Danish Ministry of the Environment
Environmental Protection Agency

Survey of 2,3-epoxypropyl-neodecanoate

Part of the LOUS review

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Preface

Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is meant as a guide for enterprises. It indicates substances of concern which uses are intended to 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 otherwise been considered of concern or in political focus. 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 in the environment, only substances which are used in Denmark in industrial settings in large quantities i.e. over 100 tonnes per year are included in the list.

During the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the uses and occurrences of the substances in Denmark and internationally, environmental and health effects, alternatives to the substances, monitoring and exposure data, and information regarding existing regulations.

The main objective of the surveys 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 *2,3-epoxypropylneodecanoate* (EPDA) (CAS: 26761-45-5) that has been included in the LOUS list due to the self-classification as Carc3;R40 R43 N;R51/53 (Carc 2; H351; H317; H411) and because EPDA is placed on the Danish market in a quantity above 100 tonnes.

The process

The survey has been undertaken by DHI from April 2014 to December 2014. The work has been followed by an advisory group consisting of:

- Mikkel Aaman Sørensen (Danish EPA), Chair of advisory group
- Magnus Løfstedt (Danish EPA)
- Katrine Smith (Danish EPA)

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 the Ecolabelling Denmark (Nordic Swan and EU Flower) and the German Blue 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);
- Data on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Chemical information from the ICIS 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.

Summary and conclusions

The substance 2,3-epoxypropylneodecanoate, EPDA, an organic epoxy compound, is mostly used as curing agent and binder in epoxy paint systems, varnishes, adhesives and construction materials within the industrial sector and by professional users. The uses registered under REACH are representing a wide range of end use sectors. Consumer use is not registered under REACH, but available material safety data sheets and the responses from the questionnaire part of this survey indicated that EPDA is applied in coating products for consumers.

EPDA is registered in REACH within the tonnage band of 10,000-100,000 tonnes per year. According to the REACH registration, there are no manufacturing sites in EU and therefore it is anticipated that the volume registered in REACH corresponds to imported volumes. In the Nordic countries there has been a reported decline in the tonnage of EPDA used in the period from 2006 to 2012 according to information in the Nordic product registers (SPIN). The total tonnage of EPDA in products placed on the Nordic market was 53 tonnes in 2012 representing paints, lacquers, varnishes, surface treatment, adhesives and construction materials.

EPDA does not have a harmonised classification, but EPDA has notified self-classifications as Muta. 2 (H341) and Carc 1B (H350). EPDA is included in the Community Rolling Action Plan and listed in the CoRAP list by the Danish EPA, due to high aggregated tonnage and exposure from wide dispersive use in addition to the meeting of the criteria as CMR/suspected CMR and suspected sensitiser.

Data on human health hazard is available from the REACH registration. No acute toxicity of EPDA has been observed in rat studies with oral, inhalation and dermal exposure to EPDA and studies on skin and eye irritation showed that EPDA is not a skin and eye irritant. Animal and human studies on skin sensitization demonstrate that EPDA is a skin sensitizer and therefore the substances are self-classified with Skin Sens. 1; H317. For repeated dose toxicity, adverse kidney events were observed in male rats in an oral study but the REACH registrant did not consider these findings relevant to human health. A 90 day repeated dose toxicity study with dermal exposure is proposed as part of the REACH registration but a decision from ECHA on the proposed test has not yet been issued. One of the tests for mutagenicity in the REACH registration demonstrates that EPDA causes gene-mutation in the liver, kidney and bone marrow of the mouse by oral route. Therefore the substance is self-classified with Muta. 2; H341 by the REACH registrant. No studies are available on carcinogenicity, reproductive toxicity or developmental toxicity. Studies have been proposed for reproductive toxicity (OECD TG 416) and developmental toxicity (OECD TG 414) as part of the REACH registration. ECHA has not yet issued a decision on these proposed studies.

Occupational exposure is expected during industrial and professional uses of EPDA for which the exposure levels are controlled by the use of risk management measures such as personal protective equipment. Exposure to consumers cannot be excluded as coating products are available to consumers according to information from safety datasheets. This is supported by information from the SPIN database indicating that one or several uses very probably leads to consumer exposure.

EPDA is self-classified for the environment as: Aquatic chronic 2; H411: Toxic to aquatic life with long lasting effects. EPDA is not considered as a PBT or a vPvB substance.

The reported acute toxicity towards aquatic organisms is between 1-5 mg/L, which is in the moderate to higher toxicity range. The highest acute toxicity is observed for algae. No data on long term effects, except for algae are reported for EPDA. EPDA is not readily biodegradable. A conclusion on persistency cannot be made based on available information since no degradation simulation studies are available as part of the REACH registration. However, the REACH registrant has concluded that EPDA fulfills the criteria for persistence (P) and not the bioaccumulation (B) criteria. Even though the toxicity data in the REACH registration indicate that EPDA does not fulfil the criteria for toxicity (T), the substance may fulfil the $T_{\text{human health}}$ criterion based on its suspected CMR properties. No environmental monitoring data are available, however, distribution modelling indicates that the substance will distribute to the soil compartment (72%), the water compartment (26%) and to the air (2%) when transformations and degradation are taken into account.

The use index of the Nordic SPIN database indicates a probable exposure of air and soil and a very probable exposure of waste water. A questionnaire on use and release of EPDA was prepared and sent to relevant European organisations. According to the answers received from the questionnaires, responses indicated that certain products do contain EPDA from which a potential for environmental release is likely during the waste stage of these products.

Waste containing EPDA is not considered to be hazardous due to the lack of harmonised classification of EPDA. However, it is anticipated that waste from the use of coatings containing EPDA by either industry or professional is treated as hazardous waste according to the recommendations in the safety datasheets for coating products.

Possible alternatives to EPDA have been identified and are under preliminary considerations. Experiences from the use of the alternatives are still limited. The alternative substances to EPDA are Di-isopropanolamin (CAS: 110-97-4) and P-toluenesulfonic acid (CAS: 104-15-4).

Sammenfatning og konklusion

Stoffet 2,3-epoxypropylneodecanoat, EPDA, en organisk epoxyforbindelse, anvendes hovedsagligt som hærder og bindemiddel i epoxy malingssystemer, lakker, klæbestoffer og byggematerialer inden for den industrielle sektor og af professionelle brugere. De anvendelser, der er registreret i henhold til REACH, repræsenterer en lang række slutanvendelsessektorer. Privat brug er ikke registreret i henhold til REACH, men tilgængelige sikkerhedsdatablade og svarene fra spørgeskemadelen af denne kortlægning tyder på, at EPDA anvendes i overfladebehandlingsprodukter til forbrugere.

EPDA er registreret i REACH inden for mængdeintervaller på 10.000-100.000 tons om året. Ifølge REACH registreringen er der ikke produktion i EU, og derfor forventes det, at mængden, der er registreret i REACH, svarer til importerede mængder. I henhold til oplysninger fra de nordiske produktregistre (SPIN) har der været et rapporteret fald i tonnagen af EPDA anvendt i perioden 2006-2012 i de nordiske lande. Den samlede tonnage for EPDA i produkter, der markedsføres på det nordiske marked, var 53 tons i 2012, hvilket repræsenterer maling, lak, fernis, overfladebehandling, klæbestoffer og byggematerialer.

EPDA har ikke en harmoniseret klassificering, men der er anmeldt selvklassificeringer for EPDA som Muta. 2 (H341) og Carc 1B (H350). EPDA indgår i den rullende fælledskabshandlingsplan og er opført i CoRAP listen af den danske Miljøstyrelse på grund af en høj samlet tonnage og eksponering fra udbredt anvendelse samt opfyldelse af kriterierne som CMR/mistænkt CMR og mistænkt allergen.

Data om sundhedsfare for mennesker er tilgængelige fra REACH registreringen. Der er ikke observeret akut toksicitet af EPDA i rottestudier med oral, inhalation og hudeksponering for EPDA, og studier på hud- og øjenirritation viste, at EPDA ikke er hud- og øjenirriterende. Dyre- og humane studier på hudsensibilisering viser, at EPDA er hudsensibiliserende, og derfor er stofferne selvklassificeret med Skin Sens. 1; H317. I et oralt studie på toksicitet ved gentagen dosering observeredes der utilsigtede nyrehændelser i hanrotter, men REACH registranten anså ikke disse resultater for at være relevante for menneskers sundhed. Der foreslås et 90 dages gentagen doseringsstudie med dermal eksponering som en del af REACH registreringen, men der er endnu ikke blevet truffet en afgørelse fra ECHA om det foreslåede forsøg. En af mutagenicitetstestene i REACH registreringen viser, at EPDA forårsager genmutation i lever, nyre og knoglemarv i mus ved oral indgift. Stoffet er derfor selvklassificeret med Muta. 2; H341 af REACH registranten. Der findes ingen tilgængelige studier på carcinogenicitet, reproduktionstoksicitet eller udviklingstoksicitet. Studier for reproduktionstoksicitet (OECD TG 416) og udviklingstoksicitet (OECD TG 414) er blevet foreslået som en del af REACH-registreringen. ECHA har endnu ikke truffet en afgørelse om de foreslåede studier.

