



Danish Ministry of the Environment  
Environmental Protection Agency

# Survey of biphenyl (CAS no. 92-52-4)

Part of the LOUS review

Environmental project No. 1722, 2015

**Title:**

Survey of biphenyl (CAS no. 92-52-4)

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**Published by:**

The Danish Environmental Protection Agency  
Strandgade 29  
1401 Copenhagen K  
Denmark  
[www.mst.dk/english](http://www.mst.dk/english)

**Year:**

2015

**ISBN no.**

978-87-93352-35-3

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# Preface

## Background and objectives

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of concern whose use should be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 (Danish EPA, 2011), includes 40 chemical substances and groups of substances which have been documented as dangerous or which have been identified as problematic 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 biphenyl (CAS 92-52-4). This substance was not included in the first LOUS list in 1998, but was included in the second list in 2000 and has remained on the list since that time (i.e. also included in the fourth list in 2009). The main reason for the inclusion in LOUS is due to its harmonised classification as:

- Skin Irrit. 2 H315: Causes skin irritation
- Eye Irrit. 2 H319: Causes serious eye irritation
- STOT Single Exp. 3 H335: May cause respiratory irritation
- Aquatic Acute 1 H400: Very toxic to aquatic life
- Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects

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 FORCE Technology from April to November 2014. The project team was:

- Maria Strandesen, FORCE Technology, Project Manager
- Larisa Maya-Drysdale, FORCE Technology, Contributor
- Pia Brunn Poulsen, FORCE Technology, Contributor

The work has been followed by an advisory group consisting of:

- Jesper Gruvmark, Danish EPA
- Sidsel Dyekjær, Danish EPA
- Katrine Smith, Danish EPA

### **Data collection**

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

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

- Legislation in force from Retsinformation (Danish legal information database) and EUR-Lex (EU legislation database);
- Ongoing regulatory activities under REACH and intentions listed on ECHA's website (including 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 ECHA's 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);
- Data 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 Naturvårverket), 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 sent to Danish and European trade organisations and a few key market actors in Denmark.

# Summary and conclusion

The main objective of this study is to provide background for the Danish EPA's consideration regarding the need for potential further risk management measures of biphenyl. Biphenyl is on The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) due to its environmental classification and use in Denmark above 100 tonnes annually.

Biphenyl has a harmonised classification as:

- Skin Irrit. 2 H315: Causes skin irritation
- Eye Irrit. 2 H319: Causes serious eye irritation
- STOT Single Exp. 3 H335: May cause respiratory irritation
- Aquatic Acute 1 H400: Very toxic to aquatic life
- Aquatic Chronic 1 H410: Very toxic to aquatic life with long lasting effects

Below is shortly summarised the findings in the different sections of the present report. Biphenyl is still used in Denmark above 100 tonnes annually, and because of the environmental classification as Aquatic Acute 1 H400 and Aquatic Chronic H410 biphenyl fulfils the LOUS criteria.

## Regulatory framework

Biphenyl is limited in foodstuffs and may no longer be used as a feed additive. Furthermore, biphenyl is no longer allowed as food additive (formerly biphenyl was used as anti-fungicide primarily on citrus fruits). A threshold limit value of 1 mg/m<sup>3</sup> is set for the working environment regarding biphenyl in the EU<sup>1</sup>. A limit value of 0.005 mg/m<sup>3</sup> for concentrations of biphenyl in the air, measured at the property line of the companies, has been set for companies in Denmark. The European water quality requirement for biphenyl is 1 µg/l. Furthermore, as a hazardous substance, biphenyl is subject to specific regulation regarding transportation of dangerous goods<sup>2</sup>.

Biphenyl has been registered under REACH in a tonnage band of 1,000 – 10,000 tonnes per annum, but it is neither on the Candidate list of substances of very high concern nor on any of ECHA's Registry of intentions. Biphenyl is on the CoRAP list of substances<sup>3</sup> and was entered on the list in 2012 for evaluation by Portugal in 2013 (CoRAP, 2012), but the evaluation has not been finalised yet. The initial grounds for concern for biphenyl are listed as 1) Environment – suspected PBT and 2) Exposure – high aggregate tonnage. The Swedish Chemicals Agency has included biphenyl in their PRIO database as a “priority risk reduction substance”, which means that the user of the substance is recommended to review the risk of the envisaged use.

Biphenyl is not mentioned directly in any eco-labelling criteria, but will be restricted in any eco-labelling scheme as no or a very small amount of chemicals classified as dangerous for the environment in are allowed in eco-labelled products.

## Manufacturing and uses

No production of biphenyl takes place in Denmark, and the production in the EU has declined during the last decades. The main production of biphenyl, hence, takes place outside of the EU. Only one producer was identified in the EU (UK).

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<sup>1</sup> Directive 91/322/EEC

<sup>2</sup> Directive 2008/68/EC

<sup>3</sup> <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

The latest registered annual production of biphenyl worldwide is from 1998, where an annual capacity of 80,000 tonnes/year was estimated (WHO, 1999). No later figure was possible to retrieve. It was not possible to retrieve publicly available import/export data regarding EU, neither from confidential sources nor through interviews with some of the registrants in ECHA (ECHA RSD, 2014). In Denmark the import of biphenyl was 3,362.4 tonnes (2011).

Biphenyl is found in nature and from anthropogenic sources. When biphenyl is produced it is used as an intermediate for manufacturing of other chemicals or incorporated into final products and technical applications. According to literature sources and interviews with the ECHA registrants, the most common applications of biphenyl since 2009 and until now are in final products, which are:

- heat transfer fluids
- dyestuff carriers for textiles
- preservatives for citrus fruit
- dyestuff carriers for copying paper
- solvents for pharmaceutical production

The use of biphenyl as an intermediate in the production of other chemicals is expected to be minor in the EU, and the dominant application nowadays seems to be its use as constituent in heat transfer fluids. In Denmark and other Nordic countries the use of biphenyl in heat transfer agents is also reported, and also its use in non-agricultural pesticides and preservatives as well as in fuel additives. It has not been possible to determine in which products the non-agricultural pesticides and preservatives are used.

The historical trends worldwide indicate a shift in the use of biphenyl for PCBs and other applications, to be mainly used in heat transfer fluid applications and dyestuff carriers for textiles worldwide. This trend can also be extrapolated to the EU and the Nordic countries.

#### Waste management

Generally, industrial spills or uncontrolled releases of biphenyl during manufacturing are infrequent as biphenyl as product is generally contained. Due to the high costs of cleaning-up and the fact that the substance is toxic, it is expected that its handling at all the European production sites occurs properly.

Waste related to the use of biphenyl as intermediate is assumed to be minor, since the substance is converted to other chemical substances. Economically it is most effective to use all of the produced/purchased biphenyl, thus the amount of pure biphenyl as waste is assumed to be minor – and primarily in the form of remains in containers (in which the biphenyl was delivered). This amount of biphenyl will be handled as chemical waste (i.e. burned at companies specialised to handle chemical waste). Heat transfer fluids (of which some contain biphenyl (up to 27% is reported)) are primarily used in closed piping systems, thus the ‘waste’ generated during use is assumed to be minor. When the fluid is due to replacement, it will be handled as chemical waste, as described above. Biphenyl is used as dyestuff carrier in textile production – thus biphenyl can end up in waste water from textile production. If assumed that creosote consists of around 1% biphenyl, the amount of biphenyl in waste in the form of creosote treated wood is assumed to be approximately 18 ton/year in Denmark. Waste treatment of creosote treated wood happens in Denmark at special waste treatment plants that are authorised to burn the creosote treated waste. The use of creosotes for wood preservation is now restricted in Denmark.

Generally articles (creosote treated wood, acrylic nails) will be incinerated in Denmark whereas waste in the form of chemical mixtures will be treated as hazardous waste (at special sites authorized to handle hazardous waste).



Biphenyl is expected to be released mainly in the solid fraction from wastewater treatment, particularly in sewage sludge. It is not expected to be found in the treated liquid effluent from wastewater treatment, as it will probably be degraded into other substances or adsorbed into the solid fraction. When disposed as hazardous waste from industrial processes, incineration or further processing for energy recovery in cement kilns are the most likely disposal routes. In both of them it is important to mix biphenyl with alcohol-based solvents or other highly combustible materials to enhance the combustion process. Otherwise, biphenyl will be released as a fugitive emission.

#### Environmental effects and fate

The toxicological data for biphenyl suggests that biphenyl has a high acute and chronic toxicity to aquatic organisms. However, as biphenyl presents a low solubility in water and a high volatility, the nominal concentrations often used in toxicity tests may not correspond to the effective concentrations. Biphenyl does have a harmonised classification with respect to environmental effects as acute and chronic toxic to the aquatic environment ('*Aquatic Acute 1, H400 (very toxic to aquatic life)*'), and as '*Aquatic Chronic 1, H410 (very toxic to aquatic life with long lasting effects)*').

Biphenyl is considered to stay in the medium where it is released, particularly in the air and soil compartments due to its physicochemical properties. When released to water and moist sediments, it tends to volatilise until it gets in contact with solids where it will get adsorbed. Once biphenyl is retained in the released compartment, it biodegrades rather quickly in a matter of a few days to a few weeks. Overall, biphenyl can probably not be considered to be a PBT substance. The EU persistence criterion and toxic criterion could be met (because of ambiguous results on the genotoxicity potential of biphenyl), but biphenyl is probably not bioaccumulative by use of the data presented in this report. Portugal evaluates biphenyl (CoRAP, 2012) for its suspected PBT properties at the moment, but this evaluation is not finalised, so the conclusions from Portugal cannot be included in this report.

The main sources of release for biphenyl are from industrial processing emissions (mainly to air and to the wastewater effluent), from waste disposal (mainly to sediment and soil, in the case the sewage sludge is applied to land) and from combustion processes where biphenyl is formed (mainly to air and to the wastewater effluent).

In Canada, it has been possible to calculate Predicted Environmental Concentrations (PEC) to fill in data gaps and establish risk quotients for different organisms in air, water, sediment and soil. All reported risk quotients (RQ) were below 1, indicating no negative effects on the environment. The Danish monitoring data primarily in water and sludge is of the same order of magnitude as the Canadian data used for calculation of risk quotients. Thus, results from monitoring data and the subsequent calculated environmental impact of biphenyl show that biphenyl does not present a risk to the environment. In spite of its high usage and its observed toxicity for aquatic life, biphenyl does not enter the environment in quantities or concentrations which poses an immediate or long-term harmful effect.

#### Human health effects

Biphenyl is rapidly and readily absorbed following oral exposure. Biphenyl can also be absorbed through dermal exposure. No data on absorption through inhalation was available. Absorbed biphenyl is generally not stored in tissues and is rapidly excreted – primarily through the urine (USEPA, 2013; Danish EPA, 2013a). Biphenyl does not cause acute toxicity at low levels of exposure. The critical effect in humans following exposure to biphenyl by inhalation is considered to be effects observed in the respiratory tract and the lungs. An acceptable daily intake is 0.05 mg/kg bw/day for oral exposure.

Biphenyl can cause skin irritation as well as eye irritation. The US EPA has classified biphenyl as a Group D, not classifiable as causing human carcinogenicity. The investigations of the genotoxicity

potential of biphenyl have provided mixed results, thus it cannot be ruled out that biphenyl has genotoxic effects.

The three major uses of biphenyl is 1) as a constituent in heat transfer fluids, 2) as a constituent in coal tar 3) as intermediate in the production of other chemicals. In terms of exposure to biphenyl contained in heat transfer fluids, the exposure to consumers is minimal, due to the fact that heat transfer fluids primarily are used in closed piping systems – though some exposure to workers may happen in the case of fumes being released from the system. Biphenyl as a constituent in coal tar is not likely to cause concern. According to Environmental Health Canada (2013) the use of coal-tar in pavements (by consumers) is not likely to pose a risk due to the low content of biphenyl in coal-tar and the physical and chemical properties of biphenyl. The use of biphenyl as intermediate is neither likely to cause concern, since the substance in these cases is converted to another substance. An area, however, which may cause concern is the use of biphenyl as dye stuff carrier in the textile industry. Here it may end up in the waste water, which – if not treated properly – may cause problems for organisms in the environment.

All in all, Environmental Health Canada (2013) concludes or proposes that biphenyl does not enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

#### Alternatives

Information on the use of biphenyl in general is very limited, for which reason alternative substitutions for biphenyl are even more difficult to find. This may be because biphenyl is not represented in common consumer products and therefore has not been subject to public concerns about the related health risks. However, biphenyl has appeared in products with a direct risk of contact to the consumer, such as in preservatives for citrus fruits, where it has recently been restricted in both the EU and the US. A desktop survey also noticed the use of biphenyl in dyes is subject of increasing awareness.

In terms of alternatives for use of biphenyl as heat transfer agents, the identified alternatives are found to be less toxic to the environment and others more toxic to humans. It is important to notice that according to EU legislation alternatives should be less hazardous than the substance being substituted. It has not been possible to find information about actual alternatives to the use of biphenyl in dyestuff, neither has it been possible to identify alternatives to substitute the use of biphenyl in pharmaceutical products.

It may be presumed that the global production of biphenyl in the nearest future will continue in present rate which has been more or less constant the previous 25 years. The production in the EU has, however, declined during the last decades.

#### Data gaps

The following data gaps have been identified:

- Information about the emission factors/emission values of biphenyl at combustion processes is limited. It is well-known that biphenyl will be emitted from different combustion processes, but the knowledge about the exact emission factors is limited.
- Monitoring data concerning biphenyl is limited. Biphenyl is part of the NOVANA programme in Denmark, but this programme only covers monitoring data concerning water and sludge. No monitoring data with respect to emissions of biphenyl to air has been identified in Denmark.
- The issue of possible environmental concern for organisms in the aquatic environment if biphenyl is released to waste water in the textile industry (used as dye stuff carrier) could be relevant to investigate further.

# Sammenfatning og konklusion

Hovedformålet med denne rapport er at tilvejebringe baggrundsinformationer til Miljøstyrelsens arbejde vedrørende behovet for eventuelle yderligere forholdsregler for risikostyring af biphenyl. Biphenyl er på Miljøstyrelsens Liste over Uønskede Stoffer (LOUS) pga. biphenyls miljøklassificering samt forbrug i Danmark på over 100 ton årligt.

Biphenyl har en harmoniseret klassifikation som:

- H315: Forårsager hudirritation
- H319: Forårsager alvorlig øjenirritation
- H335: Kan forårsage irritation af luftvejene
- H400: Meget giftig for vandlevende organismer
- H410: Meget giftig med langvarige virkninger for vandlevende organismer

Nedenfor opsummeres kort resultaterne fra de forskellige afsnit i denne rapport. Biphenyl anvendes stadig i Danmark med over 100 ton om året, og pga. miljøklassificeringen med H400 og H410 opfylder biphenyl LOUS-kriterierne.

## Lovgivningsmæssige rammer

Biphenyl er begrænset i fødevarer og må ikke længere anvendes som et tilsætningsstof til foder. Desuden er biphenyl ikke længere tilladt som tilsætningsstof til fødevarer (tidligere blev biphenyl brugt som anti-svampemiddel primært på citrusfrugter). En grænseværdi på 1 mg/m<sup>3</sup> er fastsat for biphenyl i arbejdsmiljøet i EU<sup>4</sup>. En grænseværdi på 0,005 mg/m<sup>3</sup> for koncentrationer af biphenyl i luften, målt ved firmaernes skel, er blevet fastsat for firmaer i Danmark. Det europæiske vandkvalitetskrav for biphenyl er 1 µg/l. Som farligt stof er biphenyl desuden underlagt særlige bestemmelser med hensyn til transport af farligt gods<sup>5</sup>.

Biphenyl er registreret under REACH i et tonnagebånd på 1.000 – 10.000 ton pr. år, men det er hverken på Kandidatlisten over særligt problematiske stoffer (Substances of Very High Concern, SVHC) eller på nogen af ECHA's Register over hensigter (Registry of intentions). Biphenyl er på CoRAP (Community Rolling Action Plan) listen over stoffer<sup>6</sup> og kom på listen i 2012 til vurdering af Portugal i 2013 (CoRAP, 2012), men vurderingen er ikke afsluttet endnu. De oprindelige grunde til bekymring over biphenyl er opført som 1) Miljøet – mistænkt PBT og 2) Eksponering – høj tonnage. Kemikalieinspektionen i Sverige har inkluderet biphenyl i deres PRIO-database som et "priority risk reduction substance", hvilket betyder, at brugeren af stoffet anbefales at undersøge risikoen ved brugen af stoffet.

Biphenyl er ikke direkte nævnt i kriterier for miljømærkning, men vil blive begrænset i ethvert miljømærket produkt, da ingen eller kun en meget lille mængde kemikalier, som er klassificeret som farligt for miljøet, er tilladt i miljømærkede produkter.

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<sup>4</sup> Directive 91/322/EEC

<sup>5</sup> Directive 2008/68/EC

<sup>6</sup> <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

### Fremstilling og anvendelser

Produktion af biphenyl finder ikke sted i Danmark, og produktionen i EU er faldet gennem de sidste årtier. Hovedproduktionen af biphenyl finder derfor sted udenfor EU. Der blev kun identificeret en producent i EU (UK).

Den sidste registrering af den årlige produktion af biphenyl i hele verden er fra 1998, hvor der blev estimeret en årlig kapacitet på 80.000 ton/år (WHO, 1999). Det har ikke været muligt at finde nogle nyere tal. Det har heller ikke været muligt at finde offentlig tilgængelige import/eksportdata vedrørende EU, hverken fra fortrolige kilder eller gennem interviews med nogle af de registrerede firmaer i ECHA (ECHA RSD, 2014). I Danmark var importen af biphenyl 3.362,4 ton (2011).

Biphenyl findes i naturen og fra menneskeskabte kilder. Når biphenyl er produceret, bruges det som mellemstof til fremstilling af andre kemikalier eller indarbejdes i slutprodukter og tekniske anvendelser. Ifølge litteraturkilder og interviews med registrerede firmaer i ECHA er de mest almindelige anvendelser af biphenyl siden 2009 og op til nu i slutprodukter, som er

- varmeoverførende midler
- farvestofbærere til tekstiler
- konserveringsmidler til citrusfrugter
- farvestofbærere til kopipapir
- opløsningsmidler til farmaceutisk produktion

Brugen af biphenyl som mellemstof i produktionen af andre kemikalier forventes at blive mindre i EU, og den dominerende anvendelse nu til dags ser ud til at være som indholdsstof i varmeoverførende midler. I Danmark og andre nordiske lande rapporteres der også om brug af biphenyl i varmeoverførende midler samt i pesticider (der ikke er beregnet til landbruget), konserveringsmidler og tilsætningsstoffer til brændsel. Det har ikke været muligt at finde frem til i hvilke produkter disse pesticider og konserveringsmidler bliver brugt.

De historiske tendenser verden over indikerer et skifte i brugen af biphenyl til PCB'er og andre anvendelser, men hovedsageligt til anvendelser i varmeoverførende midler og farvestofbærere i tekstiler verden over. Denne tendens kan også blive ekstrapoleret til EU og de nordiske lande.

### Affaldsbehandling

Generelt er industrielt affald eller ukontrollerede frigivelser af biphenyl under fremstilling sjælden, da biphenyl som produkt generelt er begrænset. På grund af de høje omkostninger til rengøring og det faktum, at stoffet er giftigt, forventes det, at håndteringen af stoffet på alle europæiske produktionssteder sker på en forsvarlig måde.

Mængden af affald, der er relateret til brugen af biphenyl som mellemstof, antages at være lille, da stoffet er omdannes til andre kemiske stoffer. Økonomisk set er det mest effektivt at anvende alt det producerede/købte biphenyl, og derfor formodes det, at mængden af rent biphenyl som affald vil være lille – og primært i form af rester i beholdere (som biphenylen leveres i). Denne mængde biphenyl vil blive håndteret som kemisk affald (dvs. afbrændt hos firmaer der specialiserede i at håndtere kemisk affald). Varmeoverførende midler (hvor nogle af dem indeholder biphenyl (op til 27% er blevet indberettet)) anvendes primært i lukkede rørsystemer, således at det "affald", der genereres under brug, formodes at være lille. Når midlet udskiftes, bliver det behandlet som kemisk affald, som beskrevet ovenfor. Biphenyl anvendes som farvestofbærere i tekstilproduktioner – således kan biphenyl ende i spildevandet fra tekstilproduktion. Hvis det formodes, at kreosot består af ca. 1% biphenyl, formodes mængden af biphenyl i affaldet i form af kreosot-behandlet træ at være ca. 18 ton/år i Danmark. Affaldsbehandling af kreosot-behandlet træ sker i Danmark på specielle affaldsbehandlingsanlæg, som er autoriserede til at brænde det kreosot-behandlede affald. Brugen af kreosot til trækonservering er i dag begrænset i Danmark.

Generelt vil artikler (kresot-behandlet træ/akrylnegle) blive brændt i Danmark, hvorimod affald i form af kemiske blandinger vil blive behandlet som farligt affald (på særlige steder, som er autoriserede til at håndtere farligt affald).

Biphenyl forventes primært at blive frigjort i den faste fraktion fra spildevandsbehandlingen, især i kloakslammet. Det forventes ikke at blive fundet i det udledte flydende spildevand fra spildevandsbehandlingen, da det sandsynligvis vil blive nedbrudt til andre stoffer eller adsorberet ind i den faste fraktion. Når det bortskaffes som sundhedsfarligt affald fra industrielle processer, er forbrænding eller yderligere bearbejdning til energiudvinding i cementovne de mest sandsynlige bortskaffelsesveje. I begge tilfælde er det vigtigt at blande biphenyl med alkohol-baserede opløsningsmidler eller andre stærkt brændbare materialer for at forstærke forbrændningsprocessen. Ellers bliver biphenyl frigivet som en flygtig emission.

#### Miljømæssige effekter og skæbne

De toksikologiske data for biphenyl tyder på, at biphenyl har en høj akut og kronisk toksicitet over for vandlevende organismer, men da biphenyl har en lav opløselighed i vand og en høj flygtighed, svarer de nominelle koncentrationer, som ofte bruges i toksicitetstests, måske ikke til de effektive koncentrationer. Biphenyl har en harmoniseret klassificering med hensyn til miljømæssige effekter som akut og kronisk giftig på vandmiljøet ("*H400 Meget giftig for vandlevende organismer*" og som "*H410 Meget giftig med langvarige virkninger for vandlevende organismer*").

Biphenyl forventes at blive i det miljø, hvor det frigøres – især i luft og jord på grund af dets fysisk-kemiske egenskaber. Når det frigøres til vand og fugtigt bundfald, har det en tendens til at fordampe, indtil det kommer i kontakt med faste stoffer, hvor det vil blive adsorberet. Når biphenyl engang er udledt til miljøet bionedbrydes det ret hurtigt i løbet af nogle få dage til nogle få uger. Alt i alt kan biphenyl sandsynligvis ikke betragtes at være et PBT-stof. EU's persistenskriterium og toksicitetskriterium (på grund af uklare resultater vedrørende biphenyls genotoksiske potentiale) kan være opfyldt, men biphenyl kan sandsynligvis ikke betragtes som værende bioakkumulerende, når de fremlagte data i denne rapport bruges. Portugal evaluerer i øjeblikket biphenyl (CoRAP, 2012) for dets mistænkte PBT-egenskaber, men denne evaluering er ikke afsluttet, så konklusionerne fra Portugal kan ikke inkluderes i denne rapport.

Hovedkilderne for frigørelse af biphenyl er fra emissioner fra industriel bearbejdning (primært til luft og spildevandsudledning, fra affaldsbortskaffelse (primært til bundfald og jord, i tilfældet af, at spildvandslammet anbringes på land) og fra forbrændingsprocesser, hvor biphenyl dannes (primært til luft og til spildevandsudledning).

