Danish Ministry of the Environment
Environmental Protection Agency

Survey of 2,2'-iminodiethanol

A report under the LOUS review project

Final report 07.07.2014.

Environmental Project No. xxxx, 2014

Consultation draft

Title: Survey of 2,2'-iminodiethanol

Survey of 2,2'-iminodiethanol

Authors and contributors:

Sonja Hagen Mikkelsen, Marlies Warming; COWI A/S, Denmark
Jytte Syska, Al Voskian; Syska Consulting

Published by:

The Danish Environmental Protection Agency
Strandgade 29
1401 Copenhagen K
Denmark
www.mst.dk/english

Photography:

[Name]

Illustration:

[Name]

Year:

2014

Map:

[Name]

ISBN no.

[xxxxxx]

Contents

Preface

Background and objectives

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

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

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 2,2'-iminodiethanolamine. This substance was included in the second list in 2000 and has remained on the list since that time.

The entry in LOUS for this substances is 2,2'-iminodiethanolamine. The main reason for the inclusion in LOUS is the classification with Xn; R48/22 according to Directive 67/548/EEC or STOT RE 2 according to Regulation No. 1272/2008 (CLP) and the volume used in Denmark.

The main objective of this study is, as mentioned, to provide background for the Danish EPA's consideration regarding the need for further risk management measures.

The process

The survey has been undertaken by COWI A/S and Syska Consult from September 2013 to June 2014. The work has been followed by an advisory group consisting of:

- Peter Hammer Sørensen, Danish EPA, Chemicals
- Anette Harbo Dahl, The Danish Coatings and Adhesives Association (DFL)
- Sonja Hagen Mikkelsen, COWI

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 Danish ecolabel secretariat (Nordic Swan and EU Flower) and the German Angel.
- Pre-registered and registered substances from ECHA's website;
- Production and external trade statistics from Eurostat's databases (Prodcom and Comext);
- Export of dangerous substances from the Edexim database;
- Data on production, import and export of substances in mixtures from the Danish Product Register (confidential data, not searched via the Internet);
- Date on production, import and export of substances from the Nordic Product Registers as registered in the SPIN database;
- Information from Circa on risk management options (confidential, for internal use only, not searched via the Internet)
- Monitoring data from the National Centre for Environment and Energy (DCE), the Geological Survey for Denmark and Greenland (GEUS), the Danish Veterinary and Food Administration, the European Food Safety Authority (EFSA) and the INIRIS database.
- Waste statistics from the Danish EPA;
- 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.
- PubMed and Toxnet databases for identification of relevant scientific literature.

Besides, direct enquiries were made to Danish and European trade organisations and a few key market actors in Denmark.

Background and objectives

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

Over the period 2012-2015 all 40 substances and substance groups on LOUS will be surveyed. The surveys include collection of available information on the use and occurrence of the substances, internationally and in Denmark, information on environmental and health effects, on alternatives

to the substances, on existing regulation, on monitoring and exposure, and information regarding ongoing activities under REACH, among others.

On the basis of the surveys, the Danish EPA will assess the need for any further regulation, substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

Summary and conclusions

Over the period 2012-2015, all 40 substances and substance groups on the Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) will be subject to survey and review. On the basis of the results, the Danish EPA will assess the need for any further regulation: substitution/phase out, classification and labelling, improved waste management or increased dissemination of information.

This survey concerns 2,2'-iminodiethanolamine. The substance was included in the LOUS 2000 based on the classification criteria.

2,2'-Iminodiethanolamine (DEA)
2,2'-Iminodiethanolamine or diethanolamine (DEA) belongs to the chemical family of alkanolamines and is a polyfunctional substance combining the properties of both amines and alcohols with the capability of undergoing reactions common to both groups. These properties make the substance very versatile with a variety of applications.

Regulatory framework
DEA is classified as acute toxic, skin irritating, eye damaging and with regard specific target organ toxicity following repeated exposure.

At EU level, DEA is prohibited for use in cosmetics, but not otherwise addressed specifically in any legislation relating to products, wastes, or environmental emissions. In Denmark DEA is assigned an occupational exposure limit value in the Executive Order on Occupational Limit Values for Substances and Materials and a code number in the Executive Order on Determination of Code Numbers which represent the minimum safety precautions to be taken in certain work situations.

DEA has been subject to substance evaluation under CoRAP 2012-2014 due to concerns about human health and its wide dispersive use. In February2014 a decision from ECHA was published requesting further testing and information from the registrants.

DEA is not mentioned specifically by name in any product criteria of the Nordic or European Ecolabels but is be covered by general classification criteria which trigger restrictions in some product groups such as office and hobby materials under the Nordic Swan.

DEA is not a major environmental concern ad is not mentioned in the international conventions and agreements

Manufacture and use
DEA is registered with a full registration under REACH in the tonnage band 10,000 - 100,000 t/y. The major uses for diethanolamine in Europe are as a solvent for gas desulfurisation and as an industrial intermediate for agricultural chemicals. The agricultural chemical use in Denmark has declined sharply since 2008, but the use as an intermediate for fatty acid amides and agricultural chemcials elsewhere in the EU remain significant. The use of diethanolamine in widely dispersed uses with significant worker or consumer exposure such as in lubricants, cooling and cutting oils, corrosion inhibitors, and in cosmetics and cleaning/washing agents has in Denmark already been largely reduced due to health concerns. This trend is also seen in EU and most other developed economies. Since diethanolamine can also be used to strip carbon dioxide from gas streams, it is

possible that its use might grow to control CO_2 emissions from stationary power sources if economically feasible ways to sequester or productively use the recovered CO_2 can be developed.

Waste management
DEA is not manufactured in Denmark and therefore no waste is generated from production or synthesis of the substance. Products and chemical waste containing DEA will typically be collected incinerated as organic chemical waste. Waste codes will be assigned according to the use.

Environmental fate and exposure
DEA can be regarded as easily degradable in sewage treatment plants and surface water and is rapidly decomposed by hydroxyl radicals in air (half-life of about 4.2), where concentrations of DEA are expected to be very low. Environmental distribution modelling shows that the uncharged DEA molecule will distribute nearly completely into water.

DEA is not very toxic to aquatic organisms, the lowest EC50 of the key acute studies being 2.2 mg/l (*Pseudokirchneriella subcapitata*) and the lowest chronic NOEC being 0.78 mg/l for *Daphnia magna*.

Data on industrial emissions or STP discharges of DEA are not available for Danish or European conditions. However, due to its rapid biodegradation and its low potential for bioaccumulation, the environmental exposure is expected to be very low.

Human health effects and exposure
DEA has a moderate acute oral toxicity, and is a skin and severe eye irritant. In subchronic toxicity testing conducted via the oral route in rats and mice, the main effects observed were increased organ weights and histopathology of the kidney and or liver, with the majority of other tissue effects noted only at relatively high doses.

Signs of developmental toxicity have been observed in a few studies at high doses. In a 13-week subchronic study drinking water study in male rats, toxic effects on testis were observed. As a result of the REACH substance evaluation procedure, ECHA has in the decision taken pursuant to Article 51(6) requested that the registrants provide further testing of the DEA to include an Extended One Generation Reproductive Toxicity Study in rats, oral route, according to test method OECD TG 443 with the developmental neurotoxicity and immunotoxicity (DNT/DIT) cohorts but without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation. This test is expected to contribute to fill information gaps regarding the observed testis toxicity and the potential to cause neurotoxic effects and effects on the developing immune system.

Based on animal studies and updated information from cohort studies in humans IARC has in 2012 concluded that there is "sufficient evidence" in experimental animals for the carcinogenicity of DEA and that DEA is "possibly carcinogenic to humans" (Group 2B). One of the key concerns in relation to DEA and cancer risk, is the formation of nitrosamine in the products such as cutting oils and cosmetics containing DEA. Because DEA is a secondary amine, it could react with nitrosating agents like nitrites, which are common and naturally occurring chemicals, to produce the carcinogenic nitrosamine, 2,2'-(nitroso)bisethanol (NDELA). Due to the risk of formation of nitrosamines, the decision from ECHA also requests the registrants to provide further information on the transformation product of DEA (NDELA) to be reflected in the CSR (exposure assessment and risk characterisation for carcinogenic transformation product, for workers and consumers). Dermal contact, inhalation and ingestion are considered relevant exposure routes for the general population and DMELs must be derived for all possible exposure routes.

Occupational exposure to DEA is expected to be limited in Denmark, but may occur by dermal contact, inhalation of fumes and aerosols from various processes if the necessary safety precautions are not properly implemented.

The general public will primarily be exposed through skin contact with DEA as a contaminant from primary and tertiary alkanolamines or their salts in cosmetics and from use in certain in cleaning/washing agents where DEA is present, often as a contaminant in fatty acid-diethanolamide surfactants. DEA may also be present in food contact materials. Other less frequent sources of exposure may be through construction materials additives, corrosion inhibitors, cutting oil, and others.

Consumers may also be exposed to DEA residues resulting from the use of DEA as processing aid in the production of paper, textile and leather. No exposure estimates are available and the registrants of DEA therefore also requested to provide exposure estimations and risk characterisations for human health for consumer use of plastic rubber, textile, leather and paper products according to the substance evaluation procedure in order to demonstrate safe use.

Secondary exposure to DEA may also be expected due to releases from articles which have been treated with DEA in detergents, cleaners or wood protection formulations. The registrants of DEA have therefore also been requested to provide additional exposure scenarios and estimations for residues on textiles and food contact materials. Furthermore the registrants are requested to provide scenarios for secondary exposure to wood protection formulations, including sanding of treated wood by adults, chewing of treated wood by children, inhalation of volatilised residues indoors by adults and children playing and mouthing on treated structure.

The decisions also requests the registrants to provide supplementary information in relation to different other consumer scenarios, such as use of DEA in concrete and cement, use of DEA in detergents and cleaners, and use of DEA in wood protection formulations.

In the Danish EPA consumer survey programme, DEA has been identified in 3 out of 82 products identified as being used for cleaning of smoke-damaged private homes following a fire and in one out of eight sanitary towels selected for chemical analysis in a study investigating chemicals in this type of products.

As illustrated by the request for further information in the decision from ECHA as a result of the substance evaluation procedure, there is not sufficient information available to evaluate the risk from both occupational and consumer use of the DEA including the potential risk from exposure to NDELA.

Information on alternatives

Alternatives are however available for most uses of DEA, which has already been replaced in many end uses which involve significant worker or consumer exposure. It is likely that the remaining high-exposure end uses will also undergo substitution to other substances, except in very specific applications. This is a global trend, as well as in Denmark.

The use of diethanolamine for gas treatment is likely to grow, although other amines will compete in this end use. Additionally, the use of diethanolamine as a chemical intermediate for the production of herbicides and amides is likely to grow outside of Denmark, but not domestically.

The majority of the suggested substances also belong to the group of amines or amides which exhibit varying degree of skin and eye irritation or corrosion.

Conclusion

The major uses of DEA in Denmark are according to SPIN data the use as intermediate followed by the general use indicated as solvent or thinner. Since the year 2000 the amounts registered under cleaning and washing agents, and the amounts registered under lubricants, cooling and cutting agents have decreased considerably and consequently also the potentially related exposures.

DEA is not a major environmental concern. In relation to human health DEA is evaluated as "possibly carcinogenic to humans" by IARC. A specific concern is the formation of carcinogenic nitrosamines in the presence of nitrosating agents.

Alternatives are available for most uses. Many of the alternatives are also amines, which share some of the irritating properties of DEA. For several uses mixtures of substances are necessary to compensate for the polyfunctional properties of DEA.

The main data gaps which are identified are those defined in relation to the REACH substance evaluation procedure where ECHA has evaluated the information in the REACH registration dossier. Based on the dossier information ECHA has requested additional testing and information in order to evaluate the risk for workers and consumers exposed to work situations and products where DEA is present. The updated registration dossiers shall be submitted by 25 May 2016.

Sammenfatning og konklusion

I perioden 2012-2015 skal alle 40 stoffer og stofgrupper på Miljøstyrelsens liste over uønskede stoffer (LOUS) kortlægges og vurderes. På baggrund af resultaterne vil den danske Miljøstyrelse vurdere behovet for yderligere regulering, substitution/udfasning, klassificering og mærkning, forbedret affaldshåndtering eller yderligere informationsaktiviteter.

Denne undersøgelse vedrører 2,2 '-iminodiethanolamine. Stoffet indgik i LOUS 2000 på grundlag klassificeringskriterierne.

2,2 '-Iminodiethanolamine (DEA)
2,2 '-Iminodiethanolamine eller diethanolamin (DEA) hører til gruppen af alkanolaminer og er et polyfunktionelt stof, der kombinerer egenskaberne fra både aminer og alkoholer med evnen til at undergå reaktioner fælles for begge grupper. Disse egenskaber gør stoffet meget alsidigt og anvendeligt i en lang række applikationer.

Lovgivning og anden regulering
DEA er klassificeret som akut giftigt, hudirriterende, alvorligt øjenirriterende og med hensyn specifik målorgantoksicitet efter gentagen eksponering.

På EU-plan er DEA forbudt til brug i kosmetik, men er ikke direkte reguleret i anden lovgivning vedrørende produkter, affald, eller miljømæssige emissioner. I Danmark er der fastsat en grænseværdi for arbejdsmiljømæssig eksponering i Bekendtgørelse om Grænseværdier for Stoffer og Materialer og et kodenummer i Bekendtgørelse om Fastsættelse af Kodenumre, som repræsenterer de mindstekrav til sikkerhedsforanstaltninger, der skal træffes i bestemte arbejdssituationer.

DEA har været genstand for stofevaluering under CoRAP 2012-2014 på grund af bekymringen for sundhedsmæssife effekter og udbredt brug af stoffet. I februar2014 offentliggjorde ECHA en beslutning på baggrund af evalueringenmed anmodning om yderligere testning og data fra registranterne.

DEA er ikke nævnt specifikt ved navn i miljømærkekriterierne under det nordiske og europæiske Miljømærke men er omfattet generelle kriterier knyttet til klassificeringen, som medfører restriktioner i visse produktgrupper såsom kontor- og hobbyartikler.

DEA anses ikke for at udgøre et væsentligt miljømæssig problem og er ikke nævnt i de internationale konventioner og aftaler

Fremstilling og anvendelse
Den samlede registrerede fremstilling og import af n-hexan i EU angives at være inden for mængdeintervallet 1.000-10.000 t/år. De væsentligste anvendelser af DEA i Europa er i forbindelse med afsvovling af gas og som et industrielt mellemprodukt til fremstilling landbrugskemikalier. Anvendelsen til fremstilling af landbrugskemikalier i Danmark er faldet kraftigt siden 2008, mens anvendelsen som mellemprodukt til fremstilling af fedtsyreamider og landbrugskemikalier andre steder i EU fortsat er betydelig. Brugen af DEA i forskellige anvendelser med betydelig arbejdstager- eller forbrugereksponering, såsom i smøremidler, køle-og skæreolier, korrosionsinhibitorer, i kosmetik og rengørings / vaskemidler er allerede i vidt omfang reduceret i Danmark på grund af

sundhedsmæssige betænkeligheder. Denne tendens ses også i EU og de fleste andre udviklede økonomier. Da diethanolamin også kan bruges til at strippe kuldioxid fra gasstrømme, er det sandsynligt, at brugen vil kan vokse med henblik på, at kontrollere CO2-emissioner fra stationære kilder, såfremt der kan udvikles økonomisk gennemførlige metoder til at binde eller produktivt bruge udvundet CO2.

Affaldshåndtering
DEA fremstilles ikke i Danmark, og der genereres derfor ikke affald fra produktion eller syntese af stoffet. Produkter og kemisk affald, der indeholder DEA, vil typisk blive indsamlet med henblik på forbrænding som organisk kemisk affald. Affaldskoder vil blive tildelt i henhold til denne brug.