Der forventes erhvervsmæssig eksponering i forbindelse med industrielle og professionelle anvendelser af EPDA, for hvilke eksponeringsniveauerne kontrolleres ved brug af risikohåndteringsforanstaltninger såsom personlige værnemidler. Eksponering af forbrugere kan ikke udelukkes, da overfladebehandlingsprodukter er tilgængelige for forbrugere i henhold til oplysninger fra sikkerhedsdatablade. Dette understøttes af oplysninger fra SPIN databasen om, at en eller flere anvendelser sandsynligvis fører til eksponering af forbrugere.

EPDA er selvklassificeret for miljøet som: Aquatic Chronic 2; H411: Giftig for vandlevende organismer, med langvarige virkninger. EPDA betragtes ikke som et PBT- eller et vPvB-stof.

Den rapporterede akutte toksicitet overfor vandlevende organismer er 1-5 mg/L, som er i området moderat til højere toksicitet. Den højeste akutte giftighed observeredes for alger. Der er ikke rapporteret data på langtidsvirkning af EPDA, undtagen for alger. EPDA er ikke let biologisk nedbrydeligt. En konklusion om persistens kan ikke foretages på grundlag af de foreliggende oplysninger, da der ikke er tilgængelige nedbrydningssimuleringsstudier som en del af REACH registreringen. Imidlertid har REACH registranten konkluderet, at EPDA opfylder kriterierne for persistens (P) og ikke kriterierne for bioakkumulering (B). Selvom toksicitetsdata i REACH registreringen viser, at EPDA ikke opfylder kriterierne for toksicitet (T), kan stoffet opfylde $T_{human\ health}$ kriteriet baseret på formodede CMR-egenskaber. Der er ingen tilgængelige miljømæssige overvågningsdata, men distributionsmodellering indikerer, at EPDA vil distribuere til jordsegmentet (72%), vandsegmentet (26%) og til luftsegmentet (2%), når der tages højde for transformationer og nedbrydning.

Anvendelsesindekset fra den nordiske SPIN-database indikerer en sandsynlig eksponering af luft og jord og en meget sandsynlig eksponering af spildevand. Et spørgeskema om anvendelse og frigivelse af EPDA blev udarbejdet og sendt til relevante europæiske organisationer. De modtagne svar på spørgeskemaerne viste, at visse produkter indeholder EPDA, hvorfra et potentielt miljøudslip af disse produkter er sandsynligt under affaldsfasen.

Affald med indehold af EPDA anses ikke for at være farligt på grund af den manglende harmoniserede klassificering af EPDA. Det forventes dog, at affald fra anvendelse af overfladebehandlingsmidler indeholdende EPDA behandles som farligt affald af enten industri eller professionelle i henhold til anbefalingerne i sikkerhedsdatablade for overfladebehandlingsprodukter.

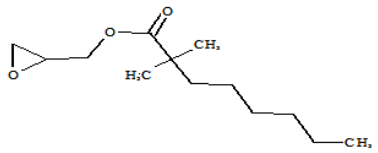
Mulige alternativer til EPDA er blevet identificeret og er under indledende overvejelse. Erfaringer fra anvendelse af alternativerne er stadig begrænset. De alternative stoffer til EPDA er di-isopropanolamin (CAS: 110-97-4) og P-toluensulfonsyre (CAS: 104-15-4)

1. Introduction to the substance

1.1 Identification of the substance

The substance identification is described in the table below.

TABLE 1-1
NAME AND OTHER IDENTIFIERS OF 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) (REACH REGRISTRATION DATA, 2014; ENVIRONMENTAL CHEMISTRY, 2014)

EPDA	
EC number	247-979-2
CAS number	26761-45-5
Synonyms	1-Propanol, 2,3-epoxy-, neodecanoate 2,3-Epoxypropyl Neodecanoate Cardura E 10 Cardura E 10P Cardura E 10S Epoxide 248 Glycidyl ester of neodecanoic acid Glycidyl neodecanoate Glydexx N 10 Neodecanoic acid, 2,3-epoxypropyl ester Neodecanoic acid, oxiranylmethyl ester
Molecular formula	$C_{13}H_{24}O_3$
Molecular weight	228.33
Structure	

1.2 Physical and chemical properties

The substance 2,3-epoxypropylneodecanoate is a colourless liquid with faint odour. The substance is slightly soluble in water and has a log Kow of 4.4 (REACH registration data, 2014).

TABLE 1-2
PHYSICAL-CHEMICAL PROPERTIES FOR 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) (REACH REGISTRATION DATA, 2014)

Property	
Physical state	liquid
Density	0.96 mg/mL (20°C)
Freezing/Melting point	-73°C
Boiling point	269 (104 kPa)
Vapour pressure	0.15 hPa (20°C)
Water solubility	70 mg/L (20°C)
Log K_{ow} (octanol/water)	4.4 (pH 6.7)
Surface tension	45.3 mN/m (22 °C) 48.9 mN/m (21 °C)
Viscosity	8.30 mm^2/s at (20 °C)

2. Regulatory framework

This chapter gives an overview of how EPDA (CAS: 26761-45-5) is addressed in existing and forthcoming EU and Danish legislation, international agreements, eco-label criteria etc. The overview reflects the findings from the data search.

EPDA does not have a harmonised classification according to Annex VI of Regulation (EC) No 1272/2008 (CLP regulation). Notified self-classifications of EPDA are included in the C&L Inventory database and the substance is self-classified as part of the REACH registration based on the data herein. The classifications are presented in section 2.2.

As a consequence of the lack of a harmonized classification, EPDA is not regulated by legislations addressing the classifications of substances such as CMR properties.

2.1 Existing legislation

TABLE 2-1
LEGISLATION ADDRESSING 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5)

Legal instrument	Reference	Requirement as concerns EPDA and national implementation
Regulation on chemical substances and mixtures		
REACH Regulation 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	Registration for manufacture and import above 1 tonnes per year (registration deadline in 2018 for 1-100 tonnes per year). Registered tonnage band: 10,000-100,000 tonnes per year
CLP 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	Notification of classification in the C&L Inventory database. Please refer to Table 2.2.

Legal instrument	Reference	Requirement as concerns EPDA and national implementation
Environment and waste regulation		
Basel Convention on the control of transboundary movements of hazardous wastes and their disposal	Global	EPDA is due to its use in paints, lacquers and varnishes included in category Y12: Wastes from production, formulation and use of inks, dyes, pigments, paints, lacquers, varnish and Y17 Wastes resulting from surface treatment of metals and plastics of Annex I (Categories of wastes to be controlled) of the Basel Convention regarding the control of transboundary movements of hazardous wastes and their disposal.
Other regulations		
Danish guidance document Guidance from the Danish EPA No. 2, 2002 "Guidance on B-Values"	DK	B-value (contribution value) for Epoxy compounds, monomers of 0.001 mg/m^3, as a limit value for each company's contribution to the air pollution in the environment.

2.2 Classification and labelling

2.2.1 Harmonised classification in the EU

There is no harmonised classification according to Annex VI of Regulation (EC) No 1272/2008 (CLP regulation) for EPDA.

2.2.2 Notified classification in the EU

The self-classifications of EPDA notified by the companies placing EPDA on the EU-market are found in the C&L Inventory database. There is a total of 840 notifications of the classification for EPDA representing the self-classifications shown in Table 2.2 (C&L Inventory database, 2014).

It should be noted that the self-classification as Muta. 1B (May cause genetic defects) has been notified by two companies and Carc. 1B (May cause cancer) by one company.

