



Danish Ministry of the Environment
Environmental Protection Agency

Survey of Cybutryne

Alias Irgarol and N-tert-butyl-N-cyclopropyl-6-(methylthio)-1,3,5-triazin-2,4-diamine

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Survey of Cybutryne

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Preface

The Danish Environmental Protection Agency's List of Undesirable Substances (LOUS) is intended as a guide for enterprises. It indicates substances of specific concern due to their adverse effects to man or the environment and their actual consumption in Denmark. The aim of the list is to encourage the use of the substances in the list to be reduced or eliminated completely. The first list was published in 1998 and updated versions have been published in 2000, 2004 and 2009. The latest version, LOUS 2009 [DEPA 2011] includes 40 chemical substances and groups of substances that have either been classified as dangerous or identified as problematic due to other concerns. The actual criteria employed by the Danish EPA for inclusion of substances in the list covers:

- Properties of concern according to the EU 'List of hazardous substances'
- Properties of concern identified using computer-based model calculations outlined in the Danish EPA's 'Advisory list for self-classification of dangerous substances' (the Self-classification list).
- PBT/vPvB substances as identified by the EU
- Substances on the EU 'Priority list of substances for further evaluation of their role in endocrine disruption'

Furthermore, a tonnage threshold has been used. Substances used in quantities exceeding 100 tons per year in Denmark and fulfilling any of the above-mentioned criteria have been included in LOUS 2009. For substances that are the subject to special focus in Denmark, the tonnage threshold may, however, be different.

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

This survey concerns Cybutryne (N-tertbutyl-N-cyclopropyl-6-(methylthio)-1,3,5-triazine-2,4-diamine). The reason for including the substance is the following properties of concern in relation to the 'Advisory List for Self-classification of Dangerous Substances': "Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment. (N; R50/53)" [LOUS 2009].

The Survey of Cybutryne was carried out from June till December 2012.

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The project was financed by the Danish Environmental Protection Agency. The report reflects the author's views and opinions, but not necessarily the views of the Danish EPA.

Summary and conclusion

Summary

Cybutryne is a biocidal active substance that is used globally as a preservative of film, textiles and building materials and in antifouling products to control algae. The use of antifouling is important for the industry and for society in order to minimize the risk of reduced manoeuvring and high energy consumption resulting in large CO₂ emission as a consequence of the presence of fouling organisms.

The substance was listed on the Danish Environmental Protection Agency's list of undesirable substances (LOUS 2009) based on its use tonnage in Denmark in 2008 and on the basis of the Danish "Advisory list for self-classification of dangerous substances", in which Cybutryne was classified as very toxic to aquatic life with long lasting effects.

Within the framework of the classification and labelling regulation in the EU (CLP), the majority of notifiers classify Cybutryne as a skin sensitizer and as being very toxic to aquatic life with long lasting effects. Cybutryne is regulated in the EU, under the Biocidal Products Directive (BPD) and the coming Biocidal Products Regulation (BPR) and is currently being reviewed under the BPD as an antifouling agent.

The use of Cybutryne in the EU as a preservative of film, textiles and building materials was phased in 2011, out. The only allowed use in the EU is in antifouling products. In Denmark, Statutory Order No. 1257 of 15 December 2011 restricts the import, sale and use of products containing Cybutryne to ships with a total length of 25 meters or more. From 2006 to 2010, the use of Cybutryne in Denmark has decreased significantly from 27.4 tonnes/year to 2.2 tonnes/year. Due to the recent phasing out at EU-level of several use categories and the restrictions of the Danish legislation as well as the possible restrictions related to the future decision on the use as antifouling agent under the biocides legislation, a further decrease is expected the next few years.

Marine waters in harbours, shipping lanes or open sea are mainly exposed to Cybutryne but also marinas can be exposed to Cybutryne if the active substance is applied to pleasure boats longer than 25 metres. The main exposure route to the environment is via leaching during service life and via discharge during application or removal of the surface treatment. Cybutryne inhibits the photosynthesis of algae and aquatic macrophytes. The substance is considered as persistent and toxic to aquatic organisms but it is not assessed to be bioaccumulating from the available data and it is therefore not classified as a PBT substance. In connection with the EU review, the Competent Authorities for biocides will decide, if Cybutryne can be considered as a 'potential' endocrine disruptor. It is still unclear when the final conclusion will be drawn on this issue. The PNEC and PEC values are currently under review by technical experts from the EU member states. At this point in time, no conclusion on the risk characterisation of Cybutryne has been made.

The draft Competent Authority report identifies Cybutryne as a skin sensitizer. No carcinogenicity studies were available. The risk assessment for human health was performed for the professional user only, as the substance is not intended for the general public. The calculation of the risk related to the use of Cybutryne is based on the development effect. The risk characterisation indicated an unacceptable risk for painters and, at a lower level, for potmen and ancillary workers. However, the draft report suggests that safe use of Cybutryne-containing paints for workers in relation to spray application of antifouling paint by professionals is demonstrated provided that adequate personal

protective equipment is applied. However, the draft report has not yet been reviewed by the EU technical experts.

There are currently 6 biocidal active substances on the market in the EU that like Cybutryne are effective against fouling algae. They are all being evaluated as a part of the BPD review programme. Besides siliconized coatings applicable on transport ships, ferries or speed boats that sail with a high speed (>15 knots), there are currently no effective non-biocidal alternatives available.

Conclusion

Cybutryne is a preservative and an antifouling agent. In the EU, its use has been restricted to antifouling products. Antifouling products containing Cybutryne are not allowed in Denmark for vessels smaller than 25 metres. The use of Cybutryne as antifouling agent is currently being reviewed under the Biocidal Products Directive 98/8/EC (BPD), focusing on professional use on commercial deep sea and coastal vessels. In the draft report Cybutryne is considered to be toxic and persistent in the aquatic environment. The draft risk characterisation identifies safe use for professional users with respect to human health, provided adequate personal protective equipment is used. However, no final conclusion has been reached at this point of time. Due to the restrictions at EU and national level, the use of Cybutryne is decreasing and is expected to decline further. Currently, there are few effective alternative substances available, and only siliconized coatings for high speed vessels appear to be an effective non-biocidal alternative.