Miljømæssige effekter, skæbne og eksponering
DEA kan betragtes som let nedbrydeligt i rensningsanlæg og overfladevand og nedbrydes hurtigt af hydroxyl radikaler i luften (halveringstid på omkring 4,2), hvor koncentrationen af DEA I øvrigt forventes at være meget lav. Modellering af fordelingen i miljøet viser, at det uladede DEA molekyle vil fordeles næsten udelukkende til vand.

DEA er ikke særlig giftig for vandlevende organismer, den laveste EC_{50} for nøglestudier af akut toksicitet var 2,2 mg / l (Pseudokirchneriella subcapitata) og den laveste kronisk NOEC var 0,78 mg / l for Daphnia magna.

Data vedrørende industrielle emissioner eller udledninger af DEA fra rensningsanlæg er ikke tilgængelige for hverken danske eller europæiske forhold. På grund af den hurtige bionedbrydelighed og ringe potentiale for bioakkumulering, forventes den miljømæssige eksponering at være meget lav.

Sundhedseffekter og eksponering
DEA har en moderat akut oral toksicitet, og er hudirriterende og alvorligt øjenirriterende. I subkroniske orale toksicitetstest i rotter og mus var de vigtigste observerede effekter øget organvægt og histopatologiske fund i nyrerne og leveren, hvorimod de fleste andre vævseffekter kun sås ved relativt høje doser.

Tegn på udviklingstoksicitet er blevet observeret i nogle få studier ved høje doser. I et 13-ugers subkronisk studie drikkevandsstudie i hanrotter, blev der observeret toksiske effekter på testiklerne. Som et resultat af REACH kemikalievurderingsproceduren, har ECHA i sin beslutning truffet i henhold til artikel 51 (6) anmodet registranterne om at udføre yderligere test af DEA i form af et udvidet en-generations reproduktionsstudie i rotter ved oral eksponering. Studiet skal ligeledes belyseeffekter som udviklingsneurotoksicitet og immunotoksicitet. Denne test forventes at bidrage til at udfylde huller i dokumentationen vedrørende de observerede effecter på rottetestikler og potentialet til at forårsage neurotoksiske virkninger og virkninger på det ikke færdigudviklede immunsystem.

Baseret på dyreforsøg og opdaterede oplysninger fra kohortestudier hos mennesker har IARC i 2012 konkluderet, at der er tilstrækkelige beviser i forsøgsdyr for den kræftfremkaldende effekt af DEA og at DEA er muligvis kræftfremkaldende for mennesker (gruppe 2B). En af de væsentligste bekymringer i forhold til DEA og kræftrisiko, er dannelsen af nitrosaminer i de produkter såsom skæreolier og kosmetik, der indeholder DEA. Da DEA er en sekundær amin, kan stoffet reagere med nitroserende stoffer som nitrit, der er et almindeligt forekommende kemikalie, og producere kræftfremkaldende nitrosaminer, 2,2 '-. (nitroso) bisethanol (NDELA). På grund af risikoen for dannelse af nitrosaminer, anmoder ECHA også registranterne om at levere yderligere oplysninger om omdannelsesprodukter af DEA (NDELA) . Disse oplysninger skal afspejles i kemikaliesikkerhedsrapporten i forbindelse med eksponeringsvurdering og risikokarakterisering for kræftfremkaldende effekter af NDELA med relevans for arbejdstagere og forbrugere).

Hudkontakt, indånding og indtagelse anses for relevante eksponeringsveje for den almene befolkning og DMEL skal udledes for alle relevante eksponeringsveje.

Erhvervsmæssig eksponering for DEA antages at være begrænset i Danmark, men kan forekomme ved hudkontakt, og indånding af dampe og aerosoler fra forskellige processer, såfremt de nødvendige sikkerhedsforanstaltninger ikke er fortaget.

Forbrugere vil primært blive eksponeret via hudkontakt med DEA som forurening fra primære og tertiære alkanolaminer eller deres salte indeholdt i kosmetik og fra anvendelse i visse i rengøring / vaskemidler, hvor DEA er til stede i fedtsyre-diethanolamid tensider . DEA kan også forekomme i materialer i kontakt med fødevarer. Andre mindre hyppige kilder til eksponering kan være additive I byggematerialer, korrosionsinhibitorer, skæreolier, og andre.

Forbrugerne kan også blive udsat for DEA restprodukter fra brugen af DEA som hjælpestof i produktionen af papir, tekstil og lædervarer. Ingen eksponeringsestimater er tilgængelige resistreringsdossieret for DEA. Registranterne er derfor også anmodet om at estimere eksponeringen og foretage en risikokarakterisering med hensyn til forbrugernes udsættelse via gummi-, tekstil-, læder- og papirprodukter med henblik på at demonstrere sikker anvendelse.

Sekundær eksponering for DEA kan også forventes I forbindelse med frigivelse fra artikler, som er blevet behandlet med DEA i vaskemidler, i rengøringsmidler eller i træbeskyttelsesmidler. Registranterne skal opstille yderligere scenarier og estimere eksponering for rester af DEA i tekstiler og i fødevarekontaktmaterialer. Desuden er registranterne blevet bedt om at opstille scenarier for sekundær eksponering i forbindelse med træbeskyttelse, herunder slibning af behandlet træ (voksne), tygning af behandlet træ (børn), indånding af afdampningsrester indendørs (voksne) og i forbindelse med børn, der leger og sutter på behandlet struktur.

I den danske Miljøstyrelses forbrugerprogram er DEA blevet identificeret i 3 ud af 82 produkter, som bliver brugt til rengøring af røg-beskadigede private hjem efter brand, og i én ud af otte hygiejnebind udvalgt til kemisk analyse i en undersøgelse af indholdet af kemikalier i denne type produkter.

Information om alternativer
Alternativer er tilgængelige for de fleste anvendelser af DEA. DEA er dog allerede erstattet eller begrænset i en lang række produkter, der medfører en betydelig arbejdstager- eller forbrugereksponering. Det er sandsynligt, at de resterende anvendelser med høj eksponering også vil give anledning til substitution med andre stoffer, på nær i meget specifikke applikationer. Dette er en global tendens, såvel som en tendens i Danmark.

Konklusion
De væsentligste anvendelser af DEA i Danmark er i henhold til SPIN data anvendelsen som mellemprodukt efterfulgt af den generelle brug angivet som opløsningsmiddel eller fortynder. Siden år 2000 de mængder, der er registreret under henholdsvis rengørings-og vaskemidler, og under smøremidler, og køle- skærevæsker faldet betydeligt og dermed også de potentielle eksponeringer forbundet hermed.

DEA udgør ikke en væsentlig miljømæssig bekymring. I forhold til menneskers sundhed er DEA vurderet som "muligt kræftfremkaldende for mennesker" af IARC. En særlig bekymring er dannelsen af kræftfremkaldende nitrosaminer ved tilstedeværelse af nitroserende stoffer.

Altenativer til DEA er tilgængelige for de fleste anvendelser. Mange af alternativerne er også aminer, som deler nogle af de hudirriterende egenskaber ved DEA. For flere anvendelser er

blandinger af stoffer nødvendige ved substitution for at kompensere for DEAs polyfunktionelle egenskaber.

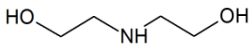
De væsentligste datamangler, der er identificeret, er beskrevet i forbindelse til REACH stof evalueringsproceduren, hvor ECHA har vurderet oplysningerne i REACH-registreringsdossieret. Baseret på disse oplysninger har ECHA anmodet om yderligere testning og yderligere data fra registranterne. Først når disse data foreligger kan der foretages den nødvendige risikovurdering forbundet med arbejdstageres og forbrugeres udsættelse for DEA. Det opdaterede registreringsdossier skal indsendes senest den 25. maj 2016.

1. Introduction to the substance

1.1 Definition of the substance

DEA belongs to the chemical family of alkanolamines and is a polyfunctional substance combining the properties of both amines and alcohols with the capability of undergoing reactions common to both groups. Chemical name and synonyms as well as other identifiers of the substances are listed in Table 1.

TABLE 1
NAME AND OTHER IDENTIFIERS OF THE SUBSTANCE OF THIS SURVEY

Substance name	2,2'-iminodiethanol
EC number	203-868-0
CAS number	111-42-2
Synonyms	Diethanolamine, DEA, di(2-hydroxyethyl)amine; 2,2'-dihydroxydiethylamine; diolamine; bis(2-hydroxyethyl)amine
Molecular formula	$C_4H_{11}NO_2$
Structure	
Molecular weight	105.14 g/mol

1.2 Physical and chemical properties

The physical and chemical properties of DEA are shown in Table 2. The listed properties mainly refer to the registration dossier available at ECHA's website. The registration dossier may include different values for the same parameter; in this case, all values are indicated. Please consult the registration for the original references.

TABLE 2
PHYSICAL AND CHEMICAL PROPERTIES OF THE SUBSTANCE (REF: REGISTATION AT ECHA WEB-SITE)

Property	Xx
Physical state	Solid (20°C and 1013 hPa)
Melting point	27 °C
Boiling point	269.9 °C (1013.25 hPa), ≥ 200 °C: Decomposition
Relative density	1.1 g/cm³ (20 °C)

Vapour pressure	0.0002 hPa (20 °C)
Surface tension	-
Water solubility	1000 g/L (20 °C) (calc.)
Log P (octanol/water)	-1.71 (25 °C)(calculated) -2.46 (25 °C) (measured) -2.18 (25 °C) (measured)

1.3 Function of the substances for main application areas

DEA has diverse industrial applications and might also be found in a few consumer relevant uses. In Denmark, it is mainly used as a process chemical in gas treatment for removal of sulfur-bearing compounds and CO_2. Furthermore, the substance functions as chemical intermediate, e.g. for the production of pesticides.

DEA is also used as a reaction intermediate in textile finishing, in photographic developing systems, in metal working fluids and as a catalyst that promote the stability during the reaction process in the manufacture of flexible and rigid urethane foams. In consumer products DEA is used as an emulsifier in cosmetics, and in cleaners and detergents ethanolamine impart a reserve alkalinity to the laundry bath contributing to efficient cleaning.

2. Regulatory framework

This chapter gives an overview of how DEA (DEA) is addressed in existing and upcoming EU and Danish legislation, international agreements and by EU and Nordic eco-label criteria. The chapter primarily focuses on legislation where DEA is addressed specifically by chemical name or CAS number. Legislation, where the substance is implicitly addressed, i.e. where DEA is included in the overall scope of a regulation/directive (e.g. due to the substance classification), is not listed.

In Appendix 1, a brief overview of legal instruments in the EU and DK and how they are related is presented. The appendix also gives a brief introduction to the chemicals legislation, explains the lists referred to in section 2.1.3on REACH, and provides a brief introduction to international agreements and the EU and Nordic ecolabelling schemes.

2.1 Legislation

This section will first list existing legislation addressing DEA, and then provides an overview of on-going activities or planned activities in relation to various REACH provisions.

2.1.1 Existing legislation

Table 3 provides an overview of existing key legislation specifically addressing DEA. As can be seen, the substance has a harmonised classification and it is prohibited for use in cosmetics. In Denmark DEA is assigned an occupational exposure limit and a code number to guide the use of safety precautions to be applied during certain work situations.

TABLE 3
LEGISLATION ADRESSING 2,2'-IMINODIETHANOL.

Legal instrument*1	Substance	EU/DK	Requirements
Legislation addressing substances (Danish EPA)			
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC	EU	2,2'-iminodiethanol ; 203-868-0; 111-42-2	Included in the List of harmonised classification and labelling of hazardous substances
Legislation addressing products (Danish EPA)			
Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products	EU	Secondary alkyl- and alkanolamines and their salts	Listed in ANNEX II, Reference number 411: List of substances prohibited in cosmetic products

Legislation addressing food contact materials (Danish Veterinary and Food Administration)			
Statutory Order No. 822 of 25 June 2013 on Food Contact Materials. (Bekendtgørelse om fødevarekontaktmaterialer)	DK	DEA	DEA is listed in Annex 3, Section B : List of substances authorised in the manufacture of regenerated cellulose film with the following entry: Aliphatic acids (C8 to C20) esterified with mono- or di-(2-hydroxyethyl)amine.
Legislation addressing work with substances and materials (Ministry of Employment)			
Statutory Order no. 507 of 17/05/2011 on occupational limit values for substances and materials (Bekendtgørelse om grænseværdier for stoffer og materialer, BEK nr 507 af 17/05/2011 – with later amendments) / MST)	DK	111-42-2, Diethanolamine	Listed in Annex 2, Section A on limit values for air pollution - List of exposure limit values for gases, vapors and particulate pollution: Limit values: 0.46 ppm, 2 mg/m³ Notation: H (substance can be absorbed through the skin)
Executive Order on Determination of code numbers, No. 301 of 13/05/1993 [Bekendtgørelse om fastsættelse af kodenumre, BEK nr 301 af 13/05/1993] /Danish Ministry of Employment **Executive Order on Work with Code-numbered products, No. 302, 13.05.1993** [Bekendtgørelse om arbejde med kodenummererede produkter, BEK nr. 301 af 13/05/1993] /Danish Ministry of Employment	DEA	DK	The Metrological Occupational Air Requirements, called MAL [Danish: Måleteknisk Arbejdshygiejnisk Luftbehov] are defined for *DEA* as follows: ***n*-Hexane content > 0%** - MAL-factor (m³ air / 10 g substance): O - Content (limit weight %) / number after the hyphen: - ≥ 2% - 10% / -2 - ≥ 10% / -3 Defines minimum safety measures which have to be applied when working with code-numbered products depending on working situations (outside, inside, large or small application areas) and processes (e.g. painting, grouting).

*1 Unofficial translation of name of Danish legal instruments.

2.1.2 Classification and labelling

Harmonised classification in the EU

Table 4 lists the harmonized classification and labelling of DEA according to Annex VI of the CLP Regulation. DEA is classified as acute toxic, skin irritating, eye damaging and may damage organs through prolonged or repeated exposure.

TABLE 4
HARMONISED CLASSIFICATION ACOORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION)

Index No	International chemical identification	CAS No	Classification		Labelling
			Hazard Class and Category Code(s)[1]	Hazard statement Code(s)[2]	Pictogram
603-071-00-1	2,2'-iminodiethanol; diethanolamine	111-42-2	Acute Tox. 4[3]	H302	
			STOT RE 2[3]	H373[4]	
			Skin Irrit. 2	H315	
			Eye Dam. 1	H318	

1 Hazard Class – Acute Tox.: Acute toxicity; STOT RE: Specific target organ toxicity — repeated exposure; Skin Irrit.: Skin irritation; Eye Dam. 1: Serious eye damage.
2 Hazard statement codes – H302: Harmful if swallowed; H373: May cause damage to organs through prolonged or repeated exposure; H315: Causes skin irritation; H318: Causes serious eye damage.
3 Minimum classification for a category.
4 Hazard statement not specifying the route of exposure as the necessary information is not available

Self-classification in the EU
The notified classification is largely congruent with the harmonised classification. Some notifiers do also report environmental hazards (Aquatic Chronic 3 (H412); 149 notifiers, and Aquatic Acute 2 (H401), 16 notifiers) out of a total of 2471 notifiers (March 2014). However, the data basis for those classifications is not available.

2.1.3 REACH

DEA is not restricted in the 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).

DEA is registered with a full registration under REACH in the 10,000 - 100,000 t/y band.

Candidate list / Authorisation List / REACH Annex XIV
2,2'-Iminodiethanol is neither on the Candidate list of Substances of Very High Concern for Authorisation, nor on the List of substances subject to authorisation (REACH Annex XIV)().