I Canada har det været muligt at udregne de forventede miljømæssige koncentrationer (Predicted Environmental Concentrations - PEC) og opstille risiko kvotienter for forskellige organismer i luft, vand, bundfald og jord. Alle de rapporterede risikokvotienter (risk quotients - RQ) var under 1, som indikerer, at der ikke er nogen negative effekter på miljøet. De danske kontroldata, primært for vand og slam, er af samme størrelsesorden som de canadiske data, som blev brugt til udregning af risikokvotienter. Således viser resultaterne af kontroldata og den efterfølgende udregnede miljømæssige indvirkning fra biphenyl, at biphenyl ikke udgør en risiko for miljøet. Til trods for dets anvendelse og den observerede toksicitet over for vandlevende organismer, kommer biphenyl ikke ud i miljøet i mængder eller koncentrationer, som udgør en øjeblikkelig eller langsigtet skadelig effekt på miljøet.

#### Effekter på menneskers sundhed

Biphenyl absorberes hurtigt og let efter oral eksponering. Biphenyl kan også blive absorberet gennem dermal eksponering. Data om absorbering gennem inhalation var ikke tilgængelig. Den absorberede biphenyl lagres generelt ikke i væv og udskilles hurtigt – primært gennem urinen (USEPA, 2013; Danish EPA, 2013a). Biphenyl forårsager ikke akut toksicitet ved lave niveauer af

eksponering. Den kritiske effekt i mennesker efterfulgt af eksponering til biphenyl ved inhalation betragtes at være effekter, som observeres i luftvejene og lungerne. Et acceptabelt dagligt indtag er 0,05 mg/kg lgv/dag for oral eksponering.

Biphenyl kan forårsage hudirritation såvel som øjenirritation. Den amerikanske miljøstyrelse har klassificeret biphenyl som en Gruppe D, dvs. ikke klassificerbar som værende kræftfremkaldende for mennesker. Undersøgelserne af genotoksicitetspotentialet for biphenyl har vist uklare resultater. Det kan således ikke udelukkes at biphenyl har genotoksiske effekter.

De tre største anvendelser af biphenyl er 1) som indholdsstof i varmeoverførende midler, 2) som indholdsstof i kultjære, 3) som mellemstof i produktionen af andre kemikalier. Med hensyn til eksponering til biphenyl indeholdt i varmeoverførende midler er eksponeringen til forbrugere minimal på grund af, at varmeoverførende midler primært bruges i lukkede rørsystemer – selvom nogen eksponering af arbejdere kan ske i tilfælde af, at dampe bliver frigjort fra systemet. Biphenyl som indholdsstof i kultjære bør ikke vække bekymring. Ifølge Environmental Health Canada (2013) udgør brugen af kultjære i fortove sandsynligvis ikke nogen risiko (for forbrugere) på grund af det lave indhold af biphenyl i kultjære og de fysiske og kemiske egenskaber for biphenyl. Brugen af biphenyl som mellemstof bør heller ikke vække bekymring, da stoffet i disse tilfælde er omdannet til et andet stof. Et område, som dog kan vække bekymring, er brugen af biphenyl som farvestofbærer i tekstilindustrien. Her kan det ende i spildevandet, som – hvis det ikke bliver behandlet ordentligt – kan forårsage problemer for organismer i miljøet.

Alt i alt konkluderer eller foreslår Environmental Health Canada (2013), at biphenyl ikke kommer ud i miljøet i en kvantitet eller koncentration eller under forhold, der udgør eller kan udgøre en fare i Canada for menneskeliv eller sundhed.

#### Alternativer

Information om brugen af biphenyl generelt er meget begrænset, hvorfor alternativer til biphenyl er endnu sværere at finde. Dette kan være, fordi biphenyl ikke er til stede i almindelige forbrugerprodukter og derfor ikke har været genstand for offentlige bekymringer om de relaterede sundhedsrisici. Biphenyl har dog været til stede i produkter med en direkte risiko for kontakt med forbrugeren, som fx i konserveringsmidler til citrusfrugter, hvor det for nyligt er blevet begrænset både i EU og i USA. I litteraturen beskrives også, at brugen af biphenyl i farvestoffer er årsag til stigende opmærksomhed.

Med hensyn til alternativer til brugen af biphenyl som varmeoverførende midler er de identificerede alternativer fundet til at være mindre toksiske for miljøet og andre til at være mere toksiske for mennesker. Det er vigtigt at bemærke, at EU's regulering på området kræver, at alternative stoffer skal være mindre farlige end dem, der substitueres. Det har ikke været muligt at finde information om aktuelle alternativer til brugen af biphenyl i farvestoffer. Det har heller ikke været muligt at identificere alternativer til at erstatte brugen af biphenyl i farmaceutiske produkter.

Det må antages, at den globale produktion af biphenyl i den nærmeste fremtid vil fortsætte med den nuværende mængde, som har været mere eller mindre konstant de sidste 25 år. Produktionen i EU er dog faldet gennem de sidste årtier.

### ***Datahuller***

Følgende datahuller blev identificeret:

- Information om emissionsfaktorer/emissionsværdier på biphenyl ved forbrændingsprocesser er begrænset. Det er velkendt, at biphenyl bliver udsendt fra forskellige forbrændingsprocesser, men viden om de nøjagtige faktorer er begrænset.
- Kontrolldata vedrørende biphenyl er begrænset. Biphenyl er en del af NOVANA-programmet i Danmark, men dette program dækker kun kontrolldata vedrørende vand og slam. Ingen kontrolldata med hensyn til emissioner af biphenyl til luft er blevet identificeret i Danmark.
- Spørgsmålet om mulig miljømæssig bekymring for organismer i vandmiljøet, hvis biphenyl frigøres til spildevand i tekstilindustrien (brugt som farvestofbærer) kunne være relevant at undersøge nærmere.

# 1. Introduction to biphenyl

Biphenyl, also named 1,1'-biphenyl, diphenyl, phenylbenzene or dibenzene, is an aromatic hydrocarbon with the molecular formula  $C_{12}H_{10}$ . Biphenyl is found as a colourless to light yellow solid at room temperature and is commonly occurring as flakes. It has a strong odour similar to that of geraniums (ECHA, 2014; Danish EPA, 2013a; WHO, 1999).

Biphenyl is found both in nature and from anthropogenic sources; it occurs naturally in coal tar and natural gas (Environment Health Canada, 2013). It was used in large volumes as an intermediate in the production of polychlorinated biphenyls (PCBs), but as the use of this substance has become highly restricted or prohibited in many countries, the demand and subsequent production of biphenyls presented a large decrease during the 80's and 90's (WHO, 1999). However, other uses have emerged along the last two decades, although not in the same volume scale (Danish EPA, 2013a; Environment Health Canada, 2013; WHO, 1999; USEPA, 1995). These are:

- As final product: Dyestuff carrier for textiles (especially polyesters), solvent in pharmaceutical production, dyestuff carrier for copying paper, fungicide for plant disease control and as preservative for citrus fruits (as fungistat).
- As an intermediate: Heat transfer medium or agent in heating fluids, emulsifiers, optical brighteners, crop protection products and precursors, in the manufacture of benzidine and auxiliaries for plastics.

When naturally present, biphenyl is found in coal tar pitch residues, coal tar-derived creosotes and as a by-product in the manufacture of high octane motor and aviation fuels (Environment Health Canada, 2013). It is also released into the atmosphere during the incomplete combustion of fossil fuels from motor vehicles, coal-burning power plants and foundries, amongst others.

Biphenyl can be produced as a by-product when producing benzene or by synthesis of benzene (Danish EPA, 2013a).

Biphenyl has a harmonised classification as amongst others of Aquatic Acute 1, H400 (very toxic to aquatic life) and Aquatic Chronic 1, H410 (very toxic to aquatic life with long lasting effects). This environmental classification is the primary reason for inclusion on the Danish EPA's list of undesirable substances. For further information regarding environmental aspects, please see chapter 5.

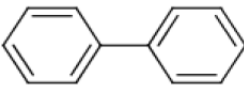
Definition and physical-chemical properties of biphenyl are given in Table 1 and Table 2.



## 1.1 Definition of the substance

TABLE 1

DEFINITION OF BIPHENYL (ECHA REGISTERED SUBSTANCES DATABASE, 2014; DANISH EPA, 2013A; ENVIRONMENT HEALTH CANADA, 2013;)

	Biphenyl
<b>EC Number</b>	202-163-5
<b>CAS Number</b>	92-52-4
<b>Synonyms</b>	1,1'-biphenyl, diphenyl, phenylbenzene, dibenzene, bibenzene, lemonene, xenene, E 230
<b>Molecular weight</b>	154.2 g/mol
<b>Molecular formula and structure</b>	C <sub>12</sub> H <sub>10</sub> <div style="text-align: center;">  </div>
<b>Degree of purity</b>	99.85% in commercial product
<b>Major impurities</b>	Terphenyl (C <sub>18</sub> H <sub>14</sub> ), sulphur (S) and benzene (C <sub>6</sub> H <sub>6</sub> )

## 1.2 Physical and chemical properties

Biphenyl has a moderate vapour pressure (7 Pa at 20 °C), which is just below the 10 Pa cut-off value often used to define volatile organic compounds (VOCs) (Jia and Batterman, 2010). Biphenyl is hence one of the least volatile VOCs – and is therefore also characterised as a semi-volatile organic compound (SVOC).

TABLE 2

PHYSICAL-CHEMICAL PROPERTIES FOR BIPHENYL (ECHA REGISTERED SUBSTANCES DATABASE, 2014; DANISH EPA, 2013A; USEPA, 1995)

Property		Reference
<b>Physical state</b>	Solid at 20°C and 1013 hPa	ECHA RSD, 2014
<b>Colour</b>	White or yellowish	ECHA RSD, 2014
<b>Odour</b>	Strong similar to that of geraniums; pleasant & peculiar	Danish EPA, 2013a; USEPA, 1995
<b>Substance type</b>	Organic	ECHA RSD, 2014
<b>Melting point</b>	68.93 °C (literature) 69.5 °C (experimental) 68 -70 °C (literature)	ECHA RSD, 2014
<b>Boiling point</b>	256.1 °C at 1000 hPa (literature) 255 °C at 1010 hPa (literature) 255.2 °C at 1013 hPa (literature)	ECHA RSD, 2014

Property		Reference
	255.25 °C at 1013 hPa (experimental)	
<b>Flash point</b>	112.85 °C at 1000 hPa (literature) 113 °C at 1000 hPa (literature) 113 to 115 °C (experimental)	ECHA RSD, 2014
<b>Autoflammability/ self-ignition temperature</b>	540 °C at 1000 hPa (literature) 570 °C at 1000 hPa (literature) 566 °C at 1013 hPa (experimental)	ECHA RSD, 2014
<b>Relative density</b>	1.18 g/cm <sup>3</sup> at 0.4 °C (literature) 1.17 g/cm <sup>3</sup> at 24.5 °C (literature) 0.97 g/cm <sup>3</sup> at 100 °C (literature)	ECHA RSD, 2014
<b>Viscosity</b>	0.95 mPa s (dynamic) at 100 °C (experimental) 0.57 mPa s (dynamic) at 150 °C (experimental) 0.38 mPa s (dynamic) at 200 °C (experimental)	ECHA RSD, 2014
<b>Vapour pressure</b>	0.007 kPa at 20 °C (literature) ≥0.008 to 0.004 kPa at 20 °C (literature) 0.00119 kPa at 25 °C (experimental) 0.1 kPa at 69 °C (literature) 1 kPa at 111.1 °C (literature) 10 kPa at 169.5 °C (literature) 100 kPa at 254.7 °C (literature)	ECHA RSD, 2014
<b>Water solubility</b>	≥7.13 to 7.35 mg/L at 24.6 °C (experimental) 7 mg/L at 25 °C (literature) 7.5 mg/L at 25 °C (literature) ≥5.95 to 8.48 mg/L at 25 °C (literature) Slightly soluble (0,1 – 100 mg/l)	ECHA RSD, 2014
<b>Log P (octanol/water)</b>	4.1 at 20 °C (experimental) 4.008 at 25 °C (experimental) 3.16 at ambient temperature (literature) 4.09 at ambient temperature (literature)	ECHA RSD, 2014

### 1.3 Definition of PAHs

The term, polycyclic aromatic hydrocarbons (PAHs), refers to a ubiquitous group of several hundred chemically-related and environmentally persistent organic compounds of various structures and varied toxicity. Many PAHs are suspected of being carcinogenic, but 15 of the PAHs were considered to have sufficient evidence for a carcinogenic effect in 2002 (European Commission, 2002).

PAH, Polycyclic Aromatic Hydrocarbons or PolyAromatic Hydrocarbons, are aromatic hydrocarbons containing only carbon and hydrogen with two or more rings (Irwin et al., 1997). In another definition PAHs consist of at least two *fused* aromatic rings that share one or more sides, with no substituent and branching on any of the ring structures. In organic chemistry, rings are *fused* if they share two or more atoms<sup>7</sup>. Though poly-, literally means "many", there is precedence in nomenclature for beginning with the two ring cases. PAH with three or more rings are considered to be true PAH.

Although biphenyl contains two linked aromatic rings and therefore is covered by the Polycyclic Aromatic Hydrocarbons (PAHs) definition (Irwin et al., 1997), there is a lack of consistency in literature on whether biphenyl is or is not a PAH. Some reports define PAHs as containing two or more fused aromatic rings whilst others do when containing three or more (Danish EPA, 2013b). In some references<sup>8</sup> biphenyl is also considered to be a PAH (but not a true one). Furthermore, the fact that biphenyl has two aromatic rings 'linked' but not 'fused' puts also its classification as PAH under scrutiny.

The US Environmental Protection Agency and the EC Joint Research Centre have, therefore, agreed that **biphenyl is not a PAH** according to its toxicity characteristics. This means it is not included in the 16 EPA PAHs neither in the 15+1 EU PAHs lists (USEPA, 2008; EC JRC, 2010).

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<sup>7</sup> [http://www.toxipedia.org/display/toxipedia/Polycyclic+Aromatic+Hydrocarbons+\(PAHs\)+--+Abridged](http://www.toxipedia.org/display/toxipedia/Polycyclic+Aromatic+Hydrocarbons+(PAHs)+--+Abridged)

<sup>8</sup> <http://www.nature.nps.gov/hazardssafety/toxic/biphenyl.pdf>

# 2. Regulatory framework

This chapter gives an overview of how biphenyl is addressed in existing and upcoming EU and Danish legislation, international agreements, eco-label criteria, information campaigns, substitution projects and voluntary agreements.

For readers not accustomed with legislative issues, Appendix 2: provides an overview of the different legislative instruments in the EU and Denmark. The appendix also gives a brief introduction to the chemicals legislation, it explains the lists referred to in this chapter, and it provides a brief introduction to international agreements and selected eco-label schemes.

## 2.1 Legislation

This section lists existing legislation addressing biphenyl, the classification of biphenyl, and finally aspects concerning REACH.

### 2.1.1 Existing legislation

Table 3 provides an overview of existing legislation and to some extent also historical legislation addressing biphenyl. For each area of legislation, the table lists the relevant legislation ('Legal instrument') – whether this is a Directive, Regulation or Danish Statutory Order. Furthermore, it is noted whether the legislation covers the EU, Denmark or both and a short description of the aspects concerning biphenyl is provided in each case. It should be noted that national rules (i.e. Statutory Orders) will only be described in case the Danish rules differ from the related EU Directive.

**TABLE 3**  
EU AND DANISH LEGISLATION ADDRESSING BIPHENYL (AS OF MAY 2014)

Legal instrument	EU/DK	Requirements which concern biphenyl
Regulation addressing chemicals		
REGULATION (EC) No 1272/2008 of 16 December 2008 on classification, labelling and packaging of substances and mixtures (CLP)	EU/DK	Biphenyl is listed in Annex VI of the Regulation with the harmonised classification. See Table 4 in this report. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1272:20110419:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2008R1272:20110419:EN:PDF</a>
REGULATION (EC) No 1907/2006 of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)	EU/DK	The provisions of REACH concerning registration, evaluation, authorisation and restriction apply for biphenyl as for most other chemical substances. <a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130421:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2006R1907:20130421:EN:PDF</a>

Legal instrument	EU/DK	Requirements which concern biphenyl
Regulation addressing foodstuffs		
DECISION of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation No 2232/96	EU/DK	<p>Biphenyl is listed in Part A “Flavouring substances” as flavour nr. 01.013 (chemical group 31). Biphenyl is listed within the section: “Substance on which additional information is to be submitted”. This means that biphenyl is allowed as a flavouring substance in foodstuffs if additional information on the substance has been submitted. However, later regulation i.e. Regulation No 524/2011 limits the use of biphenyl in foodstuffs.</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01999D0217-20090227&amp;qid=1400749377791&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01999D0217-20090227&amp;qid=1400749377791&amp;from=EN</a></p>
REGULATION (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed plant and animal origin	EU/DK	<p>The maximum residue level (MRL) for a range of pesticides has been set – including biphenyl. The MRLs have later been altered (lowered) to the limits listed in Regulation No 524/2011 listed below.</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R0396-20120101&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005R0396-20120101&amp;from=EN</a></p>
REGULATION (EU) No 524/2011 amending Annexes II and III to Regulation (EC) No 396/2005 as regards maximum residue levels for biphenyl, deltamethrin, ethofumesate, isopyrazam, propiconazole, pymetrozine, pyrimethanil and tebuconazole in or on certain products	EU/DK	<p>The maximum residue level (MRL) of biphenyl is by this regulation lowered to the lower limit of analytical determination for a long range of foodstuffs. In practise, this means that biphenyl is not allowed to be used in foodstuffs (was formerly used as anti-fungicide primarily in citrus fruits).</p> <p>Examples of MRLs for biphenyl are listed below:</p> <ul style="list-style-type: none"> <li>- Citrus fruits and a long list of berries (0.01 mg/kg)</li> <li>- Rose hips (0.02 mg/kg)</li> <li>- Miscellaneous fruits (0.01 mg/kg)</li> <li>- Root and tuber vegetables (0.01 mg/kg)</li> <li>- Fruiting vegetables such as tomatoes and cucumbers (0.01 mg/kg)</li> <li>- Leaf vegetables (0.01 mg/kg)</li> <li>- Herbs (0.1 mg/kg)</li> <li>- Beans, dry (0.01 mg/kg)</li> <li>- Tea, coffee (0.05 mg/kg)</li> <li>- Maté (0.5 mg/kg)</li> <li>- Spices (0.05 mg/kg)</li> <li>- Products of animal origin (0.01 mg/kg)</li> </ul> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0524-20110529&amp;qid=1400758584853&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02011R0524-20110529&amp;qid=1400758584853&amp;from=EN</a></p>

Legal instrument	EU/DK	Requirements which concern biphenyl
DIRECTIVE 2003/114/EC amending Directive 95/2/EC on food additives other than colours and sweeteners	EU	<p>Biphenyl (E230) is listed as a preservative in Directive 95/2/EC on food additives. However, as biphenyl falls under the definition of 'plant protection products', biphenyl should no longer be used as food additives and should go through an authorisation procedure as plant protection product. With this directive biphenyl is deleted from Annex III "Conditionally permitted preservatives and antioxidants" of Directive 95/2/EC and is no longer allowed as food additive.</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0114&amp;qid=1400832596473&amp;from=EN">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003L0114&amp;qid=1400832596473&amp;from=EN</a></p>
Regulation addressing feed/animal nutrition		
REGULATION (EC) No 230/2013 on the withdrawal from the market of certain feed additives belonging to the group of flavouring and appetising substances	EU/DK	<p>Biphenyl is listed in Part A of the Annex "Feed additives belonging to the group of flavouring and appetising substances withdrawn from the market". Part A is a list of feed additives that are withdrawn for all species and categories of animals.</p> <p>This means that biphenyl (by 10 April 2014) no longer may be used as a feed additive. Premixtures produced with additives may continue to be placed on the market and used until 10 October 2014. However, compound feed and feed materials produced with the additives and premixtures until 10 April 2015 may continue to be placed on the market and used until stocks are exhausted.</p> <p><a href="http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0230&amp;rid=17">http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013R0230&amp;rid=17</a></p>
Regulation addressing waste		
DIRECTIVE 2008/98/EC of 19 November 2008 on waste and repealing certain directives	EU	<p>General legislation on waste and description of the waste hierarchies. Biphenyl is not mentioned directly, but it is stated in annex III that waste is considered to be dangerous when it contains substances classified as dangerous (thus indirectly covers biphenyl).</p> <p><a href="http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF">http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:312:0003:0030:EN:PDF</a></p>
STATUTORY ORDER No. 1309 of 18.12.2012 on waste - and subsequent changes	DK	<p>General legislation on waste based on the EU legislation on waste. Biphenyl is not mentioned directly, but it is stated in annex 4 that waste is considered to be dangerous if it contains ecotoxic</p>

Legal instrument	EU/DK	Requirements which concern biphenyl
(e.g. 422 of 10.04.2014)		substances (a concentration limit is not specified). <a href="https://www.retsinformation.dk/Forms/RO710.aspx?id=144826#Bil4">https://www.retsinformation.dk/Forms/RO710.aspx?id=144826#Bil4</a>
Regulation addressing emissions to the environment		
GUIDANCE No. 10702 of 19.11.2008 on B values (B-værdier)	DK	Biphenyl is listed with a B value (contribution value) of 0.005 mg/m <sup>3</sup> . This is the limit value set for companies in Denmark for concentrations of biphenyl in the air, measured at the property line of the companies. Biphenyl is listed as main group 2, table 7, and class I. A special background document and datasheet have been made for the substance in 2006. <a href="https://www.retsinformation.dk/Forms/RO710.aspx?id=135894">https://www.retsinformation.dk/Forms/RO710.aspx?id=135894</a>
CONSOLIDATED ACT No. 879 of 26.6.210 on environmental protection	EU/DK	The above guidance document concerning B values is based on the Danish consolidated act concerning environmental protection, which is based on several EU directives. <a href="https://www.retsinformation.dk/Forms/RO710.aspx?id=132218">https://www.retsinformation.dk/Forms/RO710.aspx?id=132218</a>
GUIDANCE No 9810 of 31.5.2006 on connection of industrial discharge water to public sewage treatment plants	DK	Biphenyl is rated as a C/B substance, i.e. a category C substance, however, as the substances is suspected of not being anaerobic biodegradable, accumulation in sludge or aquatic sediments could occur. The water quality requirement for biphenyl is 1 µg/l according to Table 1.1 of Annex 1. <a href="https://www.retsinformation.dk/forms/RO710.aspx?id=12944">https://www.retsinformation.dk/forms/RO710.aspx?id=12944</a>
CONSOLIDATED ACT No. 879 of 26.6.210 on environmental protection	EU/DK	The above guidance document concerning industrial discharge water is based on the Danish consolidated act concerning environmental protection, which is based on several EU directives. <a href="https://www.retsinformation.dk/Forms/RO710.aspx?id=132218">https://www.retsinformation.dk/Forms/RO710.aspx?id=132218</a>
DIRECTIVE 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)	EU	The industrial emissions directive (IED) has repealed seven existing directives on the area of environmental pollution. Companies that are manufacturing or emitting a range of specific hazardous substances have to apply for an environmental permit and have to report on their emissions to air, water and soil.
LAW No. 446 of 23.5.2012 on changes of law on environmental protection	DK	No companies in Denmark are manufacturing biphenyl. However, the directive may be relevant for





Legal instrument	EU/DK	Requirements which concern biphenyl
788 of 27.6.2013 on road transport of dangerous goods		UN no. should be used during transportation. <a href="https://www.retsinformation.dk/Forms/RO710.aspx?id=152738">https://www.retsinformation.dk/Forms/RO710.aspx?id=152738</a>

### 2.1.2 Upcoming legislation

A search has been performed in the EUR-Lex database concerning legislative proposals regarding biphenyl. No upcoming legislation regarding biphenyl was identified.

### 2.1.3 Classification and labelling

The harmonised classification as well as notified self-classifications of biphenyl are listed in the sections below.

#### 2.1.3.1 Harmonised classification in the EU

The EU harmonised classification of biphenyl is presented in Table 4 below. It shows that biphenyl is among other things classified as very toxic to aquatic life and very toxic to aquatic life with long lasting effects and with a specific target organ toxicity for single exposure (STOT SE 2, H335 “May cause respiratory irritation”).

