reproduction substances above 1 tonne per year, and substances dangerous to aquatic organisms or the environment above 100 tonnes per year.
- 31 May 2013: Registration of substances manufactured or imported at 100-1000 tonnes per year.
- 31 May 2018: Registration of substances manufactured or imported at 1-100 tonnes per year.

Evaluation

A selected number of registrations will be evaluated by ECHA and the EU Member States. Evaluation covers assessment of the compliance of individual dossiers (dossier evaluation) and substance evaluations involving information from all registrations of a given substance to see if further EU action is needed on that substance, for example as a restriction (substance evaluation).

Authorisation

Authorisation aims at substituting or limiting the manufacturing, import and use of substances of very high concern (SVHC). For substances included in REACH annex XIV, industry has to cease use of those substance within a given deadline (sunset date) or apply for authorisation for certain specified uses within an application date.

Restriction

If the authorities assess that that there is a risks to be addressed at the EU level, limitations of the manufacturing and use of a chemical substance (or substance group) may be implemented. Restrictions are listed in REACH annex XVII, which has also taken over the restrictions from the previous legislation (Directive 76/769/EEC).

Classification and Labelling

The CLP Regulation implements the United Nations Global Harmonised System (GHS) for classification and labelling of substances and mixtures of substances into EU legislation. It further specifies rules for packaging of chemicals.

Two classification and labelling provisions are:

[1] Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

[2] Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

1. **Harmonised classification and labelling** for a number of chemical substances. These classifications are agreed at the EU level and can be found in CLP Annex VI. In addition to newly agreed harmonised classifications, the annex has taken over the harmonised classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.
2. **Classification and labelling inventory**. All manufacturers and importers of chemicals substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publish the classification and labelling inventory based on all notifications received. There is no tonnage trigger for this obligation. For the purpose of this report, self-classifications are summarised in Appendix 2 to the main report.

Ongoing activities - pipeline

In addition to listing substance already addressed by the provisions of REACH (pre-registrations, registrations, substances included in various annexes of REACH and CLP, etc.), the ECHA web-site also provides the opportunity for searching for substances in the pipeline in relation to certain REACH and CLP provisions. These will be briefly summarised below:

Community Rolling Action Plan (CoRAP)

The EU member states have the right and duty to conduct REACH substance evaluations. In order to coordinate this work among Member States and inform the relevant stakeholders of upcoming substance evaluations, a Community Rolling Action Plan (CoRAP) is developed and published, indicating by who and when a given substance is expected to be evaluated.

Authorisation process; candidate list, Authorisation list, Annex XIV

Before a substance is included in REACH Annex XIV and thus being subject to Authorisation, it has to go through the following steps:

1. It has to be identified as a SVHC leading to inclusion in the candidate list3
2. It has to be prioritised and recommended for inclusion in ANNEX XIV (These can be found as Annex XIV recommendation lists on the ECHA web-site)
3. It has to be included in REACH Annex XIV following a comitology procedure decision (substances on Annex XIV appear on the Authorisation list on the ECHA web-site).

The candidate list (substances agreed to possess SVHC properties) and the Authorisation list are published on the ECHA web-site.

Registry of intentions

When EU Member States and ECHA (when required by the European Commission) prepare a proposal for:

- a harmonised classification and labelling,
- an identification of a substance as SVHC, or
- a restriction.

This is done as a REACH Annex XV proposal.

The 'registry of intentions' gives an overview of intensions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,

[3] It should be noted that the candidate list is also used in relation to articles imported to, produced in or distributed in the EU. Certain supply chain information is triggered if the articles contain more than 0.1% (w/w) (REACH Article 7.2 ff).

- dossiers submitted, and
- withdrawn intentions and withdrawn submissions

for the three types of Annex XV dossiers.

International agreements

OSPAR Convention
OSPAR is the mechanism by which fifteen Governments of the western coasts and catchments of Europe, together with the European Community, cooperate to protect the marine environment of the North-East Atlantic.

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendations set out actions to be taken by the Contracting Parties. These measures are complemented by other agreements setting out:

- issues of importance
- agreed programmes of monitoring, information collection or other work which the Contracting Parties commit to carry out.
- guidelines or guidance setting out the way that any programme or measure should be implemented
- actions to be taken by the OSPAR Commission on behalf of the Contracting Parties.

HELCOM - Helsinki Convention
The Helsinki Commission, or HELCOM, works to protect the marine environment of the Baltic Sea from all sources of pollution through intergovernmental co-operation between Denmark, Estonia, the European Community, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden. HELCOM is the governing body of the "Convention on the Protection of the Marine Environment of the Baltic Sea Area" - more usually known as the Helsinki Convention.