Registry of Intentions
There are currently no intentions of submission of an Annex XV dossier for 2,2'-iminodiethanol, neither has there been a submission earlier.

Substance evaluation
DEA was included in the first Community Rolling Action Plan (CoRAP 2012-2014) for evaluation in the year 2012 by Germany due to concerns about human health and high aggregated tonnage (Table

5). A decision is available dated 25.2. 2014 taken pursuant to Article 51(6)[1] in the REACH Regulation requesting further information from the registrants pursuant to Article 46(1)[2].

TABLE 5
SUBSTANCES IN THE DRAFT COMMUNITY ROLLING ACTION PLAN, 2012-2014 (ECHA, 2014).

CAS No	EC No	Substance Name	Year	Member State	Initial grounds for concern
111-42-2	203-868-0	2,2'-Iminodiethanol	2012	Germany	Human health/Potential formation of CMR transformation products; Exposure/Wide dispersive use, high aggregated tonnage

2.1.4 Other legislation/initiatives

This section describes other legislative initiatives, guidance documents, substitution projects, company restriction lists, and information campaigns.

Some companies have developed restriction lists which are published on the company homepage. An example is the Danfoss Negative List of Chemicals (Danfoss, 2013), which sets requirements to Danfoss's suppliers and subcontractors regarding products, components and materials. This list includes DEA which exists as a corrosion inhibitor and pH stabiliser, and it restricts the maximum allowable concentration of DEA to 0.2%.

Another example is Volvo's Grey List which contains those chemical substances (including DEA), which should not be used in Volvo's production processes or be found in unreacted form in Volvo's products (SUBSPORT, 2014).

No guidance documents or information campaigns have been identified.

2.2 International agreements

DEA is not mentioned in the international conventions and agreements that are relevant for this survey (OSPAR, HELCOM, ROTTERDAM, STOCKHOLM, Basel, CLRTAP). This might not be surprising, since most of these conventions are concerned with environmental effects of chemical substances and DEA has neither persistent nor bioaccumulative properties.

2.3 Eco-labels

The EU and Nordic eco-labelling have been searched for criteria excluding or restricting the use of DEA in eco-labelled products. DEA is not mentioned specifically in any of the relevant criteria. It should, however, be noted that DEA is restricted in certain product groups due to general criteria based on the classification of the substance.

Thus certain criteria documents include the classification as H373 as an exclusion criteria for ingoing substances to chemical products. This is e.g. the case for office and hobby materials (Nordic Ecolabelling, 2014a), but not for the Nordic Ecolabelling criteria of cosmetics and cleaning products.

[1] Article 51(6) of the REACH Regulation: If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

[2] Article 46(1) of the REACH Regulation: If the competent authority considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the publication of the Community rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

2.4 Summary and conclusions

DEA is classified as acute toxic, skin irritating, eye damaging and with regard specific target organ toxicity following repeated exposure.

At EU level, DEA is prohibited for use in cosmetics, but not otherwise addressed specifically in any legislation relating to products, wastes, or environmental emissions. In Denmark DEA is assigned an occupational exposure limit value in the Executive Order on Occupational Limit Values for Substances and Materials, defining air limit values of the substance, and a code number in the Executive Order on Determination of Code Numbers representing the minimum safety precautions which have to be taken when working with code-numbered products in certain work situations.

DEA has been subject to substance evaluation under CoRAP 2012-2014 due to concerns about human health and its wide dispersive use. In February2014 a decision from ECHA was published requesting further testing and information from the registrants.

DEA is not mentioned specifically in any product criteria of the Nordic or European Ecolabels but is covered by general classification criteria in relation to product groups such as office and hobby materials.

DEA is not a major environmental concern ad is not mentioned in the international conventions and agreements

3. Manufacture and uses

3.1 Manufacturing

3.1.1 Manufacturing processes

There is only one process commercially used to manufacture diethanolamine. In this process, excess anhydrous ammonia (NH_3) is recated with ethylene oxide (C_2H_4O) in a liquid phase under high pressure and in the presence of a special catalyst to yield a mixture of mono-, di- and tri-ethanolamines:

$NH_3 + C_2H_4O \rightarrow$ Monoethanolamine, Diethanolamine, and Triethanolamine

The reaction mixture is separated into the component amines via distillation, with excess ammonia recycled (Akzo Nobel, 2014).

3.1.2 Manufacturing sites and volumes

Denmark

Diethanolamine is not produced in Denmark. The process requires ethylene oxide, which almost always is produced on-site with ethylene gas, thus usually produced at major petrochemical sites due to the difficulties of transportation.

EU

There are 5 producing sites for diethanolamine within the EU (per REACH registration data and industry contacts) and 16 registrants of DEA (per REACH registration data).

Information available in 2010 indicated that DEA was manufactured by 29 companies in the USA, seven companies in Mexico, three companies each in the People's Republic of China and the United Kingdom, two companies each in Canada, Germany, China (Hong Kong SAR) and India, and one company each in Belgium, Slovak Republic and Switzerland (IARC, 2012 (based on Chemical Sources International, 2010[3])).

The REACH registration range for DEA is 10,000 – 100,000 t/y.

In the OECD Screening Information Dataset (SIDS) Report (2007), the 2005 global capacity for ethanolamines (mono, di and tri) was stated as 1,510,000 tonnes, of which 400,000 tonnes were in Europe among 8 producing sites. According to DOW (2010 (reference to Chemical Economics Handbook, SRI Consulting, January 2009)) the global capacity for ethanolamines was 1,700,000 tonnes in 2007.

As noted above, 5 current producing sites within Europe have been identified, and it is expected that the total European capacity for ethanolamines is significantly below the 400,000 tonnes in 1985.

[3] http://www.chemsources.com/index.html

3.2 Import and export

3.2.1 Import and export of 2,2'-iminodiethanol in Denmark

Data on import and export of DEA are shown in Table 6 based on data from Statistics Denmark. DEA and its salts are combined one reporting category. The calculated net import of DEA was approximately 441 t/y on average in 2007-2011, 246 t in 2012 and 140 in 2013. There is no production of DEA in Denmark according to the Eurostat Prodcom database.

TABLE 6
DANISH PRODUCTION, IMPORT AND EXPORT OF 2,2'-IMINODIETHANOL (EUROSTAT PRODCOM, 2013; STATISTICS DENMARK, 2014).

CN8 code Diethanolamine and its salts	Import, t/y			Export, t/y			Production	
	Average 2007-2011	2012	2013	Average 2007-2011	2012	2013	Average 2007-2011	2012 2013
29 22 12 00	454	270	224	13	24	84	0	0

The statistics do not show any imports for the years 1994 – 2009, which does not seem reasonable. It is very possible that actual imports were from one or two countries- each with one producer- and thus the data was not disclosed publicly to protect competition information. It is interesting to note that there was a large import of DEA (or its salts) in 2010 (1,661 tonnes), which was much larger than in the year before or years after and causes the high average for the period from 2007 - 2011. It is very possible that this large amount was imported as the initial "charge" for a gas desulfurisation facility.

The figures from Statistics Denmark show imports mainly from EU countries with DEA production sites. The statistics also show very limited exports, and only to other Nordic countries. It is noted that exports, while small, increased sharply in 2011, from 3 tons in 2010 to approximately 22 t/y, again noting that the statistics include salts of DEA. It is possible, but not confirmed, that the exports represents by-product salts of DEA recovered from a process.

It should be noted that these figures are significantly lower that the amount registered in the Danish product Register and available in the SPIN database (SPIN, 2014) – see 3.3.2.

3.2.2 Import and export of 2,2'-iminodiethanol in EU

Import and export volumes of 2,2'-iminodiethanol in the EU are given in Table 7.

The production of 2,2'-iminodiethanol (and its salts) in the EU was on average 64,599 t/y for the period 2011-2007, while the production in 2012 was 52,205 t according to the PRODCOM database.

TABLE 7
IMPORT AND EXPORT OF 2,2'-IMINODIETHANOL (EUROSTAT, 2013)

CN8 code	Text	Import, t/y		Export, t/y	
		Average 2007-2011	2012	Average 2007-2011	2012
29 22 12 00	DIETHANOLAMINE AND ITS SALTS	7,650	7,284	34,478	29,461

3.3 Use

3.3.1 General use

Based on information published by the main producers the major global uses of DEA are listed below:

- Gas treatment solvent (removal of sulfur-bearing compounds and CO_2)
- Intermediate in production of Glyphosate herbicide (i.e. "Round-up" and "Glyphos"herbicides)

- Intermediate in production of fatty acid amides
- Intermediate in fatty acid salts
- Emulsifier and corrosion inhibitor in metalworking fluids
- Polyurethane foam catalyst/process regulator
- Cosmetics
- Cleaners and detergents.
- Intermediate for photographic chemicals

According to IHS (2012) over 30% of the global consumption of ethanolamines (monoethanolamine (MEA), diethanolamine (DEA)and triethanolamine (TEA)) in 2011 was for the production of surfactants. Herbicides (which may include some ethanolamines consumed for other agricultural chemicals) accounted for over 15% of the total consumption in 2011, followed by gas treatment applications (11%). The markets with the most growth potential are mentioned to be herbicides (for DEA), ethyleneamines (for MEA) and ester quats (for TEA). Most applications are mature and growing at rates similar to those for GDP (IHS, 2012).

The IHS report also states that in North America, ethanolamines consumption is forecast to grow at an average annual rate of about 3% between 2011 and 2017. Herbicides will drive ethanolamines consumption in both North America and the world, followed by surfactants (to a lesser extent). Gas treatment applications will also grow at a rate of over 3% per year through 2017. Overall, world ethanolamines consumption is forecast to grow at an average annual rate of 4.5–5.0% during 2011–2017, driven by consumption in China (IHS, 2012).

The world consumption by country of ethanolamines (MEA, DEA and TEA) in 2011 is shown in Figure 1.

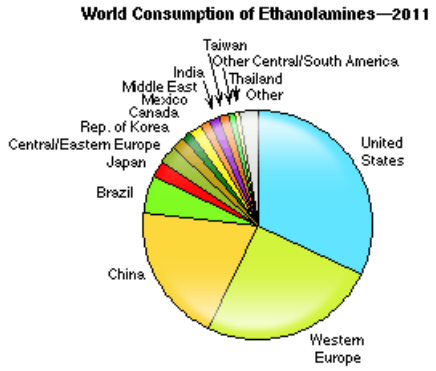


FIGURE 1.
THE WORLD CONSUMPTION OF ETHANOLAMINES (MEA, DEA AND TEA) IN 2011 (IHS, 2012)

As illustrated by the figure, Europe accounts for a relatively small part of the total global consumption of ethanolamines. Information about the distribution between the three ethanolamines is not available in the open access version of the IHS report.

Gas treatment

In gas treatment, DEA is used to remove sulfur-based contaminants from natural gas (removal of H_2S) or "refinery gas" (removal of H_2S or SO_2). In the processes, the DEA is contacted with the gas stream and absorbs the sulfur-bearing contaminant. The DEA solution is then processed to strip out the contaminant and recover elemental sulfur. The stripped DEA is continually recycled, thus reducing or eliminating DEA release.

DEA also absorbs carbon dioxide (CO_2) from natural gas or other gases. As in the case with sulfur-bearing contaminants, the CO_2 is stripped from the DEA and the DEA is recycled. The disposition of the stripped CO_2 is less certain.

Chemical intermediate
DEA is used as a chemical intermediate for the production of Glyphosate herbicides ("Roundup", "Glyphos", etc.) and other intermediates.

The process for glyphosate starting with DEA is the most widely used process on a global basis. Among other intermediate uses of DEA are DEA fatty acid amides: a "fatty acid"- i.e. long chain aliphatic monoacid, usually derived from vegetable oil or animal fat, is reacted at 140 – 1600 °C with DEA to the resultant fatty acid amide ("diethanolamide"). In diethanolamides, the acid bonds to the amine with a covalent carbonyl bond which does not readily dissociate in water. Diethanolamides act as surfactants, foaming agents, thickeners, etc. in cleaners, personal care products and cosmetics. (However, the use of diethanolamides in cosmetics is restricted according to Annex III of the Cosmetics Regulation and maximum free DEA content is limited to 0.5%.) Note that for non-cosmetic applications, many commercial diethanolamides often includes more than trace amounts of free DEA, *i.e.* up to 30% free DEA. It appears that some global suppliers of diethanolamides may only sell low-residual-DEA grades in Europe.

DEA is also used for the production of DEA salts: Reaction with fatty acids at lower temperatures produce DEA fatty acid salts, where the amine and acid have an ionic bond which easily dissociates to DEA and fatty acid in water. DEA salts are also formed with other organic and inorganic acids for a variety of end uses, including herbicides, 2,4 dichlorophenoxyacetic acid (i.e. 2,4-D, DEA salt), but the amine salt herbicide is not registered for use in Denmark, and the base 2,4 dichlorophenoxyacetic acid herbicide is not allowed for use on gardens or lawns in Denmark.

Metalworking fluids
DEA has traditionally been used in metalworking fluids as an emulsifier, surfactant and rust inhibitor. Due to a variety of concerns, the use in metalworking fluids has decreased markedly in most developed markets, as also shown in the SPIN "Cutting Fluid" data for Denmark.

Corrosion Inhibitor
DEA is cited in the literature as a corrosion inhibitor, especially for automotive coolants. DEA will maintain a basic (high pH) environment in aqueous solutions, which inhibits the formation of rust. However, it appears that DEA is no longer widely used in this application due to concerns for formation of nitrosamines, as well as higher performing alternative chemistry.

Polyurethane foam process regulator
DEA has been used to regulate the process for making polyurethane foams. However, this use has decreased markedly, as perhaps demonstrated in the SPIN data for "Process Regulators".

Cosmetics
Although the SPIN data shows a relatively small amount of DEA used in cosmetics (1.6 tonnes in 2011), its use, along with DEA salts, is prohibited per entry 411 in Annex II of the Cosmetic Regulation 1223/2009. Unless there is a mis-reporting for the SPIN database, none should be used. It is possible that DEA is being reported under "cosmetics" but actually used in personal care items which do not fall under the cosmetic definition in the regulation. For example, DEA was found in one out of eight consumer "sanitary towels" in a 2002 study by the Danish EPA. Such use could conceivably be reported as cosmetics in the SPIN registry. It is also noted that the reported DEA use in cosmetics was approximately 100 kg/year prior to 2010, increased sharply to 1000 kg in 2010, and further increased to 1600 kg in 2011.

(alkanolamines, especially secondary amines such as DEA, can form nitrosamines in situ under certain conditions, where nitrosating agents like nitrites are available)

Cleaners and washing agents
The literature reports the use of DEA in heavy-duty liquid laundry detergents, providing a reserve alkalinity to the laundry bath, essential to efficient cleaning. A scan of use in cleaners and hand soaps, at a variety of consumer and industrial product websites reporting ingredients show a very limited number of consumer or professional-use cleaners reporting DEA, generally in the range of 0.5% concentration (US NIH database), perhaps included as an impurity in diethanolamides. Some formulations of automatic car wash solutions outside of Europe contain up to 5% DEA. A major European DEA producer stated that he was not aware of cleaner or detergent use. However, it should also be noted, that formulations based on monoethanolamine (MEA) and triethanolamine (TEA) may contain DEA as a contaminant.

Paints and coatings
There are a relatively large number of preparations registered as containing DEA for paint and coatings end use, but the SPIN data shows a very small total amount of DEA (100 kg). Amines, including DEA, can be used as "hardener" in 2 component epoxy paints. The very small total amount of DEA may indicate it is carried in a formulation as an impurity in another higher molecular weight amine perhaps derived from DEA. REACH registration data also shows DEA use in wood protection formulations (biocide), which may be reported as "paint and coatings" in the SPIN data.