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

Index No	International chemical identification	CAS No	Classification	
			Hazard Class and Category Codes	Hazard Statement Codes
601-042-00-8	biphenyl diphenyl	92-52-4	Skin Irrit. 2	H315
			Eye Irrit. 2	H319
			STOT SE 3	H335
			Aquatic Acute 1	H400
			Aquatic Chronic 1	H410

H315: Causes skin irritation, H319: Causes serious eye irritation, H335: May cause respiratory irritation, H400: Very toxic to aquatic life, H410: Very toxic to aquatic life with long lasting effects

#### 2.1.3.2 Self-classification in the EU

According to the current CLP regulation companies placing chemical substances or chemical mixtures on the market in the EU are obliged to notify their self-classifications to the European Chemicals Agency, ECHA. The classifications used (and notified) by the companies can be seen at the ECHA website in the Classification & Labelling (C&L) Inventory database. ECHA maintains the Inventory, but does not verify the accuracy of the information. The notified classifications for biphenyl can be found in Table 10 in Appendix 3.

The most important information derived from the notifications is the fact that about half of the companies (393 out of 798) used the harmonised classification, while the majority of the remaining companies used notifications very similar to the harmonised classification, but with additional classification as Acute Tox. 2 (H330: Fatal if inhaled). Only a single company has notified other/additional effects, such as Acute Tox. 4 (H302: Harmful if swallowed).

#### **2.1.4 REACH**

This section contains details about biphenyl in the REACH system. The most important information is that biphenyl has been registered under REACH and has been chosen for an in depth evaluation concerning environmental and health properties.

##### **2.1.4.1 Registration**

Biphenyl has been registered under REACH in a tonnage band of 1,000 – 10,000 tonnes per annum (as of May 2014) by five registrants.

##### **2.1.4.2 Candidate list**

Biphenyl is not listed on the ECHA Candidate list of substances of very high concern for authorisation (as of May 2014). However, biphenyl is currently being evaluated for its PBT properties (see section 2.1.4.5 “Community rolling action plan”).

##### **2.1.4.3 Authorisation list/REACH Annex XIV**

Biphenyl is not listed on the ECHA Authorisation list (as of May 2014). However, biphenyl is currently being evaluated for its PBT properties (see section 2.1.4.5 “Community rolling action plan”).

##### **2.1.4.4 Restrictions concerning certain dangerous substances – Annex XVII**

Biphenyl is not restricted in Annex XVII of REACH, which contains restrictions regarding the manufacture, placing on the market, and use of certain dangerous substances, mixtures, and articles.

##### **2.1.4.5 Community rolling action plan**

The Community Rolling Action Plan is a list of substances to be evaluated by the Member States during the next three years. Biphenyl is on the CoRAP list of substances<sup>9</sup> and was entered on the list in 2012 for evaluation by Portugal in 2013 (CoRAP, 2012). The initial grounds for concern related to biphenyl are listed as:

- Environment – suspected PBT
- Exposure – high aggregate tonnage

The Portuguese Environment Agency has been contacted in order to achieve information regarding the evaluation of biphenyl. The Portuguese Environment Agency responded that the evaluation of biphenyl will not be finished before the publication of this LOUS review on biphenyl. However, they informed that the evaluation of biphenyl has focused on the PBT properties of biphenyl<sup>10</sup>. If biphenyl is considered to be a PBT, identification as a substance of very high concern and subsequent authorisation may be relevant.

##### **2.1.4.6 Registry of intentions**

Biphenyl is not on any of ECHA’s Registry of intentions (i.e. SVHC intentions, Harmonised Classification and Labelling intentions or Restriction proposal intentions) as of May 2014.

#### **2.1.5 Other legislation/initiatives**

No other legislation/initiative has been identified for biphenyl.

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<sup>9</sup> <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

<sup>10</sup> Personal communication with Lilia Martins, Portuguese Environment Agency, May 2014.

## 2.2 International agreements

A search for international agreements concerning biphenyl was performed. Biphenyl is *not* covered by the following conventions:

- Ospar Convnetion
- HELCOM – Helsinki Convention
- Stockholm Convention on Persistent Organic Pollutants (POPs)
- Rotterdam Convention

Details on the conventions can be found in Appendix 2: “Background information on regulation” to this report.

The following international agreements concerning biphenyl (directly or indirectly) were found.

### 2.2.1 Basel Convention

Protection of human health and the environment against the adverse effects of hazardous waste is covered by the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal. Details on the Basel Convention can be found in Appendix 2: “Background information on regulation” to this report. Biphenyl is not directly mentioned in the Basel Convention, but is covered by Annex III of the Convention text: “Annex III – List of hazardous characteristics”. In Annex III waste which is classified as hazardous(as biphenyl) is according to the convention text regarded as being hazardous waste if the waste is generated from special production (listed in Annex I) or if the waste is considered to be hazardous waste by national legislation. Waste containing biphenyl is thereby covered by the Basel Convention.

## 2.3 Eco-labels

Biphenyl is not mentioned directly in any eco-labelling criteria (the Nordic Swan, the European Flower or the Blue Angel). However, as biphenyl is classified as being very toxic to aquatic life, biphenyl will in many cases be restricted in eco-labelling criteria as no chemicals classified as dangerous for the environment in general are allowed in eco-labelled products. Below examples of requirements in eco-labelling criteria which restrict the use of biphenyl are presented (Table 5). All examples represent products in which the use of biphenyl could be relevant. (See chapter 3).

Criteria document	Nordic Swan	EU Flower
<b>Newspapers (printed matter)</b>	Restricted substances are classified as <sup>11</sup> : H400 and H410	Restricted substances are classified as <sup>12</sup> : H400 and H410
<b>Copying and graphic paper</b>	Restricted substances are classified as <sup>13</sup> : H400 and H410	Restricted substances are classified as <sup>14</sup> : H400 and H410
<b>Shoes and other footwear</b>	<i>No criteria</i>	Restricted dyes are classified as <sup>15</sup> : H400 and H410
<b>Textiles (and</b>	Restricted substances in dyes,	Restricted substances in dyeing,

<sup>11</sup> [http://www.ecolabel.dk/kriteriedokumenter/041e\\_5\\_5.pdf](http://www.ecolabel.dk/kriteriedokumenter/041e_5_5.pdf)

<sup>12</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:202:0026:0037:EN:PDF>

<sup>13</sup> [http://www.ecolabel.dk/kriteriedokumenter/Chemical\\_module\\_2\\_3.pdf](http://www.ecolabel.dk/kriteriedokumenter/Chemical_module_2_3.pdf)

<sup>14</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:149:0012:0024:EN:PDF>

<sup>15</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:196:0027:0035:EN:PDF>

Criteria document	Nordic Swan	EU Flower
leather)	colorants, pigments, finishing, softening agents and coatings <sup>16</sup> : H400 and H410	printing and finishing <sup>17</sup> : H400 and H410
Durable wood	A maximum treatment of 14 g/m <sup>2</sup> of substances classified with H400 and/or H410 is allowed	No criteria
Printed matter	Restricted substances are classified as <sup>18</sup> : H400 and H410	Restricted substances are classified as <sup>19</sup> : H400 and H410

H400: VERY TOXIC TO AQUATIC LIFE

H410: VERY TOXIC TO AQUATIC LIFE WITH LONG LASTING EFFECTS

**TABLE 5**

EXAMPLES OF REQUIREMENTS IN ECO-LABELLING CRITERIA WHICH RESTRICT THE USE OF BIPHENYL – ONLY THE CLASSIFICATIONS RELEVANT FOR BIPHENYL ARE LISTED IN THE TABLE

## 2.4 Other lists

Biphenyl is included in the *PRIO database*<sup>20</sup> developed by KEMI (the Swedish Chemical Agency). The PRIO database is a web-based tool which contains 4,658 substances (May 2014) with properties hazardous to health and the environment that should be prioritised in risk reduction work. Biphenyl is included in the PRIO database due to being environmentally hazardous with long term effects and is listed as a “priority risk reduction substance”, which means that the user of the substance is recommended to review the risk of the envisaged use. “I.e. manufacturers, importers, suppliers and users of chemical products and other articles should conduct a risk assessment to aid identification of necessary risk reduction measures and to ensure that the substance does not pose unacceptable risks at any stage of handling”.

Biphenyl is *not* listed in the *SIN List Database developed by the International Chemicals Secretariat (ChemSec)*<sup>21</sup> in Sweden (data search May, 2014). The SIN List includes substances which are identified by ChemSec and which fulfil the criteria for Substances of Very High Concern as defined by the REACH Regulation.

Biphenyl is *not* included in the EU list of 194 potential endocrine disruptors (Danish EPA, 2014a).

## 2.5 Other relevant information

A search has been made concerning information campaigns, substitution projects, and voluntary agreements for biphenyl. No information was identified for biphenyl.

<sup>16</sup> [http://www.ecolabel.dk/kriteriedokumenter/039e\\_4\\_0\\_1.pdf](http://www.ecolabel.dk/kriteriedokumenter/039e_4_0_1.pdf)

<sup>17</sup> [http://www.ecolabel.dk/kriteriedokumenter/16\\_e.pdf](http://www.ecolabel.dk/kriteriedokumenter/16_e.pdf)

<sup>18</sup> [http://www.ecolabel.dk/kriteriedokumenter/041e\\_5\\_4.pdf](http://www.ecolabel.dk/kriteriedokumenter/041e_5_4.pdf)

<sup>19</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:223:0055:0065:EN:PDF>

<sup>20</sup> [http://www2.kemi.se/templates/PRIOEngframes\\_4144.aspx](http://www2.kemi.se/templates/PRIOEngframes_4144.aspx)

<sup>21</sup> <http://www.chemsec.org/what-we-do/sin-list>

## 2.6 Summary and conclusions

Biphenyl has a harmonised classification of

- Skin. Irrit. 2, H315 (Causes skin irritation)
- Eye Irrit. 2, H319 (Causes serious eye irritation)
- STOT SE 3, H335 (May cause respiratory irritation)
- Aquatic Acute 1, H400 (Very toxic to aquatic life)
- Aquatic Chronic 1, H410 (Very toxic to aquatic life with long lasting effects)

However, 352 out of 798 notifiers have also notified a self-classification of Acute Tox. 2, H330 “Fatal if inhaled”.

Biphenyl is by Regulation No. 524/2011 limited in foodstuffs and may no longer be used as a feed additive according to Regulation No 230/2013. Furthermore, biphenyl is no longer allowed as food additive (formerly biphenyl was used as anti-fungicide primarily in citrus fruits) according to Directive 2003/114.

A threshold limit value of 0.2 ppm or 1 mg/m<sup>3</sup> is set for the working environment regarding biphenyl in the EU<sup>22</sup>. A limit value of 0.005 mg/m<sup>3</sup> for concentrations of biphenyl in the air, measured at the property line of the companies, has been set for companies in Denmark. The water quality requirement for biphenyl is 1 µg/l.

As a hazardous substance, biphenyl is subject to specific regulation regarding transportation of dangerous goods<sup>23</sup>.

Biphenyl has been registered under REACH in a tonnage band of 1,000 – 10,000 tonnes per annum, but it is neither on the Candidate list of substances of very high concern nor on any of ECHA’s Registry of intentions. Biphenyl is on the CoRAP list of substances<sup>24</sup> and was entered on the list in 2012 for evaluation by Portugal in 2013 (CoRAP, 2012), but the evaluation has not been finalised yet. The initial grounds for concern for biphenyl are listed as:

- Environment – suspected PBT
- Exposure – high aggregate tonnage

The Swedish Chemicals Agency has included biphenyl in their PRIO database as a “priority risk reduction substance”, which means that the user of the substance is recommended to review the risk of the envisaged use.

Biphenyl is not mentioned directly in any eco-labelling criteria, but will be restricted in any eco-labelling scheme as no chemicals classified as dangerous for the environment in general are allowed in eco-labelled products.

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<sup>22</sup> Directive 91/322/EEC

<sup>23</sup> Directive 2008/68/EC

<sup>24</sup> <http://echa.europa.eu/information-on-chemicals/evaluation/community-rolling-action-plan/corap-table>

# 3. Manufacture and uses

Information on the manufacturing and use of biphenyl have been collected from different literature sources and from information available from the producers and/or importers registered in the ECHA database (ECHA RSD, 2014). Due to confidentiality, the information from the producers was limited to uses and applications of biphenyl on a high level, and no information on annual volumes neither on concentrations could be retrieved. However, information from literature sources was enough to provide an overview of the manufacturing routes of biphenyl in the EU, location of manufacturing sites worldwide, an approximate range for the import/export of the substance in Denmark and in the EU as well as the most popular applications of the substance.

## 3.1 Manufacturing

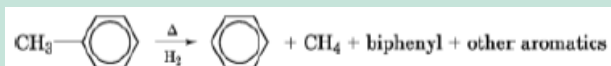
According to several literature references (USEPA, 2013; Danish EPA, 2013a; Thompson Quentin, 1992), biphenyl is primarily produced by two routes: hydrodealkylation of toluene and catalytic dehydrocondensation of benzene. Biphenyl is either isolated as a by-product (hydrodealkylation) with a yield of approx. 1%, or synthesized (dehydrocondensation), where prevalent impurities as side product are yielded as terphenyls. For the hydrodealkylation route, benzene as a raw material can be either produced from coal tar fuel oil or from petroleum (Thompson Quentin, 1992).

### 3.1.1 Manufacturing process

The technology to produce biphenyl has not changed much since the 90's up to now (US EPA, 2013; Danish EPA, 2013a; Thompson Quentin, 1992). The manufacturing of biphenyl can thus be described in two alternative processes:

- Production of benzene by **hydrodealkylation (HDA)** of toluene (C<sub>7</sub>H<sub>8</sub>) or other alkylbenzene plus hydrogen. Methane and other aromatics are also produced, together with **crude biphenyl**, which is then submitted to an additional small distillation step to obtain a final product at a technical grade of **93-97% purity**. If a higher purity is required, **zone refining or other crystallisation techniques** are applied to produce **pure biphenyl (≥ 99.9%)**. The overall yield of this manufacturing process is 1%.
- Alternatively, **pure biphenyl (≥ 99.9%)** can also be produced by the direct **dehydrocondensation** of benzene, the latter being obtained as a raw material for the manufacturing of biphenyl. The overall yield of this manufacturing process is 85 to 90% (Guidechem, 2014).

The first mentioned alternative is the most widely applied, and numerous hydrodealkylation (HDA) processes have been developed. Most have the common feature that toluene/other alkylbenzene plus hydrogen is passed under pressure through a tubular reactor at high temperature. Dealkylation conditions are sufficiently severe to cause some de-hydrocondensation of benzene and toluene molecules (see image 1) and therefore, in spite of the low yield, crude biphenyl can be used for applications where technical grades of 93-97% are enough. Furthermore, because of the large scale of HDA operations around the world, this process step provides an ample source of this grade (Thompson Quentin, 1992).



**IMAGE 1**

PRODUCTION OF CRUDE BIPHENYL AT A YIELD OF 1%; BENZENE AND METHANE BEING THE MAIN PRODUCTS (FROM THOMPSON QUENTIN (1992)).

Fewer suppliers produce biphenyl by dehydrocondensation of benzene (Thompson Quentin, 1992). However, this may have changed along the last decade as no updated information is publicly available. By the time of this abovementioned study, only Monsanto (USA & UK), Bayer (Germany), Nippon Steel (Japan) and companies in Russia used this route to produce pure biphenyl ( $\geq 99.9\%$ ) for heat-transfer applications (Thompson Quentin, 1992). Industrial production is carried out in gas or electrically heated tubular reactors at  $700 - 800$  °C with residence and contact times of only a few seconds. Valuable by-products are produced (terphenyls) which come in the form of ortho-, meta-, para-, tri- and poly- terphenyl isomers as well as tars. Little demand exists for these isomers in pure form, and thus only a mixture is routinely produced. Small amounts of acetone, ethanol, or ethanol are used to promote dehydrocondensation, and as a result, minor amounts of methyl- or methylene-substituted polyphenyls accompany the biphenyl and terphenyls produced. For most purposes, the level of such products ( $<1\%$ ) is so small that their presence can be ignored (Thompson Quentin, 1992).

### 3.1.2 Manufacturing sites

#### Worldwide

According to Guidechem (2014), there are about 100 suppliers of biphenyl around the world registered in their database: 77% from China, 10% from the USA, 3% from India, 3% from Germany, 2% from Japan, 1% from the UK, 1% from Taiwan and Hong Kong, and 3% from other countries. This indicates that the vast majority of manufacturers registered for trading are in China and according to this trading guide, also the top suppliers (i.e. those selling the largest volumes).

There is no indication on what technology is applied in these sites, but according to the trends discussed in some literature sources (USEPA, 2013; Thompson Quentin, 1992), the partition between hydrodealkylation and dehydrocondensation applications has shifted more towards dehydrocondensation in the last two decades. In spite the dehydrocondensation process appears to be more costly (Thompson Quentin, 1992), the higher efficiency of this process may accelerate the production of pure biphenyl. Furthermore, according to the applications and current trends in the market, the use of pure biphenyl may well be increasing as it is this technical grade which is used for heat-transfer applications and this has been reported as the most important emerging application of biphenyl around the world. For more details on the use, see section 3.3.

#### The European Union (EU)

According to ECHA's website (ECHA RSD, 2014)<sup>25</sup>, the following five companies have registered biphenyl under REACH:

- DOW BENELUX B.V. - OR1, in the Netherlands
- Lanxess Deutschland GmbH, in Germany
- RÜTGERS Novares GmbH, in Germany
- Solutia Europe SPRL/BVBA OR1 Corporate Village, in Belgium
- Solutia UK Ltd, in the United Kingdom

Information provided by some of these companies indicates that at least one of these (i.e. Solutia UK) produces biphenyl in the EU, whilst three of them (Lanxess, Solutia Europe and DOW

<sup>25</sup> <http://echa.europa.eu/en/information-on-chemicals/registered-substances>

BENELUX) do not. Furthermore, Solutia Europe does not produce nor use biphenyl (as confirmed with the contact person in Solutia UK Ltd).

According to information in DOW's website<sup>26</sup>, DOW BENELUX in Terneuzen is a big refinery plant where naphtha and LPG are turned into ethylene, propylene, butadiene, and benzene. There is no production of biphenyl as reported in the website, and according to the usages investigated, it is very likely that DOW BENELUX uses biphenyl as a constituent of heat transfer fluids during their refinery operations (see section 3.3.2 for more details). This leads to the conclusion that Lanxess and DOW are importers, RÛTGERS may be an importer/producer and Solutia UK is a producer, whilst Solutia Europe is none.

As additional information and according to Thompson Quentin (1992), Monsanto in the UK and Bayer in Germany were important producers of this substance by then, and other producers mentioned were Koch Chemical Co. and Chemol Inc., both having sales or production locations in Europe at this time.

According to Guidechem (2014), two additional suppliers of biphenyl are located in Germany and one in the UK, compared to the abovementioned ECHA list:

- Campro Scientific GmbH, in Germany
- CFM Oskar Tropitzsch, in Germany
- Fisher Scientific, in the UK

However, these suppliers may only be traders and therefore simply receive the chemical product from one of the manufacturing/import sites mentioned in ECHA RSD (2014). Another reason for them not to be included in the ECHA list is that their import or trading volume may be lower than the minimum required for registration (i.e. 1 tonne/year).

## Denmark

No production of biphenyl takes place in Denmark, so all the registrations of use in the SPIN database refer to import of the substance.

### 3.1.3 Manufacturing volumes

There is in general a lack of data concerning the manufacturing volumes of biphenyl worldwide. However, based on historical data and the production volume reported according to ECHA, it seems that the EU is a small producer of biphenyl on the world market, that the US is a larger producer of biphenyl than the EU (or on the same level) and that the largest production of biphenyl must be found elsewhere (e.g. in the East).

## Worldwide

It has not been possible to retrieve information regarding the current total volume of biphenyl produced worldwide. However, the historical trends showed a major decline during the early 80s due to the phase out of polychlorinated biphenyls (PCBs) (WHO, 1999). A steady growth in the vapour-phase heat-transfer market during the late 80s and early 90s revived, however, the trade and subsequent production of the chemical worldwide (Thompson Quentin, 1992). This is aligned to the production trend reported in the US, where 24,000 tonnes/year were produced in 1990, in comparison to 19,000 tonnes/year in 1989 (USEPA, 1995). This increase was reported by four manufacturers: Monsanto, Koch Chemical Co., Chevron and Sybron Chemicals. In 1998, a world's production capacity was estimated at 80,000 tonnes/year (WHO, 1999).

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<sup>26</sup> <http://www.dow.com/benelux/over/producten/index.htm>



## The European Union (EU)

According to ECHA Registered Substance Database (2014), a tonnage band of 1,000 – 10,000 tonnes/year is registered for biphenyl in the European Union, which is imported from abroad or produced in the EU. No more specific information publicly available that gives a better indication of its current production volume could be found, and the companies registered could not provide an indication of production and/or import volumes. The production and import of biphenyl in the EU in 2011/2012 are considered to be much closer to the high end of the tonnage band (10,000 tonnes) than to the low end of the tonnage band.

According to WHO (1999), the estimated production capacities of biphenyl in Western Europe were 30,000 tonnes/year in 1984; 6,000 of these were produced in Germany. This, compared to the estimated world's production capacity by WHO mentioned above, gives more than a third produced in Western Europe. However, the production in Germany by 1989 was already down to 2,000 – 2,500 tonnes/year (WHO, 1999), indicating a steep decline.

### 3.2 Import and export

According to Regulation No. 927/2012 concerning statistical nomenclature and the common customs tariff, biphenyl does not have a specific CN code (combined nomenclature), but is grouped together with terphenyls under the CN code 29029030 "*Biphenyl and terphenyls*". This CN code, however, was only effective until 2008 – from 2009 and until today "biphenyl and terphenyls" have been merged into one large CN code 29029000 named "Other cyclic hydrocarbons excluding cyclanes, cyclenes, benzene, toluene, xylenes, styrene, ethylbenzene and cumene)". Actually the following former CN codes have been merged together into the overall CN code 29029000:

- 29029010 – Naphthalene and anthracene
- 29029030 – Biphenyls and terphenyls
- 29029050 – Vinyltoluenes
- 29020960 – 1,3-Diisopropylbenzene
- 29029080 – Cyclic hydrocarbons (excluding cyclane, cyclenes, benzene, toluene, xylenes, styrene, ethylbenzene, cumene, naphthalene, anthracene, biphenyl, terphenyls, vinyltoluenes and 1,3-diisopropylbenzene)
- 29029090 – Cyclic hydrocarbons (excluding cyclane, cyclenes, benzene, toluene, xylenes, styrene, ethylbenzene, cumene, naphthalene, anthracene, biphenyl and terphenyls)

As there is no specific CN code for biphenyl (only an overall CN code covering other cyclic hydrocarbons), no import and export statistics are presented as they will not provide a realistic picture of the import and export of biphenyl in Denmark or the EU.

#### 3.2.1 Import and export of biphenyl in Denmark

A search in the SPIN database (Substances in Preparations in Nordic countries) demonstrates that the import of biphenyl in chemical preparations to Denmark has been on almost the same level (i.e. about 3,000 tonnes annually) since 2003. The import in 2011 was 3,362.4 tonnes. The exact figures for the years 2000 to 2011 can be found in Appendix 4: "Use pattern of biphenyl in Denmark from 2000 to 2011".

According to Figure 2, the imported amount of biphenyl has been around the same level since 2003, ranging from 2,360.4 to 3,529.2 tonnes/year. The import in 2011 was 3,362.4 tonnes and export volumes accounted only for about 1% of total imports volume.

Contact to Danish importers of chemical preparations containing biphenyl has revealed that the two major areas where biphenyl-contained chemical products are being imported to Denmark are:

- Import of coal tar for naphthalene production – accounts for approximately 1,700 tonnes of biphenyl/year

- Import of heat transfer fluids – accounts for at least 100 kg of biphenyl/year

These two areas are described in more details below. The difference between the total import of biphenyl from SPIN of 3,362.4 tonnes for 2011 and the import of about 2,000 tonnes (representing 2013 values) is due to differences in the percentage of biphenyl in coal tar. Confidential data received from the Danish Product Register illustrate that they have used a higher percentage of biphenyl contained in coal tar compared to the information received for use in this report.