TABLE 2-2
NOTIFIED CLASSIFICATIONS OF 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) (C&L INVENTORY DATABASE, 2014)

Chemical identification (CAS No)	Self-Classifications		
	Hazard Class and Category Code(s)	Hazard statement Code(s)	Number of notifiers applying this classification
EPDA (CAS: 26761-45-5)	Skin Irrit. 2	H315	103
	Skin Sens. 1	H317	760
	Eye Irrit. 2	H319	1
	STOT SE 3	H335	1

Chemical identification (CAS No)	Self-Classifications		
	Hazard Class and Category Code(s)	Hazard statement Code(s)	Number of notifiers applying this classification
	Muta. 1B	H340	2
	Muta. 2	H341	70
	Carc. 1B	H350	1
	Aquatic Chronic 2	H411	809
	Aquatic Chronic 2	H413	1
	No classification	-	28

2.2.3 Classification from the REACH registration

The self-classification of EPDA according to the REACH registration is shown in Table 2-3.

TABLE 2-3
CLASSIFICATION OF 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) ACCORDING TO THE REACH REGISTRATION (REACH REGISTRATION DATA , 2014)

Chemical identification (CAS No)	Self-Classification	
	Hazard Class and Category Code(s)	Hazard statement Code(s)
EPDA (26761-45-5)	Skin Sens. 1	H317
	Muta. 2	H341
	Aquatic Chronic. 2	H411

H317: May cause an allergic skin reaction; H341: Suspected of causing genetic defects, H411: Toxic to aquatic life with long lasting effects.

2.3 REACH

EPDA has been registered under REACH within the tonnage band of 10,000- 100,000 tonnes per year. According to the REACH registration, one lead registration dossier has been submitted covering two companies that have registered the substance: Momentive Specialty Chemicals BV and REACH Compliance Services Limited.

As part of the REACH procedures, EPDA is included in the Community Rolling Action Plan and listed in the CoRAP list by the Danish EPA. The justification for the selection of EPDA for the CoRAP inclusion is that EPDA is meeting the criteria as CMR/suspected CMR and suspected sensitiser, and has a high aggregated tonnage (t/a>1000) and exposure from wide dispersive use (ECHA CoRAP list of substances, 2014). The substance evaluation will be conducted in 2014-15 and will primarily assess the mutagenicity potential of EPDA and whether or not a more stringent classification is warranted (Muta. 1B). During this evaluation, the REACH registrants may be required to conduct further testing or to submit other types of information in order to clarify the identified concerns.

2.4 Other legislation/initiatives

2.4.1 International agreements

No other agreements or legislations have been identified for EPDA.

2.4.2 Eco labels

The Nordic and EU Eco-labelling criteria documents (Nordic Swan and EU flower) and the Blue Angel, a national German eco-label, are not addressing EPDA (CAS: 26761-45-5) as an ingredient.

2.5 Summary and conclusions

EPDA is registered according to the REACH regulation at a tonnage band of 10,000-100,000 tonnes per year. EPDA does not have a harmonised classification. As a consequence, the substance is not included by legislations addressing the classifications of substances such as CMR properties. EPDA does have notified self-classifications as Muta. 2 (H341) and Carc 1B (H350). EPDA is included in the Community Rolling Action Plan and listed in the CoRAP list by the Danish EPA, due to high aggregated tonnage and exposure from wide dispersive use in addition to the meeting of the criteria as CMR/suspected CMR and suspected sensitiser.

3. Manufacturing and use

3.1 Manufacturing processes

No manufacturing is identified as part of the REACH registrations (REACH registration data, 2014).

3.2 Manufacturing sites and volumes

According to the REACH registration, there are no manufacturing sites in EU. However, manufacture in volumes from 1 up to 100 tonnes per year may be registered before 30th May 2018 and manufacture in volumes up to 1 tonnes per year may take place without REACH registration.

3.3 Import and export

Since no production sites have been identified for Europe, it is anticipated that the volumes registered under the REACH registration data correspond to the volumes imported into the EU. Several companies in China are identified as manufacturers of EPDA (Lookchem.com, 2014).

3.4 Use

The structure of EPDA holds an epoxy group, which is very reactive. It reacts with molecules containing reactive hydrogen such as amines, acids, acid anhydrides, phenols, alcohols and thiols by opening of the O-ring. This makes EPDA useful in a range of applications. EPDA is used to produce resins or as epoxy resin diluent and is mainly used in coatings, paints and dyes such as two-component systems consisting of resins and hardeners. EPDA may also occur in solvents for these systems. During the use, EPDA is reacted and therefore EPDA should not be present in end-products or in waste.

Identified uses in the EU

The substance EPDA is frequently used as a curing agent and a binder in paint systems, varnishes, adhesives, putty, sanding materials and in the manufacture of plastic and rubber materials. The substance is used both industrially and professionally. An overview of the identified uses by the registrant is shown in the table below (REACH registration data, 2014). Additional uses may be added at the next registration deadline in 2018 representing manufacture and imports within the tonnage band 1-100 t/a.

The identified uses are described in general terms in the REACH registration and the uses cover a wide range of sectors of end uses for industrial and professional applications.

TABLE 3-1
REGISTERED USES ACCORDING TO ECHA'S DATABASE OF REACH REGISTERED SUBSTANCES (REACH REGISTRATION DATA, 2014)

Use of EPDA	Corresponding Sector of End-Use categories (SU)
Formulation	Not applicable for formulation
Uses at Industrial Sites	SU 1: Agriculture, forestry and fishing SU 2a: Mining (without offshore industries) SU 2b: Offshore industries SU 5: Manufacture of textiles, leather, fur SU 6a: Manufacture of wood and wood products SU 6b: Manufacture of pulp, paper and paper products SU 7: Printing and reproduction of recorded media SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 15: Manufacture of fabricated metal products, except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment SU 18: Manufacture of furniture SU 19: Building and construction work SU 23: Electricity, steam, gas water supply and sewage treatment SU 24: Scientific research and development
Uses by Professional Workers	SU 1: Agriculture, forestry and fishing SU 5: Manufacture of textiles, leather, fur SU 6a: Manufacture of wood and wood products SU 6b: Manufacture of pulp, paper and paper products SU 7: Printing and reproduction of recorded media SU 8: Manufacture of bulk, large scale chemicals (including petroleum products) SU 9: Manufacture of fine chemicals SU 10: Formulation [mixing] of preparations and/or re-packaging (excluding alloys) SU 11: Manufacture of rubber products SU 12: Manufacture of plastics products, including compounding and conversion SU 13: Manufacture of other non-metallic mineral products, e.g. plasters, cement SU 15: Manufacture of fabricated metal products,

Use of EPDA	Corresponding Sector of End-Use categories (SU)
	except machinery and equipment SU 16: Manufacture of computer, electronic and optical products, electrical equipment SU 17: General manufacturing, e.g. machinery, equipment, vehicles, other transport equipment SU 18: Manufacture of furniture SU 19: Building and construction work SU 24: Scientific research and development

No customer use has been identified (non-professional uses) or subsequent “service life" in the REACH registration (REACH registration data, 2014).

However, data from the SPIN database indicate that one or several uses very probably leads to consumer exposure as well as occupational exposure. Also one or several uses indicate a very probable use in article productions (SPIN database, 2014).

A google search was performed in order to identify uses of EPDA as well as EPDA-containing products and suppliers. The table below presents some of the products identified based on information in safety data sheets (SDSs). It is emphasised that the data do not necessarily cover all product types and uses. The results indicate that the substance is applied mainly in products for industrial and professional uses. However, some coating products may also be applied by consumers. The reported percentage of EPDA within the products varies and is up to 35%.

EPDA has not been identified or included in surveys conducted by the Danish EPA of chemical substances in consumer products (Danish EPA, 2014).