Anti-set-off and anti-adhesive agents
There was significant use of DEA in this category in 2010 and 2011 (3000 and 3500 kg respectively per SPIN data), but only in 4 preparations in each year. No references describing this use can be found, thus it is suspected, but not confirmed, that this is a very specific and highly specialised use.

The uses of DEA as registered under REACH are summarized in Table 8. As indicated earlier, the predominating applications are within use at industrial sites, while consumer relevant uses are restricted to fewer applications including use in wood protection formulations, use as additive in concrete and cement, ink and toners as well as in leather tanning, textile dye, finishing, impregnation and care products. It has not been possible to obtain information on how much of the European consumption is allocated to each use category.

TABLE 8
USES REGISTERED UNDER REACH.

	Manu-facture	Formu-lation	Use at industri-al sites	Profes-sional use	Consu-mer use
Manufacture of substance	✔		✔		
Formulation of products (preparations)		✔	✔		
Metalworking fluids,			✔	✔	
Lubricants, greases, release products			✔		
Laboratory reagent			✔	✔	
Use as an intermediate			✔		
Gas Treatment			✔		

	Manu-facture	Formu-lation	Use at industri-al sites	Profes-sional use	Consu-mer use
Use in detergents and cleaners			✔	✔	✔
Used as a fuel			✔	✔	✔
Use in lube oil/ashless dispersants			✔	✔	
Use as an additive in fuel			✔		
Use in wood protection formulations			✔	✔	✔
Use as additive in concrete and cement				✔	✔
Ink and toners			✔	✔	✔
Leather tanning, textile dye, finishing, impregnation and care products			✔	✔	✔
Paper and board dye, finishing and impregnation products			✔	✔	
Use as additive in plastic, e.g. rubber			✔	✔	✔

Use in fuels is also included in the registration dossier. DEA is according to patent information also listing a European manufacturer used in a "fuel lubricity additive comprising a blend of (i) biodiesel, said biodiesel comprising lower alkyl esters of a mixture of saturated and unsaturated, straight-chain fatty acids of from 12 to 22 carbon atoms, derived from vegetable or oleaginous seeds, and (ii) a DEA derivative, wherein said DEA derivative is selected from the group consisting of fatty acid amides of DEA, fatty acid esters of DEA and mixtures thereof" (Boliven Pro, 2014).

According to the ECHA web site, the classification of DEA has been notified to ECHA by a total of 2500 companies. This indicates the number of European companies that are using the substance in products that they place on the market. (The twelve companies that have registered DEA are included in this number). This number does not give any information as to how many products are on the market containing DEA.

3.3.2 Consumption in Denmark

Confidential data on diethanolamine registered in the Danish Product Register were retrieved in March 2014.

The Danish Product Register includes hazardous chemical substances and mixtures which are produced or imported for professional use in quantities of 100 kg or more per year. Hazardous substances and mixtures include:

- Substances and materials that are classified as hazardous under the Danish Ministry of the Environment's regulations, or contain 1% or more of a substance classified as hazardous to health or environment.
- Substances and mixtures assigned an occupational exposure limit in the WEA list of Limit Values for Substances and Materials.
- Mixtures that contain 1% or more of a substance that has been assigned an occupational exposure limit in the WEA list of Limit Values for Substances and Materials

Non-confidential data are shown in the SPIN-database including information from the Nordic Product Registers.

Use as intermediate

The by far largest application area of 2,2'-iminodiethanol is according to SPIN the use as an intermediate (Figure 2) followed by the general use as solvent and thinner. According to Product Registry data, this use of DEA represented 86% of total DEA use in Denmark in 2011.

It should be noted that it is assumed that the SPIN data for "intermediates" most likely applies to glyphosate production. That data shows a sharp decrease in DEA consumption from 2008 to 2009. We have confirmed that a Danish producer of glyphosate changed their process in 2009 and no longer use DEA, thus explaining the significant decrease in Danish imports of DEA, and a similar sharp decrease in the SPIN data.

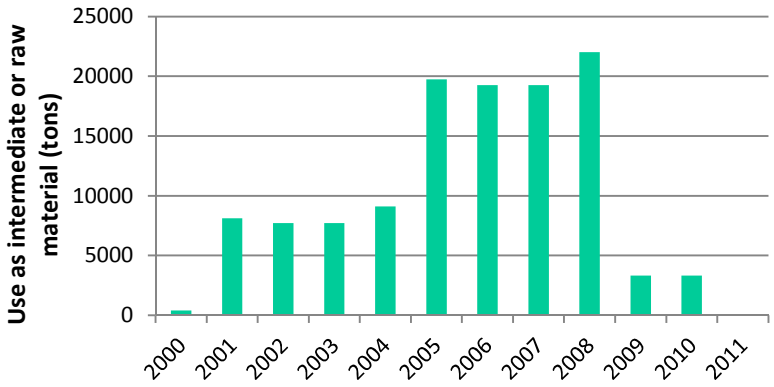


FIGURE 2.
USE AS AN INTERMEDIATE OF 2,2'-IMINODIETHANOL IN DEMARK (DATA FROM THE SPIN DATABASE 2013)

Other uses

Figure 3 shows the volumes of other use categories. Amongst those, the use as a solvent has increased and been the predominant during the recent years.

It is expected that the SPIN "solvent" category is reporting the uses of DEA for gas treatment, as the amine is typically referred to as a solvent (for the sulfur-bearing compounds or CO_2). Figure 3 also illustrates that the uses in lubricants, cooling and cutting oils, in cleaning/washing agents, and corrosion inhibitors have declined significantly since 2000.

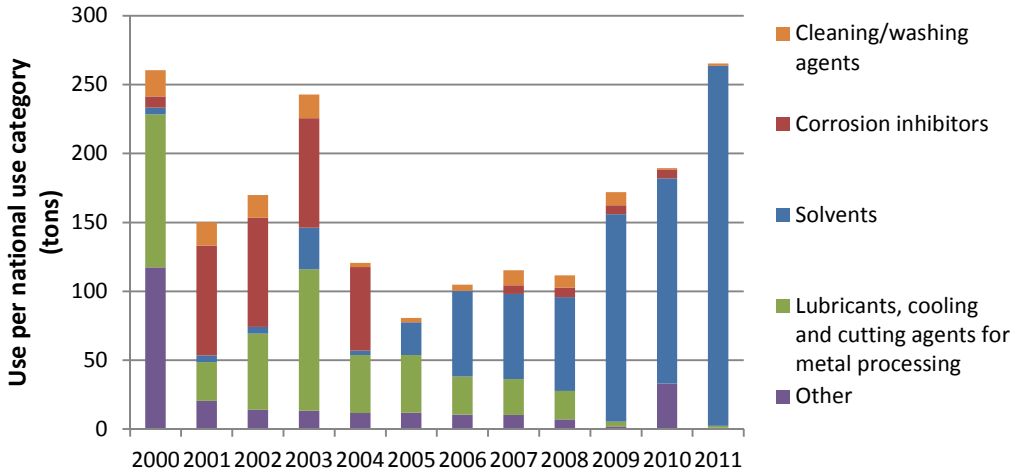


FIGURE 3.
USE PER NATIONAL USE CATEGORY OF 2,2'-IMINODIETHANOL IN DEMARK (DATA FROM THE SPIN DATABASE 2013).

Summary of 2011 Danish Product Registry (SPIN) End Use Volume is presented in tonnes.

TABLE 9
SUMMARY OF 2011 END USE VOLUME (SPIN)

End Use	Number of Preparations	Volume (tonnes)
Solvents	7	261.30
Intermediates	11	25.30
Cleaning/washing agents	130	3.80
Anti-set-off and antiadhesive agents	4	3.50
Others	18	2.60
Cosmetics	16	1.60
Cutting fluids	25	1.50
Process regulators	6	0.60
Lubricants and additives	6	0.40
Construction materials	5	0.30
Surface-active agents	9	0.30
Adhesives, binding agents	10	0.20
Grinding materials	7	0.20
Surface treatment	20	0.20
Corrosion inhibitors	12	0.10
Non-agricultural pesticides and preservatives	7	0.10
Paints, laquers and varnishes	112	0.10
Colouring agents	7	<0.10
Total	**412**	**302**

Data in SPIN also show that the consumption of DEA for lubricants, cooling and cutting oil has decreased significantly in the period from 2000 to 2011. The same is the situation for DEA in cleaning and washing agents.

Consumer product
Consumer products containing DEA on the Danish market include cosmetics, and cleaning and washing agents. DEA is generally expected to be present in small amounts in the products.

In addition DEA is used as a processing chemical in the production of various articles and may therefore be present as a residue in paper, textile and leather products. DEA may also be present in small amounts in food contact materials. No detailed information regarding the range of products and the amounts of DEA in consumer products is available.

3.4 Historical trends in use

EU
Ethanolamines became available commercially in the early 1930s. They assumed growing commercial importance as intermediates after 1945, because of the large-scale production of ethylene oxide. Since the mid-1970s, economical production of very pure, colourless ethanolamines has been possible. Worldwide production of ethanolamines in 1985 was approximately: USA, 220 000 t; *western Europe, 145 000 t*; southeastern Asia, 40 000 t; South America, 18 000 t; and *eastern Europe, 4 000 t*. Of the world production of ethanolamines in 1985, approximately 50% was monoethanolamine, 30-35% DEA and 15-20% triethanolamine (IARC, 2000).

Specific information to illustrate the development in Europe has not been identified. However, in the United States the estimated annual production of DEA in the period 1960 to 1995 has steadily grown from 24 000 tonnes to 106 000 tonnes and it has continued to increase.

In EU and also globally there have been growing concerns regarding the safe use of DEA (and nitrosamines) for some applications at least since the 1990s and DEA has been substituted or the amounts have been reduced in many consumer products and also professional products since then. No detailed information has been identified.

Denmark
The total use of DEA has been fairly constant during the mid ’00, but decreasing since 2009 to < 400 tons in 2011 (Figure 4).

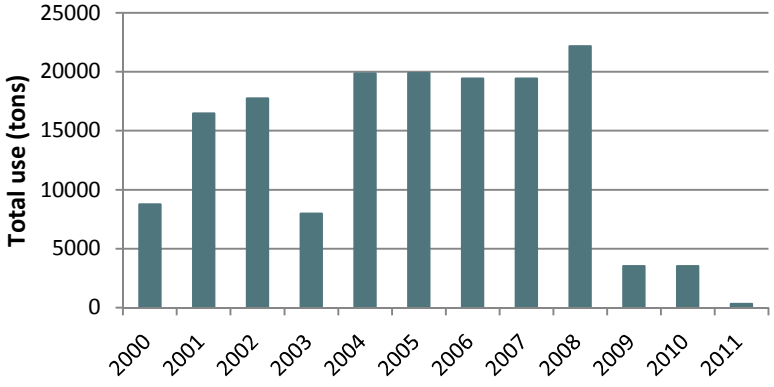


FIGURE 4
TOTAL USE OF 2,2'-IMINODIETHANOL IN DEMARK (DATA FROM THE SPIN DATABASE 2013).

As noted in section 3.3, the use of DEA in most end uses has decreased markedly over the past 6 years. A closer look at the Product Registry data, however, shows that the use of DEA in widely

dispersed uses with significant worker and/or consumer exposure started decreasing sharply in 2003-2004 (most likely due to the health effects of DEA), while use in closed-system end uses (chemical intermediate and gas treatment) increased, thus the total use reported in the Product Registry was approximately constant until 2009, when the large volume use in the production of glyphosate ended. The remaining large volume use in gas desulfurization should continue, and possibly increase if either refinery expands operation, or if higher sulfur-content feedstocks (crude oil or natural gas) are used.

3.5 Summary and conclusions

DEA is registered with a full registration under REACH in the tonnage band 10,000 - 100,000 t/y.

The major uses for DEA in Europe are as a solvent for gas desulfurisation and as an industrial intermediate for agricultural chemicals. The agricultural chemical use in Denmark has declined sharply since 2008, but the use as an intermediate for fatty acid amides and agricultural chemcials elsewhere in the EU remain significant. The use of DEA in widely dispersed uses with significant worker or consumer exposure such as in lubricants, cooling and cutting oils, corrosion inhibitors, and in cosmetics and cleaning/washing agents has in Denmark already been largely reduced due to health concerns. This trend is also seen in most other developed economies. Since DEA can also be used to strip carbon dioxide from gas streams, it is possible that its use might grow to control CO_2 emissions from stationary power sources if economically feasible ways to sequester or productively use the recovered CO_2 can be developed.

4. Waste management

4.1 Waste from manufacture and industrial use of 2,2'-iminodiethanol

There is no manufacture of 2,2'-iminodiethanol in Denmark and therefore no waste generation from processes related to the synthesis and production of the substance in Denmark.

The OECD SIDS (2007) has reviewed data on emissions via waste water treatment effluent from 2,2'-iminodiethanol production sites. Data were available from a single production site in France, where the loss via the aqueous effluent resulting from production was estimated at < 0.001 ton TOC/ton DEA produced.

In other industrial applications, DEA functions as an intermediates or additive in the manufacture of chemicals and chemical products (e.g. detergents, textile and leather chemicals, emulsifiers; OECD, 2007). Such wastes will typically be collected and treated as organic chemical waste, in which case the waste is incinerated and the substance will be completely destroyed.

Due to its classification (section 2.1.2) in accordance with the Danish Statutory order on waste (BEK no. 1309 of 18/12/2012) Annex 4, products and mixtures containing DEA must be disposed of as hazardous waste.

Wastes containing DEA will be disposed of according to the origin and processing of the waste containing the substance.

4.2 Waste from the use in mixtures and articles

Due to its classification (section 2.1.2) and in accordance with the Danish Statutory order on waste (BEK no. 1309 of 18/12/2012) Annex 4, products and mixtures containing DEA must be disposed of as hazardous waste if they contain more than 10% DEA.

In Denmark, liquid waste containing DEA will typically be collected and treated as organic chemical waste, in which case the waste is incinerated and the substance is completely destroyed. Waste disposal key numbers from the European Waste catalogue must be assigned depending on the use of the products or chemical waste containing DEA.

DEA from use in detergents and cleaners will be transported to waste water treatment plants, or be dispersed in the environment.

Solid waste from consumer products containing DEA is expected enter into the waste stream through the municipal collection of domestic waste.

The disposal method depends on the actual uses of the different materials as indicated in TABLE 10. As mentioned, waste containing more than 10% DEA should be disposed of as hazardous waste. Data on the actual quantities disposed of as hazardous waste are not available.

TABLE 10
DISPOSAL OF DEA IN POST-CONSUMER WASTE IN DENMARK

Product group	Concentration in materials, %	Potential quantities of SCCP, t/y *2	Disposal method in Denmark
Cleaning/washing agents	< 0.06	3.8 *1	Incineration:
Cutting fluids	< 30 *2	1.5 *1	Incineration/hazardous waste incineration
Cosmetics	≤ 0.5 *2	1.6 *1	Incineration
Paints, lacquers and varnishes		0.10 *1	Incineration: Residues and paints, lacquers and varnishes attached to combustible waste
Paper and board, leather	-	-	Incineration
Plastic/rubber	-	-	Incineration
Construction materials (concrete and cement)	< 5 *2	-	Concrete and cement are to a large extent recycled

*1 Volumes reported in the SPIN database (2011).

*2 Percentages from exposure scenarios from Akzo Nobel extended safety data sheet:
http://www.alliancechemicals.com/wp-content/uploads/2011/10/DEAmsds.pdf

4.3 Release of 2,2'-iminodiethanol from waste disposal

The physical-chemical properties of DEA indicate, that the chemical will be rapidly degraded in the environment. Therefore the potential for releases from waste disposals is limited.