#### Import of coal tar

As biphenyl also is present in coal tar products, the import of coal tar products into Denmark has been investigated. A search for coal tar products in the Classification & Labelling Database of ECHA reveals about 100 different coal tar compounds. Of these only a few can be found in the SPIN database (i.e. are used in Denmark) and only some of these coal tar compounds contain biphenyl. The search gave very sparse information as all of the import amounts of the coal tar compounds that contain biphenyl are confidential. However, according to Koppers Denmark ApS<sup>27</sup> they are the only importer of coal tar (to their knowledge) today and they import only one specific type of coal tar. They annually import around 150,000 – 170,000 tonnes coal tar containing around 0.1 to 1.0% biphenyl<sup>28</sup>. This coal tar is used in a distillation process to produce pure naphthalene. This means that Koppers Denmark ApS imports around 150 to 1,700 tonnes biphenyl in their coal tar products each year. This biphenyl is contained in the different by-products they produce such as coal tar pitch. According to Koppers Denmark A/S these by-products are all being exported. I.e. the main import of biphenyl contained in chemical products to Denmark is being exported again.

#### Import of heat transfer fluid

Contact to one Danish importer of heat transfer fluid revealed that at least around 100 kg pure biphenyl is being imported (2013) contained in heat transfer fluids. They import each year 400 kg heat transfer fluid, which contains 27% biphenyl. According to the Danish Product Register only two companies import heat transfer fluids in Denmark. It is therefore expected that the total import of biphenyl in heat transfer fluids is at least 100 kg, but maximum 200-500 kg annually. Heat transfer fluids are used in closed systems (see section 3.3 “Use”).

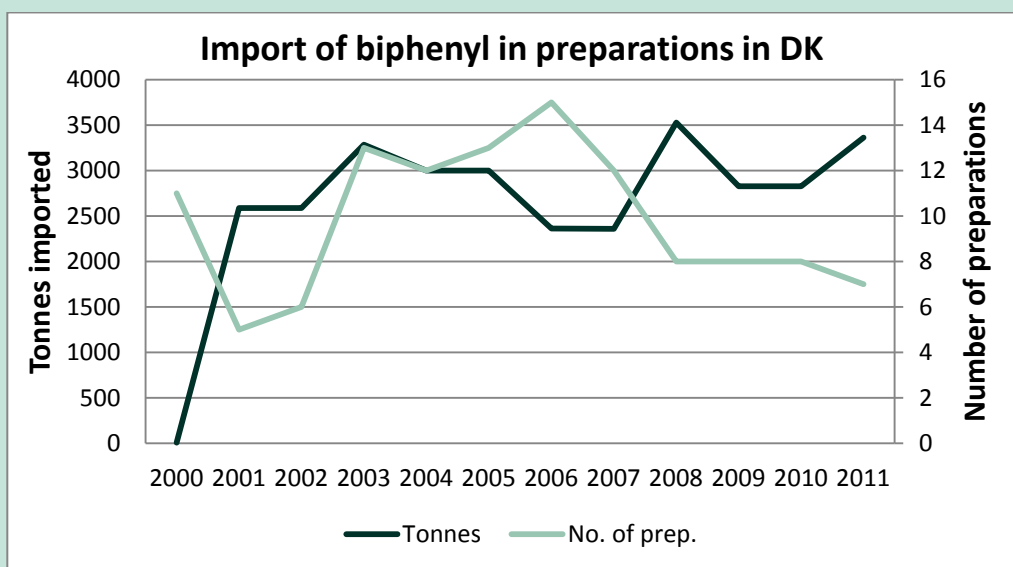


FIGURE 2  
IMPORT OF BIPHENYL IN CHEMICAL PREPARATIONS IN DENMARK 2000 TO 2011

<sup>27</sup> Personal communication with Koppers Denmark ApS in connection with the LOUS project on naphthalene.

<sup>28</sup> <https://www.amsa.gov.au/environment/maritime-environmental-emergencies/national-plan/Supporting-Documents/documents/Coal%20Tar%20MSDS.pdf>

### 3.2.2 Import and export of biphenyl in the EU

No publicly available information was available for the amounts of biphenyl imported and exported in and out of the EU.

### 3.3 Use

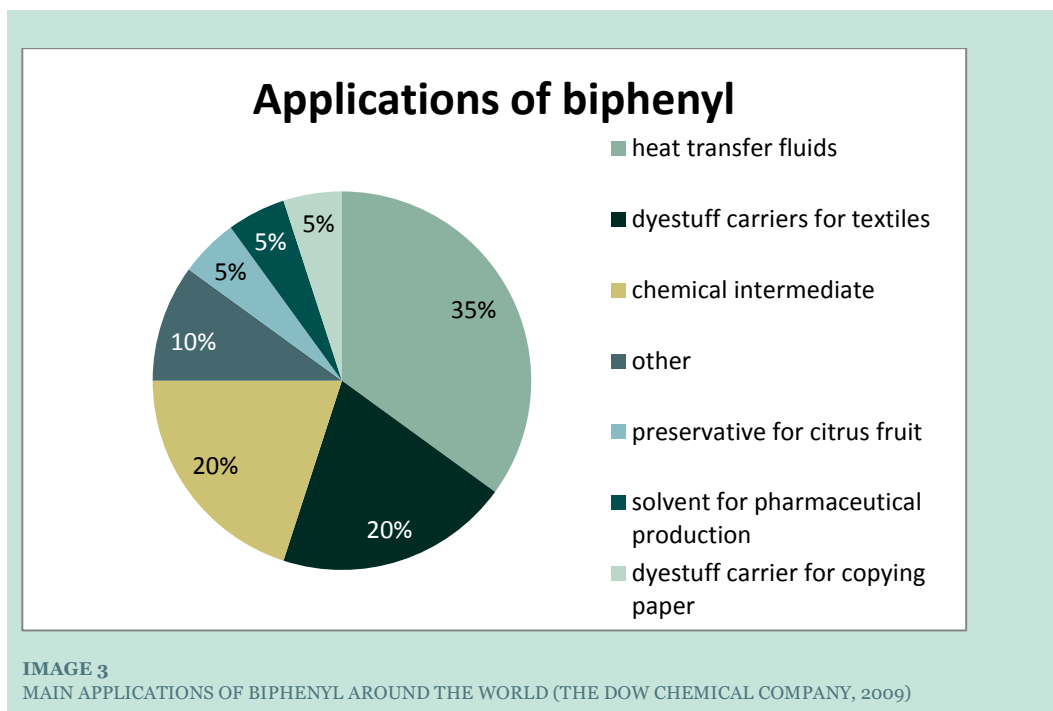
Biphenyl is found both in nature and from anthropogenic sources; it occurs naturally in coal tar and natural gas (Environment Health Canada, 2013). It was used in large volumes as an intermediate in the production of polychlorinated biphenyls (PCBs), but as the use of this chemical has become highly restricted or prohibited in many countries, the demand and subsequent production of biphenyls presented a large decrease during the 80's and 90's (WHO, 1999). However, other uses have emerged along the last two decades, although not in the same volume scale (Danish EPA, 2013a; Environment Health Canada, 2013; WHO, 1999; USEPA, 1995). These are:

- **As final product:**
  - Constituent in heat transfer fluids
  - Dyestuff carrier for textiles
  - Solvent in pharmaceutical production
  - Dyestuff carrier for copying paper
  - Fungicide and pesticide for plant disease control
  - Preservative for wood (biphenyl is present in creosote; however it is no longer in use in Denmark<sup>29</sup>)
  - Preservative for citrus fruits (as fungistat which has been recently restricted in the US and the EU)
- **As an intermediate:**
  - In the production of emulsifiers
  - In the production of leather tanning agents
  - In the production of optical brighteners
  - In the production of crop protection products
  - Precursors in the manufacture of benzidine
  - Auxiliaries for plastics, including in the preparation of flame retardants
  - Thickener in carriers for printing

From information provided by the ECHA registered companies, the main application of biphenyl in the EU is as a constituent of heat transfer fluids. Other uses named by them are listed above. Furthermore, according to The Dow Chemical company (2009), the distribution of the main applications of biphenyl around the world by 2009 is reported in image 3 below.

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<sup>29</sup> Creosote treated wood is no longer used for treatment of wood in Denmark (has been restricted since 1997). However, creosote treated wood may still be in use in Denmark (Hansen et al., 2008).



#### 3.3.1 Main uses of biphenyl in Denmark and the other Nordic countries

The main industrial uses of biphenyl in Denmark are as part of an ancillary product used during production process activities and as a raw material for production or applied directly to final products (information from the Danish Product Register (April 2014)).

According to the SPIN database, the main applications of biphenyl in other Nordic countries have been, from 2002 to 2011:

- Non-agricultural pesticides and preservatives
- Fuel additives
- Heat transferring agents/heat transfer fluids

However, today the main application of biphenyl in Denmark is as use in heat transfer fluids according to SPIN and according to the contacted importers of biphenyl-containing chemical products.

Biphenyl has also been found in acrylic nails, which is a consumer product, particular in the powder used to build up artificial nails (Danish EPA, 2008). In this report 21 products for artificial nails were screened by use of GC-MS for the content of ingredients. In 6 of 7 acrylic nail powders biphenyl was detected. No applied concentrations were available from any of these products. It is emphasised in the project that the screening analysis is *not* a 100% valid identification, but is based on comparison with GC-MS data in a mass-spectres library and the report suggests that several of the analysed substances may be present as impurities. Biphenyl is not available in the EU CosIng database (the European Commission database with information on cosmetic substances and ingredients), and no other information about the use of biphenyl in cosmetic products has been found, which could suggest that the use of biphenyl in cosmetic products is not common.

##### 3.3.1.1 Heat transfer fluids

Biphenyl as a raw material for the production of heat transfer fluids is by far the most cited application by different references and registrants in ECHA (ECHA RSD, 2014).

The ECHA registrant, Solutia UK provided FORCE with an overview of the application of heat transfer fluids both orally and by accessing their website for their heat transfer fluids applications

(Eastman Chemical Company & subsidiaries, 2014). According to them, these fluids are used in a range of processing applications where high performance and stability are needed during the operational performance. The range of temperature operation varies from -115°C to 400°C which may be different for other products, but in any case this shows the great applicability of these products. The processes applying applications using heat transfer fluids shown by Eastman Chemical Company & subsidiaries (2014) are shown below, and a few of them coincide with some of the applications listed at the beginning of section 3.3:

- *Hydrocarbon processing*: Oil and gas processing, natural gas purification, refining, asphalt processing and storage and gas to liquid operations. Heat transfer fluids can e.g. be used in oil and gas processing for facilitating heating and regeneration of glycols, which are used to remove water from the natural gas produced.
- *Plastics processing*: Plastics and polymer manufacturing, speciality heat sensitive polymer manufacturing, synthetic fibre manufacturing and plastic moulding. Heat transfer fluids can e.g. be used in plastics and polymer manufacturing to ensure both heating and cooling of the reaction vessels. Can be used in e.g. production of PET and HDPE.
- *Chemical processing*: Pharmaceutical manufacturing, chiral chemical processes, environmental test chambers, speciality chemical manufacturing and chemical manufacturing. Heat transfer fluids can e.g. be used in pharmaceutical manufacturing to ensure both heating and cooling of the pharmaceuticals in the manufacturing process.
- *Alternative energy and technologies*: Concentrated solar power, organic rankine cycle, biofuel manufacturing and desalination. Heat transfer fluids can e.g. be used in the manufacturing of biofuel that requires efficient heating and cooling in the production process.
- *Food and beverage processing*: Vegetable oil deodorising, food additive manufacturing, food packaging production and food preparation. Furthermore, when operating temperatures prohibit the use of steam or steam is not readily available, synthetic based heat transfer fluids can provide safe and efficient operation in a heat transfer system used for food processing.

A search on the internet concerning the heat transfer fluid market reveals that beside the Eastman (Solutia) company in the US and the EU, the following companies are also major players in this area: Dow Chemical Company (US and EU), ExxonMobil Cooperation (US), BP (UK) and Shell (the Netherlands). Together, these five major players on the heat transfer fluid market accounted for 76% of the overall market in 2011<sup>30</sup>.

When investigating their heat transfer fluid products the following was observed:

- Three out of 17 heat transfer fluid products observed from Eastman (Solutia) contain biphenyl in a concentration of 5-10%, 16% and 26.5% respectively<sup>31</sup>
- One out of 7 heat transfer fluid products observed from Dow Chemical Company contains biphenyl. No information about concentration was found<sup>32</sup>.
- Zero out of 4 heat transfer fluid products observed from ExxonMobil Cooperation contains biphenyl<sup>33</sup>.
- Limited information from Shell, but it seems that zero out of 3 heat transfer fluid products contains biphenyl<sup>34</sup>.
- Limited information from BP, but it seems that zero out of 3 heat transfer fluid products contains biphenyl<sup>35</sup>.

<sup>30</sup> [https://www.asdreports.com/news.asp?pr\\_id=1149](https://www.asdreports.com/news.asp?pr_id=1149)

<sup>31</sup> <http://www.therminol.com/resources/therminol-heat-transfer-fluid-information-library>

<sup>32</sup> <http://www.dow.com/heattrans/products/synthetic/dowtherm.htm>

<sup>33</sup> <http://www.msds.exxonmobil.com/IntApps/psims/SearchResults.aspx>

<sup>34</sup> [http://www.farleycompany.com/pdf/data-sheets/shell/d-antifreeze-coolants/tds\\_heattransferfluid\\_industrial.pdf](http://www.farleycompany.com/pdf/data-sheets/shell/d-antifreeze-coolants/tds_heattransferfluid_industrial.pdf)

Overall, it can therefore be concluded that it is only a limited number of heat transfer fluid products on the market (we found 4 out of 34) that contain biphenyl. Which of the products that sells the most is unknown.

No information regarding the total volume of the heat transfer fluid market today was identified. However, a report<sup>36</sup> from 2012 estimates the global market of thermic fluids/heat transfer fluids to be around 640,000 tonnes by 2019.

Contact to Danish importers of heat transfer fluid revealed that at least around 100 kg biphenyl is imported (2013) contained in heat transfer fluids (400 kg with a content of 27% biphenyl). One company could inform that they use the heat transfer fluid in a closed system for production of fibres in the hygiene industry (production of diapers, tampons, wet tissues etc.). Biphenyl is, hence, not in contact with the finished products.

Europe is the world's largest market of heat transfer fluids consuming nearly one third of the total demand<sup>37</sup> and the global market of heat transfer fluids is expected to be growing at a rate of about 7.4% per year from 2012 to 2017<sup>38</sup>.

### 3.4 Historical trends in use

Until the early 70s, biphenyl was used mainly as an intermediate in the production of PCBs around the world. During the early 80s, biphenyl was mainly used as a heat-transfer medium in heating fluids, as a dyestuff carrier for textiles or for the manufacture of emulsifiers and optical brighteners (WHO, 1999).

Although this was the general trend around the world, in the USA and Germany (who were major producers and/or users of the chemical) the trend changed after the restriction of the PCBs. The trend shifted towards less use of biphenyl in textile dyeing during the 80s (Thompson Quentin, 1992). At the same time, a steady growth in the vapour-phase heat-transfer market made this application the most important in the American and German markets, continuing until now as the most important application in the EU but shifting back in the US where its application for dyestuff carriers for textiles is now re-gaining momentum.

From the 90s until now, the uses of biphenyl have remained more or less constant, with the general trends varying slightly. The other applications appear to have slowly and gradually increased in the same way in both parts of the world (USEPA, 2013; Danish EPA, 2013a), whereas the use of biphenyl for food/feedstuff flavourings and nutrients has been restricted since 2003. No information exists for the uses of biphenyl in China, but this is expected to be of importance, due to the current developments in the Chinese market and the demand for industrial chemicals, as well as China's primary role in the trade of this chemical substance.

### 3.5 Summary and conclusions

No production of biphenyl takes place in Denmark, and the production in the EU has declined during the last decades. The main production of biphenyl, hence, takes place outside of the EU. Today, biphenyl is mainly used in heat transfer fluids and as dyestuff carriers for textiles.

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<sup>35</sup> <https://www.ils.co.nz/ils/assets/downloads/SKU%20MSDS/3406266.pdf>,  
[http://msdspds.bp.com/ussds/amersdsf.nsf/o/6ED0D3845D489C9586257307004F7E67/\\$file/014224US-Lubes%20Americas-BP%20\(Wayne,%20NJ%20US\).pdf](http://msdspds.bp.com/ussds/amersdsf.nsf/o/6ED0D3845D489C9586257307004F7E67/$file/014224US-Lubes%20Americas-BP%20(Wayne,%20NJ%20US).pdf),  
[http://msdspds.castrol.com/ussds/amersdsf.nsf/o/DB903F8EE09A185E8625764F003A7BF6/\\$file/001671.pdf](http://msdspds.castrol.com/ussds/amersdsf.nsf/o/DB903F8EE09A185E8625764F003A7BF6/$file/001671.pdf)

<sup>36</sup> <http://www.marketsandmarkets.com/PressReleases/thermic-fluids.asp>

<sup>37</sup> <http://www.marketsandmarkets.com/PressReleases/thermic-fluids.asp>

<sup>38</sup> [https://www.asdreports.com/news.asp?pr\\_id=1149](https://www.asdreports.com/news.asp?pr_id=1149)

### *Manufacturing*

Manufacturing of biphenyl is worldwide, whilst in Europe only one producer was identified in the UK. There are two identified major manufacturing routes: hydrodealkylation and dehydrocondensation. In spite of hydrodealkylation being more widely applied, it is the dehydrocondensation route which seems to produce the highest volumes of biphenyl. This is due to its application for producing high-purity biphenyl, which is increasingly used in heat-transfer fluids, which is the most widely application of biphenyl in the world.

Five companies are registered as importers and/or producers of biphenyl in the ECHA database (ECHA RSD, 2014). Information provided by some of these companies suggests that only three are users of the substance and one produces it. No production of biphenyl takes place in Denmark.

### *Production volumes*

The latest registered annual production of biphenyl worldwide is from 1998, where an annual capacity of 80,000 tonnes/year was estimated (WHO, 1999). No later figure was possible to retrieve, but considering the historical trend in use, it is expected that this old volume has not changed dramatically due to the increase of its use as heat-transfer fluid counteracted by its decrease in other applications. However, it is expected that a switch in production locations has occurred, as the range of production in the EU presents a steep decline from about 30,000 tonnes/year estimated in 1984 (WHO, 1999) to less than 10,000 tonnes/year. The figures are, however, uncertain (ECHA, RSD, 2014).

### *Import and export*

It was not possible to retrieve publicly available import/export data, neither from confidential sources nor through interviews with some of the registrants in ECHA (ECHA RSD, 2014).

In Denmark the annual import of biphenyl has not changed much since 2003, ranging from 2,360.4 to 3,529.2 tonnes, according to data from the SPIN database. The latest annual data registered is from 2011, with 3,362.4 tonnes. The exported amount by then accounted for 1% of the imports, indicating that most of what is imported is further used as an intermediate, used as ingredient in consumer products, or used in applications in industrial processes.

### *Uses and trends*

Biphenyl is found in nature and from anthropogenic sources. When biphenyl is produced it is further used as an intermediate for manufacturing of other chemicals or incorporated into final products and technical applications. According to literature sources and interviews with the ECHA registrants, the most common applications of biphenyl since 2009 and until now are in final products, which are:

- heat transfer fluids
- dyestuff carriers for textiles
- preservatives for citrus fruit
- dyestuff carriers for copying paper
- solvents for pharmaceutical production

The use of biphenyl as an intermediate in the production of other chemicals is expected to be minor in the EU, and the dominant application nowadays seems to be its use as constituent in heat transfer fluids.

In Denmark and other Nordic countries the use of biphenyl in heat transfer agents is also reported, and also its use in non-agricultural pesticides and preservatives as well as in fuel additives. Furthermore, its use as an ingredient in powder for acrylic nails in Denmark has been registered, although neither concentration nor volume data could be retrieved. Thus, this use seems to be of minor importance in relation to the other applications.

The historical trends worldwide indicate a shift in the use of biphenyl for PCBs and other applications, to be mainly used in heat transfer fluid applications and dyestuff carriers for textiles worldwide. This trend can also be extrapolated to the EU and the Nordic countries.



# 4. Waste management

Information regarding biphenyl in waste related to the primary uses of biphenyl as well as the manufacturing of biphenyl is presented in this section. Most of this information has been retrieved from literature sources, from producers or other organisations.

## 4.1 Waste from production of biphenyl

In this section waste from manufacturing of biphenyl is described. Waste from use of biphenyl (i.e. the major uses) is described in the following section (4.2).

Generally, it can be said, that according to The Dow Chemical Company (2009), industrial spills or uncontrolled releases of biphenyl during manufacturing are infrequent as biphenyl as product is generally contained. Due to the high costs of cleaning-up and the fact that the substance is toxic, it is expected that its handling at all the European production sites occurs as The Dow Chemical Company describes it.

Waste from manufacturing of biphenyls is therefore expected to be in the form of biphenyl, i.e. chemical waste. Uncontrolled spills and leftovers of biphenyl are expected to be minor.

## 4.2 Waste from the use of biphenyl

The main uses of biphenyl (as described in section 3.3 “Use”) is as intermediate chemical for production of other chemical products or as a constituent in chemical products such as dyestuff carriers or in heat transfer fluids. Below waste aspects related to these major uses are described.

### Waste from use of biphenyl as intermediate

Waste related to the use of biphenyl as intermediate is assumed to be minor, since the substance is converted to other chemical substances. Economically it is most effective to use all of the produced/purchased biphenyl, thus the amount of pure biphenyl as waste is assumed to be minor – and primarily in the form of remains in containers (in which the biphenyl was delivered). This amount of biphenyl will be handled as chemical waste (i.e. burned at companies specialised to handle chemical waste). According to European legislation on waste, waste generated from manufacture or from industrial use of biphenyl has to be treated as hazardous waste if the waste contains substances in an amount that according to classification rules for chemical substances and preparations would result in classification for either physico-chemical toxicological or environmental properties (Directive 2008/98/EC on waste, 2008).

### Heat transfer fluids

Heat transfer fluids are primarily used in closed piping systems, thus the ‘waste’ generated during use is assumed to be minor. When the fluid is due to replacement, it will be handled as chemical waste, as described above. However, as described in chapter 5 there may be release as fume during biphenyls use as a heat transfer fluid, and in the wastewater effluent due to potential leaking of heat exchangers.

### Dye stuff carriers

Biphenyl is used as dyestuff carrier in textile production – thus biphenyl can end up in waste water from textile production. The consequences hereof is described further in chapter 5.

### Coal-tar derived creosotes

According to Environment Health Canada (2013), biphenyl has also been detected in coal-tar derived creosotes which is used for creosote treated wood; however, the content is expected to be low. Today, the use of creosotes for wood preservation is restricted in Denmark. However, biphenyl may be present in small quantities in waste products of creosote treated wood. The content is expected to be low, as data on the concentrations of biphenyl in creosote has been found to be less than 5%<sup>39</sup>, between 1-5%<sup>40</sup>, 1.03%<sup>41</sup> and less than 0.5%<sup>42</sup>. It is estimated that impregnated wood as a waste product constitutes around 100,000 tonnes each year in Denmark (Regeringen, 2003). This amount is, however, all impregnated wood, i.e. impregnated with CCA (chromium, copper and arsenic), tin and creosote. Hansen et al. (2008) estimates that the amount of waste for creosote treated wood will be around 12,000 tonnes each year in Denmark. The amount of creosote in creosote treated wood is 15%<sup>43</sup>. If assumed that creosote consists of around 1% biphenyl, the amount of biphenyl in waste in the form of creosote treated wood is therefore around 18 ton each year in Denmark. Waste treatment of creosote treated wood happens in Denmark at special waste treatment plants that are authorised to burn the creosote treated waste.

All in all, Environment Health Canada (2013) describes that biphenyl does not seem to be used directly in consumer products. Waste in the form of creosote treated wood from mainly railway sleepers is therefore expected to be the only waste ‘article’ containing biphenyl. However, biphenyl has been found in acrylic nails, particular in the powder used to build up artificial nails. Yet, it is expected that the content of biphenyl is minor and that biphenyl is found as an impurity. Biphenyl may therefore also be released from household waste, in the case the powder used in acrylic nails is disposed in an unfinished state. It is, however, expected that the amount is insignificant.