TABLE 3-2
IDENTIFIED PRODUCTS CONTAINING 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) BASED ON GOOGLE SEARCH

Product name	Company	% EPDA in the product	Stated use	Typical application	Reference
Sigma mortar primer 2K EP hardener	PPG Coatings AC EMEA	25-<35	Hardener, coating	Coatings, consumer and professional use	Safety data sheet 00346617 2013.04.24
DELTA EP System H (Härter)	CD-Color GmbH & Co. KG	15-25	Hardener	Not stated	Safety data sheet 120648DE 2010.07.29
Sigma mortar primer 2K EP base	PPG Coatings AC EMEA	2.5-< 25	Base, coating	Coatings, consumer and professional use	Safety data sheet 00346616 2013.04.24
HEMPADUR MULTI-STRENGTH 35539	Hempel A/S	2.5 - < 25	Primer	Industrial application	Hempel Safety Data sheet version 0.01 31 January 2014

Product name	Company	% EPDA in the product	Stated use	Typical application	Reference
HEMPEL'S CURING AGENT 97382	Hempel A/S	2.5 - < 25	Curing agent	Industrial application	Hempel Safety Data sheet version 0.03 31 January 2014
EPIKOTE™ Resin 816 MV	Momentive	15-20	Epoxy resin	Industrial application	Momentive Safety data sheet 01/02/2013
EPIKOTE 255	Albion Chemical Group	10-20	NA	NA	Safety Data Sheet EPIKOTE 255 14/02/2008.
StoJet IHS Komp. A	Sto Danmark A/S	≥ 10 - < 20	Injection resin	Industrial and professional use	Safety data sheet MA10002357 2014.01.23
Catalyst 0656 13058	Esbjerg Farve- & Lakfabrik A/S	2.50 - 10	Paint	Surface treatment of metal	Safety data sheet 0656 13058 2014.03.31
Tremco CS175A	Tremco Illbruck	5 - <10	Epoxy resin – primer/sub-coating	NA	Tremco Illbruck Safety data sheet version 1 21/02/2013
StoPox WHG Grund 100 Komp. A	Sto Danmark A/S	≥ 2,5 - < 10	Coating material	Industrial and professional use	Safety data sheet 130000005679/E 2014.01.31
Tremco CS100 A	Tremco Illbruck	1 -<5	Epoxy resin – primer/sub-coating	NA	Tremco Illbruck Safety data sheet version 1 13/02/2013
MASTERTOP TC 473,T.A RAL 7035	BASF	≥ 0.5 - ≤2.5	Product applied in construction chemicals	Professional	Safety data sheet , MASTERTOP TC 473,T.A RAL 7035 (Version 1.0) 2010.08.17
StoPox Mörtel fein Komp. A	Sto Danmark A/S	≥ 1 - < 2.5	Mortar	Industrial and professional use	Safety data sheet MA10004006 2013.03.12
PercoTop ® 531 CS912	Axalta Coating Systems Germany GmbH	0.10 - < 0.20	Binder	Industrial and professional use	Safety data sheet 1250066027 v11.24 2014.02.05
EV350 IMRON® INDUSTRY PUR MATT BINDER	Dupont	0.10 - < 0.20	Paint	Painting of vehicles by professional painter	Safety data sheet, EV350 2010.11.26

Product name	Company	% EPDA in the product	Stated use	Typical application	Reference
Permaflex Iron Mica Binder Series 510 IM 510	Spies Hecker	0.10 - < 0.20	Binder	Industrial and professional use	Safety data sheet 4025331708780 v8.0 2011-01-07
Cardura E 10P	Momentive	NA	Reactive diluent for epoxy resins	Compositions for the building and civil engineering industries (e.g. flooring compounds, adhesives, mortars and grouts), for laminating binders, solvent-free and high solids coatings.	Product bulletin Cardura E 10P (2011)
CC6600 CROMAX ® PRO STAR CLEAR	Dupont	0.10 - < 0.20	SU 3, SU 22 PC9a, PC9b	Industrial and professional use	Safety data sheet, CC6600 2011.05.05

NA: NOT AVAILABLE

As part of this survey the Danish Chemical Industry, which is part of the Danish Chamber of Commerce was asked about the use and import of EPDA by its members, but no responses were received from the members. Furthermore a questionnaire was prepared and sent to the European organisations CEPE (European Council of the Paint, Printing Ink and Artists) and FEICA (The European Adhesive and Sealant Industry), as well as the Danish Coatings and Adhesives Association.

A total of 20 responses were received of which 11 companies responded that they do not use EDPA. The responses to the questionnaires are summarised in the table below. One of the companies is importing the products containing EPDA from outside EU. According to the results from the questionnaires, EPDA is used in products for industrial and professional uses and in formulation of articles or treatment of articles. The products are described as raw material for polymer production (epoxy resin), epoxy resins, epoxy paint, binders and primers for epoxy paint, coatings and catalysts. The responses from the questionnaires indicated that products are available for consumer use.

According to the responses from the questionnaires, EPDA is reacting chemically during the use in the epoxy paint. However, for some end products, the presence of EPDA is reported. This is the case for treated products such as enamels and coated steel and aluminium sheet.

TABLE 3-3
IDENTIFIED USES OF 2,3-EPOXYPROPYLNEODECANOATE BASED ON ANSWERS TO QUESTIONNAIRE.

Company	Type of use (sector)	Product type and content of EPDA	Concentration of EDPA in the end product
1	Industrial/Professional Formulation/mixing	Binder for paint (0.7%) Paint (0.3%)	No information
2	Industrial/Professional Formulation/mixing	Epoxy resin (10-20%) Base components, primers (1.5-6%)	Reacted in final product
4	Industrial Formulation/mixing	Catalyst (5%)	0.075-0.15 % in products Bound in the material
8	Industrial	Catalyst (<5%)	0.12% in enamels
3	Industrial/Professional	Epoxy resin (18-30%)	No information
5	Industrial/Professional	Epoxy resin (12.5-15%) Primers (<2%) Vehicle refinish products (>2.5%)	No information
7	Industrial/Professional	Raw material for polymer production (100%) Formulated paint (<30%)	Bound in the paint matrix. Up to 5% in epoxy based paints
9	Industrial/Professional	Coatings: Professional (< 0.05%) Industrial (0.4-14%)	Bound in the paint matrix <0.0004% in coated steel and aluminium sheet
6	Professional	Formulated paint (2-16%)	Reacted into the paint matrix

Use in 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. The database summarized information from the Nordic product registers on the common use of chemical substances in different types of products and industrial areas. Information of use volumes and information on the tonnage of substances in preparation in the Nordic countries has been retrieved (SPIN database, 2014).

Figure 3.1 below displays the numbers of preparations in which EPDA is applied in the Nordic countries. For Sweden, Finland and Norway there has been a marked increase in the numbers of preparations containing EPDA during the period from 2006 to 2012, whereas the number of preparations in Denmark has been almost constant.

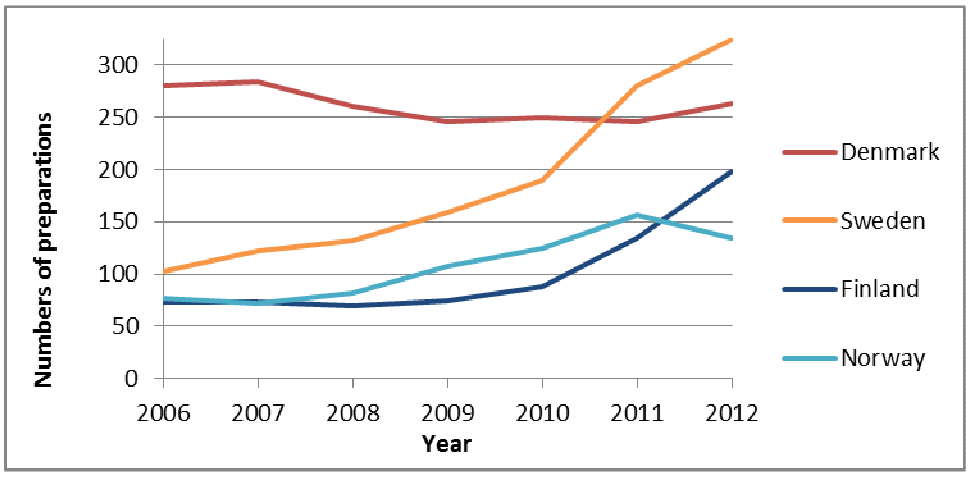


FIGURE 3.1
NUMBERS OF PREPARATIONS IN WHICH 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) IS APPLIED (SPIN DATABASE, 2014).

EPDA is present in varying concentrations in the preparations. Therefore, the number of preparations has to be considered together with information on the tonnes of EPDA in the preparations. Figure 3.2 shows the tonnage of EPDA applied in the Nordic countries (SPIN database, 2014). In spite of the increasing number of preparations containing EPDA for Sweden, Finland and Norway, the tonnage seems to decline during the years from 2006 to 2012. The decline is most pronounced, for Finland. Also the registered tonnage for Denmark has been decreasing in the period from 2006 to 2012. The total tonnage of EPDA in products in the Nordic countries is 53 tonnes in 2012.

In the figure, the reported tonnages for 2011 for Denmark (752 tonnes) and Norway (263 tonnes) have not been included as they are considered as errors since they differed markedly from the tonnage reported for previous years (SPIN database, 2014). According to information from the Danish product registry, the reported tonnages for 2011 and 2012 were errors and the corrected volume of EPDA registered for Denmark in 2012 (10 tonnes) was submitted and included in the figure (Data received August 2014).