Sammenfatning og konklusion

Sammenfatning

Cybutryne er et biocidaktivstof, der anvendes globalt til konservering af overfladefilm, tekstiler samt byggematerialer og i bundmalingsprodukter til bekæmpelse af alger. Begroning mindsker manøvreedygtighed og giver et højt energiforbrug, der resulterer i høj CO₂-udledning, hvorfor Cybutrynes anvendelse som bundmaling betydningsfuld for industrien og for samfundet som helhed.

Stoffet er opført på Miljøstyrelsens Liste over uønskede stoffer (LOUS 2009) på baggrund af dens tonnage i Danmark i 2008, og fordi stoffet figurerer på den danske "Vejledende liste til selvklassificering af farlige stoffer", hvor det er klassificeret som værende meget giftigt for organismer, der lever vand og for at kunne forårsage uønskede langtidsvirkninger i vandmiljøet.

Under klassificeringsforordningen (CLP) klassificerer flertallet af anmeldere Cybutryne som "hudsensibiliserende" og som "meget giftig med langvarige virkninger for vandlevende organismer". Cybutryne er i EU desuden reguleret under biociddirektivet (BPD) og den nye biocidforordning, hvor stoffet i øjeblikket er under vurdering som bundmalingsstof.

I EU blev brugen af Cybutryne til konservering af overfladefilm, af tekstiler og i bygningsmaterialer udfaset i 2011, og stoffet må i dag udelukkende anvendes i bundmalingsprodukter. I Danmark begrænser bekendtgørelse nr.1257 af 15. december 2011 import, salg og anvendelse af produkter, der indeholder Cybutryne til skibe med en totallængde på 25 meter eller mere. Fra 2006 til 2010 faldt forbruget af Cybutryne i Danmark fra 27,4 til 2,2 ton/år. Forbruget forventes at falde yderligere i de kommende år på grund af den nylige udfasning af flere brugskategorier i EU og de begrænsninger den danske lovgivning fastsætter, hvortil kommer mulige restriktioner i forbindelse med den kommende konklusion af EU-vurderingen af stoffets brug i bundmaling.

Den miljømæssige eksponering for Cybutryne forekommer primært i havne, sejlrender og det åbne hav; men også lystbådehavne kan blive eksponeret for stoffet, hvis det bliver påført lystbåde på over 25 meter. Den vigtigste eksponeringsvej for miljøet er gennem udvaskning i løbet af skibets levetid og gennem spild under påføring eller ved fjernelse af overfladebehandlingen. Cybutryne blokerer fotosyntesen hos alger og akvatiske makrofyter. Stoffet betragtes som værende persistent og giftigt for vandlevende organismer, men det er ud fra de tilgængelige data ikke vurderet at være bioakkumulerende, og stoffet klassificeres derfor ikke som værende et PBT-stof (persistent/bioakkumulerende/toksisk). I forbindelse med EU-vurderingen af Cybutryne vil de kompetente myndigheder for biocider beslutte, om stoffet er potentielt hormonforstyrrende. Det er endnu uklart, hvornår der tages beslutning om dette. PNEC- og PEC- værdierne er i øjeblikket under vurdering blandt tekniske eksperter fra EU's medlemslande. Der foreligger i dag ikke nogen endelig konklusion om risikokarakteriseringen af Cybutryne.

I forhold til sundhedsvurdering identificerer udkastet til EU-risikovurderingsrapporten for Cybutryne i bundmaling som allergifremkaldende ved hudkontakt. Der mangler data for kræftfremkaldende virkning. Risikovurderingen mht. sundhed omfatter udelukkende den professionelle bruger, idet stoffet ikke tiltænkes den private bruger. Vurderingen benytter dosisniveauet for effekter i på fosteudviklingen som udgangspunkt for beregningen af risikoen ved brug af stoffet. Rapportudkastets risikokarakterisering peger på en uacceptabel risiko for den

professionelle maler, og, på et lavere niveau, for opfyldere og medhjælpere. Imidlertid er der demonstreret sikker anvendelse af stoffet, når bundmalingen med Cybutryne påsprayes af professionelle, under forudsætning af, at værnemidler anvendes. Rapporten er dog endnu ikke blevet vurderet af den EU's tekniske ekspertgruppe for biocider.

Der er i øjeblikket 6 biocidaktivstoffer på markedet i EU, der Cybutryne er effektive mod begroningsalger. Stofferne er under vurdering under BPD revurderingsprogrammet. Der er udviklet en silicone-overfladebehandling, som dog kun kan anvendes på transportskibe, færger og speedbåde, der sejler med høj hastighed (>15 knob). Der findes i øjeblikket ingen effektive ikke-biocid alternativer for andre skibe.

Konklusion

Cybutryne er et konserveringsmiddel og et antibegroningsmiddel. I EU er kun sidstnævnte anvendelse endnu tilladt. I Danmark må antibegroningsmidler, der indeholder Cybutryne, ikke anvendes på skibe under 25 meter. I EU vurderes anvendelsen af Cybutryne som antibegroningsmiddel i øjeblikket under biociddirektivet. Stoffet bliver i den forbindelse alene vurderet for professionel anvendelse på handelsskibe og kystnære skibe. Cybutryne anses for at være giftigt og persistent i vandmiljøet. Stoffet er ifølge udkastet til rapporten allergifremkaldende ved hudkontakt. Rapportudkastet viser, at der er sikker anvendelse af stoffet, når det indgår i bundmaling, som sprayes på af professionelle, under forudsætning af, at værnemidler anvendes. Rapporten er dog ikke vedtaget endnu. Forbruget af Cybutryne forventes at falde yderligere i de kommende år på grund EU og nationale restriktioner. Der findes i dag få alternative antibegroningsstoffer til Cybutryne på markedet, og, som det eneste ikke-biocid alternativ er i dag en silicone-coating, der dog kun er effektiv på skibe, der sejler med høj hastighed.