No studies regarding release of the substance from disposal of waste containing the substance have been identified. Release from incineration is not relevant.

4.4 Summary and conclusions

DEA is not manufactured in Denmark and therefore no waste is generated from production or synthesis of the substance.

Products/articles and chemical waste containing DEA will typically be collected and incinerated as organic chemical waste. Waste codes will be assigned according to the use.

5. Environmental effects and exposure

5.1 Environmental fate and distribution

Several environmental fate and distribution data on 2,2'-iminodiethanol have been compiled, calculated and evaluated in the OECD SIDS (2007).

pKa values of 8.92 – 9.01 indicate that the molecule will predominantly occur in the charged (cationic) form at environmentally typical conditions of pH 5 – 8. At pH values > 9, 2,2'-iminodiethanol will predominantly be present as the uncharged species.

2,2'-Iminodiethanol is completely miscible with water and has a negligible vapour pressure at ambient temperature. Hydrolysis is not expected to be a relevant degradation process due to the absence of hydrolysable groups.

The Henry's law constant of $3.97 \cdot 10^{-6}$ Pa m^3/mol can be seen as an indication of low volatility and resulting low concentrations in air. Therefore, photodegradation is not considered to be a significant degradation pathway in air. A half-life of about 4.2 hours by indirect photodegradation through reaction with hydroxyl radicals in the atmosphere has been calculated (OECD, 2007). Studies on photodegradation in water have not been available in neither the SIDS (OECD, 2007), nor in ECHA's registrations of the substance.

Therefore, according to the Mackay Level I modelling presented in the OECD assessment (2007), 2,2'-iminodiethanol will distribute nearly completely into water (99.99 %). Only very small amounts will partition to air (0.001 %), sediment ($5.2 \cdot 10^{-5}$ %), and soil ($5.3 \cdot 10^{-5}$ %). However, these results were estimated for the uncharged molecule, even though the charged species would be the more relevant to estimate in environmental conditions.

The potential for biodegradation of 2,2'-iminodiethanol has been comprehensively investigated. A manometric respirometry test according to OECD 301 F (reliability 1)[4] showed that 2,2'-iminodiethanol is readily biodegradable since the degradation after 28 days was 93 % related to BOD. Results from other biodegradation tests (ready, inherent, and one simulation test according to OECD 303A, all reliability 2) indicate that 2,2'-iminodiethanol is easily eliminated from sewage treatment plants and from surface water.

Of the studies investigating degradation in sludge, 7 out of 9 determined a biodegradation ≥ 94% within 3 – 10 days. Acclimated microorganisms may more readily oxidize 2,2'-iminodiethanol compared to non-adapted bacteria from sewage. Tests with STP effluent water found degradation rates ranging from 2 – 100% within 5 – 19 days for non-adapted bacteria and 77-94 % degradation within 5 – 30 days for adapted bacteria. In studies with freshwater samples and non-adapted

[4] The reliability index quality screening procedure for environmental and toxicity studies. Any source document is screened according to a set of criteria, and finally assigned a reliability index, describing in how far the study lives up to e.g. GLP (Good Laboratory Practices) or OECD guidelines: 1 = reliable without restrictions, 2 = reliable with restrictions, 3 = not reliable, 4 = not assignable.

bacteria 1.2 – 97 % degradation was observed. Anaerobic degradation in river sediments has also been demonstrated.

No experimental data on bioaccumulation are available. A bioconcentration factor (BCF) of 3.16 was calculated with BCFWIN v2.15, using a measured log K_{OW} of -2.18. Based on this, the potential of 2,2'-iminodiethanol to bioaccumulate was expected to be very low (OECD, 2007).

The calculated K_{OC} of uncharged 2,2'-iminodiethanol is 1 (corrected log K_{OC} = 0). Consequently, the potential for adsorption to organic matter in soil, sediment, and suspended solid is assessed to be low. However, binding of the substance to soil matrices with high capacities for cation exchange (e.g. clay) cannot be excluded for the charged molecule (OECD, 2007).

5.2 Environmental hazard

5.2.1 Environmental classification

2,2'-Iminodiethanol is not classified as hazardous to the environment according to the CLP Regulation.

5.2.2 Environmental effects

Many aquatic toxicity data on effects of 2,2'-iminodiethanol to fish, invertebrates, algae and microorganisms are available in the OECD (2007) assessment report.
All tests, apart from a chronic study with *Daphnia magna*, were assigned reliability 2 due to missing analytical verification of the test concentrations.

2,2'-Iminodiethanol toxicity appears to be enhanced when test solutions were not neutralized. Increased toxicity at alkaline pH values may therefore be due to higher toxicity of the uncharged species or general higher susceptibility of the organisms in more alkaline environments.

Acute toxicity tests on fish were conducted with six freshwater species (*Pimephales promelas, Gambusia affinis, Lepomis macrochirus, Carassius auratus; Cyprinodon variegatus* (the latter can also be found in brackish/marine environments)) in the period of 1954-1987. The LC50 values ranged from > 100 - > 5000 mg/L. Several studies determined concentrations around 1500 mg/L as the lowest LC50 concentration. Chronic fish tests or newer studies are not available (according to the US EPA ECOTOX Database).

A number of Daphnia studies as well as several other freshwater and marine invertebrate studies (*Ceriodaphnia dubia, Gammarus fasciatus Asellus intermedius, Artemia salina, Helisoma trivolvis, Dugesia tigrina, Lumbriculus variegatus*) are available. The effect concentrations in acute tests range from 1.0 – 2800 mg/L, while most values are around 100 mg/L. The study with the lowest effect concentration (1.0 – 5.1 mg/L,96-h LC50, published 2006) was not selected as key study because it deviated from the current OECD test guidelines.

Regarding potential growth inhibiting effects of 2,2'-iminodiethanol to algae, 10 short-term tests covering seven species (*Ankistrodesmus bibraianus, Chlorella vulgaris, Desmodesmus subspicatus, Microcystis aeruginosa, Pseudokirchneriella subcapitata, Scenedesmus quadricauda, Skeletonema costatum*) are available. The 50% effect concentrations range from 2.2 – 735 mg/L, with *Pseudokirchneriella subcapitata* being the most susceptible species.

There are numerous published studies on the effect of 2,2'-iminodiethanol on microorganisms reporting effect concentrations ranging from 16 – 10,000 mg/L.
The lowest toxic threshold concentration (TTC, comparable to EC3) was obtained with *Pseudomonas putida* under non-neutralized test conditions. A nitrification inhibition test with *Nitrosomonas sp.* showed no inhibition of ammonia oxidation at 100 mg/l after 2 h of incubation.

An overview of the results of the key studies from is presented in below (Table 11).

TABLE 11
OVERVIEW OF KEY STUDIES ON AQUATIC ORGANISMS (OECD, 2007)

Group	Species	Study type	Endpoint	Value (mg/l)
Fish, freshwater	*Pimephales promelas*	96 h, static, non-neutralized	LC50	1370
Invertebrates, freshwater	*Daphnia magna*	48 h	EC50	55
	Daphnia magna	21 d	NOEC	0.78
Algae	*Pseudokirchneriella subcapitata*	96 h	E_rC50	2.2
Microorganisms	*Pseudomonas sp.*	16 h, [~EC3]	TTC [~EC3]	16

No data on acute or chronic toxicity of 2,2'-iminodiethanol to terrestrial organisms are available.

5.3 Environmental exposure and monitoring

Generally, data on environmental exposure of 2,2'-iminodiethanol, as well as monitoring data are sparse.
2,2'-Iminodiethanol is not included in the Danish environmental surveillance programme, NOVANA.

The use of 2,2'-iminodiethanol as a stabilizer or inhibitor in pesticide formulations applied to agricultural crops pre-emergence has been reported (US EPA, 2006). However, it can be expected that the substance will be degraded rapidly in the soil environment.

2,2'-Iminodiethanol may also be released from manufacturing or processing industries.
In the ECHA registration, the following environmental release categories are listed:

- ERC 1: Manufacture of substances
- ERC 2: Formulation of preparations
- ERC 4: Industrial use of processing aids in processes and products, not becoming part of articles
- ERC 5: Industrial use resulting in inclusion into or onto a matrix
- ERC 6a: Industrial use resulting in manufacture of another substance (use of intermediates)
- ERC 8d: Wide dispersive outdoor use of processing aids in open systems
- ERC 9b: Wide dispersive outdoor use of substances in closed systems

Category 1 will not be relevant for the Danish situation. Releases might, however, occur from the use of 2,2'-iminodiethanol as chemical intermediate, even though the use for pesticide production has declined (see chapter 3). Releases can also be expected in relation to the use in gas treatment. According the ECHA registration, dispersive releases origin from the use of 2,2'-iminodiethanol in metal working fluids, uses as fuels, and from concrete and cement.

5.4 Environmental impact

A systematic environmental impact assessment for 2,2'-iminodiethanol is not available and it is beyond the scope of this survey to conduct such one. In the OECD SIDS (2007), 2,2'-iminodiethanol is evaluated as a substance of low priority for further work with respect to the environment. The substance has properties indicating a hazard for the environment (based on acute toxicity to green algae and *Daphnia magna*: EC50 between 1 and 100 mg/l). However, due to its rapid

biodegradation and its low potential for bioaccumulation, the environmental exposure is generally expected to be very low. Continuous emissions may though lead to locally high concentrations.

Large releases of DEA may react with acidic compounds and can affect the pH of nearby water and wastewater treatment facilities, resulting in possible toxic shock to biologically active species and poor treatment in wastewater treatment facilities. Reaction with acidic compounds may produce undesirable odours (DOW, 2010).

5.5 Summary and conclusions

2,2'-Iminodiethanol (DEA) can be regarded as easily degradable in sewage treatment plants and surface water.

Hydrolysis is not expected to be a relevant degradation process due to the absence of hydrolysable groups. The substance can be rapidly decomposed by hydroxyl radicals in air (half-life of about 4.2), however, this pathway is probably not very important, since air concentrations of DEA can be expected to be very low.

Environmental distribution modelling shows that the uncharged 2,2'-iminodiethanol molecule will distribute nearly completely into water (99.99 %). The distribution for the charged molecule, as it usually will be present in environmental conditions, can be expected to be similar, even though a larger fraction may be retained in the soil environment.

Experimental data on bioaccumulation are not available. Based on a bioconcentration factor of 3.16 and a log K_{OW} of -2.18, the potential of 2,2'-iminodiethanol to bioaccumulate is expected to be very low.

A number of data on the aquatic toxicity of 2,2'-iminodiethanol to fish, invertebrates, algae and microorganisms are available from the OECD SIDS (2007).
The LC50 values range from > 100 - > 5000 mg/L in the fish studies. Invertebrate studies have resulted in EC50 values from 1.0 to 2800 mg/L. The 50% effect concentrations range from 2.2 – 735 mg/L for algae, and range from 16 to 10,000 mg/L for microorganisms.

Thus, 2,2'-iminodiethanol is not very toxic to aquatic organisms, the lowest EC50 of the key acute studies being 2.2 mg/l (*Pseudokirchneriella subcapitata*) and the lowest chronic NOEC being 0.78 mg/l for *Daphnia magna*.

Acute or chronic toxicity data for terrestrial organisms are not available.

Data on industrial emissions or STP discharges of 2,2'-iminodiethanol are not available for Danish or European conditions. However, due to its rapid biodegradation and its low potential for bioaccumulation, the environmental exposure is expected to be very low.

In the OECD SIDS, 2,2'-iminodiethanol is evaluated as a substance of low priority for further work with respect to the environment.

6. Human health effects and exposure

6.1 Human health hazard

Toxicity of 2,2'-iminodiethanol has earlier been reviewed in a Danish survey of chemical substances from sanitary towels (Pors and Fuhlendorff 2002). Moreover, data on human health are available from an IARC monograph (IARC, 2000), an OECD SIDS initial assessment profile (OECD, 2007).

6.1.1 Classification

DEA is subject to harmonised classification as acute toxic (cat. 4), toxic after repeated exposure (cat. 2), skin irritating (cat. 2), and eye damaging (cat. 1) (Table 12).

TABLE 12
HARMONISED CLASSIFICATION ACOORDING TO ANNEX VI OF REGULATION (EC) NO 1272/2008 (CLP REGULATION).

Index No	International chemical identification	CAS No	Classification	
			Hazard Class and Category Code(s)	Hazard statement Code(s)
603-071-00-1	2,2'-iminodiethanol; diethanolamine	111-42-2	Acute Tox. 4 * STOT RE 2 * Skin Irrit. 2 Eye Dam. 1	H302 H373 ** H315 H318

* Minimum classification for a category.
** Hazard statement not specifying the route of exposure as the necessary information is not available

6.1.2 Toxicokinetics

DEA is well absorbed following oral administration in rats (57%) and to a lower degree following dermal administration (3-16% in rats; 25 – 60% in mice) (OECD, 2007).

Dermal absorption of 2,2'-iminodiethanol has been studied *in vivo* with rats and mice, and *in vitro* with full-thickness skin preparations from rats, mice, rabbits and humans.

Human skin proved to be the best barrier against aqueous 2,2'-iminodiethanol (37%, w/w) followed by rat, rabbit and mouse skin. The total absorbed dose from aqueous 2,2'-iminodiethanol was greater (0.23–6.68%) than that from undiluted material (0.02–1.3%) (IARC, 2000).

Later studies on the penetration of [^{14}C]diethanolamine from cosmetic formulations such as shampoo hair dyes and body lotions through human skin samples indicated that approximately 0.1% of the applied dose of shampoo and hair dye formulations was absorbed into the receptor fluid after 5-30 minutes (IARC, 2012). In another 72-hour repeated-dose study with a body lotion formulation nearly 30% of applied DEA accumulated in the upper levels of the skin and

approximately 1% was absorbed in the receptor fluid (Kraeling et al., 2004). Skin levels of DEA can therefore not be directly used to estimate systemic absorption of in exposure assessments

However, the combined data from several studies showed that in rats the absorption rate increased linearly with the dose (single), and that a 100-fold increase in the dose of 2,2'-iminodiethanol (188–19,720 µg/cm²) resulted in a 450-fold increase in absorption rate (0.113–45.0 µg/cm²/h) (IARC, 2000), thus indicating that 2,2'-iminodiethanol facilitates its own absorption (OECD, 2007).

Most of the 2,2'-iminodiethanol was retained in tissues at high concentrations. Tissue-blood-ratios were 150–200 for the liver and kidney, 30–40 for the lung and spleen and 10–20 for the heart, brain and muscle (IARC, 2000). Distribution to the tissues does not depend on administration route (OECD, 2007).

2,2'-Iminodiethanol is incorporated into membrane phospholipids and interacts with lipid metabolism *in vivo*, for example by inhibiting incorporation of the natural substrates ethanolamine and choline into phospholipids in rat liver and kidney. Synthesis of liver phospholipids *in vitro* has been shown to be competitively inhibited by 2,2'-iminodiethanol. The catabolism of 2,2'-iminodiethanol-containing lipids is likewise slower than that of the corresponding choline and ethanolamine-containing derivatives. Generally, 2,2'-minodiethanol is conserved and metabolized by biosynthetic routes common to the biogenic ethanolamine (IARC, 2000).
Absorption, retention and metabolism of 2,2'-iminodiethanol in human and rat liver slices have been reported to be similar (IARC, 2000).

After single oral and intravenous administrations of 2,2'-iminodiethanol to rats, the compound is excreted predominantly unchanged via urine (20 – 30%). Only smaller fractions are excreted as mono- and dimethylated derivatives. Less than 3% of administered 2,2'-iminodiethanol were found in faeces and only 0.2% or less was exhaled (as CO_2) within 48 h. A whole-body elimination half-life of about six days has been estimated for the rat (IARC, 2000).