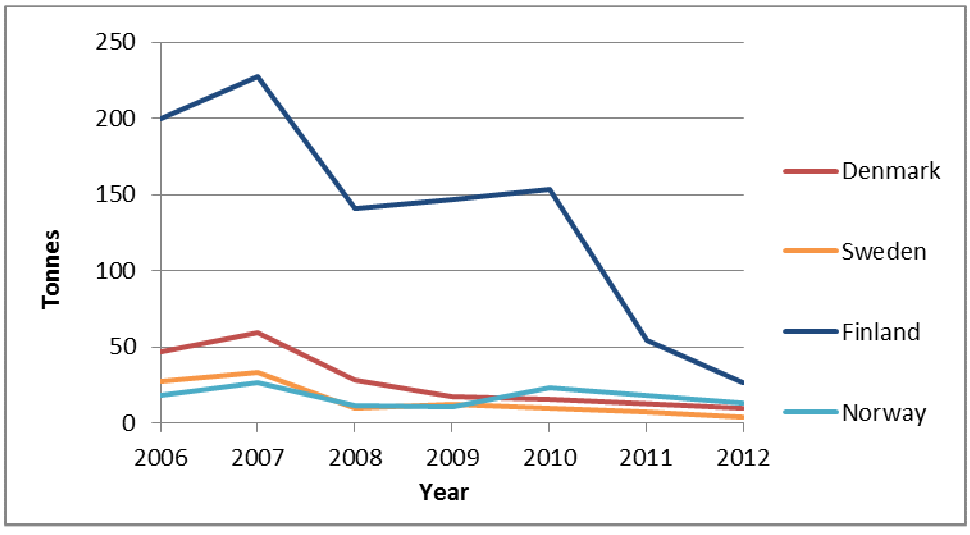


FIGURE 3.2
TONNES OF 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) APPLIED IN PREPARATIONS ON THE NORDIC COUNTRIES (SPIN DATABASE, 2014).

The same product categories for products containing EPDA in Denmark have been reported to the Nordic SPIN database from 2006 to 2012 (SPIN database, 2014).

The numbers of products in the categories are shown in Table 3-4 for 2012. Products registered in the other Nordic countries are within the same categories as in Denmark: Paints, lacquers and varnishes, surface treatment, adhesives, binding agents and construction materials. Furthermore, the product categories: Viscosity adjustors (Finland), laboratory chemicals (Norway) and process regulators (Sweden) have been reported. From the data it can be seen that in Sweden, Finland and Norway there is a general increase in the number of preparations with the highest increase within the product category "Paint, lacquers and varnishes". This increase is also covering preparations with no content of EPDA.

TABLE 3-4
TYPES OF PRODUCTS CONTAINING 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) AND CORRESPONDING NUMBER OF PRODUCTS WITHIN EACH CATEGORY IN DENMARK (SPIN DATABASE, 2014)

Product category	Number of products (2012)
Paints, lacquers and varnishes	179
Surface treatment	18
Adhesives, binding agents	14
Construction materials	7
Fillers*	7
Solvents*	4
Total	**229**

*According to information from SPIN, fillers and solvents are not contributing to the tonnes of EPDA (SPIN database, 2014).

Types of products which contain EPDA and which were reported to the Danish Product Registry (August, 2014) represent a wider group of products categories. The product categories and typical concentration of EPDA within the products are presented in Table 3-5. The number of products containing EPDA is 194 products reported by 42 companies.

The data indicate that EPDA is present in a wide range of products within coatings, paints and construction materials. In addition to this, EPDA is reported in surfactants and in car care products. However, these products may be related to the application of coatings and paints.

TABLE 3-5
TYPES OF PRODUCTS CONTAINING 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5) AND TYPICAL CONCENTRATION (%) REPORTED FOR THESE PRODUCT TYPES ACCORDING TO INFORMATION RECEIVED FROM THE DANISH PRODUCT REGISTRY (AUGUST, 2014)

Product category	Typical concentration (%)
Solvents and thinners	<100
Binders	< 25
Floor coverings	<25
Paint and varnish	<25
Surfactants and products	<15
Coatings non-metallics	<15
Fillers	<15

Product category	Typical concentration (%)
Dyes	<5
Hardeners	<5
Paint- and lacquer additives	<5
Toners	<5
Car care product	<1
Gloss altering agents	<1
Glazes and enamels etc.	<1
Metal coatings	<1
Raw materials	<1
Inks	<1

3.5 Trends in use

In the Nordic countries, the types of preparations in which EPDA is applied has been the same since 2006 and forward. Before 2006, EPDA was registered in same categories including process regulator and viscosity regulator (Spin database, 2014). A decline in the tonnage of EPDA in products placed on the Nordic market is observed in the period from 2006 to 2012.

In the answers to the questionnaire part of this survey and which were received from companies that confirmed that they use EPDA in their products, two companies indicated an increase in the use of EPDA during the last 10 years, another four companies indicated a decline and one company responded that the use is unchanged.

3.6 Summary and conclusions

According to the REACH registration, there are no manufacturing sites in the EU and therefore it is anticipated that the volume registered under the REACH registration data correspond to the volume imported into the EU. EPDA is used within the industrial sector and by professional users. The uses registered under REACH are representing a wide range of end use sectors. Frequent uses are as a curing agent and binder in epoxy paint systems, varnishes, adhesives and construction materials. EPDA is also used for surface treatment, in surfactants and in car care products. In the Nordic countries, EPDA has been registered within the same product categories since 2006. Available material safety data sheets and the responses from the questionnaire indicate that EPDA is applied in products for consumers. However, consumer use is not registered under REACH. In the Nordic countries there has been a decline in the tonnage of EPDA in the period from 2006 to 2012. The total tonnage of EPDA in products in the Nordic countries was 53 tonnes in 2012.

4. Waste management

4.1 Waste from manufacture and use of EPDA

According to the EU and Danish statutory order on waste, waste generated during manufacturing or from industrial use has 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 physical-chemical, toxicological or environmental properties (Danish Ministry of Environment, 2012; Directive 2008/98/EC). As mentioned in chapter 2, EPDA does not have a harmonised classification according to the CLP Regulation (EC) No 1272/2008 and waste containing EPDA is therefore not to be treated as hazardous waste.

In safety datasheets for coating products containing EPDA along with other substances it is recommended to consider waste as hazardous waste applying the following waste code: 08 01 11* waste paint and varnish containing organic solvents or other dangerous substances. This recommendation is based on the whole product which is typically composed of epoxy resins, solvents, pigments etc. of which some may be hazardous. It is therefore anticipated that industrial waste and waste from professional uses containing EPDA are treated as hazardous waste.

According to the answers received from industry , some end-products do not contain EPDA as the substance is reacted and bound in the paint matrix. However, some companies answered that products do contain EPDA and that solid waste is the only waste fraction relevant for EPDA. The responses indicated that certain products do contain EPDA (Table 3-3), but in low concentrations (<0.15%). A potential for environmental release is likely through the use and the waste stage of these products. For instance solid materials which have been treated with EPDA-containing products (paint, primers etc.) or putty or sanding materials when applied in construction work, may release EPDA when deposited on landfills or during weathering (no data on releases are however available).

4.2 Waste treatment

No information available. However, as the waste containing EPDA and other organic substances is rich in energy, the waste may be incinerated.

4.3 Summary and conclusions

EPDA does not have a harmonised classification (EC No 1272/2008) and is therefore not to be treated as hazardous waste. From the recommendations in safety datasheets for coating products, it is anticipated that industrial waste and waste from professional uses containing EPDA are treated as hazardous waste. According to the answers received from the questionnaire, some end-products do not contain EPDA. However, responses also indicated that certain products do contain EPDA from which a potential for environmental release is likely during the waste stage of these products.

5. Environmental effects and exposure

5.1 Environmental hazard

The information reported in this section is based on the available IUCLID datasheet (2000) as well as the information registered under REACH (REACH registration data, 2014).

EPDA possess environmental hazards leading to the environmental self-classification as (REACH registration data, 2014):

Aquatic chronic 2; H411: Toxic to aquatic life with long lasting effects.

5.1.1 Toxicity to aquatic organisms

Information on the aquatic toxicity is available for EPDA (CAS: 26761-45-5). Information covers the acute toxicity towards algae, crustacean and fish and is presented in Table 5-1. No data on long term effects, except for algae were available (REACH registration data, 2014). The highest acute toxicity is observed for algae where an ErC50 of 2.9 mg/L and an EbC50 of 1.2 mg/L was found after exposure of *Pseudokirchnerella subcapitata* for 72h.