1. Introduction

1.1 Survey background

DHI has been contracted by the Danish EPA to collect and provide background information on the markets, uses, releases of and alternatives for Cybutryne: EC No. 248-872-3, CAS No. 28159-98-0.

This substance was listed on LOUS based on marketed tonnage and on QSAR-based recommendation to classify the substance as N; R50/53 "Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment."

1.2 Methods

1.2.1 Databases

For this survey, the data from the SPIN database was used. Information from web searches on the use and production of Cybutryne was also reported. The publicly available part of the draft Competent Authority report under the BPD was used in the section on environmental and human health of this report.

1.2.2 Industry information

DHI was provided with contact details of companies that had preregistered Cybutryne under REACH. Furthermore, other relevant industry within coating and antifouling and relevant network organisations were contacted. Altogether 35 contact points within industry were approached with a questionnaire regarding use, volumes, alternatives etc. of Cybutryne. Some representatives engaged in interviews with DHI.

1.2.3 Authority information

DHI prepared a questionnaire for selected competent authorities in and outside of the EU. Altogether 17 contact points were approached with a questionnaire regarding use, volumes, alternatives etc. of Cybutryne. Some representatives engaged in interviews with DHI. The Danish EPA provided information on projects on development on alternatives.

2. Identity of the substance

2.1 Identity, names and composition of the substance

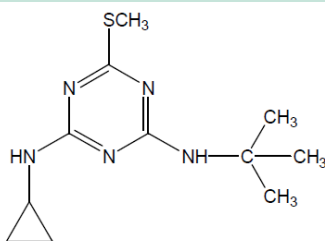
Cybutryne belongs to the chemical group of triazines and prevents the growth of algae on terrestrial and aquatic surfaces (US EPA, 2010). Cybutryne is a biocide mainly used as antifouling agent in antifouling paints for protection against “soft fouling” due to algae. Most antifouling paints are copper based. As copper is not as effective in deterring algal growth, Cybutryne is added to copper-based antifouling paints in order to improve the algal deterring effect. Therefore, Cybutryne is categorized as a booster biocide (Lambert *et al.*, 2006). Its mode of action is the inhibition of photosynthetic electron transport in the chloroplast (photosystem II) (US EPA, 2010).

When present in biocidal products, the substance is typically identified under the commercial names as: Cybutryne, Irgarol, Irgarol (R), Irgarol 1051, Irgarol 1071, Irgarol Pestanal, Vinkocide. Table 2.1 presents the identity and composition of Cybutryne.

TABLE 2.1
IDENTITY, NAMES AND COMPOSITION OF CYBUTRYNE (NETHERLANDS, 2011)

Property	Value
EC No.	248-872-3
Chemical name (CA)	<i>N</i> -cyclopropyl- <i>N'</i> -(1,1 –dimethylethyl)-6-(methylthio)-1,3,5-triazine-2,4-diamine
CAS No.	28159-98-0
Chemical name (IUPAC)	<i>N</i> ² -tert-butyl- <i>N</i> ⁴ -cyclopropyl-6-methylthio-1,3,5-triazine-2,4-diamine ¹
Molecular formula	C ₁₁ H ₁₉ N ₅ S
Molecular mass	257.37
Minimum purity as manufactured (g/kg)	970 g/kg

Structural formula



1) This name was used in LOUS.

2.2 Physico-chemical properties

TABLE 2.2
PHYSICO-CHEMICAL PROPERTIES OF CYBUTRYNE (NETHERLANDS, 2011)

Property	Value
Appearance (purity)	White cloddy powder with garlic like odour (98.6%)
Melting/freezing point	128.4°C (98.6%)
Boiling point	347.3-375°C
Relative density	1.11 g/m ³
Vapour pressure	3.4×10 ⁻⁵ Pa at 25°C
Surface tension	56.2 mN/m at 90% saturation
Water solubility (mg/L)	pH 5: 11.1 mg/L (20°C)
	pH 7: 9.0 mg/L (20°C)
	pH 9: 8.8 mg/L (20°C)
Partition coefficient (Log Pow)	pH 5: 3.2 at 10°C and 25°C
	pH 7: 3.2 at 10°C and 3.1 at 25°C
	pH 9: 3.2 at 10°C and 3.1 at 25°C
Flash point	Not applicable, substance is a solid
Flammability	Not highly flammable; not auto-flammable
Explosive properties	Not explosive
Oxidizing properties	Non oxidizing
Stability in organic solvents and identity of relevant degradation products	Not applicable, no organic solvent present in manufactured active substance.
Dissociation constant	pKa = 4.12 in methanol
Viscosity	Not applicable, substance is a solid
Auto flammability	Not auto-flammable
Reactivity towards container material	Stable in the tested containers (PVC, plastic, cardboard, aluminium and tin plate) over a period of 4 years (55 months) at room temperature (22°C–30°C).
Thermal stability	No exothermic reaction was seen up to the melting point

3. Regulatory framework

3.1 Danish regulation

In Denmark, there is currently no authorisation procedure for placing antifouling products on the market. However, the use of Cybutryne in antifouling products is regulated by the Danish Statutory Order No. 1257 of 15 December 2011, restricting the import, sale and use of biocidal anti-fouling. The wording of paragraph 2 of the statutory order is as follows:

“The import, sale and use of antifouling paint containing the biocides diuron (CAS No. 330-54-1) or irgarol (CAS No. 28159-98-0) on ships with a total length of less than 25 metres, is prohibited.”

This means that, for vessels smaller than 25 metres, no Cybutryne antifouling products are allowed to be used. Thus, restriction is depending only on the length of the vessel.