In pursuing this objective and vision the countries have jointly pooled their efforts in HELCOM, which is works as:

- an environmental policy maker for the Baltic Sea area by developing common environmental objectives and actions;
- an environmental focal point providing information about (i) the state of/trends in the marine environment; (ii) the efficiency of measures to protect it and (iii) common initiatives and positions which can form the basis for decision-making in other international fora;
- a body for developing, according to the specific needs of the Baltic Sea, Recommendations of its own and Recommendations supplementary to measures imposed by other international organisations;
- a supervisory body dedicated to ensuring that HELCOM environmental standards are fully implemented by all parties throughout the Baltic Sea and its catchment area; and
- a co-ordinating body, ascertaining multilateral response in case of major maritime incidents.

Stockholm Convention on Persistent Organic Pollutants (POPs)
The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have adverse effects to human health or to the environment. The Convention is administered by the United Nations Environment Programme and is based in Geneva, Switzerland.

Rotterdam Convention
The objectives of the Rotterdam Convention are:

- to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm;
- to contribute to the environmentally sound use of those hazardous chemicals, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties.
- The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure. It built on the voluntary PIC procedure, initiated by UNEP and FAO in 1989 and ceased on 24 February 2006.

The Convention covers pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by Parties and which have been notified by Parties for inclusion in the PIC procedure. One notification from each of two specified regions triggers consideration of addition of a chemical to Annex III of the Convention. Severely hazardous pesticide formulations that present a risk under conditions of use in developing countries or countries with economies in transition may also be proposed for inclusion in Annex III.

Basel Convention
The Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal was adopted on 22 March 1989 by the Conference of Plenipotentiaries in Basel, Switzerland, in response to a public outcry following the discovery, in the 1980s, in Africa and other parts of the developing world of deposits of toxic wastes imported from abroad.

The overarching objective of the Basel Convention is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as “hazardous wastes” based on their origin and/or composition and their characteristics, as well as two types of wastes defined as “other wastes” - household waste and incinerator ash.

The provisions of the Convention center around the following principal aims:

- the reduction of hazardous waste generation and the promotion of environmentally sound management of hazardous wastes, wherever the place of disposal;
- the restriction of transboundary movements of hazardous wastes except where it is perceived to be in accordance with the principles of environmentally sound management; and
- a regulatory system applying to cases where transboundary movements are permissible.

Eco-labels
Eco-label schemes are voluntary schemes where industry can apply for the right to use the eco-label on their products if these fulfil the ecolabelling criteria for that type of product. An EU scheme (the flower) and various national/regional schemes exist. In this project we have focused on the three most common schemes encountered on Danish products.

EU flower
The EU ecolabelling Regulation lays out the general rules and conditions for the EU ecolabel; the flower. Criteria for new product groups are gradually added to the scheme via 'decisions'; e.g. the Commission Decision of 21 June 2007 establishing the ecological criteria for the award of the Community eco-label to soaps, shampoos and hair conditioners.

Nordic Swan

The Nordic Swan is a cooperation between Denmark, Iceland, Norway, Sweden and Finland. The Nordic Ecolabelling Board consists of members from each national Ecolabelling Board and decides on Nordic criteria requirements for products and services. In Denmark, the practical implementation of the rules, applications and approval process related to the EU flower and Nordic Swan is hosted by Ecolabelling Denmark "Miljømærkning Danmark" (http://www.ecolabel.dk/). New criteria are applicable in Denmark when they are published on the Ecolabelling Denmark's website (according to Statutory Order no. 447 of 23/04/2010).

Blue Angel (Blauer Engel)
The Blue Angel is a national German eco-label. More information can be found on: http://www.blauer-engel.de/en.

Appendix 2

Potential candidates for alternatives to C.I. Pigment Yellow 34 (Swedish Chemical Agency 2012)

C.I. Pigment Yellow 1
C.I. Pigment Yellow 10
C.I. Pigment Yellow 100
C.I. Pigment Yellow 101
C.I. Pigment Yellow 104
C.I. Pigment Yellow 108
C.I. Pigment Yellow 109
C.I. Pigment Yellow 110
C.I. Pigment Yellow 111
C.I. Pigment Yellow 113