TABLE 5-1
AQUATIC TOXICITY DATA FOR 2,3-EPOXYPROPYLNEODECANOATE (CAS: 26761-45-5)

Organism	Name	Duration	Endpoint	Effect (mg/L)	Reference
Fish	*Oncorhynkus mykiss*	96 h	LC_{50}	5	IUCLID Datasheet, 2000 REACH registration data, 2014
Crustacean	*Daphnia magna*	48 h	EC_{50}	4.8	IUCLID Datasheet, 2000 REACH registration data, 2014
Algae	*Pseudokirchnerella subcapitata*	72 h	E_rC_{50} E_bC_{50}	2.9 1.2	REACH registration data, 2014
Algae	*Selenastrum capricornutum*	72 h	EbC_{50} NOEC (biomass)	3.5 1	IUCLID Datasheet, 2000

EbC50: EFFECT ON BIOMASS (b)
ErC50: EFFECT ON GROWTH RATE (r)

5.1.2 Toxicity to sediment living organisms

No data available.

Predicted No Effect Concentration (PNEC) – Aquatic organisms
In the REACH registration data, a PNEC value has been calculated for the aquatic compartment. The PNEC = 0.0012 mg/L and 0.00012 mg/L for freshwater and marine water, respectively (REACH registration data, 2014). These values are based on the acute toxicity towards algae resulting in an EC_{50} of 1.2 mg/L (assessment factor = 1000 and 10,000 for fresh water and marine water respectively).

Predicted No Effect Concentration (PNEC) – sediment organisms
No data available.

5.1.3 Toxicity to microorganisms

Results from a test in accordance with the OECD Guideline 209 (Activated Sludge, Respiration Inhibition Test) is available resulting in a 3h NOEC > 500 mg/L (REACH registration data, 2014).

Predicted No Effect Concentration (PNEC) – microorganisms
Based on the result obtained during the study with microorganisms, a PNEC = 50 mg/L has been calculated for sewage treatment plants, applying an assessment factor of 10 (REACH registration data, 2014).

5.1.4 Toxicity to terrestrial organisms

No data available.

Predicted No Effect Concentration (PNEC) – terrestrial organisms
No PNEC has been calculated for this compartment.

5.2 Environmental fate

5.2.1 Distribution in the environment

In the REACH registration data results from a distribution modelling (Calculation according to Mackay, Level I) is presented. According to the results, EPDA will mainly distribute to the air compartment (99.7%) (see Table 5-2) (REACH registration data, 2014).

The Mackay Level I fugacity model is a very simple distribution modelling which does not take transformations or degradation into account. As part of this survey, a distribution modelling was done according to Mackay Level III taking transformation and degradation in air, water, soil and sediment into account. The results of the Mackay Level III modelling shown in Table 5-2 indicate that the substance is primarily distributed to the soil compartment (72%) and to a lesser degree to the water compartment (26%). Only a small part of the substance (2%) will distribute to the air compartment when transformations and degradation are taken into account. In the Mackay Level III, emissions to the air, water and soil is 1000 kg/hr and the model uses the following half-lives: 26.6 hr (air), 360 hr (water), 720 hr (soil) and 3240 hr (sediment). It should be noted that the two Mackay models are operating with different volumes of the environmental compartments also in relation to each other thus the results are not directly comparable.

TABLE5-2
RESULTS FROM DISTRIBUTION MODELLING (CALCULATION ACCORDING TO MACKAY, LEVEL I (REACH REGISTRATION DATA, 2014) AND LEVEL III FUGACITY MODEL (EPISUITE CALCULATION))

Compartment	Level I (%)	Level III (%)
Air	99.7	1.98
Water	0.23	25.6
Soil	0.08	72.1
Sediment	<1	0.277

5.2.2 Bioaccumulation

The log Kow of 4.4 is indicating a low to moderate potential for 2,3 -epoxypropylneodecanoate to bioaccumulate from water into aquatic organisms (REACH registration data, 2014).
QSAR calculations resulted in a BCF of 371.6 L/kg (log base regression model) (REACH Registration data, 2014).

5.2.3 Environmental degradation

Phototransformation

The atmospheric degradation half-life of EPDA was determined to be 0.9 days (experimental value) QSAR estimates show a half-life of 1.11 days (key study)(REACH registration data, 2014).

Hydrolysis

Hydrolysis has been studied according to the OECD TG 111 (Hydrolysis as a function of pH). Results showed that the test substance had a hydrolysis half-life of 8.8 - 9.8 days at 25 °C (over the pH range of 4 – 9). The primary hydrolysis product of the test substance, EPDA was the diol-structure (REACH registration data, 2014).

Biodegradation

Several tests on the aerobe biodegradation of EPDA have been performed according to OECD TG 301. According to the results obtained from the tests, EPDA is not readily biodegradable (7-8% degradation after 28 days). EPDA has been reported both as inherently biodegradable (68% degradation after 36 days) and not inherently biodegradable (-1% after 28 days) based on test results from the OECD TG 302 (REACH registration data, 2014).

5.2.4 PBT

EPDA is not readily biodegradable and not inherently biodegradable (REACH registration data, 2014). No results on persistency from simulation studies are available. Based on screening data and QSAR estimates, the REACH registrant concludes that EPDA is fulfilling the criteria as very Persistent (vP).

A predicted BCF of 371.6 L/kg (log base regression model) and an experimental Log K_{ow} = 4.4 is reported in the REACH registration and it is concluded that EPDA is not fulfilling the B criteria based on these data (REACH registration data, 2014).

EPDA is not toxic towards aquatic organisms (REACH registration data, 2014). Therefore it is concluded in the REACH registration that EPDA is not fulfilling the T criteria. However, it should be noticed, that the substance may fulfil the $T_{human\ health}$ criterion (based on its suspected CMR properties).

In conclusion, EPDA is not considered as a PBT or a vPvB substance (Registration data, 2014).

5.3 Environmental exposure

5.3.1 Sources of release

In the REACH registration data (2014), environmental release categories (ERCs) are reported. The ERCs describe the level of exposure to the environment. In the table below, the ERCs and the related default worst case release factors (ECHA, 2012) are presented.

From the ERCs, it is anticipated that EPDA is released to the environment during formulation and use at industrial sites and when used by professionals. The ERCs describing the uses of EPDA indicate that the main release of EPDA is to air and water and only a minor part is released to soil.

The estimated releases are reported in the Chemical Safety Report (CSR) of the REACH registration and included in the confidential part of this report (Appendix B).

TABLE 5-3
IDENTIFIED ENVIRONMENTAL RELEASE CATEGORIES (ERC) (REACH REGISTRATION DATA, 2014)

	ERC	Default worst case release factors (ECHA, 2012)
Formulation	ERC 2: Formulation of preparations	Air: 2.5%; Water: 2%; Soil: 0.01%
Uses at Industrial Sites	ERC 0: Other: mERC I.1, mERC I.2	Specific release factor (presented in Appendix B)
	ERC 6d: Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers	Air: 35%; Water: 0.005%; Soil: 0.025%
Uses by Professional Workers	ERC 0: Other: mERC I.2	Specific release factor (presented in Appendix B)
	ERC 8d: Wide dispersive outdoor use of processing aids in open systems	Air: 100%; Water: 100%; Soil: 20%
	ERC 8a: Wide dispersive indoor use of processing aids in open systems	Air: 100%; Water: 100%; Soil: N.A.

5.3.2 Monitoring data

No data available.

5.4 Environmental impact

No environmental monitoring data are available and no predicted environmental concentration (PEC) has been calculated for the environmental compartments.

EPDA is not readily biodegradable, and the reported acute toxicity towards aquatic organisms is between 1-5 mg/L, which is in the moderate to higher toxicity range although not fulfilling the criteria for T. The calculated BCF value for the substance is well below the criteria for B. However, the Log K_{ow} is 4.4, which is just below the screening criteria of 4.5.

Distribution modelling (Mackay Level III) indicates that the substance will distribute to the soil compartment (72%) and to a lesser degree to the water compartment (26%). Only a small part of the substance (2%) will distribute to the air distribute to the air compartment when transformations and degradation are taken into account (Please refer to Table 5-2).

The use index of the Nordic SPIN database indicates a probable exposure of air and soil and a very probable exposure of waste water. The exposure of surface water is indicated as potential (SPIN database, 2014). This is in accordance with the description and the selected ERCs (see Table 5-3) for the identified uses in the REACH registration (2014).

5.5 Summary and conclusions

Information on the aquatic toxicity is available for EPDA, however, no data on long term effects, except for algae are available. The reported acute toxicity towards aquatic organisms is between 1-5

mg/L, which is in the moderate to higher toxicity range. The highest acute toxicity is observed for algae.