The use of Cybutryne as a preservative of film-coatings, textiles and building materials has been prohibited since 2011 (see section below).

3.2 EU regulation: Directive 98/8/EC concerning the placing of biocidal products on the market (BPD)

Within the countries of the EU and the EEA, all import and placing on the market of Cybutryne as a biocidal active substance or a biocidal product are regulated by the biocidal products directive (BPD). The BPD includes a review programme to investigate every supported biocidal active substance and biocidal product within the EU. The review programme sets out criteria for the harmonized use of biocidal active substances in biocidal products in order to assure that the related products on the market are effective and safe for humans and the environment. The extensive review programme of the BPD investigates the active substance as such and the biocidal products containing the active substance. The active substance is reviewed by an EU expert group and the individual products are later authorized at national level. The biocidal active substances are evaluated according to their use and are categorized into different product types. Cybutryne has been notified in product type (PT) 7 (film preservatives), PT 9 (textile preservatives), PT 10 (masonry preservatives) and PT 21 (antifouling products).

3.2.1 PT 21 Antifouling products - under evaluation

Cybutryne is presently under evaluation under the BPD for the use within product type 21 “Antifouling products”. The dossier was submitted to the Rapporteur Member State, the Netherlands, and the summary version of the draft Competent Authority report was published on the CIRCA website in 2011 (CIRCA, 2011). In the dossier, the intended use of antifouling products containing Cybutryne within the EU is for application on commercial deep sea and coastal vessels by professionals.

3.2.2 PT 7 Film preservatives - phased out

Cybutryne has been used in products preserving films or coatings such as paints, plastics, sealants, fillers, etc. These biocidal products are defined as product type 7 “Film preservatives” under the BPD. The industry did not support the review of Cybutryne with a dossier within this product type. Since 1 November 2011, no biocidal products within the product type 7 containing Cybutryne have been allowed to be placed on the market within the EU (EU COM, 2010b).

3.2.3 PT 9 Fibre, leather, rubber and polymerized materials preservatives - phased out

Cybutryne has been used in products preserving textiles such as running equipment. Biocidal products within this category of use are defined in product type 9 “Fibre, leather, rubber and polymerized materials preservatives” under the BPD. The industry did not support the review of Cybutryne with a dossier within this product type. Since 9 February 2011, no biocidal products within the product type 9 containing Cybutryne have been allowed to be placed on the market within the EU (EU COM, 2010a).

3.2.4 PT 10 Masonry preservatives - phased out

Cybutryne has been present in products preserving construction materials such as masonry and composite material. Biocidal products within this category of use are defined in product type 10 “Masonry preservatives” under the BPD. The industry did not support the review of Cybutryne with a dossier within this product type. Since 11 November 2011, no biocidal products within the product type 10 containing Cybutryne have been allowed to be placed on the market within the EU (EU COM, 2010b).

3.3 EU Regulation 528/2012 concerning the making available on the market and use of biocidal products (BPR)

From September 2013, the biocidal products regulation (BPR) will replace the biocidal products directive. To a large extent, the BPR will continue the requirements laid down in the BPD but it will open up a number of different authorisation procedures. However, for antifouling agents, the procedure of national authorisation of the products will be maintained.

3.4 Other national provisions on Cybutryne in biocidal products

TABLE 3.1
OTHER NATIONAL PROVISIONS ON CYBUTRYNE IN BIOCIDAL PRODUCTS

Country	Cybutryne CAS No. 28159-98-0
SE	The Swedish authorities banned pleasure boat paints containing Cybutryne for use on the east coast from January 2001. Cybutryne is registered as an active ingredient in antifouling products on the Swedish market but is gradually being phased out for amateur use. When the approval for a product runs out, a new one is not authorized (KemI, 2012).
NO	There is no special national legislation on the use of antifouling products in Norway. There are no restrictions on the use of Cybutryne containing antifouling products. Both amateur and professional use is allowed (Klif, 2012).
FI	Antifouling products containing Cybutryne as active substance are not presently authorized in Finland (TUKES, 2012).
UK	Cybutryne-based antifouling products are regulated under the UK national pesticides legislation, the Control of Pesticides Regulations (COPR). In 2000, the UK adopted a policy, in which Cybutryne products could not be approved for amateur use, and professional use products were restricted to a maximum concentration of 10% and for use on vessels above 25 metres in length. In addition, data requirements were laid down for the active substance if products were to remain on the UK market. Currently, there are no Cybutryne-based antifouling products approved for use in the UK (HSE, 2012).

Country	Cybutryne CAS No. 28159-98-0
US federal level	Cybutryne is regulated under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Cybutryne is registered for use as an antifoulant to boat hulls, and as a preservative in paints, caulks, coatings, sealants, grouts, vinyl roofing, roof coatings, cements, stucco, wood stains, adhesives, plasters and incorporated into boat hulls themselves. The US EPA periodically re-evaluates pesticides to make sure that as changes occur, products in the market can be used safely. In 2010, such a re-evaluation process was started for Cybutryne. The process is set to be finished by December 2015 (US EPA, 2010).
State of California	Registration of Cybutryne for use in formulating antifouling paints approved. The typical active ingredient concentration in end-use formulations was submitted to be between 1.5% and 3.0% (NZ EPA 2011).

3.5 REACH

Cybutryne has been pre-registered to ECHA in relation to the REACH regulation. However, until now the substance is not registered, i.e. no registration dossier has been submitted to ECHA and thus no further information can be obtained from this source.

3.6 Classification

3.6.1 Current classification

There is no harmonized classification of Cybutryne in the Annex VI of Regulation on classification, labelling and packaging of substances and mixtures (EC) No 1272/2008 with amendments.