6.1.3 Acute and chronic effects

Human observations

The only data available on human exposure to airborne DEA is from clinical provocation tests, causing 2,2'-iminodiethanol-induced occupational asthma. The positive reaction was observed in a 39-year-old male metal worker after a 30-min or 45-min inhalation exposure to aerosols from a warmed cutting fluid (40°C) containing 0.15% 2,2'-iminodiethanol and 0.32% triethanolamine, as well as after a 15-min exposure to pure 2,2'-iminodiethanol at aerosol concentrations of 0.75 and 1.0 mg/m³ (IARC, 2000).

Animal observations

The toxicity of DEA (as well as of mono- and triethanolamine) has been reviewed in a number of experiments with mice, rats and rabbits.

The LD50 for 2,2'-iminodiethanol (by intraperitoneal injection) was 2.3 g/kg bw for mice. At this dose, liver changes, including extensive vacuolization and fat droplets, were observed 4 h after dosing (IARC, 2000).

Groups of 10 male rats were given 0, 320, 630, 1250, 2500 or 5000 ppm 2,2'-iminodiethanol in the drinking-water (equivalent to 25–440 mg/kg bw per day), while groups of 10 females were given 0, 160, 320, 630, 1250 or 2500 ppm (equivalent to 15–240 mg/kg bw per day). Two male rats died in the highest-dose group and both male and female rats lost weight in a dose-dependent fashion. Further effects were described as follows in the IARC (2000) monograph:
"Poorly regenerative microcytic anaemia developed within two weeks, without observed changes in bone marrow. Moreover, increased kidney weight, tubular necrosis and loss of kidney function

occurred after two weeks. Epithelial cell necrosis in kidney tubules was seen only at the highest dose in both sexes. Some mild changes in the liver were observed, such as weight increase. Demyelination in the medulla oblongata (brain) and spinal cord was found after 13 weeks in both males and females".

Thus, at high doses DEA adversely affects blood, kidney, liver, and the nervous system. Similar effects were observed in a concurrent study with mice.

Subjected to dermal exposure (32–500 mg/kg bw on five days per week) during a 13-week study, rats at the highest dose also developed ulcerative skin lesions at the site of application, accompanied by inflammation and further epidermis effects (IARC, 2000). Otherwise the effects were similar to those following oral exposure. A corresponding experiment with mice gave similar results.

Eye and skin irritation after application of pure (98%) 2,2'-iminodiethanol was investigated in rabbits. After 72 h, irritation of the skin was moderate, whereas irritation of the eye was severe (IARC, 2000). 2,2'-iminodiethanol has been concluded not to be a skin sensitizer in animals, which is also suggested by the available information for humans (OECD, 2007).

Upper respiratory tract irritation was caused in rats by inhalation exposure to 2,2'-iminodiethanol, while no information on respiratory irritation in humans is available (OECD, 2007).

A large number of studies have been reviewed in the OECD SIDS (2007). The acute and chronic effect concentrations are summarized in Table 13. The lowest NOAEC for respiratory tract irritation upon inhalation exposure was found at 3 mg/m³. The lowest LOAEL for the systemic effects of local skin irritation after dermal exposure was 32 mg/kg bw. With respect to oral exposure, the LOAEL for anaemia was found to be 14 mg/kg bw.

TABLE 13
EFFECT CONCENTRATONS FOR ACUTE AND CHRONIC EFFECTS (DATA FROM OECD, 2007).

Organism	Exposure conditions	Effect	Effect level *	Concentration
Rat	Oral	Mortality	LD50	780 -3,540 mg/kg bw
Mice	Oral	Mortality	LD50	3,300 – 4,570 mg/kg bw
Mice**	Oral	Mortality	LD50	2,300 mg/kg bw
Rabbit	Oral	Mortality	LD50	2,200 mg/kg bw
Rabbit	Dermal	Mortality	LD50	13,000 mg/kg bw
Rat	Inhalation	Systemic effects	NOAEC	15 mg/m³
Rat	Inhalation	Upper respiratory tract irritation	NOAEC	3 mg/m³
Rat	Dermal (repeated unoccluded dermal application of ethanolic 2,2'-iminodiethanol solutions	Systemic effects or local skin irritation	LOAEL	32 mg/kg bw
Mice	Dermal (repeated unoccluded dermal application of ethanolic 2,2'-iminodiethanol solutions	Systemic effects or local skin irritation	LOAEL	80 mg/kg bw
Rat (female)	Oral (subchronic treatment via the drinking water)	Mortality	n.s.	≥ 2500 ppm

Organism	Exposure conditions	Effect	Effect level *	Concentration
Rat (male)	Oral (subchronic treatment via the drinking water)	Mortality	n.s.	≥ 5000 ppm
Rat (female)	Oral (subchronic treatment via the drinking water)	Impaired body weight gain	LOEL	320 ppm
Rat (male)	Oral (subchronic treatment via the drinking water)	Impaired body weight gain	LOEL	630 ppm
Rat (female)	Oral (subchronic treatment via the drinking water)	Anaemia	LOAEL	14 mg/kg bw / 160 ppm
Rat (male)	Oral (subchronic treatment via the drinking water)	Anaemia	LOAEL	25 mg kg bw / 320 ppm
Mice (female)	Oral (subchronic exposure)	Necrotic liver damage	LOAEL	142 mg kg bw/630 ppm
Mice (male)	Oral (subchronic exposure)	Necrotic liver damage	LOAEL	104 mg kg bw /630 ppm
Rat	Oral (subacute, 14 days)	Red blood cell alteration	LOAEL	50 mg/kg bw
Mice	Oral (subacute, 14 days)	Red blood cell alteration	LOAEL	100 mg/kg bw

* n.s. – not specified

** Data from IARC (2000)

6.1.4 Reproductive and developmental effects

The reproductive and developmental toxicity of DEA tested has been reviewed (IARC, 2000). DEA was administered by gavage to rats on days 6–15 of gestation at dose levels of 0, 50, 200, 500, 800 or 1200 mg/kg bw/day. Rats receiving 500 mg/kg bw or higher doses either died or were killed due to moribund condition. Maternal body weight gain was reduced in the 200 mg/kg bw-group, but none of the gestational parameters in the treated groups was significantly different from those of the controls (IARC, 2000).

In a dermal exposure experiment, 2,2'-iminodiethanol was applied as an aqueous solution on the skin of CD rats on days 6–15 of gestation at dose levels of 0, 150, 500 and 1500 mg/kg bw per day. Apart from skin irritation in the high dose-groups, there was no effect of any treatments on fetal weight or on the incidence of external, visceral or skeletal abnormalities, but delayed ossification of the axial skeleton and distal appendages was observed in fetuses of the 1500-mg/kg bw group (IARC, 2000). No effect on development or on the incidence of external, visceral or skeletal abnormalities was observed in a comparable experiment with rabbits.

A few studies detect developmental toxicity. In all cases, pre- and postnatal developmental toxicity was only observed in the presence of clear maternal toxicity and at dose levels considered as high (OECD, 2007).

In a 13-week subchronic study with male rats, testis and epididymis weights were decreased at 2,2'-iminodiethanol doses of 1200 ppm or more in the drinking water. Reduced sperm count and motility as well as degeneration of the seminiferous tubules were found at a dose of 2500 ppm.

Effect concentration data for reproductive and developmental effects are summarised in Table 14. Several studies find no-effect levels for dermal exposure in the range of 35 - 50 mg/kg, while the lowest effect level are about one magnitude larger.

TABLE 14
REPRODUCTIVE AND DEVELOPMENTAL EFFECT CONCENTRATONS FOR DIFFERENT EXPOSURE CONDITIONS (DATA FROM OECD, 2007).

Organism	Exposure conditions	Effect	Effect level *	Concentration
Rat	Inhalation (for 3-month)	Male fertility parameters	NOAEC	0.15 mg/L
Rat	Oral (via the drinking water for 13 weeks)	Fertility effects in males	NOAEL	48 mg/kg bw
Rat	Inhalation (aerosol nose-only exposure system)	Maternal and prenatal developmental toxicity	NOAEC	0.05 mg/L
Rat	Dermal	Maternal toxicity	LOAEL	150 mg/kg
Rat	Dermal	Prenatal developmental toxicity	LOAEL	380 mg/kg
Rat	Dermal	Teratogenicity	NOAEL	1500 mg/kg bw
Rabbit	Dermal	Maternal toxicity	NOAEL	35 mg/kg bw
Rabbit	Dermal	Prenatal developmental toxicity	NOAEL	>350 mg/kg bw
Rabbit	Dermal	Developmental toxicity	NOAEL	50 mg/kg

ECHA (2014a) has in the decision taken based on the REACH substance evaluation, requested that the registrants provide further testing of the DEA to include an Extended One Generation Reproductive Toxicity Study in rats, oral route, according to test method OECD TG 443 with the developmental neurotoxicity and immunotoxicity (DNT/DIT) cohorts but without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation. This test is expected to contribute to fill information gaps regarding the observed testis toxicity and the potential to cause neurotoxic effects and effects on the developing immune system.

6.1.5 Genetic and related effects

2,2'-Iminodiethanol was neither mutagenic to several *Salmonella typhimurium* strains in three studies, to *Saccharomyces cerevisiae* strain JD1, nor to *Escherichia coli* (WP2 uvrA) in a single study in the presence or absence of exogenous metabolic activation.

Genetic effects (micronuclei induction, mutations, induction of sister chromatid exchanges, induction of chromosomal aberrations, cell transformations) were investigated in larvae of the newt *Pleurodeles waltl*, in mouse lymphoma L5178Y cells, Chinese hamster ovary cells, rat liver cells, and in a Syrian hamster embryo clonal assay. In none of the test systems DEA induced genetic effects.

Another study with Syrian hamster embryo clonal assay on cell transformations demonstrated a positive dose-related response to DEA up to 500 µg/mL that could be abolished by co-administration with 30 mM choline (IARC, 2000). Additionally, it is known that deprivation of choline (induced by DEA) in the diet of rodents predisposes to the appearance of hepatocellular carcinomas. DEA–induced choline deficiency thus provides a mechanism for the tumourigenesis noted in mice but not in rats (IARC, 2000).

6.1.6 Carcinogenicity

IARC summarises epidemiological cancer studies as follows: "Two cohort studies and two nested case–control studies looked at cancer mortality or incidence among workers using metalworking fluids with ethanolamines as additives, with or without sodium nitrite. Small excesses were observed for cancers at various sites, in particular the stomach, oesophagus and larynx. In most of these studies, only associations with use of soluble oils or synthetic fluids were presented and no results were given specifically in relation to DEA exposure. It is difficult to draw conclusions regarding DEA using data from studies of exposures to these complex mixtures."

Human model studies with mice and rats gave contradicting results with respect to carcinogenic effects in liver, kidney and skin.

Consequently, IARC evaluates that "there is inadequate evidence in humans for the carcinogenicity" of DEA. With respect to animals, "there is limited evidence for the carcinogenicity" of DEA. Therefore, it is concluded that DEA is not classifiable as to its carcinogenicity to humans (Group 3) (IARC, 2000).

IARC has in 2012 updated the evaluation of DEA. Examination of cohort studies of workers exposed to waterbased metalworking fluids published since the previous review did not provide new evidence for a statistically significant association between DEA exposure and elevated cancer risk. The conclusion regarding evidence in humans is therefore unchanged.

Results in male and female mice showed that dermal application of DEA increased the incidence of hepatocellular carcinoma and hepatocellular adenoma, and of hepatoblastoma in males. The incidence of renal tubule adenoma was also increased in males. IARC (2012) also concludes that there is weak evidence that a genotoxic mechanism is involved in the induction of liver tumours by DEA, and that there is moderate experimental support for choline deficiency as a mechanism for DEA-induced liver cancer in rodents. It is also mentioned that the human relevance of this mechanism cannot be excluded, especially for subgroups that are highly susceptible to dietary choline deficiency.

Based on the new information available, IARC (2012) has evaluated that there is "sufficient evidence" in experimental animals for the carcinogenicity of DEA. The overall evaluation is therefore that DEA is "possibly carcinogenic to humans (Group 2B).

One of the key concerns in relation to DEA and cancer risk is the formation of nitrosamine in the products such as cutting oils and cosmetics containing DEA. Because DEA is a secondary amine, it could react with nitrosating agents (like nitrites, which are common and naturally occurring chemicals) to produce nitrosamines (2,2'-(nitroso)bisethanol). Nitrites can also be found in drinking water and food stuffs. 2,2'-(Nitroso)bisethanol (NDELA), cas. no. 1116-54-7, is a classified carcinogen.

Due to the risk of formation of nitrosamines ECHA (2014a) has in the decision taken based on the REACH substance evaluation, requested that the registrants provide further information on the transformation product of DEA (NDELA) to be reflected in the CSR (exposure assessment and risk characterisation for carcinogenic transformation product, for workers and consumers). Dermal

contact, inhalation and ingestion are considered relevant exposure routes for the general population and DMELs must be derived for all possible exposure routes.

6.1.7 Mode of action

Functional and structural alterations induced by 2,2'-iminodiethanol in liver mitochondria may ensue from its adverse effects on membrane lipid metabolism (IARC, 2000). It has been shown to be incorporated as the head group in phospholipids, presumably using the same enzymatic pathways as ethanolamine (OECD, 2007).

In mice, DEA alters choline homeostasis in a manner resembling choline deficiency. DEA induces choline deficiency since it is competitively metabolized with choline. For example, DEA inhibited the uptake of choline into mammalian cells.

Another effect is the reduction in the hepatic concentration of phosphocholine, which is the intracellular storage form of choline. Moreover, the pattern by which choline metabolites were altered was similar to the pattern of change that has been observed following dietary choline deprivation in rodents. Excess choline also prevents 2,2'-iminodiethanol-induced inhibition of phosphatidylcholine synthesis and incorporation of 2,2'-iminodiethanol into cell phospholipids (IARC, 2000).

6.1.8 No-effect levels

Occupational exposure limit values

Occupational exposure limit values for DEA for selected European countries are presented in Table 15.

TABLE 15
OCCUPATIONAL EXPOSURE LIMIT VALUES FOR DEA FOR SELECTED COUNTRIES (GESTIS DATABASE)

	Limit value 8-hours		Limit value short term	
	ppm	mg/m³	ppm	mg/m³
Austria	0.46	2	0.92	4
Belgium	0.46	2		
Denmark	0.46	2		
France	3	15		
Germany		1(1)		1(2)
Sweden	3	5	6(1)	30(1)

(1) Inhalable fraction and vapour; (2) 15 minutes reference period

No EU indicative exposure limit value is established.

Derived no-effect levels and limit values

Derived no-effect levels for DEA registered under REACH are shown in Table 16. The DNELs are from a joint submission and are established by the registrant for systemic effects from long term exposure in the different exposed populations by inhalation or the dermal route, and for the general population also from the dermal route. ECHAs dissemination website does not include the full justification behind the values. DNELs are used for risk assessment of specific exposure situations.

The DNELs submitted with the registration dossier have been challenged in the decision taken in relation to the substance evaluation process (according to Article 44-48 in REACH) and the

decision taken pursuant to article 46(1) in REACH requesting further information from the registrant (see 2.1.3).