C.I. Pigment Yellow 115
C.I. Pigment Yellow 116
C.I. Pigment Yellow 117
C.I. Pigment Yellow 119
C.I. Pigment Yellow 12
C.I. Pigment Yellow 120
C.I. Pigment Yellow 123
C.I. Pigment Yellow 124
C.I. Pigment Yellow 126
C.I. Pigment Yellow 127
C.I. Pigment Yellow 128
C.I. Pigment Yellow 129
C.I. Pigment Yellow 13
C.I. Pigment Yellow 137
C.I. Pigment Yellow 138
C.I. Pigment Yellow 139
C.I. Pigment Yellow 14
C.I. Pigment Yellow 147
C.I. Pigment Yellow 148
C.I. Pigment Yellow 15
C.I. Pigment Yellow 150
C.I. Pigment Yellow 151
C.I. Pigment Yellow 152
C.I. Pigment Yellow 153
C.I. Pigment Yellow 154
C.I. Pigment Yellow 155
C.I. Pigment Yellow 157

C.I. Pigment Yellow 158
C.I. Pigment Yellow 159
C.I. Pigment Yellow 16
C.I. Pigment Yellow 160
C.I. Pigment Yellow 161
C.I. Pigment Yellow 162
C.I. Pigment Yellow 163
C.I. Pigment Yellow 164
C.I. Pigment Yellow 168
C.I. Pigment Yellow 169
C.I. Pigment Yellow 17
C.I. Pigment Yellow 170
C.I. Pigment Yellow 171
C.I. Pigment Yellow 174
C.I. Pigment Yellow 175
C.I. Pigment Yellow 176
C.I. Pigment Yellow 177
C.I. Pigment Yellow 179
C.I. Pigment Yellow 18
C.I. Pigment Yellow 18 (fugitive), benzoate
C.I. Pigment Yellow 18, phosphotungstate
C.I. Pigment Yellow 18, tannic acid salt
C.I. Pigment Yellow 180
C.I. Pigment Yellow 181
C.I. Pigment Yellow 182
C.I. Pigment Yellow 183
C.I. Pigment Yellow 184

C.I. Pigment Yellow 185
C.I. Pigment Yellow 188
C.I. Pigment Yellow 191
C.I. Pigment Yellow 192
C.I. Pigment Yellow 194
C.I. Pigment Yellow 2
C.I. Pigment Yellow 213
C.I. Pigment Yellow 24
C.I. Pigment Yellow 3
C.I. Pigment Yellow 31
C.I. Pigment Yellow 32
C.I. Pigment Yellow 33
C.I. Pigment Yellow 36
C.I. Pigment Yellow 36:1
C.I. Pigment Yellow 38
C.I. Pigment Yellow 4
C.I. Pigment Yellow 40
C.I. Pigment Yellow 42
C.I. Pigment Yellow 43
C.I. Pigment Yellow 49
C.I. Pigment Yellow 5
C.I. Pigment Yellow 53
C.I. Pigment Yellow 55
C.I. Pigment Yellow 57
C.I. Pigment Yellow 6
C.I. Pigment Yellow 60
C.I. Pigment Yellow 61

C.I. Pigment Yellow 61:1
C.I. Pigment Yellow 62
C.I. Pigment Yellow 62:1
C.I. Pigment Yellow 63
C.I. Pigment Yellow 65
C.I. Pigment Yellow 7
C.I. Pigment Yellow 73
C.I. Pigment Yellow 74
C.I. Pigment Yellow 75
C.I. Pigment Yellow 77
C.I. Pigment Yellow 81
C.I. Pigment Yellow 83
C.I. Pigment Yellow 87
C.I. Pigment Yellow 9
C.I. Pigment Yellow 93
C.I. Pigment Yellow 94
C.I. Pigment Yellow 95
C.I. Pigment Yellow 97
C.I. Pigment Yellow 98

Survey of C.I. Pigment Yellow 34

A survey has been performed of the substance C.I. Pigment Yellow 34, which is listed on the Danish EPA's List of Undesired Substances (LOUS). The hazardous effects of C.I. Pigment Yellow are due to its content of lead and chromium, which are highly toxic. C.I. Pigment Yellow 34 is thus classified as toxic to reproduction, carcinogenic, toxic to several organs and toxic for the aquatic environment.

This survey gives an updated status on regulation, use, effects on health and environment, waste management and alternatives.

C.I. Pigment Yellow 34 is extensively regulated at EU level as it is covered by the general regulation for lead and/or chromium compounds. Denmark furthermore has a national regulation for lead, and the uses of C.I. Pigment Yellow 34 are thus even more limited in Denmark.

C.I. Pigment Yellow 34 is mainly used as a colouring agent in plastics, paint and coatings in EU. In Denmark the substance is, primarily used as a raw material for colouring of products that are exported to other countries. As C.I. Pigment Yellow 34 is placed on the authorisation list under the REACH Regulation, the use is, however, expected to be phased out in both Denmark and EU by 2015.

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