3.6.2 Self classification

The classification and labelling of Cybutryne has been notified to ECHA by 189 importers and manufacturers (ECHA, 2012). The notifications are published in the Classification and Labelling Inventory. Table 3.2 gives an overview of the different classifications of the notifiers. The majority classified Cybutryne as follows:

Hazard class and category code

Skin Sens. 1	H317	May cause an allergic skin reaction
Aquatic Acute 1	H400	Very toxic to aquatic life
Aquatic Chronic 1	H410	Very toxic to aquatic life with long lasting effects

TABLE 3.2
NOTIFIED CLASSIFICATIONS ACCORDING TO CLP CRITERIA OF CYBUTRYNE ACCORDING TO CLP CRITERIA (ECHA, 2012)

Hazard Class and Category Code(s)	Hazard Statement Code(s)	Notifiers
Skin Sens. 1	H317	184
Aquatic Acute 1	H400	166
Aquatic Chronic 1	H410	161
Not classified		5

3.7 Waste management

Based on the hazard classification, residues of Cybutryne and products or waste streams containing significant amounts of Cybutryne will be classified as hazardous waste in accordance with the EU waste legislation and the Danish Statutory Order on waste.

3.8 Summary

The use of Cybutryne as a film, textile and masonry preservative has been phased out at EU-level and Cybutryne is only allowed in antifouling products. In the EU, Cybutryne is regulated under the Biocidal Products Directive (BPD) and in connection with this the professional use as an antifouling active substance is currently under review by technical experts at EU-level. Until a decision is made, products containing this substance have to comply with the national legislation. In Denmark, a statutory order prohibits the application of Cybutryne-containing antifouling products to vessels smaller than 25 metres. There is no restriction for the application of antifouling products containing Cybutryne on vessels longer than 25 metres. The majority of notifiers to the EU Classification and Labelling Inventory classify Cybutryne as a skin sensitizer and as very toxic to the aquatic life with long lasting effects.

4. Manufacture, import and use

4.1 Information on manufacture and import

4.1.1 Manufacturing sites

EU: Cybutryne is manufactured outside the EU. The main manufacturer of Cybutryne exporting to the EU is the company AGAN Chemical Manufacturers Ltd. based in Israel.

4.1.1.1 Outside the EU

According to industry, there are four Chinese manufacturers producing Cybutryne under the commercial name of Irgarol and Vinkocide.

4.1.2 Manufacturing volumes

The volumes of Cybutryne manufactured by AGAN Chemical Manufacturers Ltd. or other manufacturers were not made available to this report

4.1.3 Import volumes

BASF is the main importer of Cybutryne in the EU. The total import volumes were not made available to this report.

4.2 Information on use

4.2.1 Uses within the EU

The only biocidal use of Cybutryne still allowed in the EU is in antifouling products. According to the legal requirements of the BPD, products within the product types “film preservatives”, “fibre, leather, rubber and polymerized materials preservatives” and “masonry preservatives” containing Cybutryne were phased out by February and November 2011, respectively. According to the feedback from industry, the group of users of antifouling products containing Cybutryne includes professionals as well as amateurs. In Denmark, the use is only allowed for vessel sized larger than 25 m for both professionals and amateurs.

4.2.1.1 Use volumes in the Nordic countries

The total use volumes reported from the SPIN database of the Nordic countries are shown in Figure 4.1 and Table 4.1. A peak in the consumption in Denmark in 2007 and 2008, which had brought the consumption above the 100t criterion on the List of Undesirable Substances, has been corrected in the Danish Product Register in relation to this survey. The data are commented in Section 4.2.1.3.

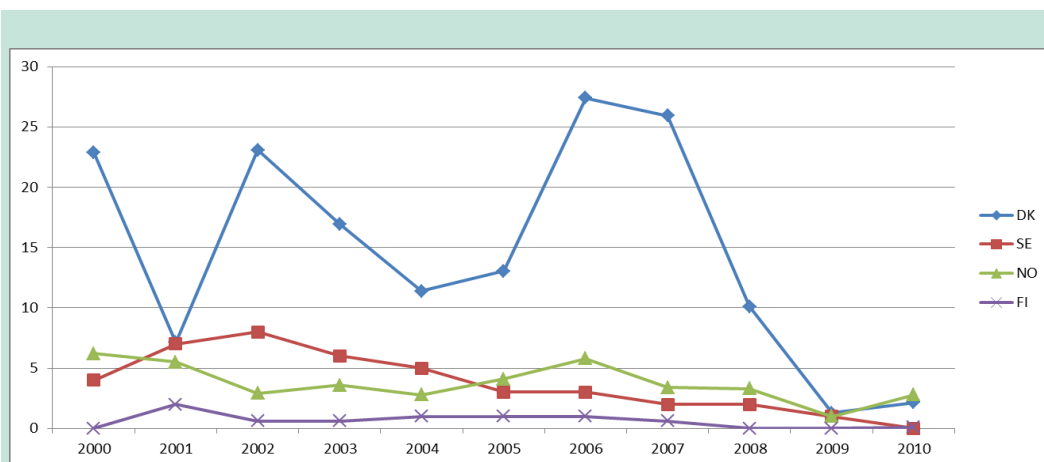


FIGURE 4.1
TOTAL AMOUNT/TONNES OF CYBUTRYNE MARKETED IN DENMARK, NORWAY, SWEDEN AND FINLAND FROM YEAR 2000 TO 2010 (SPIN, 2012)

TABLE 4.1
TOTAL AMOUNT (TONNES/YEAR) OF CYBUTRYNE PLACED ON THE MARKETS IN THE NORDIC COUNTRIES FROM YEAR 2000 TO 2010 (SPIN, 2012)

Year	DK	SE	NO	FI
2000	22.9	4	6.2	0
2001	7.2	7	5.5	2
2002	23.1	8	2.9	0.6
2003	17	6	3.6	0.6
2004	11.4	5	2.8	1
2005	13.1	3	4.1	1
2006	27.4	3	5.8	1
2007	25.9	2	3.4	0.6
2008	10.1	2	3.3	0
2009	1.3	1	1	0
2010	2.2	0	2.8	0.1

4.2.1.2 Use categories and volumes in Denmark

The use categories and volumes from Denmark are shown in Figure 4.2 and Table 4.2. The Danish product register has registered the use of Cybutryne in products that were either “paints, lacquers and varnishes” or “non agricultural pesticides and preservatives (biocides)”. Due to a low number of products in other use categories, no details can be made publicly available due to confidentiality. In the years 2000 to 2002, a relatively large amount of Cybutryne (between 7.15 and 19.98 tons) is covered by confidentiality. From 2003 to 2010, this has decreased to a level between 0 and 2.16 tonnes.