## **4.3 Release of biphenyl from waste disposal**

When biphenyl is disposed as hazardous waste or when contained in other materials due to spills, it is recommended to send these to incineration (Guidechem, 2014; ECHA RSD, 2014). Guidechem (2014) suggests mixing these waste fractions with high combustible materials such as paper, carton or alcohol-based solvents so the breakdown of biphenyl is increased by enhancing the combustion process. Eastman Newport (2014) as a manufacturer of biphenyl, amongst others, reports that 95% of their hazardous waste has been sent to cement kilns where cement is manufactured. The hazardous waste from Eastman Newport is processed further to reach an optimal level for combustion efficiency which complies with the specifications for cement manufacturing.

Biphenyl is therefore expected to be released mainly in the solid fraction from wastewater treatment, particularly in sewage sludge. It is not expected to be found in the treated liquid effluent from wastewater treatment, as it will probably be degraded into other substances or adsorbed into the solid fraction. When disposed as hazardous waste from industrial processes, incineration or further processing for energy recovery in cement kilns are the most likely disposal routes. In both of them it is important to mix biphenyl with alcohol-based solvents or other highly combustible materials to enhance the combustion process. Otherwise, biphenyl will be released as a fugitive emission. Biphenyl may also be released from household waste; in the case the powder used in acrylic nails is disposed in an unfinished state. Either by disposing it properly as hazardous waste or

<sup>39</sup> <https://www.amsa.gov.au/environment/maritime-environmental-emergencies/national-plan/Supporting-Documents/documents/CREOSOTE%20MSDS.pdf>

<sup>40</sup> <http://www.birdbrand.co.uk/msds/Traditional%20Creosote%20SDS%202010.pdf>

<sup>41</sup> [http://ilrc.ucf.edu/documents/ILRC%200000445/NCFS\\_445%20Creosote%20Coal%20Tar.pdf](http://ilrc.ucf.edu/documents/ILRC%200000445/NCFS_445%20Creosote%20Coal%20Tar.pdf)

<sup>42</sup> [http://www.poles.se/pdf/en\\_ko\\_wei\\_typ\\_b.pdf](http://www.poles.se/pdf/en_ko_wei_typ_b.pdf)

<sup>43</sup> <http://www.rhinehartrailroad.com/Docs/RRC/creosotetreatedwoodrailroadtiemsds.pdf>

by mixing it in the household waste, this product will probably be incinerated and therefore undergo the same route as industrial hazardous waste.

In Denmark and the EU, hazardous waste is handled separately and it is usually sent to incineration at special sites, which are authorised to handle hazardous waste. In Denmark, the different municipalities are responsible for making sure that hazardous waste from different companies is handled correctly. In Denmark, the company Nord (which is a company authorised to handle hazardous waste) categorises biphenyl as waste category H: Organic chemical waste without halogen or sulphur<sup>44</sup>. Nord disposes of the chemical waste by burning it at a temperature of approximately 1200 °C. Burning biphenyl will result in the formation of carbon dioxide and water and thus will not result in the release of any hazardous emission in the flue gas or bottom ash. When biphenyl is sent to cement kilns in other EU countries, it will follow the same fate as in the incineration plants, as it reaches a temperature of about 1500 °C. Therefore in all these cases, no special regulation apart from that of handling hazardous waste will apply.

#### **4.4 Summary and conclusions**

##### *Waste aspects related to manufacturing of biphenyl*

Generally, industrial spills or uncontrolled releases of biphenyl during manufacturing are infrequent as biphenyl as product is generally contained. Due to the high costs of cleaning-up and the fact that the substance is toxic, it is expected that its handling at all the European production sites occurs properly.

##### *Waste aspects related to use of biphenyl*

Waste related to the use of biphenyl as intermediate is assumed to be minor, since the substance is converted to other chemical substances. Economically it is most effective to use all of the produced/purchased biphenyl, thus the amount of pure biphenyl as waste is assumed to be minor – and primarily in the form of remains in containers (in which the biphenyl was delivered). This amount of biphenyl will be handled as chemical waste (i.e. burned at companies specialised to handle chemical waste).

Heat transfer fluids (of which some contain biphenyl (up to 27% is reported)) are primarily used in closed piping systems, thus the ‘waste’ generated during use is assumed to be minor. When the fluid is due to replacement, it will be handled as chemical waste, as described above.

Biphenyl is used as dyestuff carrier in textile production – thus biphenyl can end up in waste water from textile production.

If assumed that creosote consists of around 1% biphenyl, the amount of biphenyl in waste in the form of creosote treated wood is assumed to be approximately 18 ton/year in Denmark. Waste treatment of creosote treated wood happens in Denmark at special waste treatment plants that are authorised to burn the creosote treated waste. The use of creosotes for wood preservation is now restricted in Denmark.

Consumer products containing small amounts of biphenyl will enter into the waste stream through municipal collection of domestic waste. The only consumer product expected to contain biphenyl is powder used to build up artificial acrylic nails. It is, however, expected that the content of biphenyl in this type of waste is insignificant.

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<sup>44</sup> <http://www.nordgroup.eu/da-DK/Hvorfor-NORD/Gode-r%C3%A5d-om-h%C3%A5ndtering/Sorteringsvejledning.aspx>

Generally articles (creosote treated wood, acrylic nails) will be incinerated in Denmark whereas waste in the form of chemical mixtures will be treated as hazardous waste (at special sites authorized to handle hazardous waste).

*Release of biphenyl from waste disposal*

Biphenyl is expected to be released mainly in the solid fraction from wastewater treatment, particularly in sewage sludge. It is not expected to be found in the treated liquid effluent from wastewater treatment, as it will probably be degraded into other substances or adsorbed into the solid fraction. When disposed as hazardous waste from industrial processes, incineration or further processing for energy recovery in cement kilns are the most likely disposal routes. In both of them it is important to mix biphenyl with alcohol-based solvents or other highly combustible materials to enhance the combustion process. Otherwise, biphenyl will be released as a fugitive emission.

# 5. Environmental effects and fate

Release of biphenyl into the environment may occur from industrial processing, from final products containing biphenyl, from indirect emissions (mainly from combustion of fossils) and from waste disposal also containing biphenyl.

Emissions are released to air, in wastewater effluents, in sludge from wastewater treatment or to soil from applying contaminated sludge to land or by uncontrolled spills of the substance.

The following sections describe the environmental fate and effects related to the release of biphenyl to the environment. The information presented is mostly based on Guidechem (2014), Australia Environment (2014), Danish EPA (2013), Environment Health Canada (2013), The Dow chemical company (2009), WHO (1999) and the USEPA (1995). Information from ECHA RSD (2014) has also been used.

## 5.1 Environmental hazard

The toxicity data for biphenyl suggests that biphenyl has a high acute and chronic toxicity to aquatic organisms. Biphenyl has a harmonised classification with respect to environmental effects as 'Aquatic Acute 1, H400 (very toxic to aquatic life)', and as 'Aquatic Chronic 1, H410 (very toxic to aquatic life with long lasting effects)'.

### 5.1.1 Toxicity to aquatic organisms

Biphenyl presents a low solubility in water and a high volatility, and therefore the nominal concentrations often used in toxicity tests may not correspond to effective concentrations. It is thus important to observe lowest reported effect concentrations in which loss of the test substance is minimised (WHO, 1999). Similarly, Environment Health Canada (2013) reports critical toxicity values (CTV), which are also based on the lowest identified toxicity values.

Data on acute toxicity tests on invertebrates and fish is available from a few sources, whilst data for the same tests on algae is more limited. The same occurs for data on chronic tests, where so far only results from two tests are available. However, this is based on reported data on lowest effect concentration as described in the above paragraph. Results are shown in Table 6, based on empirical data reported by both literature sources referred above, plus one set of data from ECHA RSD (2014) which is not overlapping results from the other references. The lowest toxicity-values to aquatic organisms are observed for *Daphnia magna* (LC<sub>50</sub> 48 h) at 0.36 mg/L corresponding to a classification of Aquatic Acute 1, H400 (very toxic to aquatic life) according to CLP (table 4.1.10). Furthermore, Environment Health Canada (2013) concludes that, based on CTV data, effects on pelagic species (based on tests on *Daphnia magna*) reported a chronic maximum allowable toxic concentration (MATC) of 0.23 mg/L, a non-observed effect concentration (NOEC) of 0.17 mg/L, and the lowest-observed effect concentration (LOEC) of 0.32 mg/L.

Test organism	Type of test	Endpoint	Value	Reference
<b>Acute toxicity</b>				
<i>Mytilus edulis</i> (marine mussel)	Acute (40 min)	EC <sub>50</sub> (inhibition of food intake)	0.3 mg/L	Donkin et al. (1991)
<i>Chlamydomonas angulosa</i> (unicellular green algae)	Acute (3 h)	EC <sub>50</sub> (reduction of photosynthesis)	1.28 mg/L	Hutchinson et al. (1978)
<i>Chlorella vulgaris</i> (unicellular green algae)	Acute (3 h)	EC <sub>50</sub> (reduction of photosynthesis)	3.86 mg/L	Hutchinson et al. (1978)
<i>Daphnia magna</i> (water flea)	Acute (48 h)	LC <sub>50</sub>	0.36 mg/L	Gersich et al. (1989)
<i>Daphnia magna</i> (water flea)	Acute (24 h)	LC <sub>50</sub>	1.3 mg/L	Gersich et al. (1989)
<i>Oncorhynchus mykiss</i> (rainbow trout)	Acute (96 h)	LC <sub>50</sub>	1.5 mg/L	Dill et al. (1982)
<i>Artemia salina</i> (brine shrimp larvae)	Acute (24 h)	LC <sub>50</sub>	4.01 mg/L	Abernethy et al. (1986)
<i>Cyprinodon variegates</i> (sheepshead minnow)	Acute (96 h)	LC <sub>50</sub>	4.6 mg/L	Dill et al. (1982)
<i>Brachydanio rerio</i> (zebra fish)	Acute (96 h)	LC <sub>50</sub>	39 mg/L	European Commission (2000)
<b>Chronic toxicity</b>				
<i>Daphnia magna</i> (water flea) <24 h old	Chronic (21 days)	NOEC	0.17 mg/L	Gersich et al. (1989)
<i>Oncorhynchus mykiss</i> (rainbow trout)	Chronic (87 days)	NOEC	0.229 mg/L	Study report (1988) – in ECHA RSD (2014)

**TABLE 6**  
EMPIRIC DATA FOR AQUATIC TOXICITY REPORTED IN LITERATURE (ENVIRONMENT HEALTH CANADA, 2013; WHO, 1999; ECHA RSD, 2014)

### 5.1.2 Toxicity to microorganisms

The only information available on toxicity to microorganisms has been retrieved from WHO (1999). They report results from an acute test on *Photobacterium phosphoreum* with a 30-min EC<sub>50</sub> of 1.9 mg/L in a bioluminescence inhibition test. ECHA RSD (2014) shows results from six studies but all of them are classified as non-reliable and are therefore not included in this report.

### 5.1.3 Toxicity to sediment living organisms

No information on the toxicity to sediment living organisms was identified.

### 5.1.4 Toxicity to terrestrial organisms

Similarly as for toxicity to aquatic organisms, Environment Health Canada (2013) reports toxicity to terrestrial organisms based on selected references giving critical toxicity values (CTV), which are the lowest identified toxicity values. Results from these references are given in Table 7, which are also partly reported by WHO (1999) and ECHA RSD (2014). The results are classified by exposure channels to biphenyl, according to Environment Health Canada (2013). The lowest toxicity-value to terrestrial organisms is observed for lettuce.

Test organism	Type of test	Endpoint	Value	Reference
<b>Ingestion exposure</b>				
<i>Agelaius phoeniceus</i> (red-winged black bird)	Not stated	Oral LD <sub>50</sub>	96 mg/kg	Schafer et al. (1983)
<b>Plant exposure (terrestrial receptors)</b>				
<i>Sorghum bicolor</i> (sorghum)	21 days	EC <sub>50</sub>	> 1000 mg/kg dry soil	Windeatt et al. (1991)
<i>Glycine max</i> (soybean)	21 days	EC <sub>50</sub>	> 1000 mg/kg dry soil	Windeatt et al. (1991)
<i>Helianthus annuus</i> (sunflower)	21 days	EC <sub>50</sub>	> 1000 mg/kg dry soil	Windeatt et al. (1991)
<i>Lactuca sativa</i> (lettuce)	7 & 14 days	EC <sub>50</sub>	54 mg/kg soil & 68 mg/kg soil	Hulzebos et al. (1993)

**TABLE 7**  
EMPIRIC DATA FOR TERRESTRIAL TOXICITY REPORTED IN LITERATURE (ENVIRONMENT HEALTH CANADA, 2013;  
WHO, 1999)

In other studies with numerous mould fungus species, biphenyl caused a reversible inhibition (50-10%) when applied as vapour or imbedded in solid media. Furthermore, the occurrence of biphenyl-resistant mutants was observed in *Penicillium digitatum* and *Diplodia natalensis*, whilst yeast species showed little or no inhibition of cell proliferation following exposure to biphenyl (WHO, 1999).

### 5.1.5 Toxicity to the atmosphere

No information on the biotic or abiotic effects in the atmosphere was identified.

### 5.1.6 Classification

Biphenyl has a harmonised classification as (ECHA RSD, 2014):

- Aquatic Acute 1, H400 (very toxic to aquatic life)
- Aquatic Chronic 1, H410 (very toxic to aquatic life with long lasting effects)

Other environmental hazard statements and risk phrases, which are not harmonised but are self-declared by some registrants, i.e. relevant self-classifications, are (ECHA RSD, 2014):

- H412: Harmful to aquatic life with long lasting effects
- H410: Very toxic to aquatic life with long lasting effects

## 5.2 Environmental fate

Literature sources referred by Environment Health Canada (2013) state that when biphenyl is released to the environment (air, water, soil and sediment compartments), it will largely reside in the medium to which is released. The Henry's law constant of biphenyl of  $3 \times 10^{-4} \text{ atm} \cdot \text{m}^3/\text{mol}$  suggests that the substance could undergo volatilisation from aqueous solutions and moist soil surfaces, specially at shallow levels (Guidechem, 2014; WHO, 1999; USEPA, 1995). The environmental fate of biphenyl is shown in Table 8, when discharged 100% to the different environmental compartments. This is based on Level III fugacity modelling, based on the substance physical and chemical properties (Environment Health Canada, 2013). The table shows the substance remains largely where it is released. The highest transport is from water to air when biphenyl is 100% released to water, which is still only 4.01% of the total substance released to water.

Emission profile	Fraction of biphenyl partitioning into each compartment (%)			
	Air	Water	Soil	Sediment
Substance released to:				
<b>Air (100%)</b>	98.4	1.15	0.42	Negligible
<b>Water (100%)</b>	4.01	95.8	0.02	0.19
<b>Soil (100%)</b>	0.04	0.02	99.9	Negligible

**TABLE 8**  
ENVIRONMENTAL FATE OF BIPHENYL FROM LEVEL III FUGACITY MODELLING, BASED ON SUBSTANCE'S PHYSICAL & CHEMICAL PROPERTIES (ENVIRONMENT HEALTH CANADA, 2013).

The fate of biphenyl in each environmental compartment is summarised below in sections 5.2.1 to 5.2.5.

### 5.2.1 Air

When biphenyl is released to air, it remains there to later break down to other chemicals and eventually settling as dry deposits to water or land (Australia Environment, 2014; The Dow chemical company, 2009). According to gas/particle partitioning modelling, biphenyl, with a vapour pressure of 0.000119 kPa at 25°C, is expected to exist as vapour in the atmosphere just after being released and remains there, with only small amounts expected to partition to water and soil (Guidechem, 2014; Environment Health Canada, 2013). This is because biphenyl has been found partly in the particle-sorbed phase in the atmosphere, therefore indicating that it may be physically removed from the air by dry deposition (Guidechem, 2014). Vapour-phased biphenyl is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals, undergoing photolysis. The duration of this process is only a bit more than a couple of days, indicated by a half-life of this reaction between 1.5 to 2.2 days at 25°C. Direct photolysis is not likely to occur, as biphenyl absorbs very little light at wavelengths above 290 nm. It is neither expected that biphenyl reacts with other photo-oxidative species, e.g. tropospheric ozone and nitrate, in the atmosphere.



Therefore it is expected that reactions with hydroxyl radicals will be the most important fate process in the atmosphere for this substance, with a small fraction settling to water or land by dry deposition. Biphenyl has the potential to be transported over moderate distances in the atmosphere, meaning that it will reach areas moderately far from its emission sources before it is degraded as described previously. (Guidechem, 2014; Environment Health Canada, 2013; WHO, 1999; USEPA, 1995). The degradation products with hydroxyl radicals were not identified in available literature.

### 5.2.2 Water

Microbial populations from natural waters have shown to mineralise biphenyl into other chemicals, reporting a half-life of 2-3 days under aerobic conditions in river water and reporting 100% of degradation after 4 days (Guidechem, 2014; USEPA, 1995). In surface water the degradation half-life of 1.5 days has been established with river water. However, other estimates of half-life of biphenyl in water range up to 2.8 months (Environment Health Canada, 2013).

Therefore the main environmental pathways of biphenyl in water are microbial degradation and photolysis, the latter being concluded from an experiment where the substance degraded 50% over 4 hours by UV radiation (USEPA, 1995).

Concerning microbial degradation, the degradation of biphenyl proceeds via aromatic hydroxylation to 2-, 3-, and 4-hydroxybiphenyl, with further hydroxylation to 2-, 3-dihydroxybiphenyl. The degradation rates for biphenyl under various conditions have been investigated through different modelling and experimental studies (USEPA, 1995; WHO, 1999). The degradation rates reported were as follows:

- 100% in 8 hours by an aerated lagoon
- 100% in 96 hours by a retention pond
- 100% in 7 days by an anaerobic digester
- 87% in 24 hours /100% in 5 days by industrial wastewater treatment - no treatment technologies specified, but assumed those mentioned in chapter 4 (suggested by Guidechem (2014) and Eastman Newport (2014)): activated carbon, resin adsorption and fixed film
- 79% in 5 days by domestic wastewater treatment
- 74% in 14 days /66% in 14 days by activated sludge

QSAR predictions regarding the persistence of biphenyl all result in half-life of biphenyl in water being <182 days (Environment Health Canada, 2013), which is the Canadian criteria for persistence in a PBT assessment. In contrast the persistence criteria used in the EU (ECHA) is a half-life in water, in fresh water of >40 days and in marine waters of >60 days (ECHA, 2011). The above data and the QSAR predictions described in Environment Health Canada (2013) lead to the conclusion by Environment Health Canada that biphenyl biodegrades relatively fast, and that biphenyl by their criteria is not persistent in water. In contrast the EU persistence criterion is met. However, biodegradation of biphenyl may be very slow in unpolluted seawater (Guidechem, 2014), and its half-life might be affected by processes such as sedimentation, bioturbation and desorption (Environment Health Canada, 2013). The PBT properties of biphenyl are discussed in details in section 5.2.6 "PBT".

Volatilisation from water surfaces presents half-lives of 4 hours in rivers and 6 days in lakes, estimated from models using a Henry's law constant of  $3.08 \times 10^{-4} \text{ atm} \cdot \text{m}^3/\text{mole}$ . Furthermore, biphenyl is expected to adsorb to suspended solids and sediment rather quickly, due to its  $K_{oc}$  value (Guidechem, 2014).

According to Guidechem (2014), wastewater treatment processes that successfully remove biphenyl from the wastewater effluent make use of activated carbon and resin adsorption. Another treatment process called 'concentration process' is also cited. Furthermore, Eastman Newport (2014)

mentions that since the implementation of a fixed film design plant that treats their effluent, the toxicity levels of their wastewater discharge have been successfully lowered. All these technologies, with the exception of the concentration process, transport biphenyl to the solid part of the treatment basin, where the bacteria degrades the chemical substance to other substances or simply stores it to be disposed in the sludge. The concentration process enables the possibility for recycling of the chemical substance. If the sewage sludge is applied to land, it is likely that the substance will end up in soil (Environment Health Canada, 2013). However, according to USEPA (1995), soil microorganisms may metabolise biphenyl to the more polar hydroxyl biphenyl and dihydroxy biphenyl which both may subsequently leach into groundwater. According to WHO (1999), concentrations of biphenyl have been measured in sewage sludge between 16 and 1.730 mg/kg. This is, however, old data (from 1990). No newer information has been found.

### 5.2.3 Sediment

Once biphenyl reaches moist soil surfaces and sediment, volatilisation is expected to be an important fate process given its Henry's law constant. However, this decreases once the substance reaches dry soil and with increased soil depths (Guidechem, 2014). Also, biphenyl is expected to adsorb to suspended sediments based on its octanol/water coefficient  $\log K_{ow}$  of about 3.16 to 4.1 (ECHA RSD, 2014), with a measured half-life of 333 days (Environment Health Canada, 2013). There is no indication that biphenyl undergoes hydrolysis, and it will therefore go straight to biodegradation, with a calculated half-life of 1.5 to 7 days using scientific judgement and based on the acclimated aqueous aerobic biodegradation half-life (Environment Health Canada, 2013).

### 5.2.4 Soil

When biphenyl is released into soil, it is not expected to volatilise from dry soil surfaces. It will only do so when released to moist soil surfaces as described in the paragraph above. Also, when the substance reaches deeper soil levels, it will tend to remain in soil with increased depth (Guidechem, 2014). Once in soil biphenyl presents low mobility, based on laboratory and calculated values for soil sorption coefficient ranging from 870 to 18,000 (Guidechem, 2014; WHO, 1999). From diverse experiments a calculated mean value of 4,230 (WHO, 1999) was established, which also indicates a low probability of groundwater infiltration. In spite the fact that biphenyl presents low mobility, no significant geoaccumulation is expected under aerobic conditions, owing to its degradation by microbial organisms (WHO, 1999). The main removal process for biphenyl in soil is thus biodegradation, via cytochrome P-450 to 2,3-dihydroxybiphenyl (Environment Health Canada, 2013; USEPA, 1995).

### 5.2.5 Biota

The highest  $\log K_{ow}$  of biphenyl reported is 4.1 (ECHA RSD, 2014). This indicates that biphenyl has only moderate potential to bioaccumulate in biota (Environment Health Canada, 2013), and also indicates an affinity of the chemical to lipids (USEPA, 1995).

Diverse bioaccumulation factors (BAF) are reported from experimental tests (Environment Health Canada, 2013; WHO, 1999; USEPA, 1995). These are summarised below:

- 2,835 on benthic amphipods (*rhepoxynius abronius*) – calculated on wet weight
- 540 on algae – calculated on dry weight
- 473 on *daphnia magna* – calculated on wet weight
- 436 on rainbow trouts
- 282 on orfe
- 57 on marine mussel – calculated on wet weight

The literature also indicates that most of the reported bioconcentration factors (BCF) are typically below 600, resulting in low BAF/BCF values indicating moderate potential for bioaccumulation (Environment Health Canada, 2013).

The log  $K_{ow}$  value reported by Environment Health Canada (2013) (experimental results) indicates a potential for bioaccumulation of biphenyl. However, volatilisation, adsorption to sediment/soil and degradation are expected to reduce the bioavailability of biphenyl – thus minimising the risk of bioaccumulation. Therefore this fate mechanism should be of minor importance for aquatic organisms (WHO, 1999).

### 5.2.6 PBT

As described in section 2.1.4.5 “Community rolling action plan”, Portugal evaluates biphenyl (CoRAP, 2012) for its suspected PBT properties at the moment. This evaluation is not finalised, so no information can be used for this report. In this section, an evaluation of the PBT properties of biphenyl is presented based on the available data and recent reports on biphenyl. The assessment is based on ECHA’s Guidance on information requirements and chemical safety assessment, Chapter R.11: PBT Assessment<sup>45</sup>.