EPDA is not ready biodegradable. EPDA has been reported both as inherently biodegradable and not inherently biodegradable.

According to the REACH registration (2014), EPDA does fulfil the criteria for persistence (P) but not the bioaccumulation (B) criteria. Even though the toxicity data in the REACH registration (2014) indicate that EPDA does not fulfil the criteria for toxicity (T), the substance may fulfil the $T_{human\ health}$ criterion based on its suspected CMR properties. EPDA is not considered as a PBT or a vPvB substance.

EPDA is self-classified for the environment as: Aquatic chronic 2; H411: Toxic to aquatic life with long lasting effects.

No environmental monitoring data are available, however, distribution modelling indicates that the substance will distribute to the soil compartment (72%), the water compartment (26%) and to the air (2%) when transformations and degradation are taken into account. The use index of the Nordic SPIN database indicates a probable release to air and soil and a very likely release via waste water.

6. Human health effects and exposure

6.1 Human health hazard

The information reported in this section is based on the information from the REACH registration of the substance. Also, conclusions on the human health hazard in this chapter are cited from the registration dossier (REACH registration data, 2014).

As it is expected that the mutagenicity will be critically evaluated by the Danish authorities as part of the EU's substance evaluation in 2015/2016, this chapter holds only a summary of the information and conclusions drawn in the REACH registration dossier and not a critical survey of the information and conclusions from the REACH registration.

Based on the toxicological data, DNEL-values (Derived No Effects Levels) have been elaborated in the registration. Data from studies of effect on fertility, which was considered as the most sensitive endpoint, were used. However, no studies on toxicity to reproduction are available in the registration dossier. A 28-day repeated dose toxicity study with oral doses to rats is available for which a NOAEL of 5000 ppm is derived. Only derived no effect levels (DNELs) for systemic effects for long term exposures have been derived for workers and for the general population. The DNELs as provided by the REACH registrants are shown in the table below.

TABLE 6-1
DNELS FOR LONG TERM SYSTEMIC EFFECTS FOR 2,3-EPOXYPROPYL NEODECANOATE DERIVED AS PART OF THE REACH REGISTRATION (REACH REGISTRATION DATA, 2014)

	Exposure route	DNEL
Workers	Inhalation	1.965 mg/m^3
	Dermal	1.4 mg/kg bw/day
General population	Inhalation	1 mg/m^3
	Dermal	0.7 mg/kg bw/day
	Oral	1.1 mg/kg bw/day

6.1.1 Classification

As described in Section 2.1.1, EPDA (CAS no. 26761-45-5) is self-classified for human health as part of the REACH registration as (REACH registration data, 2014):

Skin Sens. 1; H317: May cause an allergic skin reaction
Muta. 2; H341: Suspected of causing genetic defects.

6.1.2 Absorption, Distribution, Metabolism and Excretion of EPDA

Data from *in vitro* studies using diffusion cell technology with skin samples from rats, mice and humans demonstrated that an EPDA-isomer was metabolized in skin samples from rat, mouse and humans and that rat skin was most permeable to the test substance isomer. The degree of metabolism was not stated. Human skin samples were approximately one order of magnitude less permeable to the EPDA-isomer than rodent skin.
The predominant pathway of detoxication of EPDA was found to be epoxide hydrolase and carboxylesterase hydrolysis. To a lesser extent EPDA was metabolised by glutathione conjugation. Estimation of *in vivo* clearance based on *in vitro* kinetic data and following scaling suggested that the human detoxication rate may be approximately an-order-of-magnitude slower relative to rodents. (REACH registration data, 2014).

6.1.3 Acute toxicity

No acute toxicity of EPDA has been observed in studies with oral, dermal and inhalation doses of EPDA to rats (REACH registration data, 2014).

In an acute oral toxicity study according to OECD TG 420, no adverse findings attributed to the test substance administration were observed. Single oral administration of EPDA at a dose level of 2000 mg/kg caused no death in a group of ten fasted rats. The acute median lethal oral dose level (LD50) was found to exceed 2000 mg/kg body weight (REACH registration data, 2014).

Inhalation exposure of rats to a saturated vapour concentration of EPDA of approximately 240 mg/m^3 (26 ppm) performed according to a non-guideline standard method resulted in no mortalities. Therefore, the acute 4 hr LC50 value for EPDA is > 240 mg/m^3 (26 ppm) (REACH registration data, 2014).

The acute dermal toxicity of EPDA to male and female rats was assessed in an OECD TG 402 study. No mortalities or significant adverse clinical signs were observed. The slight erythematous reactions observed proved to be transient. The acute median lethal dermal dose level (LD50) for the test substance was found to exceed 2000 mg/kg body weight (REACH registration data, 2014).

6.1.4 Irritation

Studies on skin and eye irritation showed that EPDA is not an irritant (REACH registration data, 2014).

Under the conditions of an OECD TG 404 study undiluted EPDA was not irritating to rabbit skin following four hours of exposure (REACH registration data, 2014).

EPDA was evaluated for eye irritation potential in an OECD TG405. Instillation of 0.1 mL EPDA into the conjunctival sac of three rabbits caused transient conjunctival changes that resolved within 24 hours. The iris and cornea were overtly unaffected by instillation of the test article. Therefore, under the conditions of this study, EPDA was considered to be non-irritant to the rabbit eye (REACH registration data, 2014).

6.1.5 Sensitization

Animal and human studies on skin sensitization demonstrate that EPDA is a skin sensitizer and therefore the substances is self-classified with Skin Sens. 1; H317 by the REACH registrants (REACH registration data, 2014).

In an OECD TG 406 study (Guinea Pig Maximisation Test), EPDA inducted positive dermal reactions in 4/20 and 9/20 animals at 25% and 50% concentrations respectively. Therefore, under the conditions of this study EPDA is a mild to moderate dermal sensitizer (REACH registration data, 2014).

A patient was presented with severe dermatitis on the hands, arms, face, neck and genital area. The patient had been working for nine days filling undiluted epoxy resins hardeners and reactive diluents in drums (REACH registration data, 2014).

A male individual exposed to epoxy resins, epoxy resin hardeners and reactive diluents including EPDA was patch tested to determine skin sensitivity. The patient elicited positive dermal responses to epoxy resin at 0.001% and to EPDA at a concentration of 0.01%. The data demonstrate that EPDA can elicit a positive dermal reaction in humans previously sensitized to epoxy resins and/or components used in the manufacture of epoxy resins (REACH registration data, 2014).

6.1.6 Repeated dose toxicity

In an oral study, male and female Wistar rats were exposed up to a high dose of 10,000 ppm EPDA in their feed for a period of five weeks. The study was conducted by a method similar to OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity in Rodents) with an extension of the exposure period to 35 days. A variety of apparent adverse findings including: decrements in body weight gain, reduced feed consumption, increases in relative liver & kidney weights, changes in clinical chemistry parameters, reduced hemoglobin & hematocrit values (males only) and kidney histopathology occurred at 5000 and 10,000 ppm. However, due to palatability issues of the test substance, the NOAEL for this study based on expert judgement is 5000 ppm EPDA in the feed. The REACH registrant did not consider the adverse kidney events observed in male rats in this study as relevant to human health (REACH registration data, 2014).

A study for dermal exposure (Subchronic Dermal Toxicity: 90-Day Study, OECD Guideline 411) has been proposed by the REACH registrant, but a test proposal decision has not yet been issued from ECHA (REACH registration data, 2014).

6.1.7 Mutagenicity

The substance is self-classified with Muta. 2; H341 (REACH registration data, 2014). The following results are included in the REACH registration and referenced directly here (REACH registration data, 2014):

A bacterial reverse mutation assay (OECD TG 471;) was found positive when using metabolic activation.

Further a positive *in vivo* response was found in a transgenic rodent mutagenicity assay (OECD TG 488) as EPDA was shown to be a gene-mutagen in the liver, kidney and bone marrow of the MutaMouse demonstrating that the test substance is a systemic mutagen in mice by the oral route of exposure.

Negative results were obtained in an *in vitro* mammalian chromosome aberration test using CHO cells (OECD TG 473) and in a yeast cytogenetic assay (OECD TG 481; Genetic Toxicology: *Saccharomyces cerevisiae*, Mitotic Recombination Assay) both with and without metabolic activation.

EPDA did not induce DNA repair in an OECD TG 486 (Unscheduled DNA Synthesis (UDS) Test with Mammalian Liver Cells *in vivo*)

6.1.8 Carcinogenicity

No data available.