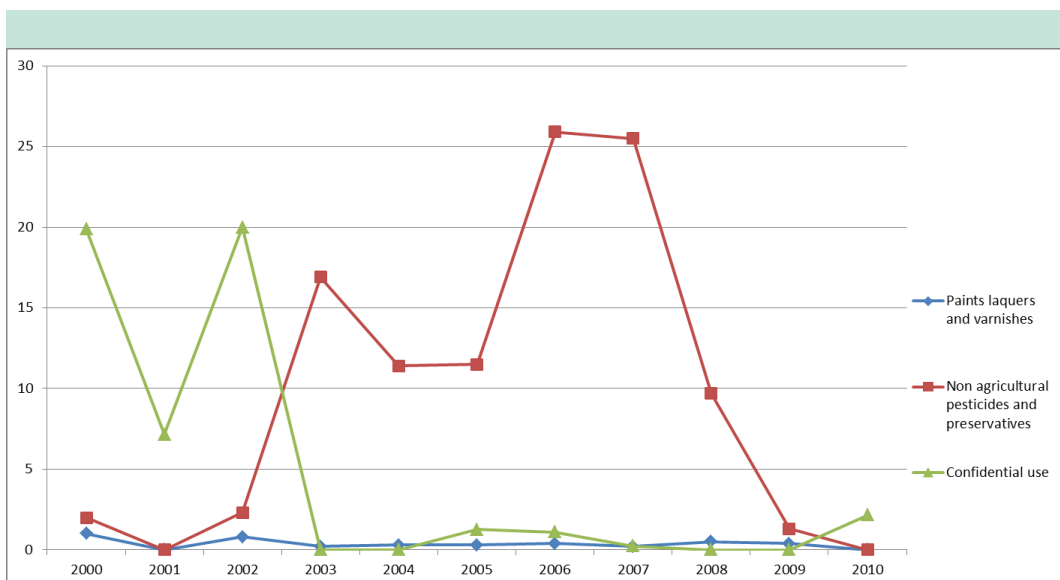


FIGURE 4.2
USE CATEGORIES AND AMOUNT/TONNES OF CYBUTRYNE IN DENMARK FROM YEAR 2000 TO 2010 (SPIN, 2012)

TABLE 4.2
USE CATEGORIES AND AMOUNT (IN TONNES) OF CYBUTRYNE IN DENMARK FROM YEAR 2000 TO 2010 (SPIN, 2012)

Year	Paints, laquers and varnishes	Non agricultural pesticides and preservatives	Confidential use
2000	1	2	19.87
2001	0	0	7.15
2002	0.8	2.3	19.98
2003	0.2	16.9	0
2004	0.3	11.4	0
2005	0.3	11.5	1.26
2006	0.4	25.9	1.09
2007	0.2	25.5	0.24
2008	0.5	9.7	0
2009	0.4	1.3	0
2010	0	0	2.16

4.2.1.3 Estimated trends in use in Denmark and the Nordic countries

From 2000 to 2010, there was a significant decrease in all Nordic countries in the total amount of Cybutryne on the markets. Denmark was the Nordic market that used most Cybutryne with levels of up to 27.4 tonnes/year during the period. Also, the most rapid decline of Cybutryne has been on the Danish market, decreasing from 27.4 tonnes in 2006 to 2.2 tonnes in 2010. Sweden has gradually phased out products containing Cybutryne from 8 tonnes in 2002 to close to zero on the Swedish market in 2010. Finland has also decreased its total amounts from 2 tons in 2001 to 100 kg in 2010. In Norway, the amount of Cybutryne on the market has varied between 1 and 6.2 tonnes per year and continues to stay at this level with a total of 2.8 tonnes in 2010. From 2011, Cybutryne has only been allowed in antifouling products in the EU. It is expected that this provision will decrease the

amount on the Nordic markets even more in the coming years. The outcome of the review of Cybutryne under the BPD/BPR may also influence the EU market.

4.2.2 Uses outside the EU

In the USA, besides its use in antifouling products, Cybutryne is also used as materials preservative for exterior paints, coatings, stains, building materials, latex- and solvent-based paints, semitransparent stains, solid stains, vinyl roofing, elastomeric roofing, wall coatings, mastics, caulks, sealants, joint cements, spackling, stucco, grouting, applied film of paint, masonry coatings, wood protective stains, adhesives, roof coatings, plasters, sealants and fillers used for architectural products, finishes and special purpose coatings, hulls on ships, boats, barges, yachts and running gear (US EPA, 2010).

4.3 Summary

Cybutryne has been used worldwide in a range of products for preservation, including antifouling. The substance is still used outside the EU in a number of applications. In Denmark, Cybutryne has been used to a minor extent in the use category “paints, laquers and varnishes” and to a major extent, in the use category “non-agricultural pesticides and preservatives” (biocides). From 2000-2010, there is an overall decrease in total amount of Cybutryne placed on the Danish market from around 25 tonnes to less than 5 tonnes. This tendency is expected to continue due to the phasing out of the uses within PT 7 (Film preservatives), PT 9 (Fibre, leather, rubber and polymerized materials preservatives) and PT 10 (Masonry preservatives) by 2011, due to the existing Danish Statutory Order No. 1257 restricting the import, sale and use of biocidal antifouling and due to the BPD and BPR restricting the future use of Cybutryne in antifouling products within the EU.