Detailed literature and experimental results from a PBT assessment are presented in ECHA RSD (2014) as well as e.g. Environment Health Canada (2013). The data indicates that biphenyl probably does not meet the screening criteria for PBT (Persistence, Bioaccumulation, Toxicity). Biphenyl could be persistent and could be toxic, but probably not bioaccumulative. This is based on the following observed results:

- The major part of the different tests showed biphenyl to be degraded sooner than what established by the criteria of persistent (P) and very persistent (vP): a half-life of at least 40 days (in fresh or estuarine water), 120 days (in fresh or estuarine sediment), and 120 days (in soil). However, a half-life of 333 days in sediment suggests that biphenyl falls under the persistent criteria. Moreover, Environment Health Canada (2013) presents older estimates of the half-life of biphenyl in water of up to 2.8 months. Most data on biodegradability in water indicates a relatively fast rate of biotransformation under aerobic conditions. However, data for sediment and one set of data for water indicates that the substances potentially could meet the criteria for persistency according to the PBT criteria by ECHA.
- A key study showed a whole body BCF of 1,900 L/kg in fish. This value is close to the threshold for bioaccumulation (B) which is 2,000 L/kg. However, as most reported BCF values are below 600 biphenyl is probably not bioaccumulative. This also indicates that biphenyl does not fall under the classification of very bioaccumulative (vB). Because of differences in the criteria for the PBT assessment and the classification criteria, biphenyl is probably not bioaccumulative (B), but is classified as Aquatic Chronic 1, H410 “Very toxic to aquatic life with long lasting effects”.
- Two studies showed that the NOEC value was  $\geq 0.01$  mg/L for marine and fresh water organisms, and not  $\text{NOEC} < 0.01$  mg/L, which is the limit for fulfilling the T criterion. Furthermore, the substance does neither meet the criteria for classification with regards to any known or potential CMR properties, nor with regards to any known or potential long-term or target-organ effects in category 1 or 2. However, as the genotoxicity potential of biphenyl have provided ambiguous results, and it therefore cannot be ruled out that biphenyl has genotoxic effects, this means that biphenyl potentially could meet the criteria for **toxicity** (T) according to the PBT criteria by ECHA (see more details in section 6.1.8 on genotoxicity).

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<sup>45</sup> [http://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r11\\_en.pdf](http://echa.europa.eu/documents/10162/13632/information_requirements_r11_en.pdf)

### 5.3 Environmental exposure

No production of biphenyl takes place in Denmark and therefore no emissions from manufacturing are expected. Five companies within the EU produce or import the substance, and according to information available from one of the producers (Eastman Newport, 2014), biphenyl is released as air emission and, potentially, as part of polychlorinated biphenyl (PCB) in their wastewater effluent. In spite that Eastman Newport (2014) claims that the discharge of PCB in their effluent is a 'legacy' substance (i.e. a residue from past manufacturing activities during the 50's), Thompson Quentin (1992) refers to several data sources to argue that when biphenyl is discharged in the wastewater effluent, there is a chance that this converts to PCB if a chlorination step is applied during wastewater treatment. Therefore PCB may be a sign of biphenyl being released to the wastewater effluent, although it is likely that biphenyl is either degraded or ends up in the sludge due to its observed biodegradability and its high octanol/water partition coefficient (USEPA, 1995; Environment Health Canada, 2013). However, there is no data to support this and it is therefore uncertain whether this process (formation of PCB) will take place. Furthermore, the inclusion of chlorination in wastewater treatment practices has decreased over the last two decades due to the environmental problems the by-products formed cause.

#### 5.3.1 Main sources of release

According to several literature sources (Environment Health Canada, 2013; WHO, 1999; USEPA, 1995; Thompson Quentin, 1992), release of biphenyl into the environment may occur from the following sources:

- Industrial processing emissions from manufacture of chemical intermediates and of final products containing biphenyl.
- Industrial emissions (release as a fume) during its use (e.g. mainly its use as heat transfer fluid, and in the wastewater effluent when leaking of heat exchangers).
- Released in the wastewater effluent from textile mills that use it as a dye carrier.
- Converted into PCB from wastewater chlorination (from treatment of industrial effluent containing biphenyl) – although this process (formation of PCB) seems to be more theoretical.
- Emissions from products used by consumers, mostly wood articles preserved with biphenyl-containing creosotes, fungicides, solvents and powder used in acrylic nails.
- Indirect emissions, mainly from combustion of fossil products and organic matter, such as motor vehicle exhaust, heating devices and cigarette smoke.
- Emissions from waste disposal, particularly in sewage sludge and hazardous waste (including contaminated packaging).

This means that most of the release of biphenyl into the environment will end up in industrial air fumes and in wastewater treatment systems which will likely lead biphenyl to the sludge if it does not undergo biodegradation. Furthermore, when biphenyl is produced locally in the EU, it will also end up in the air emissions of the factory or in the wastewater sludge. Finally, when released to air as part of indirect emissions or from final products, biphenyl is likely to remain in the atmosphere and degrade or eventually settle in dry deposits in water or soil (The Dow chemical company, 2009). Other emissions will be from hazardous waste and sewage sludge handling, which will not be in the form of biphenyl due to degradation and breakdown during the incineration and treatment process. Therefore, emissions from these sources are not expected to be hazardous as described earlier. Finally, biphenyl emissions from uncontrolled spills will be released to soil and sediments, which are expected to be minor in the EU.

Where industrial releases of biphenyl can be controlled (by cleansing of emissions), it is more difficult to control indirect releases of biphenyl from consumer articles and combustion processes. As biphenyl is used as a chemical intermediate or as a constituent in chemical preparations for industrial uses, the most interesting source of release of biphenyl is the indirect emissions from combustion processes. This area is therefore described in more details below.

### *Direct vs. indirect emissions*

No data was available to make a comparison between emissions from production and industrial use of biphenyl and indirect emissions from other sources. However, in a survey carried out by the National Pollutant Release Inventory in Canada, it was found that on-site releases of biphenyl as air emissions, i.e. emissions from manufacturing and industrial use of biphenyl, accounted for 93% of total biphenyl emissions of the country. The remaining emissions came from refining of petroleum and coal products (Environment Health Canada, 2013). The situation in Canada is similar to that in Denmark as both countries do not produce biphenyl but are users of the substance in a range of applications. Therefore it is expected that the relationship between industrial processing and indirect emissions is exceeded by industrial emissions.

### **Indirect releases of biphenyl from combustion processes**

Biphenyl is not only released from its manufacturing and use. According to Environment Health Canada (2013) and WHO (1999), it is also released to the environment as an indirect emission from combustion processes such as:

- Mineral oil and coal combustion
- Power generation, specially, when using primarily coal as fuel (a reference emission of 1.24 mg biphenyl/kg burnt coal is presented in WHO (1999))
- Incineration of household waste
- Burning of agricultural wastes
- Incomplete combustion of fossil fuels in motor vehicles and of organic matter
- Burning of wood, for example, in residential heating
- Cigarette smoke

Other indirect emissions are related to the manufacture of fuels, such as high octane motor and aviation fuels and from foundries, where biphenyl is a by-product from the manufacturing process (Environment Health Canada, 2013).

Because biphenyl occurs naturally in coal tar, crude oil and natural gas, it can potentially be detected in all products derived from these substances (WHO, 1999). Furthermore, it can also be a by-product from their incomplete combustion, as mentioned above. A range of varying concentrations of biphenyl can be found in these fossil products, and some are presented by WHO (1999) as:

- Crude oil, up to 4 mg/g
- Natural gas, 3 to 42 g/m<sup>3</sup>
- Coal tar-derived creosotes, usually between 0.2 and 1.6%, but also up to 5% (it should, however, be noted that creosote is no longer allowed for use in creosote treated wood in Denmark)

Furthermore, biphenyl has also been identified in unused lubricating oil samples at a concentration of 1.5 mg/kg. This indicates its presence in the above cited fossil products derivatives.

This aspect of biphenyl – being released from combustion processes – is a general trend for PAHs. In contrast, biphenyl is not defined as being a PAH as its two benzene rings are not fused together. However, biphenyl is chemically similar to naphthalene (two benzene rings fused together), whereas biphenyl is two benzene rings linked together with a simple C-C bond. Naphthalene is considered to be the most simple PAH. The similar survey of naphthalene carried out for the Danish EPA (Poulsen et al., 2014) illustrated that the primary release of naphthalene to the environment and indoor air is due to release of naphthalene from different combustion processes. A similar conclusion seems valid for biphenyl as it is found in emissions from similar combustion processes as naphthalene. Literature from the US EPA<sup>46</sup> indicates that biphenyl may be released into the

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<sup>46</sup> <http://www.epa.gov/ttnchie1/ap42/cho1/final/co1so7.pdf>  
<http://www.epa.gov/ttnchie1/ap42/>

atmosphere during the burning of fossil fuels (coal). In their AP-42 programme “Compilation of Air Pollutant Emission Factors”, US EPA has listed biphenyl as a substance that is emitted during coal combustion. According to this US EPA reference from 1995, the emission factor of biphenyl ( $1.7 \times 10^{-6}$  lb/ton coal combusted) is around a factor of 10 lower compared to the emission factor of naphthalene in the same reference.

Projecting the emission value from the US (from 1995) on the Danish coal combustion in 2012, the result is an emission of biphenyl in Denmark of approximately 3.2 kg in 2012, i.e. small amounts. It should be emphasised that the emissions may be different (lower) today compared the used emission factor from almost 20 years ago.

## Biphenyl emission from burning coal

This example estimates the level of biphenyl emissions from coal burning facilities in Denmark in 2012. The following assumptions have been made:

- According to the Danish energy statistics approximately 100 million GJ coal was used in 2012 in Denmark (Energistyrelsen, 2013).
- The calorific value of coal is 24.23 GJ/tonne (Energistyrelsen, 2013).
- The measured US emission (1995) is used in the calculation, i.e.  $1.7 \times 10^{-6}$  lb/ton coal is used as the emission factor for biphenyl.
- 1 lb equals 0.453 kg.

The result is an emission of biphenyl from burning of coal in Denmark of **approximately 3.2 kg** in total for 2012.

### 5.3.2 Monitoring data

Available monitoring data regarding biphenyl in the environment is limited. This may be due to the fact that biphenyl seems to be readily biodegradable (except in sediments) and is not expected to bioaccumulate in organisms. However, during the time biphenyl exists in the environment, monitoring data has been identified from the EU, Canada and the USA. Available data in the EU and the USA is primarily from the 1980s, and this may be due to the fact that traces of biphenyl from PCB production during the 1970s were targeted during monitoring programs and that during that time the use of biphenyl in the heat-transfer market rose. More recent data for Canada has been retrieved by Environment Health Canada (2013), with a couple of extra comparative references for the USA. Data for the EU and the USA has been retrieved from measured concentrations, whilst for Canada it has been retrieved from both measured and predicted concentrations. However, in Denmark monitoring of biphenyl in waste water, in sludge and from industry has been part of the NOVANA programme (National Action Plan for the Aquatic Environment) for several years. More information is described in the following sections.

#### *The EU*

Biphenyl has been measured in ambient **air** in a city in Finland and two in Greece. In an industrialised city in Finland, biphenyl was measured in concentrations ranging from 1.7 to 26.2 ng/m<sup>3</sup> in 1985. In two Greek cities, however, all measured data was below the detection limit of 5 ng/m<sup>3</sup> in 1992 (WHO, 1999).

Eastman Newport (2014) is the only production site reporting average annual air emissions of biphenyl from all their production activities. The emissions lie in a very low range of 12.9 g/tonne of product (heat transfer fluids or other chemical products).

Biphenyl has also been measured in surface and ground **water**. In Germany, different measurements have been collected over a period of time in different points of surface water. In the German part of the Rhine River, measured concentrations declined from a maximum of 1,000 ng/L during the 70s, to levels below 500 ng/L in the mid-90s. Although measured concentrations have remained below 500 ng/L in most of the German tributaries, peak measured concentrations of 560 ng/L and 1600 ng/L were observed at the highly polluted Emscher tributary during 1993 and 1994 respectively, attributed to the vicinity of coking plants (WHO, 1999).

During 1986 to 1989, biphenyl was detected at concentrations between 10 and 100 ng/L in groundwater samples obtained near Zagreb (former Yugoslavia)(in the vicinity of a municipal landfill site). These measurements were about 10-fold higher than those detected from a heavily polluted river around the area in Zagreb, where the test was carried out in a depth of 720 meters. Concentrations of biphenyl between 2 and 17 ng/L have been measured in samples of **snow** and **rain** collected in Switzerland (WHO, 1999).

#### *Denmark*

In Denmark monitoring of biphenyl in waste water, in sludge and from industry has been part of the NOVANA programme (National Action Plan for the Aquatic Environment) for several years. The report from DMU (2006) that summarises on the NOVANA programme for the years 1998-2003 shows the following monitoring data for biphenyl:

- Concentration in **water** at point of discharge from sewage treatment plant
  - Average value: 0.005 µg/l
  - The 95% percentile value: 0.01 µg/l
  - For comparison the limit value for surface waters is 1 µg/l
  - **The total emission of biphenyl to water** at the point of discharge from sewage treatment plant was **estimated to be 3.5 kg/year** in the years from 1998-2003.
- Concentration in **sludge**:
  - Average value: 235 µg/kg dry matter
  - The 95% percentile value: 1022 µg/kg dry matter
- **The total industrial emission of biphenyl was estimated to be 0.3 kg/year** in the years from 2001-2003.

#### *Canada*

Although concentrations of biphenyl are expected to be found throughout Canada given its numerous natural and anthropogenic sources (i.e. from direct and indirect sources), no recent monitoring data for biphenyl concentrations has been measured in Canadian air, water, soil and sediment (Environment Health Canada, 2013).

Because most of the measured data is about 15 to 20 years old, Predicted Environmental Concentrations (PECs) were estimated by models using data from the National Pollutant Release Inventory (NPRI) for 2006 and 2008 in order to fill the data gaps. Conservative estimates of local exposure in the vicinity of potential sources of release to **air** and **water** were determined. For **sediment**, the exposure scenario assumes that sediment pore water has the same biphenyl concentration as surface water. For **soil**, a biosolids application scenario was developed (Environment Health Canada, 2013). Measured and modelled data are summarised in Table 9. In these cases most of the exposure to air was modelled from on-going fugitive emissions (to air) from the use of biphenyl as dye carrier in textiles. From the same source, wastewater emissions were identified as the most important exposure to water and subsequently to sediment and soil.

Media	Location	Sampling / Reporting (NRPI) period	Concentration	Reference
Air	Ottawa, Ontario	2003 (measured)	0.2 µg/m <sup>3</sup>	Zhu et al. (2005)
	Port Stanley, Point Petre and Dorset, Ontario	1991 (measured)	0.9 ng/m <sup>3</sup> 0.1 ng/m <sup>3</sup> 2.1 ng/m <sup>3</sup>	Foster et al. (1991)
	Alert, Northern Ellesmere Island, Canada	1988 (measured)	0.49–2.4 ng/m <sup>3</sup> 1.2 ng/m <sup>3</sup>	Patton et al. (1991)
	Along the Niagara river, New York State	1982 – 1983 (measured)	0.49–9.6 ng/m <sup>3</sup> (particulate) 0.69–22 ng/m <sup>3</sup> (vapour)	Hoff and Chan (1987)
	Kingston, Ontario	2008 (modelled)	265 µg/m <sup>3</sup> (1h average) 53.33 µg/m <sup>3</sup> (90d average)	Environment Canada (2010a)
Water	Toronto drinking water	2008 (measured)	< 0.6 µg/L	City of Toronto (2009)
	Mississauga, Ontario	2008 (modelled)	1.34 µg/L	Environment Health Canada (2013)
Sediment	St. Clair River, Ontario	1989 – 1990 (measured)	390 µg/kg	OME (1991)
	Artificial islands in Beaufort Sea	1981 – 1982 (measured)	60 µg/kg (dry weight)	Fowler and Hope (1984)
	Mississauga, Ontario	2008 (modelled)	344 µg/kg (dry weight)	Environment Health Canada (2013)
Soil	Mississauga, Ontario	2006 (modelled)	0.16 mg/kg	Environment Health Canada (2013)

**TABLE 9**  
MEASURED AND MODELLED CONCENTRATIONS OF BIPHENYL IN CANADIAN ENVIRONMENT (ENVIRONMENT HEALTH CANADA, 2013)

#### USA

Measured concentrations of biphenyl in air, sediment and soil in the USA have been retrieved from Environment Health Canada (2013) and WHO (1999). The results reported are from comparative



studies done from measured or modelled results in the EU and Canada, which are discussed in the previous paragraphs.

The highest measured concentration of biphenyl in ambient **air** in other countries than Canada has been retrieved from the USA by Environment Health Canada (2013), ranging from 36 to 220 ng/m<sup>3</sup> in Glendora, California, in August 1986. However, two other US cities reported mean values of only 12-119 ng/m<sup>3</sup> and 30 ng/m<sup>3</sup>, during the winter of 1988-89. An important source of release of biphenyl to the air is residential wood combustion, particularly in cold climates, which accounted for 12,151 kg release of biphenyl in 2004 in the states of Illinois, Minnesota, Ontario and Wisconsin, even though a measured concentration of only 2.1 ng/m<sup>3</sup> was the highest detected (Environment Health Canada, 2013).

The maximum reported measured concentration of biphenyl in **sediment**, in other countries than Canada, reported by Environment Health Canada (2013), is 17 mg/kg in Buffalo, New York. Other values were retrieved from a US database (by the same reference) which indicate, that from 4,100 samples only 24 had a biphenyl measured concentration higher than 1 mg/kg, and only one sample showed a concentration higher than 10 mg/kg. Most of the other samples ranged from non-detected (detection limit not stated) to 410 µg/kg.

WHO (1999) reports the maximum measured concentration of biphenyl in **soil** from a site near a wastewater pit from oil production in New Mexico, with a concentration of 13 g/kg. Environment Health Canada (2013) reports a range of measured data from non-detectable to 10 mg/kg from coal-tar contaminated soils, landfills, contaminated sites and from oil and gas wastewater disposal areas. The majority of these data range between 5 to 900 µg/kg.

Biphenyl has been found in **fish** collected from mineral oil contaminated water. Concentrations in liver samples were <25 g/kg dry weight, which is below the detection limit (WHO, 1999).

#### 5.4 Environmental impact

According to what is discussed in section 5.2, biphenyl is expected to be released primarily to air and water, but part of what is emitted to water will either volatilise and therefore relocate to ambient air, or end up in sediments and soil. This means that, when emitted to air and soil from industrial, usage, waste disposal and indirect sources, it will tend to remain in these compartments, and when released to water it will either be volatilised or eventually adsorbed to sewage sludge and soil.

Since biphenyl has a moderate potential for bioaccumulation, it has been identified in biota, particularly in aquatic species. Biphenyl is expected to biodegrade rather quickly, in a matter of days or weeks, particularly by aerobic microorganisms but also anaerobic. Biodegradation decreases in pure waters, and in deeper levels of dry soil. According to the persistence criteria, biphenyl is regarded as persistent in water and sediment. However, the persistence data in water is ambiguous, i.e. most data on the persistence in water suggests that biphenyl is not persistent, whereas other data suggests otherwise.

It can thus be concluded, that in spite of the fact that biphenyl may be discharged by many sources and in high volumes, it does not present a risk to the environment, if released in an environment where microorganisms are available to exert biodegradation. If released to more pristine environments or dry soil, it can reach organisms and pose a risk of toxicity, especially aquatic organisms. Especially if released to sediment, where biphenyl seems to be most persistent, it may pose an environmental risk.

The determination of risks quotients (RQ = PEC/PNEC) was established by WHO (1999) and Environment Health Canada (2013). The risk quotients are presented below for the different

environmental compartments as calculated by Environment Health Canada (2013) – mainly based on Canadian data. However, the Danish monitoring data from the NOVANA programme is in the same order of magnitude as the Canadian data presented in Table 9. For this reason the conclusion will be valid for the Danish data as well.

A RQ above 1 indicates problematic environmental impacts. According to WHO (1999), data on effect concentration for terrestrial organisms as well as exposure levels in air and soil are insufficient for risk characterisation for terrestrial organisms, thus a risk quotient was only estimated for aquatic organisms based on German data. Though, Environment Health Canada (2013) established risk quotients for air, water, sediments and soils. The results from both studies are presented below. From the values it can be seen that all risk quotients (RQ) are below 1, which means that biphenyl is not expected to result in any problematic environmental impacts:

#### **AIR**

- $RQ = 0.11$  on mouse (inhalation), with a PEC of 0.053 mg/m<sup>3</sup> on a 90-d average, and a PNEC of 0.5 mg/m<sup>3</sup>, based on a critical toxicity value (CTV) of 5 mg/m<sup>3</sup> – in Canada

#### **WATER**

- $RQ = 0.058$  on *daphnia magna*, with a PEC of 0.00134 mg/L, and a PNEC of 0.023 mg/L, based on a critical toxicity value (CTV) of 0.23 mg/L – in Canada
- $RQ \leq 0.29$  on *daphnia magna*, with a PEC of 0.0064 g/L, and a PNEC of 1.7 g/L, based on a LC<sub>50</sub> of 170 g/L – in Germany

#### **SEDIMENT**

- $RQ = 0.045$  on mussel, with a PEC of 0.001343 mg/L, and a PNEC of 0.03 mg/L, based on a critical toxicity value (CTV) of 0.3 mg/L – in Canada

#### **SOIL**

- $RQ = 0.09$  on earthworm, with a PEC of 0.16 mg/kg, and a PNEC of 1.78 mg/kg, based on a critical toxicity value (CTV) of 178 mg/kg – in Canada
- $RQ = 0.03$  on lettuce, with a PEC of 0.16 mg/kg, and a PNEC of 5.4 mg/kg dw, based on a critical toxicity value (CTV) of 54 mg/kg dw – in Canada

### **5.5 Summary and conclusions**

The toxicity data for biphenyl suggests that biphenyl has a high acute and chronic toxicity to aquatic organisms. However, as biphenyl presents a low solubility in water and a high volatility, the nominal concentrations often used in toxicity tests may not correspond to the effective concentrations. Biphenyl does have a harmonised classification with respect to environmental effects as '*Aquatic Acute 1, H400 (very toxic to aquatic life)*', and as '*Aquatic Chronic 1, H410 (very toxic to aquatic life with long lasting effects)*'.

#### Environmental fate of biphenyl

Biphenyl is considered to stay in the medium where it is released, particularly in the air and soil compartments due to its physicochemical properties. When released to water and moist sediments, it tends to volatilise until it gets in contact with solids where it will get adsorbed, particularly when it reaches dry soil and increased levels of depth. Once biphenyl is retained in the released compartment, it biodegrades rather quickly in a matter of a few days to a few weeks. The degradation is done by microorganisms existing in aerobic and anaerobic conditions, happening the fastest by aerobic microorganisms and being converted to 2,3-dihydroxybiphenyl. Biphenyl has a moderate potential to bioaccumulate, but its availability is reduced due to its tendency to be rapidly biodegraded. Overall, biphenyl can probably not be considered to be a PBT substance. The EU persistence criterion and toxic criterion could be met (because of ambiguous results on the genotoxicity potential of biphenyl), but biphenyl is probably not bioaccumulative by use of the data presented in this report. Portugal evaluates biphenyl (CoRAP, 2012) for its suspected PBT properties at the moment, but this evaluation is not finalised so the conclusions from Portugal cannot be included in this report.

The main sources of release for biphenyl are from industrial processing emissions (mainly to air and to the wastewater effluent) from waste disposal (mainly to sediment and soil, in the case the sewage sludge is applied to land) and from combustion processes where biphenyl is formed (mainly to air and to the wastewater effluent). When waste and sewage sludge contaminated with biphenyl are properly disposed in incineration, as suggested by ECHA RSD (2014) and done in Denmark, biphenyl breaks down to carbon dioxide and water. The same applies when disposed in cement kilns, as is the current practice by the only producer of biphenyl in the EU.