TABLE 16
DERIVED NO-EFFECT LEVELS (DNELS) FOR DEA FROM THE REGUISTRATION (ECHA, 2013) AND VALUES SUGGESTED IN THE DECISION ON SUBSTANCE EVALUATION PERSUANT TO ARTICLE 46(1) OF REACH (ECHA, 2014A)

Population / - route	Exposure	DNEL from dossier	Dose descriptor / Assessment factor	Sensitive endpoint	DNEL from decision pursuant to Article 46(1)
Workers - inhalation	Long term exposure - local	1 mg/m³	- / 1	Repeated dose toxicity	0.15 mg/m³
Workers - inhalation	Long term exposure - systemic	-	-	-	0.3 mg/m³
Workers - inhalation	Long term exposure - local	-	-	-	3 µg/cm²
Workers - dermal	Long term exposure - systemic	0.13 mg/kg bw/day	LOAEL / 60	Repeated dose toxicity	0.053 mg/kg bw/day (Local / systemic)
Gen. population - inhalation	Long term exposure - local	0.25 mg/m3	- / 2	Repeated dose toxicity	
Gen. population - dermal	Long term exposure - systemic	0.07 mg/kg bw/day	LOAEL / 120	Repeated dose toxicity	
Gen. population - oral	Long term exposure - systemic	0.06 mg/kg bw/day	NOAEL / 240	Repeated dose toxicity	
Gen. population - oral	Acute exposure - systemic	-	LD50 / 10000	-	0.16 mg/kg bw/day

-: No information

According to the decision made the registrants have agreed to derive acute DNELs for the general population.

6.2 Human exposure

6.2.1 Direct exposure

Consumers

The general public will primarily be exposed through skin contact with DEA as a contaminant from primary and tertiary alkanolamines in cosmetics and from use in certain in cleaning/washing agents where DEA is present, often as a contaminant in fatty acid-diethanolamide surfactants (IARC, 2012). DEA may also be present in food contact materials. Other less frequent sources of exposure may be through disinfectants, colouring agents, construction materials additives, corrosion inhibitors, cutting oil, and others (OECD, 2007).

In cosmetic products the potential for exposure to DEA often comes from the use of alkanolamides which are condensation products of alkanolamines and fatty acid. These ingredients are typically used in rinse-off applications such as shampoos and hair dyes and may contain DEA as a component / contaminant of the ingredients, generally in the range of 0.2-10% (Bailey, 2007).

Consumers may also be exposed to DEA residues resulting from the use of DEA as processing aid in the production of paper, textile and leather. No exposure estimates are available and the registrants of DEA therefore also requested to provide exposure estimations and risk characterisations for human health for consumer use of plastic rubber, textile, leather and paper products according to the substance evaluation procedure in order to demonstrate safe use (ECHA, 2014a).

Secondary exposure to DEA may also be expected due to releases from articles which have been treated with DEA in detergents, cleaners or wood protection formulations. The registrants of DEA have therefore also been requested to provide additional exposure scenarios and estimations for residues on textiles and food contact materials. Furthermore the registrants are requested to provide scenarios for secondary exposure to wood protection formulations, including sanding of treated wood by adults, chewing of treated wood by children, inhalation of volatilised residues indoors by adults and children playing and mouthing on treated structure (ECHA, 2014a).

The decision also requests the registrants to provide supplementary information in relation to different other consumer scenarios, such as use of DEA in concrete and cement, use of DEA in detergents and cleaners, and use of DEA in wood protection formulations.

As part of the Danish EPA surveys on chemicals in consumer products, DEA was identified in 3 out of 82 products being used for cleaning of smoke-damaged private homes following a fire (Wibroe and Pedersen, 2007). No information on concentrations in the products is provided.

Another Danish consumer survey investigated the chemical content in sanitary towels. DEA at a concentration of 7.5-13 mg/kg product (repeat determination) was found in one out of eight sanitary towels selected for chemical analysis (Pors and Fuhlendorff, 2002).

Occupational exposures
Occupational exposure to DEA may occur by dermal contact inhalation of fumes and aerosols from various processes.

Measurements from a production site in Germany are published in the OECD SIDS report (OECD, 2007). At the site DEA is produced in one production plant and is processed further within eight other operations and plants. Between January 2001 and December 2006, data on 53 workplace exposures covering all operations were collected by means of personal air sampling. The reported data are 8-hour time-weighted average (TWA) values for shifts. In the production plant, the highest value recorded was 0.026 mg/m^3; at the filling stations, the maximum value recorded was 0.062 mg/m^3; and the overall range of the measurement results was < 0.019-0.062 mg/m^3 (OECD, 2007). These levels are below the occupational exposure limits presented in Table 15.

6.2.2 Indirect exposure
No information on indirect exposures through air, soil drinking water, food or indoor climate have been identified.

6.3 Bio-monitoring data
In a study involving a small group of female human subjects (approved by the Public Health Institutional Review Board at the University of North Carolina at Chapel Hill in the US), dermal treatment for 1 month with a commercially available skin lotion containing 1.8 mg DEA per gram resulted in plasma concentrations of DEA and metabolites that were significantly increased above

blank values but that were approximately 100- to 200-fold lower than those achieved in mice treated with the 80 mg/kg/day dose. The subjects applied between 14.5 and 22.9 ml/day (based on returned bottle content of lotion). It was calculated that a 60-kg person applying 20 ml/day of this strength lotion was exposed to a DEA dose of 0.6 mg/kg/day. In a few weeks of application, the three subjects achieved concentrations of DEA and metabolites in plasma that were approximately 0.5–1% of the concentrations achieved after the mice were treated with 80 mg/kg/day for 11 days. The study also revealed that all three subjects had low, but detectable, concentrations of DEA in plasma at baseline, suggesting that humans are exposed to DEA in the environment (Craciunescu et al., 2009).

No further biomonitoring data have been identified.

6.4 Human health impact

As illustrated by the request for further information in the decision from ECHA (2014a) following the substance evaluation procedure, there is not sufficient information available to evaluate the risk from both occupational and consumer use of the DEA including the potential risk from exposure to NDELA.

Several cohort studies have examined the association between extensive exposure to metal-working fluid in e.g. the automotive industry and different types of cancers. A few studies have also calculated risk estimates for exposure to specific components of metalworking fluids (i.e. ethanolamines and nitrosamines. However, these studies involving exposure to complex mixtures, produces variable results, and cannot distinguish the carcinogenic effect of DEA alone from that of the complex mixture (IARC, 2012). IARC (2012) did also not identify any studies that evaluated human cancer associated with the use of personal care products that contain DEA.

6.5 Summary and conclusions

DEA has a moderate acute oral toxicity, and is a skin and severe eye irritant.
In subchronic toxicity testing conducted via the oral route in rats and mice, the main effects observed were increased organ weights and histopathology of the kidney and or liver, with the majority of other tissue effects noted only at relatively high doses.

Signs of developmental toxicity have been observed in a few studies at high doses. In a 13-week subchronic study drinking water study in male rats, toxic effects on testis were observed. As a result of the REACH substance evaluation procedure, ECHA has in the decision taken pursuant to Article 46(1) requested that the registrants provide further testing of the DEA to include an Extended One Generation Reproductive Toxicity Study in rats, oral route, according to test method OECD TG 443 with the developmental neurotoxicity and immunotoxicity (DNT/DIT) cohorts but without the extension of Cohort 1B to mate the F1 animals to produce an F2 generation. This test is expected to contribute to fill information gaps regarding the observed testis toxicity and the potential to cause neurotoxic effects and effects on the developing immune system.

Based on animal studies and updated information from cohort studies in humans IARC has in 2012 concluded that there is "sufficient evidence" in experimental animals for the carcinogenicity of DEA and that DEA is "possibly carcinogenic to humans (Group 2B). One of the key concerns in relation to DEA and cancer risk, is the formation of nitrosamine in the products such as cutting oils and cosmetics containing DEA. Because DEA is a secondary amine, it could react with nitrosating agents like nitrites, which are common and naturally occurring chemicals, to produce the carcinogenic nitrosamine, 2,2'-(nitroso)bisethanol (NDELA). Due to the risk of formation of nitrosamines, the decision from ECHA also requests the registrants to provide further information on the transformation product of DEA (NDELA) to be reflected in the CSR (exposure assessment and risk characterisation for carcinogenic transformation product, for workers and consumers). Dermal

contact, inhalation and ingestion are considered relevant exposure routes for the general population and DMELs must be derived for all possible exposure routes.

Occupational exposure to DEA is expected to be limited in Denmark, but may occur by dermal contact, inhalation of fumes and aerosols from various processes if the necessary safety precautions are not properly implemented.

The general public will primarily be exposed through skin contact with DEA as a contaminant from primary and tertiary alkanolamines or their salts in cosmetics and from use in certain in cleaning/washing agents where DEA is present, often as a contaminant in fatty acid-diethanolamide surfactants. DEA may also be present in food contact materials. Other less frequent sources of exposure may be through construction materials additives, corrosion inhibitors, cutting oil, and others.

Consumers may also be exposed to DEA residues resulting from the use of DEA as processing aid in the production of paper, textile and leather. No exposure estimates are available and the registrants of DEA therefore also requested to provide exposure estimations and risk characterisations for human health for consumer use of plastic rubber, textile, leather and paper products according to the substance evaluation procedure in order to demonstrate safe use.

Secondary exposure to DEA may also be expected due to releases from articles which have been treated with DEA in detergents, cleaners or wood protection formulations. The registrants of DEA have therefore also been requested to provide additional exposure scenarios and estimations for residues on textiles and food contact materials. Furthermore the registrants are requested to provide scenarios for secondary exposure to wood protection formulations, including sanding of treated wood by adults, chewing of treated wood by children, inhalation of volatilised residues indoors by adults and children playing and mouthing on treated structure.

The decisions also requests the registrants to provide supplementary information in relation to different other consumer scenarios, such as use of DEA in concrete and cement, use of DEA in detergents and cleaners, and use of DEA in wood protection formulations.

In the Danish EPA consumer survey programme, DEA has been identified in 3 out of 82 products identified as being used for cleaning of smoke-damaged private homes following a fire and in one out of eight sanitary towels selected for chemical analysis in a study investigating chemicals in this type of products.

As illustrated by the request for further information in the decision from ECHA as a result of the substance evaluation procedure, there is not sufficient information available to evaluate the risk from both occupational and consumer use of the DEA including the potential risk from exposure to NDELA.

7. Information on alternatives

7.1 Identification of possible alternatives

As noted earlier, DEA has in Europe and in Denmark already been formulated out of many end uses which involve significant human exposure such as personal care products. For specific end uses, alternatives have been identified as follows:

Gas treatment

Alternatives to DEA for gas treatment suggested by different manufacturers and suppliers (e.g. BASF[5], Dow[6], Huntsman[7]):

- Monoethanolamine (MEA)
- Triethanolamine (TEA)
- Methyl diethanolamine (MDEA)
- Amino-diethyleneglycol (ADEG)
- Diisopropanolamine (DIPA)
- 2(2-aminoethoxy)ethanol (DGA).

Intermediates

In general, where DEA is used as a chemical intermediate, the specific DEA molecule is required. However, in multistep reaction series for complex end products, alternative chemical processes can be developed using different reactants, or the initial reaction product requiring DEA can imported, depending upon the final chemical substance required. For the production of some functional chemicals, replacement with chemically-similar dialkanolamines can result in products with similar function (i.e. replacement of DEA by diisopropylamine to make a fatty acid amide with similar properties).

For the production of glyphosate, two alterative processes, neither of which use DEA as a starting material, have been reported. However, one of the alternate processes starts with hydrogen cyanide, a highly problematic substance, and the other process starts with monochloroacetic acid.

Metalworking fluids

Alternatives to DEA used as surfactant, emulsifier and for corrosion inhibition in metalworking fluids suggested by different manufacturers and suppliers (Huntsman[8], Focus Chemical[9],):

- Monethanolamine (MEA)
- Triethanolamine (TEA)

[5] http://www.basf.com/group/corporate/en/literature-document:/Brand+OASE+blue-Brochure--OASE+Gas+Treating+Excellence-English.pdf

[6] http://www.magnumsolvent.com/productdata/Product%20Literature/Dehydration%20and%20Acid%20Gas%20Removal/Gas%20treating%20products%20and%20services.pdf

[7] http://www.huntsman.com/performance_products/Media%20Library/a_MC348531CFA3EA9A2E040EBCD2B6B7B06/Key%20markets_MC348531CFD2FA9A2E040EBCD2B6B7B06/Energy_MC348531D0031A9A2E040EBCD2B6B7B06/Gas%20treating_MC348531D01FFA9A2E040EBCD2B6B7B06/files/Gas%20Treating.pdf

[8] http://www.huntsman.com/performance_products/Media%20Library/a_MC348531CFA3EA9A2E040EBCD2B6B7B06/Products_MC348531D0B9FA9A2E040EBCD2B6B7B06/Amines_MC348531D0BECA9A2E040EBCD2B6B7B06/Morpholine%20%20%20DGA_R_MC348531D0D20A9A2E040EBCD2B6B7B06/DIGLYCOLAMINE_R%20agen_MC348531D0DBAA9A2E040EBCD2B6B7B06/files/metalworking_brochure.pdf

[9] http://www.focuschemical.com/

- Polyetheramines
- Alcoholethoxylates
- Alkylphenol ethoxylates
- Fatty acid ethoxylates
- Polymerised esters
- Phosphate esters
- 2-amino 2-ethyl-1,3-propanediol (AEPD)
- Monoisopropanolamine (MIPA)
- Diisopropanolamine (DIPA)
- Triisopropanolamine (TIPA)
- 2-amino 2-methyl-1-propanol (AMP)
- 2(2-aminoethoxy)ethanol

Secondary amines appear to have

Polyurethane foam

Alternatives to DEA in polyurethane foam include a large variety of alkyl and alkanolamines which can substitute DEA in urethane foam production (American Chemistry Council, 2011):

- bis(2-Dimethylaminoethyl)ether
- N,N-Dimethylaminopropylamine (DMAPA)
- N,N-Dimethylcyclohexylamine
- Triethylenediamine
- 2(2-Dimethylaminoethoxy)ethanol
- 3-Dimethylamino-N,N-Dimethylpropionamide (DDPA)
- N-Ethylmorpholine

Although several organometallic compounds or salts may also be used as catalysts in the production of polyurethanes, many polyurethane manufacturers use either tertiary aliphatic amines or alkanolamines. Amine catalysts are typically 0.1 to 5.0 percent of a polyurethane formulation.

It should be noted that due to the toxicity of isocyanates used in the production of urethane foams, risk reduction measures are generally in place in order to avoid any exposure to the substances.

Cosmetics and personal care products

Alternatives to DEA in cosmetics suggested by different manufacturers and suppliers (e.g. Rhodia[10], Lubrizol[11], Stepan Company[12]):

- Large variety of amides, quaternary salts, non-ionic and anionic surfactants
- PEG-3 glyceryl cocoate
- PEG-7 glyceryl soyate
- Cocamide MIPA
- Lauramide MIPA

One of the technical problems with replacing substances like cocamide DEA in cosmetics is that it is a multifunctional ingredient. It helps building viscosity, stabilising foam, and can build flash foam, Furthermore it can help with grease cutting and fragrance solubilisation. It is therefore often necessary to replace the substance with a blend of other substances. An example is a blend containing oleyl betaine and sodium lauroyl lactylate (Roach and Butz, 2013).

[10] http://www.brenntagspecialties.com/en/downloads/Products/Personal_care/Rhodia/PC_Solutions_Guide.pdf
[11] http://www.essentialingredients.com/pdf/lubrizoldeaarticleall.html
[12] Stepan's CDEA Replacements: http://www.stepan.com/workarea/downloadasset.aspx?id=3234

In 2012, DEA and cocamide diethanolamine (cas no. 68608-42-9) was added to the California Proposition 65 list that includes substances as known to the state of California to cause cancer. This regulatory initiative is also expected to drive the substitution of DEA in personal care products further.