5. Environmental hazard and risk assessment

Cybutryne is currently being evaluated by the EU for the use in antifouling products within the framework of the BPD. The intended use evaluated by the EU is for application on commercial deep sea and coastal vessels by professionals. The Competent Authority of the Netherlands is the Rapporteur Member State who is in charge of the first evaluation of the dossier of Cybutryne submitted by the applicant (BASF SE). In 2011, Document I of the draft Competent Authority (CA) report on Cybutryne was made available to the public on the Communication & Information Resource Centre Administrator webpage (CIRCA, 2011). The following environmental section refers primarily to the first version of Document I of the draft CA report. They have proposed an Annex 1 inclusion of Cybutryne. Currently, this proposal is being discussed among the EU member states. The evaluation work is still on going and no decision has yet been made on whether to include Cybutryne or not in Annex 1 of the BPD. If new data are presented, the conclusions on the environmental risk assessment of Cybutryne can be altered or changed.

5.1 Exposure

In the dossier from the applicant, the use of Cybutryne containing antifouling paints is restricted to commercial marine vessels (non-pleasure vessels). From the intended uses, it follows that emission is predominantly to marine waters. The expected main routes of environmental exposure are releases into marine waters in harbours, shipping lanes or open sea. The main routes of entry into the environment are via leaching of the active substance during the service life and via discharge from docks or marine lift as a result of application and removal of antifouling. Thus, the dominant receiving compartment will be sea water.

5.2 Fate and distribution in the environment

Cybutryne is not readily biodegradable according to OECD 301B. The half-life in the water column of the major degradation product of Cybutryne in marine waters, GS 26575, is comparable to that of the parent compound (DT50: 23 days). Based on the average K_{oc} -value of 1106 L/kg for adsorption, Cybutryne is classified as having a low mobility potential in soil. The sorption characteristics of Cybutryne in combination with its low biodegradation may pose a risk of accumulation in plants and sediment. However, Cybutryne has a moderate potential to bioaccumulate in fish (BCF 250 L/kg) but is eliminated rapidly (DT50 <3 days).

5.3 Effects in the aquatic compartment

The mode of toxic action of Cybutryne, like other triazine herbicides, is the inhibition of photosynthetic electron transport. The inhibition of the photosynthetic activity occurs in photosystem II (PSII) where the incorporation of CO₂ in organic molecules is inhibited, ultimately leading to an inhibition of growth. The toxicity data with species from different phyla indicate that the primary producers, i.e. algae (*Naviculla pelliculosa*, EC₅₀ (120h) = 0.0957 µg/L and EC₁₀ (120h) = 0.04 µg/L) and aquatic macrophytes (*Lemna gibba*, EC₅₀ (14d) = 1.65 µg/L and NOEC (14d) = 0.671 µg/L), are the most sensitive group of aquatic species. Cybutryne appeared also to be highly toxic to fish (*Oncorhynchus mykiss*, LC₅₀ (96h) = 860 µg/L and NOEC (95 d) = 4 µg/L) and invertebrates (*Mysidopsis bahia*, EC₅₀ (24h) = 480 µg/L and NOEC (28d) = 110 µg/L). The mode of action in these organisms is unknown.

5.4 Risk characterisation

In the EU process of the evaluation of Cybutryne, the predicted environmental concentrations (PEC) and predicted no effect concentrations (PNEC) are still under discussion. Therefore, no clear conclusion on the risk characterisation of Cybutryne has been made at this point in time.

5.5 PBT assessment

According to the REACH related ECHA Guidance Document R. 11, the decision that a substance is not persistent (P) can be made if an OECD 301 study indicates that the substance is readily biodegradable and a simulation test indicates a half-life (DT50) of less than 1 day for the aqueous biodegradation. Cybutryne is not readily biodegradable according to OECD 301B, and the half-life in the water column of the major degradation product of Cybutryne in marine waters, the triazine compound GS 26575, is comparable to that of the parent compound (DT50: 23 days). The toxicity to aquatic organisms of GS 26575 is predicted by QSAR to be in the "Toxic" range, thus demonstrating a pesticidal activity of this degradation product. Therefore, Cybutryne fulfils the criteria for Persistence (P). The highest toxicity towards aquatic organisms was reported in relation to a NOEC value <0.05 µg/L (for invertebrates) and, therefore, Cybutryne fulfils the criterion for Toxicity (T). As the BCF in fish was determined to be 250 L/kg, Cybutryne does not fulfil the criterion for Bioaccumulation (B) and Cybutryne is thus not classified as a PBT or vPvB substance (ECHA, 2008).

5.6 Endocrine disruption

Different studies have been performed on the endocrine disrupting effects of Cybutryne on freshwater snails, *Radix balthica*, *Lymnaea stagnalis* and *Potamopyrgus antipodarum*, and on the freshwater crustacean, *Asellus aquaticus*. The results are contradictory but the available information is insufficient to identify Cybutryne as a 'potential' endocrine disrupter and are an insufficient basis for the identification or not of Cybutryne as a potential endocrine disrupter. At a technical EU meeting, it was decided that additional tests should be performed. When all necessary information is available, the Competent authorities for biocides will decide, if Cybutryne can be considered as a 'potential' endocrine disrupter.

5.7 Summary

Marine waters in harbours, shipping lanes or open sea are exposed to Cybutryne. The main route of entry into the environment is via leaching during service life and via discharge as a result of application and removal. Cybutryne is not readily biodegradable. The toxic mode of action of Cybutryne is the inhibition of photosynthesis. Algae and aquatic macrophytes are most sensitive to Cybutryne. Due to uncertainty of PNEC and PEC values, no clear conclusion on the risk characterisation of Cybutryne can be made at this point in time. Cybutryne is considered as persistent and toxic to aquatic organisms, but is not assessed to be bioaccumulating and is therefore not classified as a PBT substance. The EU has not yet decided whether Cybutryne can be considered as a 'potential' endocrine disrupter in the environment.