6.1.9 Reproduction and Developmental toxicity

No study available, therefore the following studies have been proposed as part of the REACH registration (REACH registration data, 2014):

OECD TG 416 (Two-Generation Reproduction Toxicity Study) – inhalation study

OECD TG 414 (Prenatal Developmental Toxicity Study) – dermal study

OECD TG 414 (Prenatal Developmental Toxicity Study) – inhalation study

For the prenatal developmental toxicity studies, a study in rabbits by the dermal route is proposed. An inhalation study is also proposed because toxicokinetic data demonstrate that there is little or no penetration of human skin by the test substance.

6.2 Human exposure

6.2.1 Direct exposure

6.2.1.1 Consumers

Based on the identified uses in the REACH registration, direct exposure to consumers is not expected, as no consumer uses or service life have been registered (REACH registration data, 2014). Based on the results from the questionnaire part of this survey, no exposure to consumers is identified. EPDA is used in formulation of articles or treatment of articles. The substance is bound (reacted) in the finished article so no exposure will occur during service life of the article. However, the responses from the questionnaire indicated that products are available also for consumer use.

From the search on safety datasheets on EPDA-containing products, it is concluded that most products are products for industrial and professional users. However, some coating products apply to consumers and therefore the exposure of consumers to EPDA cannot be excluded.
Exposure data from the SPIN database indicate that one or several uses very probably may lead to consumer exposure (SPIN database, 2014).

6.2.1.2 Occupational exposure

Occupational exposure is expected during industrial and professional use of EPDA. In the REACH registration data (2014), process categories (PROCs) are used to describe the activities and the level of occupational exposure. In the table below, the PROCs including the description of the related activity are presented. Based on the PROCs, dermal and inhalatory exposure by of workers and professionals are estimated. However, risk management measures may be used to eliminate or reduce the level of exposure.

The occupational exposure is supported by exposure data from the SPIN database (2014) indicating that one or several uses very probably leads to occupational exposure.

The answers to the questionnaire indicate that dermal exposure may occur during formulation, industrial use and professional use. It is however pointing out that inhalation and dermal exposure levels are controlled by the use of personal protective equipment.

TABLE 6-2
IDENTIFIED PROCESS CATEGORIES (PROC) (REACH REGISTRATION DATA, 2014)

	PROCs
Formulation	PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities
Uses at Industrial Sites	PROC 1: Use in closed process, no likelihood of exposure PROC 2: Use in closed, continuous process with occasional controlled exposure PROC 3: Use in closed batch process (synthesis or formulation) PROC 4: Use in batch and other process (synthesis) where opportunity for exposure arises PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 7: Industrial spraying PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 16: Using material as fuel sources, limited exposure to unburned product to be expected PROC 19: Hand-mixing with intimate contact and only PPE available.
Uses by Professional Workers	PROC 5: Mixing or blending in batch processes for formulation of preparations and articles (multistage and/or significant contact) PROC 6: Calendering operations PROC 8a: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at non-dedicated facilities PROC 8b: Transfer of substance or preparation (charging/discharging) from/to vessels/large containers at dedicated facilities PROC 9: Transfer of substance or preparation into small containers (dedicated filling line, including weighing) PROC 10: Roller application or brushing PROC 11: Non industrial spraying PROC 13: Treatment of articles by dipping and pouring PROC 14: Production of preparations or articles by tableting, compression, extrusion, pelletisation PROC 15: Use as laboratory reagent PROC 16: Using material as fuel sources, limited exposure to unburned product to be expected PROC 19: Hand-mixing with intimate contact and only PPE available.

	PROCs
	PROC 20: Heat and pressure transfer fluids in dispersive, professional use but closed systems

6.2.2 Indirect exposure

No data are available on indirect exposure to EPDA in the available sources.

Indirect exposure is reported in the CSR which is considered confidential. Information on indirect exposure is therefore included in Appendix B (confidential).

6.3 Bio-monitoring data

No data available.

6.4 Human health impact

The human health impact is done based on the overall results from the CSR and therefore included in Appendix B (confidential).

6.5 Summary and conclusions

Data on human health hazard is available from the REACH registration.

No acute toxicity of EPDA has been observed in rat studies with oral, inhalation and dermal exposure to EPDA and studies on skin and eye irritation showed that EPDA is not a skin and eye irritant. Animal and human studies on skin sensitization demonstrate that EPDA is a skin sensitizer and therefore the substances is self-classified with Skin Sens. 1; H317. In vitro studies indicate that EPDA is metabolized in skin samples from rat, mouse and humans. For repeated dose toxicity, adverse kidney events were observed in male rats in an oral study. However, the REACH registrants did not consider these findings as relevant to human health. Study for repeated dermal exposure to EPDA is planned as part of the REACH registration. Test for mutagenicity part of the REACH registration demonstrates that EPDA causes gene-mutation in the liver, kidney and bone marrow of the mouse by oral route. Therefore the substance is self-classified with Muta. 2; H341. No studies are available on carcinogenicity, reproductive toxicity or developmental toxicity. Studies have been proposed for reproductive and developmental toxicity as part of the REACH registration.

Exposure to consumers cannot be excluded as coating products are available to consumers according to information from safety datasheets. This is supported by information from the SPIN database indicating that one or several uses very probably leads to consumer exposure. No consumer exposures are indicated in the REACH registration. Occupational exposure is expected during industrial and professional uses of EPDA for which the exposure levels are controlled by the use of risk management measures such as personal protective equipment.

7. Information on alternatives

Based on the responses to the questionnaire part of this survey, possible alternatives to EPDA have been identified. The substances are under preliminary considerations and experiences are limited.

Alternative substances to EPDA may be Di-isopropanolamin (CAS: 110-97-4) and P-toluensulfonic acid (CAS: 104-15-4).

Di-isopropanolamin (CAS no.: 110-97-4) is registered under REACH as "1,1'-iminodipropan-2-ol" at a tonnage band of 1,000+ per year. According to information from the C&L Inventory the substance has a harmonized classification as H319 (Causes serious eye irritation). There is no classification regarding the environment (REACH registration data 2014; C&L Inventory database, 2014).

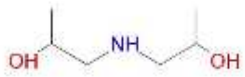


FIGURE 7.1
CHEMICAL STRUCTURE OF DI-ISOPROPANOLAMIN (CAS NO.: 110-97-4).

Di-isopropanolamin was included in the list for substance evaluation under REACH - the Community Rolling Action Plan (CoRAP) in 2013 due to high aggregated tonnage, exposure from wide dispersive use including exposure of consumer and workers in addition to the meeting of the criteria as CMR/suspected CMR and suspected sensitiser. However, Di-isopropanolamin is not on the Candidate List of Substances of Very High Concern for Authorisation.

P-toluensulfonic acid (CAS no.: 104-15-4) is registered under REACH at a tonnage band of 10,000-100,000 tonnes per year. There is a harmonized classification for the substance. The classifications only addresses human health: H315 (Causes skin irritation); H319 (Causes serious eye irritation) and H335 (May cause respiratory irritation) (REACH registration data 2014; C&L Inventory database, 2014).

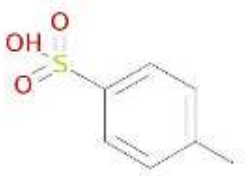


FIGURE 7.2
CHEMICAL STRUCTURE OF P-TOLUENSULFONIC ACID (CAS NO.: 104-15-4).

7.1 Summary and conclusions

Based on the responses to the questionnaire, possible alternatives to EPDA have been identified. The substances are under preliminary considerations and experiences are limited. Alternative substances to EPDA may be Di-isopropanolamin (CAS: 110-97-4) and P-toluensulfonic acid (CAS: 104-15-4).

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Safety data sheet 0656 13058 (2014.03.31): Katalysator 0656 13058, Esbjerg Farve- & Lakfabrik A/S

Safety data sheet 00346616 (2013.04.24): Sigma morter primer2K EP Base. PPG Coatings AC EMEA

Safety data sheet 00346617 (2013.04.24): Sigma mortar primer 2K EP hardener. PPG Coatings AC EMEA

Safety data sheet MA10002357 (2014.01.23): StoJet IHS Komp. A, Sto Danmark A/S

Safety data sheet MA10004006 (2013.03.12): StoPox Mörtel fein Komp. A, Sto Danmark A/S

Safety data sheet 130000005679/E (2014.01.31): StoPox WHG Grund 100 Komp. A, Sto Danmark A/S

Safety data sheet 1250066027 v11.24 (2014.02.05): PercoTop R 531 CS912, Axalta Coating Systems Germany GmbH

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Appendix A: Background information to chapter 2 on legal framework

The following appendix 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

[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

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. **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,
- 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.

[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).

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.

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