Cleaners and washing agents

Alternatives to DEA in cleaners and washing agents include:

- Fatty acid amides of diethanolamine
- Fatty acid salts of diethanolamine
- Coconut diethylamide
- Other high pH substances
- Silicates
- Ethoxylate surfactants

Paints and coatings

Alternatives to diethanolamine in paints and coatings:

- 2-Amino-2-methyl-1-propanol
- Ethylenediamine
- Diaminopropane
- 2(2-aminoethoxy)ethanol
- N-methylethanolamine
- Various higher molecular weight amines

7.1.1 Hazard classification of suggested alternatives

The hazard classifications of the substances suggested as alternatives to DEA in the different application areas are shown in Table 17. For substances without a harmonised classification, the industry classification suggested by the majority of notifiers is shown.

Alternatives that are not identified by CAS number or chemical name are not included, e.g. "alkyl and alkanol amines" and "various higher molecular weight amines".

TABLE 17
CLASSIFICATION OF SUGGESTED ALTERNATIVES TO *N*-HEXANE (ECHA)

Substance name	CAS no.	Suggested application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Pictograms
Harmonised classifications				
Chloroacetic acid	79-11-8	Herbicides	Acute Tox. 3 H301 Acute Tox. 3 H311 Skin Corr. 1B H314 Acute Tox. 3 H331 Aquatic Acute 1 H400	
Monoethanolamine (MEA)	141-43-5	Gas treatment Metalworking fluids	Acute Tox. 4 H302 Acute Tox. 4 H312 Skin Corr. 1B; H314 Acute Tox. 4;H332	
Triethanolamine (TEA)	102-71-6	Gas treatment Metalworking fluids	Eye Irrit. 2; H319 (Most common notification)	
Methyldiethanolamine (MDEA)	105-59-9	Gas treatment	Eye Irrit. 2; H319	

Substance name	CAS no.	Suggested application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Pictograms
Amino-diethyleneglycol / 2(2-aminoethoxy)ethanol (DGA)	929-06-6	Gas treatment Metalworking fluids	Met. Corr. 1; H290 Skin Corr. 1C.; H314 Eye Dam. 1;H318 (Most common notification)	
Diisopropanolamine (DIPA)	110-97-4	Gas treatment Metalworking fluids	Eye Irrit. 2; H319	
1-Amino-2-propanol (isopropanolamine, MIPA)	78-96-6	Metal working fluid Cleaners and washing agents Cosmetics	Skin Corr. 1B; H314	
isopropanolamine (TIPA)	122-20-3	Metalworking fluids	Eye Irrit. 2; H319	
2-amino 2-ethyl-1,3-propanediol (AEPD)	115-70-8	Metalworking fluids	Eye Irrit. 2; H319 (Most common notification)	
2-amino 2-methyl-1-propanol (AMP)	124-68-5	Metalworking fluids Paints and coatings	Skin Irrit. 2.; H315 Eye Irrit. 2; H319 Aquatic Chronic 3; H412	
bis(2-Dimethylaminoethyl)ether	3033-62-3	Polyurethane foam	Acute Tox. 4 H302 Acute Tox. 3 H311 Skin Corr. 1B; H314 Eye Dam. 1;H318 Acute Tox. 4;H332 (Most common notification)	
N,N-Dimethylamino-propylamine (DMAPA)	109-55-7	Polyurethane foam	Flam. Liq. 3; H226 Acute Tox. 4; H302 Skin Corr. 1B.; H314 Skin Sens, 1; H317	
N,N-Dimethyl-cyclohexylamine	98-94-2	Polyurethane foam	Flam. Liq. 3; H226 Acute Tox. 3; H301 Acute Tox. 3; H311 Skin Corr. 1B.; H314 Eye Dam. 1; H318 Acute Tox. 3; H331 Aquatic chronic 3; H411 (Most common notification)	
Triethylenediamine	121-44-8	Polyurethane foam	Flam. Liq. 2; H225 Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1A.; H314 Acute Tox. 4; H332	
2(2-Dimethylamino-ethoxy)ethanol	1704-62-7	Polyurethane foam	Acute Tox. 4; H312 Skin Corr. 1C.; H314 Eye Dam. 1; H318 (Most common notification)	

Substance name	CAS no.	Suggested application area	Hazard Class and Category Code(s) and Hazard Statement Codes	Pictograms
3-Dimethylamino- N,N-Dimethylpropionamide (DDPA)	17268-47-2	Polyurethane foam	Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1B.; H314	
N-Ethylmorpholine	100-74-3	Polyurethane foam	Flam. Liq. 3; H226 Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1B.; H314 (Most common notification)	
Coconut diethylamide (Cocamide DEA)	68603-42-9	Cleaners and washing agents	Skin Irrit. 2.; H315 Eye Irrit. 2; H319 (Most common notification)	
Ethylenediamine	107-15-3	Paints and coatings	Flam. Liq. 3; H226 Acute Tox. 4; H302 Acute Tox. 4; H312 Skin Corr. 1B.; H314 Skin Sens, 1; H317 Resp. Sens.1; H334	
Diaminopropane	109-76-2	Paints and coatings	Flam. Liq. 3; H226 Acute Tox. 4; H302 Acute Tox. 2; H310 Skin Corr. 1B.; H314 Skin Sens, 1B; H317 Eye Dam. 1; h318 Resp. Sens.1; H334 Aquatic chronic 3; H412 (Most common notification)	
N-methylethanolamine	109-83-1	Paints and coatings	Flam. Liq. 3; H226 Acute Tox. 4; H302 Acute Tox. 2; H310 Skin Corr. 1B.; H314 Skin Sens, 1B; H317 Resp. Sens.1; H334 Aquatic chronic 3; H412 (Most common notification)	
N-(2-hydroxypropyl)-dodecanamide (Lauramide MIPA)	142-54-1	Cleaners and washing agents Cosmetics	Eye Irrit. 2; H319 (Most common notification)	
Coconut monoisopropanolamide (Cocamide MIPA)	68333-82-4	Cleaners and washing agents Cosmetics	Eye Dam. 1; H318 (Most common notification)	

As demonstrated by the classifications in the table, some of the alternatives have health properties, such as skin and respiratory sensitising properties, that would be a concern for both professional and consumer uses. The majority of the suggested substances also belong to the group of amines or amides which exhibit varying degree of skin and eye irritation or corrosion.

7.2 Historical and future trends

As noted elsewhere, the use of DEA in applications involving significant exposure to workers or the general population have decreased markedly over the past 10 years. The use of DEA as an intermediate in herbicide production, primarily for glyphosate, will continue to grow outside of Denmark, as may its use to remove sulfur from natural gas and refinery gases. If economical and environmentally sound disposition of recovered CO2 can be developed, the use of DEA to remove CO2 from combustion gases may significantly increase, although other amines can also be used for this application. Also, the use of diethanolamides and DEA fatty acid esters to improve the lubricity of biodiesel fuel has been cited in a patent, but there is no evidence of the technology in commercial use.

7.3 Summary and conclusions

Alternatives are available for most uses of DEA, which has already been replaced in many end uses which involve significant worker or consumer exposure. It is likely that the remaining high-exposure end uses will also undergo substitution to other substances, except in very specific applications. This is a global trend, as well as in Denmark.

The use of DEA for gas treatment is likely to grow, although other amines will compete in this end use. Additionally, the use of DEA as a chemical intermediate for the production of herbicides and amides is likely to grow outside of Denmark, but not domestically.

The majority of the suggested substances also belong to the group of amines or amides which exhibit varying degree of skin and eye irritation or corrosion.

8. Abbreviations and acronyms

CLP	Classification, Labelling and Packaging Regulation
DEA	Diethanolamine
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DFL	Trade organisation for the paint and adhesives industry in Denmark
EC_n	Effect concentration where n % of the species tested show the effect
ECHA	European Chemicals Agency
EPA	Environmental Protection Agency
EU	European Union
HELCOM	The Baltic Marine Environment Protection Commission (Helsinki Commission)
IARC	International Agency for Research on Cancer
Kow	Octanol/water partitioning coefficient
Koc	Organic carbon/water partitioning coefficient
Kp	Partial pressure equilibrium constant
LC	Lethal effect concentration
LOUS	List of Undesirable Substances (of the Danish EPA)
MEA	Monethanolamine
NDELA	N-nitrosodiethanolamine
NOAEL	No observable adverse effect level
NOEC	No observable effect concentration
NOVANA	Danish national monitoring and assessment programme
OECD	Organisation for Economic Co-operation and Development
OSPAR	Convention for the Protection of the Marine Environment of the North-East Atlantic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
QSAR	Quantitative Structure and Activity Relationship
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SIDS	Screening Information Data Sets
SPT	Association of Danish Cosmetics, Toiletries, Soap and Detergent Industries
STP	Sewage treatment plant
SVHC	Substance of Very High Concern
TEA	Triethanolamine
TGD	Technical guidance document

References

Akzo Nobel (2014). Patented Production Process. Accessed April 2014 at: https://www.akzonobel.com/ea/our_products/ethanolamines/patented_production_process/

American Chemistry Council (2011). Polyurethane Amine catalysts: Safe Handling Guidelines. Issue AX173, July 2011. http://polyurethane.americanchemistry.com/resources-and-document-library/3852.pdf

Bailey J. (2007). DEA in consumer products is safe. The Journal of the Federation of American Societies for Experimental Biology. January 2007 (21). http://www.fasebj.org/content/21/1/295.full.pdf+html?sid=74892290-5bcd-47a7-8e29-98dc1786540d

Boliven (2014). Online information portal for IP, R&D and business development professionals in science and technology intensive industries. http://www.boliven.com/patent/US5891203?q=classification%3A44%2F399*

Craciunescu C.N., Niculescu M.D., Guo Z., Johnson A.R., Fischer L., Zeisel S.H. (2009). Dose response effects of dermally applied diethanolamine on neurogenesis in fetal mouse hippocampus and potential exposure of humans. Toxicol Sci. 2009 Jan;107(1):220-6. http://toxsci.oxfordjournals.org/content/107/1/220.long

Danfoss (2013). Danfoss Negative List of Chemicals. Accessed March 2014 at: http://www.danfoss.com/AboutUs/Corporate+Citizenship/NegativeList.htm.

DOW (2010). DOW™ Diethanolamine. Product Safety Assessment. The Dow Chemical Company, 18 March 2010.

ECHA (European Chemicals Agency, 2013). Registered substances. Available at: http://echa.europa.eu/information-on-chemicals. Accessed December 2013.

ECHA (2014). CoRAP list of substances. Draft Community Rolling Action Plan 2012-2014 (CoRAP). European Chemicals Agency. Accessed January 2014 http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan.

ECHA (2014a). Decision on substance evaluation pursuant to article 46(1) of Regulation (EC) No. 1907/2006. For 2,2'-iminodiethanol – CAS No. 111-42-2 (EC No. 203-868-0). Helsinki 25.02.2014. http://echa.europa.eu/documents/10162/d34b5848-6b8e-4944-8ce7-4d0200ea43d7

GESTIS. International limit values for chemical agents. Occupational exposure limits OELs). IFA, Institut für Arbeitsschutz der Deutchen Gesetzlichen Unfallversicherung. http://www.dguv.de/ifa/Gefahrstoffdatenbanken/GESTIS-Internationale-Grenzwerte-f%C3%BCr-chemische-Substanzen-limit-values-for-chemical-agents/index-2.jsp (accessed March 2013)

IARC (2012). Some chemicals present in industrial and consumer products, food and drinking-water. IARC monographs on the evaluation of carcinogenic risks to humans. Volume 101. International Agency for Research on Cancer, WHO.

IARC (2000). DIETHANOLAMINE. IARC monographs on the evaluation of carcinogenic risks to humans ; Volume 77. International Agency for Research on Cancer (IARC).

IHS (2012). Chemical Insight and Forecasting. August 2012. http://www.ihs.com/products/chemical/planning/ceh/ethanolamines.aspx

Kraeling, M.E.K., Yourick, J.J., and Bronaugh, R.L. (2004). In vitro human skin penetration of diethanolamine. Food and chemical toxicology, 42(10), 1553-1561.

Nordic Ecolabelling (2014a). Svanemærkning af Kontor-og Hobbyartikler. Version 4.0 • 11. December 2013 - 31. December 2018. Ecolabelling Denmark, Danish Standards Foundation.

Roach T. and Butz S.S. (2013). A Comprehensive Approach to Replacing DEA in Formulations. Lubrizol Advanced Materials Inc. http://www.essentialingredients.com/pdf/lubrizoldeaarticleall.html

OECD (2007). SIDS Initial Assessment Report For SIAM 24 - 2,2'-Iminodiethanol. United Kingdom. Organisation for Economic Co-operation and Development (OECD).
SUBSPORT (2014). Substitution Support Portal. http://www.subsport.eu/listoflists?suchart=fragment&choice=lcasno&search=111-42-2&type=listoflists&listid=32#18546 (Accessed February 2014)

Pors J. and Fuhlendorf R. (2002). Kortlægning af kemiske stoffer i hygiejnebind. (Survey of chemical substances in sanitary towels). Kortlægning af kemiske stoffer i forbrugerprodukter nr. 13, 2002. [In Danish] http://www2.mst.dk/udgiv/publikationer/2002/Kortlaegning/013_kortlaegning_af_kemiske_stoffer_i_hygiejnebind.pdf

Spin (2014). Nordic Product Registry, SPIN Database. http://195.215.202.233/DotNetNuke/default.aspx (Accessed January and May 2014)

US EPA (2006). ACTION MEMORANDUM: Inert Reassessment-Diethanolamine (CAS Reg. No. 111-42-2). Accessed January 2014 at http://www.epa.gov/opprd001/inerts/diathanol.pdf.

Wibroe L. and Pedersen C.L. (2007). Kortlægning af kemiske stoffer i rengøringsmidler til brug ved rengøring efter ildebrand eller røgskade i private hjem. (Survey of chemical substances in cleaning agents for cleaning after fire or smoke-damage in private homes). Kortlægning af kemiske stoffer i forbrugerprodukter nr. 83, 2007. http://www2.mst.dk/common/Udgivramme/Frame.asp?http://www2.mst.dk/Udgiv/publikationer/2007/978-87-7052-521-3/html/default.htm

Appendix 1: Background information to chapter 2 on legal framework

The following annex provides some background information on subjects addressed in Chapter 3. The intention is that the reader less familiar with the legal context may read this concurrently with chapter 3.

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[13] and the CLP Regulation[14] are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP

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

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

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

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 list[15]
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

[15] 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).

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

Work to implement the OSPAR Convention and its strategies is taken forward through the adoption of decisions, which are legally binding on the Contracting Parties, recommendations and other agreements. Decisions and recommendationsset 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.

CLRTAP - Convention on Long-range Transboundary Air Pollution
Since 1979 the Convention on Long-range Transboundary Air Pollution (CLRTAP) has addressed some of the major environmental problems of the UNECE (United Nations Economic Commission for Europe) region through scientific collaboration and policy negotiation.

The aim of the Convention is that Parties shall endeavour to limit and, as far as possible, gradually reduce and prevent air pollution including long-range transboundary air pollution. Parties develop policies and strategies to combat the discharge of air pollutants through exchanges of information, consultation, research and monitoring.

The Convention has been extended by eight protocols that identify specific measures to be taken by Parties to cut their emissions of air pollutants. Three of the protocols specifically address the emission of hazardous substances of which some are included in LOUS:

- The 1998 Protocol on Persistent Organic Pollutants (POPs); 33 Parties. Entered into force on 23 October 2003.
- The 1998 Protocol on Heavy Metals; 33 Parties. Entered into force on 29 December 2003.
- The 1991 Protocol concerning the Control of Emissions of Volatile Organic Compounds or their Transboundary Fluxes; 24 Parties. Entered into force 29 September 1997.

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.

[Back Page Title]
[Back Page Text]

Danish Ministry of the Environment
Environmental Protection Agency

Strandgade 29
1401 Copenhagen K, Denmark
Tel.: (+45) 72 54 40 00

www.mst.dk