Once released in water, biphenyl is either volatilised or adsorbed. When adsorbed it is biodegraded in a matter of a few days or weeks, except in sediment where the half-life is considerably longer. However, some data indicates a longer half-life in water. For this reason biphenyl may be classified as persistent, but is probably not bioaccumulative. Once released in sediment and soil, it will also undergo biodegradation, with reduced biodegradation when it reaches deep levels of soil. However, this is unlikely to occur. Once released in the ambient air, it will eventually break down by reactions with hydroxyl radicals, with small fractions being transported over moderate distances and settling as dry deposits to water and land.

#### *The fate of emissions from final products (and indirect emissions)*

Emissions from final products and indirect emissions will be mainly to air, with the exception of emissions to water or soil from biphenyl residues in articles in contact with these compartments. If the substance ends up in the soil, e.g. from application of sludge to land or from uncontrolled spills, soil microorganisms may metabolise biphenyl to the more polar hydroxyl biphenyls and dihydroxy biphenyls which may subsequently leach into groundwater – however, this does not seem to present a problem as at least some dihydroxy biphenyls do not have an environmental classification. The hydroxyl radicals are common by-products of biodegradation of organic matter and they are expected to be highly reactive and thereby convert to other chemicals. However, no information on their fate when being bonded to biphenyl was found in the literature.

#### *Direct vs. indirect emissions*

A Canadian survey (Environment Health Canada, 2013) has showed that emissions from manufacturing and industrial use of biphenyl account for 93% of total biphenyl emissions of the country. The remaining emissions came from refining of petroleum and coal products. It is assumed that a similar situation will be valid for Denmark, as both countries do not produce biphenyl but are users of the substance.

#### *Monitoring data*

Available international monitoring data from biphenyl is limited (and 15-20 years old). However, in Denmark monitoring of biphenyl in waste water, in sludge and from industry has been part of the NOVANA programme (National Action Plan for the Aquatic Environment) for several years. This may be due to the fact that the substance undergoes rapid degradation or simply because there was more focus on tracing biphenyl during the 80s and 90s, when the use of the substance in heat transfer applications rose. In Canada, it has been possible to calculate Predicted Environmental Concentrations (PEC) to fill in data gaps and establish risk quotients for different organisms in air, water, sediment and soil. All reported risk quotients (RQ) were below 1, indicating no negative effects on the environment.

Results from monitoring data and the subsequent calculated environmental impact of biphenyl show that biphenyl does not present a risk to the environment. In spite of its high usage and its observed toxicity for aquatic life, biphenyl does not enter the environment in quantities or concentrations which pose an immediate or long-term harmful effect.

# 6. Human health effects

The following sections describe the human health effects of biphenyl. The information presented is primarily derived from Environment Health Canada (2013), the USEPA (2013) and the Danish EPA (2013a) – three recent and internationally recognized sources of information. Where relevant, data is supplemented with information from WHO (1999), US EPA (1984) and ECHA Registered Substance Database (2014).

## 6.1 Human health hazard

### 6.1.1 Classification

Biphenyl has a harmonised classification according to CLP (as also presented in Table 4) and is classified as being a skin and eye irritant (Skin Irrit.2, H315 “Causes skin irritation” and Eye Irrit.2, H319 “Causes serious eye irritation”). Furthermore, biphenyl is classified as having a specific target organ toxicity (here the respiratory system) at single exposure (STOT SE3, H335 “May cause respiratory irritation”).

### 6.1.2 Absorption, distribution, metabolism and excretion

Animal studies indicate that biphenyl is rapidly and readily absorbed following oral exposure. Biphenyl can also be absorbed through dermal exposure (indicated by an in vitro study – short term (10 min) exposure rate: 258.3 ug equivalents/cm<sup>2</sup>/hour). No data on absorption through inhalation was available. Generally, absorbed biphenyl is not stored in tissues and is rapidly excreted – primarily through the urine (in the form of conjugated hydroxylated metabolites) (USEPA, 2013; Danish EPA, 2013a).

### 6.1.3 Acute toxicity

Below the lowest effect levels (related to acute toxicity) are presented. The data reported is from Environment Health Canada (2013).

- Lowest oral LD<sub>50</sub>: >1900 mg/kg bw (rat and mice)
- Lowest inhalation LC<sub>50</sub>: > 275 mg/m<sup>3</sup> (rat)

None of the reported oral studies regarding acute toxicity in ECHA Registered Substance Database (2014) was assignable, primarily due to lack of sufficient information. The same goes for the reported studies regarding inhalation. Two studies regarding dermal acute toxicity are reported in ECHA. However, again none of these is assignable (due to lack of sufficient data) – and is thus not presented in this report.

In workers, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation as well as toxic effects on the liver, kidneys and central and peripheral nervous systems. Symptoms include headache, gastrointestinal pain, nausea, indigestion, numbness and aching of limbs, as well as general fatigue. Biphenyl is judged (based on rat, mice and rabbit studies) to be moderate acute toxic by ingestion and low to moderate acute toxic by dermal exposure (US EPA, Hazard summary on biphenyl, 2000).

#### 6.1.4 Skin and eye irritation

According to its classification, biphenyl causes skin irritation as well as eye irritation. In workers, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation (US EPA, Hazard summary on biphenyl, 2000). The respiratory irritation threshold to biphenyl was reported to be 7.5 mg/m<sup>3</sup> (no information on exposure conditions reported) (Danish EPA, 2013a).

Reported studies regarding skin irritation in ECHA Registered Substance Database (2014) are not assignable, primarily due to lack of sufficient data. That goes for studies regarding eye irritation as well. However, one study regarding skin sensitisation is reliable and reports that biphenyl did not have skin sensitisation potential (towards guinea pigs) under the test conditions.

#### 6.1.5 Repeated dose toxicity

Lowest effect levels of biphenyl related to short-term repeated dose toxicity (based on data from Environmental Health Canada, 2013) are presented below:

- Lowest oral LOEL: *50 mg/kg-bw per day* (rat).
  - o Effects: increased relative kidney weights, polycystic renal change, increased urine volume and specific gravity (21 day study).
- Lowest dermal LOEL: *500 mg/kg-bw per day* (rabbit).
  - o Effects: decreased body weight, histopathological effects (changes in tissue structure) (28 day study).
- Lowest inhalation NOEC: *160 mg/m<sup>3</sup>* (mice).
  - o No effects observed.

Four studies regarding repeated dose toxicity (oral) are reported reliable (however with restrictions) in ECHA Registered Substance Database (2014). Of these the lowest reported oral LOEL is 1500 ppm (nominal in the diet) where an increase in simple transitional cell hyperplasia and deposit of hemosiderin was observed.

Regarding lowest dermal LOEL, none of the studies in ECHA was assignable. This goes for studies regarding inhalation as well. Thus, the above mentioned values reported by Environmental Health Canada (2013) are the lowest reported (valid) data. This data represents relatively high values, indicating that there is no significant cause for concern in terms of repeated dose toxicity of biphenyl.

For humans only few data on repeated dose toxicity has been reported and this data is from the 1960's: Occupational exposure by inhalation to biphenyl in impregnating paper production caused irritation of the respiratory tract and central and peripheral nervous system depression. Serious liver atrophy and fatty changes were also reported following inhalation, dermal and/or oral exposure of biphenyl, although mixed exposure with tri- and tetrachloroethylene could not be excluded (Danish EPA, 2013a).

#### 6.1.6 Chronic toxicity and carcinogenicity

Lowest effect levels of biphenyl related to chronic toxicity/carcinogenicity (based on data from Environmental Health Canada, 2013) are presented below:

- Lowest oral non-neoplastic LOEL: *25 mg/kg bw per day* (rat)

Three studies regarding carcinogenicity have been found reliable (however with restrictions) in ECHA Registered Substance Database (2014). The three studies are shortly described below:

- Study 1: After a single subcutaneous injection of biphenyl, a statistically significant (compared to controls) increase of the total number of tumours was observed. However, this is not relevant for the human exposure evaluation. No significant increase (compared

to controls) in number of tumours was observed after oral exposure to biphenyl. Doses: 46.4 mg/kg (injected) and 215 - 517 ppm (oral).

- Study 2: The 2-year oral administration of a biphenyl-containing diet produced dose-related increases in both benign and malignant hepatocellular tumours and pre-neoplastic liver lesions in female mice, together with non-neoplastic kidney lesions in both male and female mice. Species and sex differences were recognized in development of the biphenyl-induced carcinogenicity found in this study. Doses ranging from 667 ppm – 6,000 ppm.
- Study 3: Bladder tumours were induced in association with calculi formation and hematuria in the 4500 ppm biphenyl-exposed male rats, together with pre-neoplastic, regenerative lesions in the urinary system. No bladder tumours were identified in female rats.

None of the studies reported in ECHA presents a lower oral LOEL value than the value reported by Environmental Health Canada (2013). Information regarding the toxicological effects of biphenyl following chronic inhalation or dermal exposure were not identified (US EPA, Hazard summary on biphenyl, 2000).

The primary effect (related to chronic toxicity) seen in animal studies has been kidney effects which have been observed in rats chronically exposed to biphenyl by ingestion. Chronic exposure in humans is characterized mostly by central nervous system symptoms, such as fatigue, headache, tremor, insomnia, sensory impairment and mood changes. However, such symptoms are rare (US EPA, Hazard summary on biphenyl, 2000).

The Danish EPA (2013a) reports that no evidence of carcinogenicity was found in a case study of occupational exposure to biphenyl over 10 years (in the 1970's).

All in all, US EPA, Hazard summary on biphenyl (2000) concludes that no data on the carcinogenic effects of biphenyl in humans is available. The US EPA considers available studies on carcinogenicity in mice and rats to be inadequate. One study of mice orally exposed to biphenyl did not result in any increased incidence of tumours. A second study found tumours in treated and control rats but their occurrence was not thought to be related to biphenyl administration. The US EPA has classified biphenyl as a Group D, not classifiable as to human carcinogenicity.

#### **6.1.7 Reproductive and developmental toxicity**

Lowest effect levels of biphenyl related to developmental and reproductive toxicity (based on data from Environmental Health Canada, 2013) are presented below:

##### *Developmental:*

- Lowest oral LOEL: 500 mg/kg-bw per day (rats).
  - o Effects: fetal toxicity, including non-significant increases in foetuses with missing or non-ossified sternebrae, maternal toxicity at 1000 mg/kg-bw per day (gestation days 6-15).

One reliable (with restrictions) study regarding developmental toxicity is reported in ECHA Registered Substance Database (2014). According to this study (rats, oral), a LOEL of 1000 mg/kg bw/day was identified (10% mortality rate in animals does with 1000 mg/kg bw/day). Thus, the data from Environmental Health Canada (2013) reports the lowest LOEL.

##### *Reproductive:*

- Lowest oral LOEL: 750 mg/kg-bw per day (rat).
  - o Effects: decreased fertility, litter size and growth rate (Environmental Health Canada, 2013).

No reliable studies regarding reproductive toxicity are reported in ECHA Registered Substance Database (2014).

No information on the reproductive or developmental effects of biphenyl in humans is available. Limited data suggests that biphenyl does not cause teratogenic effects (birth effects) in animals and some evidence (not significant) of fetotoxicity has been observed in rats exposed to high levels of biphenyl via gavage (experimentally placing the chemical in the stomach) (US EPA, Hazard summary on biphenyl, 2000).

#### **6.1.8 Genotoxicity**

Lowest effect levels of biphenyl related to genotoxicity (based on data from Environmental Health Canada, 2013) are presented below:

- Evidence of chromosomal aberration in human lymphocytes following 24 hour of 50 or 70 ug/ml of exposure to biphenyl. Though, no change observed after 48 hour (in vitro).
- Evidence of chromosomal aberration in hamster cells, with activation (in vitro).
- Evidence of DNA damage in L5178Y cells, with activation (in vitro).
- Oral dose of biphenyl (100 mg/kg) in mice induced DNA damage in colon. DNA damage in stomach, liver, kidney, bladder, lung, brain and bone marrow reported 24 hour following greater than or equal to 1000 mg/kg bw exposure (in vivo).

Three reliable (no. 2 and 3 with restrictions) studies regarding in vivo genotoxicity are reported in ECHA Registered Substance Database (2014). The three studies are shortly described below:

- Study 1: Biphenyl did not induce significant increase in the frequencies of micronucleated bone marrow polychromatic erythrocytes when given as a single oral dose (ranging from 0-800 mg/kg bw/day) on two consecutive days to mice. Hence, negative result regarding genotoxicity.
- Study 2: Under conditions of this assay the test substance showed statistically significant DNA damage in all the organs studied 24 hours after the administration (of 2000 mg/kg). Increased migration was also observed in lung DNA after 8 hours. It is described that this study suffers from method deficiencies and lack of controls. It is concluded that the results are ambiguous.
- Study 3: The cytogenetic effects of biphenyl were determined on bone marrow cells of rats exposed to atmospheres containing 0, 10 and 50 ppm of the test material for 30 days. No significant difference was found on the aberration rate of metaphase chromosome of treated and control animals.

As indicated above, the investigations of the genotoxicity potential of biphenyl have provided mixed results. Danish EPA (2013a) reports on several genotoxicity studies (most of them negative, but some positive as indicated above). The Danish EPA concludes that the weight of evidence from the available studies indicates that biphenyl is not a mutagen. However, study 2 as listed above is not included in the report by the Danish EPA (2013a). Thus it cannot be ruled out that biphenyl has genotoxic effects.

#### **6.1.9 Immunotoxicity and neurotoxicity**

EPA (2013) reports on a 2-year oral bioassay in rats and mice, which included daily observations for clinical signs and histopathological examination of nervous system tissues. They found that no effects on the nervous system.

#### **6.1.10 Endocrine disruption and combination effects**

No information regarding endocrine disruption and combination effects has been identified.

#### **6.1.11 Critical effect and tolerable daily intake**

The critical effect of biphenyl exposure has been reported as development of tumours in the urinary bladder (rats) and liver (mice) following a long-term dietary exposure. An US EPA draft assessment on biphenyl was published in 2011. According to this, data is insufficient to establish a mode of action for the liver tumours in mice and it is thus assumed that they are relevant for humans as well. However, no human data concerning occupational exposure to biphenyl suggests that liver tumours are not a relevant human effect (Environment Health Canada, 2013). Based on this information the Danish EPA (2013a) concludes that the critical effect in humans following exposure to biphenyl by inhalation is considered to be effects observed in the respiratory tract and the lungs.

According to US EPA (1984), an acceptable daily intake (ADI) for biphenyl is 0.05 mg/kg bw/day for oral exposure. ADI is defined as the amount of a chemical to which humans can be exposed on a daily basis over an extended period of time (usually a lifetime) without suffering a deleterious effect.

#### **6.1.12 DNEL values**

According to ECHA Registered Substance Database (2014), the following DNEL values are reported:

- Workers (inhalation): DNEL of 11.17 mg/m<sup>3</sup>
- Workers (dermal): DNEL of 63 mg/kg bw/day
- General population (inhalation): DNEL of 3.3 mg/m<sup>3</sup>
- General population (dermal): DNEL of 38 mg/kg bw/day
- General population (oral): DNEL of 1.9 mg/kg bw/day

### **6.2 Human exposure and health impact**

Environment Health Canada (2013) has calculated the estimated daily intake of biphenyl for the general population in Canada. According to their calculations the major contributor to the indirect biphenyl exposure is indoor air, which causes about 94% of the total indirect exposure to biphenyl for both children and adults. Drinking water accounts for 2.8% and 3.6% for children and adults respectively, and food and beverages together with ambient air for the rest of the indirect exposure to biphenyl.

It is not estimated in the report (Environment Health Canada, 2013) or in other reports whether direct exposure or indirect exposure accounts for the largest biphenyl exposure. However, for the general population there is no doubt that the indirect exposure will be the highest exposure as the use of biphenyl in consumer products is very limited. For workers working with biphenyl the situation may, however, be the opposite.

#### **6.2.1 Direct exposure**

##### **6.2.1.1 Consumers**

As described in section 3, biphenyl is found both in nature and from anthropogenic sources; it occurs naturally in coal tar and natural gas (Environment Health Canada, 2013). During the later years the following uses have emerged:

- **As final product:**
  - Constituent in heat transfer fluids
  - Dyestuff carrier for textiles
  - Solvent in pharmaceutical production
  - Dyestuff carrier for copying paper
  - Fungicide and pesticide for plant disease control
  - Preservative for wood
  - Preservative for citrus fruits (as fungistat, which has been recently restricted in the US and the EU)



- **As an intermediate:**

- In the production of emulsifiers
- In the production of leather tanning agents
- In the production of optical brighteners
- In the production of crop protection products
- Precursors in the manufacture of benzidine
- Auxiliaries for plastics, including in the preparation of flame retardants
- Thickener in carriers for printing

Regarding direct exposure to ‘final products’ in which biphenyl is an ingredient, it is quite difficult to estimate the level of direct exposure, as no studies regarding exposure of biphenyl to humans, by use of the products (mentioned above) exist.

However, below some considerations regarding the potential human health impact of the major uses of biphenyl are described.

#### ***Content of biphenyl in heat transfer fluids – potential health impacts***

According to the survey performed in this project, biphenyl is found to be present in heat transfer fluids (in concentrations up to 27%). However, of the 34 identified heat transfer fluids only 4 contained biphenyl. Furthermore, heat transfer fluids are primarily used in closed piping-system, thus the exposure of biphenyl to humans is judged to be minor and of little importance – even though the amount of biphenyl may be significant. Yet, as described in section 5, biphenyl may be released as a fume during its use as a heat transfer fluid. This may give cause to concern regarding the working environment. In the case of leaking from the heat exchangers, biphenyl may also end up in the waste water effluent, however as long as the waste water is treated properly it should not give cause to concern.

#### ***Content of biphenyl in coal tar – potential health impacts***

According to Environmental Health Canada (2013) coal tar-based driveway sealants may be a source of consumer exposure to biphenyl. Coal tar-based pavement sealants are mainly applied outdoors by consumers using rollers. However, taking into account the physical and chemical properties of biphenyl and the fact, that it is likely present at a very low concentration, the use of pavement sealants would not significantly elevate the biphenyl concentration in outdoor air.

#### ***Biphenyl used as intermediate – potential health impacts***

Generally, there is no cause for concern – in terms of health impacts – when biphenyl is used as intermediate. The reason is that biphenyl is converted to other substances, and thus is not able to cause problems. However, there may be situations where companies do not handle the chemical properly (according to regulation regarding the working environment) – and thus cause situations where workers are exposed to biphenyl. If this is the case, biphenyl can cause health impacts such as eye and skin irritation as well as toxic effects on the liver, kidneys and central and peripheral nervous systems. Symptoms include headache, gastrointestinal pain, nausea, indigestion, numbness and aching of limbs, as well as general fatigue (US EPA, Hazard summary on biphenyl, 2000). There is, however, the possibility of exposure due to potential content of biphenyl impurities in the finished chemical product. However, the risk associated to this is judged to be minor and insignificant.

#### **6.2.1.2 Occupational exposure**

Occupational exposure of workers to benzyl chloride may occur:

- In workplaces where benzyl chloride is manufactured
- In workplaces where benzyl chloride is used as an intermediate chemical to produce other chemicals
- In workplaces where biphenyl is used as a heat transfer fluid (and fumes are allowed to be emitted).

As mentioned previously, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation as well as toxic effects on the liver, kidneys and central and peripheral nervous systems in workers. Symptoms include headache, gastrointestinal pain, nausea, indigestion, numbness and aching of limbs, as well as general fatigue (US EPA, Hazard summary on biphenyl, 2000).

## **6.2.2 Indirect exposure**

### **6.2.2.1 Air**

Although exposure to biphenyl may occur from ingestion of contaminated food or water, the most likely route of exposure is expected to be inhalation of air. The upper-bounding estimate of daily intake for the general Canadian population ranges from 0.32 ug/kg bw/day for adults (above 60 years of age) to 0.95 ug/kg bw/day for children aged ½-4 years – with indoor air as the major source of exposure (Environmental Health Canada, 2013).

Environmental Health Canada (2013) reports a few studies that measure the level of biphenyl in indoor and outdoor air. These are shortly described below:

- Study 1: Indoor concentrations of about 1 ug/m<sup>3</sup> (1991, 757 Canadian homes). However, this study suffers from lack of concurrent measurements of standard samples.
- Study 2: Indoor air concentration of 0.05 ug/m<sup>3</sup> (10 child day care centres, spring 1997, North Carolina).
- Study 3: Indoor concentration at an Italian Airport revealed concentrations from 0.02 – 1.6 ug/m<sup>3</sup>, with an average concentration of 0.35 ug/m<sup>3</sup>.
- Study 4: Indoor concentrations up to 1.7 ug/m<sup>3</sup> with an average 0.2 ug/m<sup>3</sup> (74 randomly selected residences in Ottawa, Ontario, winter 2002). Outdoor concentrations ranged from not detected to 0.2 ug/m<sup>3</sup> with an average of 0.05 ug/m<sup>3</sup>.
- Study 5: Outdoor air samples ranging from 0.003 – 0.016 ug/m<sup>3</sup> were found at 10 child day care centres, spring 1997, North Carolina. Mean value of 0.009 ug/m<sup>3</sup>.
- Study 6: Outdoor air samples from Niagara River in Southern Ontario (September 1982) revealed a mean concentration of 0.007 ug/m<sup>3</sup>, whereas a slightly higher level of 0.02 ug/m<sup>3</sup> was detected in samples collected in January 1983.

Thus, the highest reported indoor air concentration of biphenyl is 1.7 ug/m<sup>3</sup>, and the highest reported outdoor concentration is 0.02 ug/m<sup>3</sup>. In comparison, the limit (contribution) value for companies in Denmark (regarding emission of biphenyl to the air (i.e. B-Values)) is 0.005 mg/m<sup>3</sup> – thus there is a large safety margin.

Levels in indoor air are likely caused by cigarette smoke and emissions from residential heating devices (Environmental Health Canada, 2013).

Finally, it should be mentioned, that biphenyl is released to the air through combustion processes – for instance, incomplete combustion of fossil fuels. As described in the similar survey of naphthalene, the primary cause for release of naphthalene to the air is from different combustion processes. This may also be true for biphenyl. Yet, the emission factor of biphenyl is a factor of 10 lower, compared to naphthalen. The emission factor is 1.7 x 10<sup>-6</sup> lb/ton coal combusted. If one gathered data regarding the total combustion of fossil fuels in Denmark, it would be possible to estimate a figure of released amount of biphenyl – however, it would not be possible to evaluate whether this would be a cause for concern in Denmark.

### **6.2.2.2 Soil**

According to Environmental Health Canada (2013) no monitoring data on biphenyl in soil has been identified.

### **6.2.2.3 Drinking water**

Biphenyl was analyzed in drinking water samples from plants and distribution sites in the City of Toronto collected between January and December 2008 and in all samples biphenyl was detected at or below the detection limit of 0.6 µg/L (Environmental Health Canada, 2013). In comparison the water quality requirement for biphenyl in the EU is 1 µg/l (according to GUIDANCE No 9810 of 31.5.2006 on connection of industrial discharge water to public sewage treatment plants).

According to WHO (1995), care should be taken to prevent biphenyl from reaching drains and watercourses in the event of spillage, due to its toxicity to aquatic organisms.

### **6.2.2.4 Food**

According to Environmental Health Canada (2013), biphenyl has been reported as being used as a fungistat in packaging for citrus fruits. In 1988, 32% of tested citrus samples in the UK contained residues of biphenyl – however, over the period from 1988 to 1997, frequency and percent occurrence decreased steadily and in 1997, no residues were detected in test samples. In Malaysia, biphenyl was found in imported apples and imported oranges at concentration ranges of 0.16 to 0.71 µg/g and 0.35 to 1.65 µg/g respectively. In a total diet study in the United States from 1991–1993 through to 2003–2004, approximately 280 foods were sampled and analyzed. Traces of biphenyl were detected in a few food items including bread, cereals, lettuce, cabbage, English muffin, baby food biscuit, baby food cookies, baby food oatmeal and zwieback toast. Generally, only one out of the 44 analyzed samples of each food type contained detectable traces of biphenyl except for baby food oatmeal, in which biphenyl was detected in one out of the four analyzed samples.

Dietary intake was lowest in the 20-59 and the 60+ age groups with an intake estimate of 0.003 µg/kg-bw per day and highest in 0-0.5-year age group at 0.013 µg/kg-bw per day. English muffins were the primary contributors to dietary intake estimates. As mentioned previously, the acceptable daily intake of biphenyl, according to US EPA (1984), is 0.05 mg/kg bw/day – thus there is a very large safety margin.

It should be noted that use of maximum concentrations may overestimate potential dietary exposure to biphenyl, particularly since concentrations vary widely among published data sets and maximum values were extended to all foods within a food group (Environmental Health Canada, 2013).

### **6.2.2.5 Indoor climate**

See section 6.2.2.1 Air.

## **6.3 Bio-monitoring data**

As biphenyl is rapidly excreted in urine and does not accumulate in the body bio-monitoring data in humans would only express the exposure a short time before the measurement.

No bio-monitoring data has been found.

## **6.4 Summary and conclusions**

The critical effect in humans following exposure to biphenyl by inhalation is considered to be effects observed in the respiratory tract and the lungs. The highest exposure will occur for workers (occupational exposure) and by indirect exposure to biphenyl by indoor air; however, these exposures are not considered to cause human health effects.

*Absorption, distribution, metabolism and excretion*

Animal studies indicate that biphenyl is rapidly and readily absorbed following oral exposure. Biphenyl can also be absorbed through dermal exposure. No data on absorption through inhalation was available. Absorbed biphenyl is generally not stored in tissues and is rapidly excreted – primarily through the urine (USEPA, 2013; Danish EPA, 2013a).

#### *Acute toxicity*

Lowest oral LD<sub>50</sub> value is > 1900 mg/kg bw (rat and mice) and lowest inhalation LC<sub>50</sub> value is >250 mg/m<sup>3</sup> (rat) – thus biphenyl does not cause acute toxicity at low levels of exposure. In workers, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation as well as toxic effects on the liver, kidneys and central and peripheral nervous systems.

#### *Skin and eye irritation*

According to its classification, biphenyl causes skin irritation as well as eye irritation. In workers, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation (US EPA, Hazard summary on biphenyl, 2000). The respiratory threshold to biphenyl was reported to be 7.5 mg/m<sup>3</sup> (Danish EPA, 2013a).

#### *Repeated dose toxicity*

Lowest oral LOEL is 50 mg/kg-bw per day (rat). Lowest dermal LOEL is 500 mg/kg-bw per day (rabbit). Lowest inhalation NOEC is 160 mg/m<sup>3</sup> (mice). All are relatively large values indicating that there is no significant cause for concern in terms of repeated dose toxicity of biphenyl.

#### *Chronic toxicity and carcinogenicity*

Lowest oral non-neoplastic LOEL is 25 mg/kg bw per day (rat). Information regarding the toxicological effects of biphenyl following chronic inhalation or dermal exposure were not identified (US EPA, Hazard summary on biphenyl, 2000). Limited data on the carcinogenic effects of biphenyl in humans are available. The Danish EPA (2013a) reports that no evidence of carcinogenicity was found in a case study of occupational exposure to biphenyl over 10 years (in the 1970's). The US EPA considers available studies on carcinogenicity in mice and rats to be inadequate, and has classified biphenyl as a Group D, not classifiable as causing human carcinogenicity.

#### *Reproductive and developmental toxicity*

Lowest oral LOEL (developmental toxicity) is 500 mg/kg-bw per day (rats) and lowest oral LOEL (reproductive toxicity) is 750 mg/kg-bw per day (rat). Again these are rather large levels indicating no significant cause for concern. No information on the reproductive or developmental effects of biphenyl in humans is available.

#### *Genotoxicity*

The investigations of the genotoxicity potential of biphenyl have provided mixed results. Thus it cannot be ruled out that biphenyl has genotoxic effects.

#### *Immunotoxicity and neurotoxicity*

EPA (2013) reports on a 2-year oral bioassay in rats and mice which included daily observations for clinical signs and histopathological examination of nervous system tissues. They found no effects on the nervous system.

#### *Endocrine disruption and combination effects*

No information regarding endocrine disruption and combination effects has been identified.

#### *Critical effect and tolerable daily intake*

The critical effect of biphenyl exposure has been reported as development of tumours in the urinary bladder (rats) and liver (mice) following a long-term dietary exposure. However, no human data concerning occupational exposure to biphenyl suggests that liver tumours are not a relevant human

effect (Environment Health Canada, 2013). The Danish EPA (2013a) concludes that the critical effect in humans following exposure to biphenyl by inhalation is considered to be effects observed in the respiratory tract and the lungs. According to US EPA (1984), an acceptable daily intake (ADI) for biphenyl is 0.05 mg/kg bw/day for oral exposure.

#### *DNEL values*

DNEL values are presented below:

- Workers (inhalation): DNEL of 11.17 mg/m<sup>3</sup>
- Workers (dermal): DNEL of 63 mg/kg bw/day
- General population (inhalation): DNEL of 3.3 mg/m<sup>3</sup>
- General population (dermal): DNEL of 38 mg/kg bw/day
- General population (oral): DNEL of 1.9 mg/kg bw/day

#### *Direct exposure to consumers – potential health impacts*

The three major uses of biphenyl is 1) as a constituent in heat transfer fluids, 2) as a constituent in coal tar 3) as intermediate in the production of other chemicals. In terms of exposure to biphenyl contained in heat transfer fluids, the exposure to consumers is minimal, due to the fact that heat transfer fluids primarily are used in closed piping systems – though some exposure to workers may happen in the case of fumes being released from the system. Biphenyl as a constituent in coal tar is not likely to cause concern. According to Environmental Health Canada (2013) the use of coal-tar in pavements (by consumers) is not likely to pose a risk due to the low content of biphenyl in coal-tar and the physical and chemical properties of biphenyl. The use of biphenyl as intermediate is neither likely to cause concern, since the substance in these cases is converted to another substance. An area, however, which may cause concern is the use of biphenyl as dye stuff carrier in the textile industry. Here it may end up in the waste water, which – if not treated properly – may cause problems for organisms in the environment.

#### *Direct occupational exposure*

Occupational exposure of workers to benzyl chloride may occur in workplaces where benzyl chloride is manufactured or in workplaces where benzyl chloride is used as an intermediate chemical to produce other chemicals. As mentioned previously, acute exposure to high levels of biphenyl has been observed to cause eye and skin irritation as well as toxic effects on the liver, kidneys and central and peripheral nervous systems in workers. Symptoms include headache, gastrointestinal pain, nausea, indigestion, numbness and aching of limbs, as well as general fatigue (US EPA, Hazard summary on biphenyl, 2000).

#### *Indirect exposure – air/indoor climate*

The most likely route of exposure to biphenyl is through inhalation of air and especially indoor air, which is considered to be responsible for about 94% of the indirect exposure to biphenyl. An estimate of the daily intake for the general Canadian population ranges from 0.32 – 0.95 ug/kg bw /day – which is way below the tolerable daily intake of 0.05 mg/kg bw/day for (oral) exposure. The highest reported indoor air concentration of biphenyl is 1.7 ug/m<sup>3</sup>, and the highest reported outdoor concentration is 0.02 ug/m<sup>3</sup>. In comparison, the limit (contribution) value for companies in Denmark (regarding emission of biphenyl to the air (i.e. B-Values)) is 0.005 mg/m<sup>3</sup> – thus there is a large safety margin.

#### *Indirect exposure – soil*

According to Environmental Health Canada (2013), no monitoring data on biphenyl in soil has been identified.

#### *Indirect exposure – drinking water*

Biphenyl was analyzed in drinking water samples from plants and distribution sites in Toronto (2008) and in all samples biphenyl was detected at or below the detection limit of 0.6 µg/L

(Environmental Health Canada, 2013). In comparison the water quality requirement for biphenyl in the EU is 1 µg/l (according to GUIDANCE No 9810 of 31.5.2006 on connection of industrial discharge water to public sewage treatment plants).

#### *Indirect exposure – food*

Previously (1988) citrus fruits in the UK contained residues of biphenyl (which was used as fungistat in packaging of citrus fruits). However, in 1997 no residues were detected in samples. Traces of biphenyl have previously also been detected in a range of food items (bread, cereals, lettuce, cabbage, baby food cookies, baby food oatmeal etc.). Generally 1 out of 44 samples (for each food item) contained detectable traces of biphenyl – except for baby food oatmeal, in which biphenyl was detected in one out of the four analyzed samples. Up to 1.65 µg/g biphenyl was detected in apples and oranges from Malaysia. Dietary intake was lowest in the 20-59 and the 60+ age groups with an intake estimate of 0.003 µg/kg-bw per day and highest in 0-0.5-year age group at 0.013 µg/kg-bw per day. English muffins were the primary contributors to dietary intake estimates. As mentioned previously, the acceptable daily intake of biphenyl, according to US EPA (1984), is 0.05 mg/kg bw/day – thus there is a very large safety margin.

#### *Bio-monitoring data*

As biphenyl is rapidly excreted in urine and does not accumulate in the body, bio-monitoring data in humans would only express the exposure a short time before the measurement. No bio-monitoring data has been found.

#### *Conclusion on human health impact*

Environmental Health Canada (2013) concludes or proposes that biphenyl does not enter the environment in a quantity or concentration or under conditions that constitute or may constitute a danger in Canada to human life or health.

# 7. Information on alternatives

Biphenyl has previously been used in large scale as intermediate in the production of polychlorinated biphenyls (PCB). After the restriction of this chemical in many countries, the overall demand and production of biphenyl experienced a decline during the '80s and '90s (WHO, 1999), from where the uses of biphenyl have remained more or less constant.

The uses of biphenyl today are both found in final products as heat transfer agents, dyestuff carriers, preservatives, solvents and as intermediate in the manufacturing of other chemicals. However, biphenyl as intermediate is expected to be minor in the EU, for which reason in order to identify alternatives for the use of biphenyl, it is only considered relevant to investigate possibilities for substitution for the use in final products.

## 7.1 Identification of possible alternatives

According to the Directive on the protection of health and safety of workers from the risks related to chemical agents at work (98/24/EC) it is a requirement that alternatives should be less hazardous than the substance being substituted. For several of the proposed alternatives listed this is not the case and therefore they will not be useful from a working environment point of view.

### 7.1.1 Alternatives for use in final products

The following uses of biphenyl, where biphenyl is a part of the final product, are described further:

- Heat transfer agents
- Dyestuff carriers for textiles and copying papers
- Preservatives for citrus fruits
- Solvents for pharmaceutical production

#### 7.1.1.1 Heat transfer agents

Biphenyl has the ability to perform as a rather stable non-reactive compound which makes it useful as heat transfer agent. It is far from all heat transfer agents that contain biphenyl. Eastman and DOW are identified as two of the major producers on the market of heat transfer agents. It was found that Eastman has a total of 17 different variants of heat transfer fluids of which four are shown to contain biphenyl<sup>47</sup>. Alternative heat transfer agents found are benzene-alkylated or benzene ethylenated compounds such as e.g. <sup>48</sup>:

- CAS No. 68855-24-3 – Benzene, C14-30-alkyl derivs.:
  - Not classified (370 notifiers)
  - Aquatic Chronic 4, H413 (49 notifiers)
- CAS No. 68608-82-2 – Benzene, ethylenated, by-products:
  - Eye Irrit. 2, H319; Aquatic Acute 1, H400; Aquatic Chronic 1, H410 (28 notifiers)
  - Asp. Tox. 1, H304; Skin. Irrit. 2, H315; Skin. Sens. 1, H317; Aquatic Chronic 1, H410 (18 notifiers)
- CAS No. 67774-74-7 – Benzene, C10-13-alkyl derivs.:
  - Not classified (1146 notifiers)

<sup>47</sup> <http://www.therminol.com/resources/therminol-heat-transfer-fluid-information-library#SDS>

<sup>48</sup> H413 "May cause long lasting harmful effects to aquatic life"; H319 "Causes serious eye irritation"; H400 "Very toxic to aquatic life"; H410 "Very toxic to aquatic life with long lasting effects"; H304 "May be fatal if swallowed and enters airways"; H315 "Causes skin irritation"; H317 "May cause an allergic skin reaction"; H411 "Toxic to aquatic life with long lasting effects".

- Asp. Tox. 1, H304 (208 notifiers)
- CAS No. 25265-78-5 – Tetrapropylenebenzene:
  - Eye Irrit. 2, H319; Aquatic Chronic 2, H411 (121 notifiers)
  - Asp. Tox. 2, H304; Aquatic Chronic 4, H413 (37 notifiers)
- CAS No. 84961-70-6 – Benzene, mono-C10-13-alkyl derivs., distn. residues:
  - Not classified (66 notifiers)
  - Asp. Tox. 1, H304 (31 notifiers)

Of these alternatives listed, some of them are less toxic to the environment compared to biphenyl, but some of the alternatives may be more toxic to humans (classified with Asp. Tox. 1, H304 “May be fatal if swallowed and enters airways”).

DOW produces thermal fluids and heat transfer agents in 7 different variants, of which one is shown to contain biphenyl (DOWTHERM A)<sup>49</sup>.

Different heat transfer agents have different liquid and vapour phases. For this reason heat transfer agents not containing biphenyl may lack certain properties and therefore they may not in all cases represent actual alternatives to biphenyl-based heat transfer agents.

#### **7.1.1.2 Dyestuff carriers for textiles and copying papers**

Biphenyl used in dyestuff is used in textiles and leather products. Information regarding biphenyl used in dyes is very scarce. One study which compared biphenyl and flourene compounds showed that biphenyl performed better in terms of thermal stability (Baheti et al., 2011). A recent study (Christie, 2014) investigates alternative reaction mechanisms to minimise or avoid PCB-based pigments in products with no concrete results. The study addresses the need to find “PCB-free” alternatives. It has not been possible to find information about actual alternatives to the use of biphenyl in dyestuff.

#### **7.1.1.3 Preservatives for citrus fruits**

The use of biphenyl as a preservative for food has recently been restricted in both the EU<sup>50</sup> and the US. Other alternatives for fruit preservation are sodium benzoate, sulphur dioxide and citric acid, where the first and last-mentioned alternatives seem to be safer and more environmental friendly alternatives based on their classifications according to ECHAs Classification & Labelling Database:

- Sodium benzoate (CAS 532-32-1):
  - Not classified (1125 notifications)
  - Eye Irrit. 2, H319 – Causes serious eye irritation (546 notifications)
- Sulphur dioxide (CAS 7446-09-5): Harmonised classification of:
  - Press. Gas; Skin Corr. 1B, H314 – Causes severe skin burn and eye damage; Acute Tox. 3, H331 – Toxic if inhaled
- Citric acid (CAS 77-92-9):
  - Eye Irrit. 2, H319 – Causes serious eye irritation (2368 notifications)
  - Skin Irrit. 2, H315 – Causes skin irritation; Eye Dam. 1, H318 – Causes serious eye damage, STOT SE 3, H335 – May cause respiratory irritation (271 notifications)

#### **7.1.1.4 Solvents for pharmaceutical production**

Biphenyl is used in the pharmaceutical industry for various purposes of medicine and drugs. It has not been possible to find information about alternatives to substitute the use of biphenyl in pharmaceutical products.

<sup>49</sup> <http://www.dow.com/heattrans/products/synthetic/dowtherm.htm>

<sup>50</sup> EU Directive 2003/114



## 7.2 Historical and future trends

Biphenyl has historically been used in large scale as an intermediate in the production of PCB. After the restrictions of PCB in both the EU and the US, the trend shifted towards less use of biphenyl in textile dyeing during the '80s (Thompson Quentin, 1992). At the same time, a steady growth in the heat transfer market made this application the most important in the American and German markets, continuing until now as the most important application in the EU, but shifting back in the US where its application for dyestuff carriers for textiles is now regaining momentum.

From the '90s until now, the uses of biphenyl have remained more or less constant, with the general trends varying slightly. Other applications appear to have slowly and gradually increased in the same way in both parts of the world (USEPA, 2013; Danish EPA, 2013a), whereas the use of biphenyl as preservative has been restricted since 2003.

China may be assumed to comprise a major part of global biphenyl production due to the current developments in the Chinese market and the demand for industrial chemicals, as well as China's primary role in the trade of this chemical substance. One report was found to cover this topic<sup>51</sup>.

It has not been possible to find overall predictions for the future trends and use of biphenyl.

## 7.3 Summary and conclusions

Information on the use of biphenyl in general is very limited, for which reason alternative substitutions for biphenyl are even more difficult to find. This may be because biphenyl is not represented in common consumer products and therefore has not been subject to public concerns about the related health risks. However, biphenyl has appeared in products with a direct risk of contact to the consumer, such as in preservatives for citrus fruits, where it has recently been restricted in both the EU and the US. A desktop survey also noticed the use of biphenyl in dyes is subject of increasing awareness.

In terms of alternatives for use of biphenyl as heat transfer agents, the identified alternatives are found to be less toxic to the environment and others more toxic to humans. It is important to notice that according to EU legislation alternatives should be less hazardous than the substance being substituted. It has not been possible to find information about actual alternatives to the use of biphenyl in dyestuff, neither has it been possible to identify alternatives to substitute the use of biphenyl in pharmaceutical products.

It may be presumed that the production of biphenyl in the nearest future will continue in present rate which has been more or less constant the previous 25 years.

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<sup>51</sup> <http://www.marketsnresearch.com/report/181939.php>

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## Appendix 1: Abbreviations and acronyms

ADI	Acceptable daily intake
BCF	Bioconcentration factor
CLP	Classification, Labelling and Packaging Regulation
DEFRA	Department for Environment, Food and Rural Affairs (UK)
ECB	European Chemicals Bureau
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EPA	Environmental Protection Agency
EU	European Union
HELCOM	The Baltic Marine Environment Protection Commission (Helsinki Commission)
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)
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
SPIN	Substances in Preparations in the Nordic countries
SVHC	Substance of Very High Concern
TDI	Tolerable daily intake
WE	Western Europe

## Appendix 2: Background information on regulation

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

### EU and Danish legislation

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

#### There are four main EU legal instruments:

- Regulations (DK: Forordninger) are binding in their entirety and directly applicable in all EU Member States.
- Directives (DK: Direktiver) are binding for the EU Member States as to the results to be achieved. Directives have to be transposed (DK: gennemført) into the national legal framework within a given timeframe. Directives leave margin for manoeuvring as to the form and means of implementation. However, there are great differences in the space for manoeuvring 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<sup>52</sup> and the CLP Regulation<sup>53</sup> are the overarching pieces of EU chemicals legislation regulating industrial chemicals. The below will briefly summarise the REACH and CLP provisions and give an overview of 'pipeline' procedures, i.e. procedures which may (or may not) result in an eventual inclusion under one of the REACH procedures.

### (Pre-)Registration

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

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

### Evaluation

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

### Authorisation

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

### Restriction

If the authorities assess that 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

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<sup>52</sup> Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

<sup>53</sup> Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures

classifications in Annex I of the previous Dangerous Substances Directive (67/548/EEC); classifications which have been 'translated' according to the new classification rules.

- Classification and labelling inventory.** All manufacturers and importers of chemical substances are obliged to classify and label their substances. If no harmonised classification is available, a self-classification shall be done based on available information according to the classification criteria in the CLP regulation. As a new requirement, these self-classifications should be notified to ECHA, which in turn publishes 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 substances 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:

- It has to be identified as a SVHC leading to inclusion in the candidate list<sup>54</sup>
- 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)
- 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 intentions in relation to Annex XV dossiers divided into:

- current intentions for submitting an Annex XV dossier,
- dossiers submitted, and
- withdrawn intentions and withdrawn submissions

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<sup>54</sup> 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).



for the three types of Annex XV dossiers.

## **International agreements**

### **OSPAR Convention**

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

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

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

### **HELCOM - Helsinki Convention**

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

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

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

### **Stockholm Convention on Persistent Organic Pollutants (POPs)**

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

## **Rotterdam Convention**

The objectives of the Rotterdam Convention are:

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

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

## **Basel Convention**

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

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

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

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

## **Eco-labels**

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

### **EU flower**

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

**Nordic Swan**

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

**Blue Angel (Blauer Engel)**

The Blue Angel is a national German eco-label. More information can be found on:

<http://www.blauer-engel.de/en>.

### Appendix 3: Self classification

Classification		No. of notifiers (798 notifiers in total)
Hazard Class and Category Codes	Hazard Statement Codes	
<b>Skin Irrit. 2</b> <b>Eye Irrit. 2</b> Acute Tox. 2 <b>STOT SE 3</b> <b>Aquatic Acute 1</b> <b>Aquatic Chronic 1</b>	<b>H315</b> <b>H319</b> H330 <b>H335</b> <b>H400</b> <b>H410</b>	352 notifiers
<b>Skin Irrit. 2</b> <b>Eye Irrit. 2</b> <b>STOT SE 3</b> <b>Aquatic Acute 1</b> <b>Aquatic Chronic 1</b>	<b>H315</b> <b>H319</b> <b>H335</b> <b>H400</b> <b>H410</b>	123+93+35+34+30 +28+25+7+6+4+4+ 2+1+1 = 393 notifiers*
<b>Skin Irrit. 2</b> <b>Eye Irrit. 2</b> <b>STOT SE 3</b> <b>Aquatic Chronic 1</b>	<b>H315</b> <b>H319</b> <b>H335</b> <b>H410</b>	29+13 = 42 notifiers*
<b>Skin Irrit. 2</b> <b>Eye Irrit. 2</b> <b>STOT SE 3</b> <b>Aquatic Acute 1</b> Aquatic Chronic 3	<b>H315</b> <b>H319</b> <b>H335</b> <b>H400</b> H412	6 notifiers
Reported as 'blank' <b>Skin Irrit. 2</b> <b>Eye Irrit. 2</b> <b>Aquatic Acute 1</b> <b>Aquatic Chronic 1</b>	<b>H335</b> <b>H315</b> <b>H319</b> <b>H400</b> <b>H410</b>	4 notifiers
Reported as 'blank' Reported as 'blank'	<b>H410</b> H302	1 notifier

H302: Harmful if swallowed, H315: Causes skin irritation, H319: Causes serious eye irritation, H330: Fatal if inhaled, H335: May cause respiratory irritation, H400: Very toxic to aquatic life, H410: Very toxic to aquatic life with long lasting effects, H412: Harmful to aquatic life with long lasting effects  
 \* Several identical classifications are for some reason listed separately in the C&L Database, but have in this table been joined (listed in the same row).

**TABLE 10**

NOTIFIED CLASSIFICATIONS FOR BIPHENYL – CAS 92-52-4 (FROM ECHA C&L DATABASE, MAY, 2014).  
CLASSIFICATIONS IDENTICAL TO THE HARMONISED CLASSIFICATION ARE MARKED IN BOLD.

#### Appendix 4: Use pattern of biphenyl in Denmark from 2000 to 2011

The use pattern of biphenyl in Denmark from 2000 to 2011 is listed below in Table 11. The data has been retrieved from the SPIN database (May 2014).

Year	Total tonnage (tonnes)	No. of products	Description
2000	7.3	11	<i>No use descriptions listed for Denmark</i>
2001	2587.2	5	
2002	2587.2	6	
2003	3286.6	13	
2004	3001.5	12	
2005	3001.5	13	
2006	2363.8	15	
2007	2360.4	12	
2008	3529.2	8	
2009	2828.2	8	
2010	2828.2	8	
2011	3362.4	7	

**TABLE 11**  
USE PATTERN OF BIPHENYL IN DENMARK FROM 2000 TO 2011 (SPIN DATABASE, 2014)

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### **Survey of biphenyl (CAS no. 92-52-4)**

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The survey concerns the aromatic organic substance biphenyl. This substance was included in the LOUS list in 2000. The report defines the substance and present information on the use and occurrence of biphenyl internationally and in Denmark, information on existing regulation, on environmental and health effects, on monitoring and exposure, on waste management and on alternatives to the substance.

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Kortlægningen omhandler det aromatiske organiske stof bifenylyl. Rapporten definerer stoffet og indeholder blandt andet en beskrivelse af brugen og forekomsten af bifenylyl internationalt og i Danmark, om eksisterende regulering, en beskrivelse af miljø- og sundhedseffekter af stoffet, af monitoringsdata, af affaldsbehandling samt alternativer til stoffet.



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