6. Human health hazards and risk assessment

Cybutryne is currently being evaluated by the EU for the use in antifouling products within the framework of the BPD. In 2011, Document I of the draft Competent Authority (CA) report on Cybutryne from the Netherlands was made available to the public on the Communication & Information Resource Centre Administrator webpage (CIRCA, 2011). The following human health risk section refers primarily to the first version of the Document I of the draft CA report.

6.1 Exposure

The draft CA report includes the use of Cybutryne in antifouling products for application only on commercial deep sea and coastal vessels (not for pleasure boats) and by professionals during production and use. Therefore, the report assumes that exposure is restricted to professionals only. Also, no exposure of the general public is included in the calculations. The antifouling paint is applied mainly by high pressure airless spraying. The main routes of exposure are by inhalation and by dermal exposure. Painting results in the highest exposure and thus the internal systemic exposure of painters is estimated to be 5.6 mg/day by the inhalation route and 30 mg/day by the dermal route if no personal protective equipment (PPE) is used. When using PPE, the internal exposure is estimated to be 0.14 mg/day for inhalation exposure and 0.6-1.6 mg/day for dermal exposure. In the calculation of the internal dose, an absorption factor of 100% was applied for inhalation exposure and an absorption factor of 0.5% was applied for dermal exposure. Although not given in the draft CA report, similar exposure scenarios could be anticipated for non-professionals although they may rarely be involved in painting of large commercial ships and not as frequently as a professional painter. On the other hand, correct use of PPE cannot be expected from amateurs.

6.2 Hazard assessment

Cybutryne is not skin or eye irritating. Cybutryne is a skin sensitizer. In the subacute, subchronic and chronic studies in the rat, there does not seem to be an effect of prolonging the exposure duration as the NOAELs are in the same range (7.3, 9.6 and 12.2 mg/kg bw/day respectively), the effects reported being reduced body weight gain, food consumption and increased cholesterol levels. No carcinogenicity studies were available. The NOAEL of 15mg/kg bw/day (with a corresponding LOAEL of 45mg/kg bw/day) was reported from a rabbit developmental study with respect to post-implantation loss and reduced body weight of the foetuses was chosen as the overall NOAEL for the risk assessment.

6.3 Risk characterisation

Assuming an absorption rate of 25% from the oral studies with experimental animals, the NOAEL value of 15 mg/kg bw/day was converted into an internal systemic NOAEL of 3.75 mg/kg bw/day. From this value, the draft CA report derived an acceptable occupational exposure level (AOEL) of 2.7 mg/day as internal dose when multiplying by 70 kg of body weight and dividing by an overall assessment factor of 100 (10 for interspecies variation \times 10 for intraspecies variation). When calculating the risk characterisation using the exposure estimate given in Section 6.1, the value of 13.3 indicated an unacceptable risk for painters. Potmen and ancillary workers would also encounter unacceptable risk although at lower levels. However, when personal protective

equipment was used, an RCR of 0.05 was obtained indicating no risk for the painters. As it is assumed that non-professional use will not be relevant, no risk characterisation for this population group is included in the draft CA-report.

6.4 Summary

The draft CA report identifies Cybutryne to be skin sensitizer. The NOAEL value of 15 mg/kg bw/day from the developmental toxicity was chosen for the risk assessment. The risk characterisation indicated an unacceptable risk for painters, potmen and ancillary workers. However, safe use of Cybutryne-containing paints in relation to spray application of antifouling paint by professionals was demonstrated provided that adequate personal protective equipment is applied in this draft report. There may be a data gap on carcinogenicity, as no carcinogenicity studies were available.

7. Information on alternatives

Industry and private consumers use biocide-containing antifouling paints to control foulant organisms. Antifouling paints are used to reduce the attachment of microorganisms, plants, algae or animals to the submerged surfaces of ships, boats and aquatic structures (Lambert *et al.*, 2006). The control of these foulant organisms is especially important since an overgrown ship hull leads to a decrease of maneuverability, transfer of invasive species and an increase in energy consumption and CO₂ emission.

7.1 Biocidal alternatives

In the EU there are currently 10 biocidal active substances (including Cybutryne) for use in antifouling products under evaluation in the review programme of the BPD (Table 7.1). The evaluation will either result in an inclusion or a non-inclusion to Annex I of the BPD. Currently, no decisions have been made on any of the active substances. As long as the evaluation is going on, the 10 active substances are in a transitional phase, meaning that they can be marketed in the EU but they have to comply with the national legal provisions of the country, in which they are marketed. Apart from these 10 active substances, there are 2 new active biocidal substances that are being supported with a dossier within PT 21. They are currently under evaluation but will not be allowed in any antifouling products before an inclusion decision has been made.

Biofouling organisms can be split into two main groups: “Soft fouling organisms” comprises bacteria, fungi, algae and invertebrates, such as soft corals, sponges, anemones, tunicates and hydroids and “Hard fouling organisms” comprising invertebrates such as barnacles, mussels and tubeworms (Callow & Callow, 2002). The target organisms of the 10 active substances of PT21 are presented in Table 7.1. Cybutryne is only effective against algae. Cybutryne is a “booster” biocide typically mixed in an antifouling paint formulation with a hard fouling controlling active substance like copper in order for the paint to have a wider range of target organisms (Hempel, 2012). There are 6 biocidal active substances that can also control algae and constitute the biocidal alternatives to Cybutryne: Tolyfluanid, Dichlofluanid, Zineb, Zinc pyrithione, Copper pyrithione and DCOIT.

TABLE 7.1
ACTIVE SUBSTANCES WITHIN PT21 UNDER EVALUATION IN THE EU AND THEIR TARGET ORGANISMS

Active substance	EC No.	CAS No.	Target organisms
Tolyfluanid	211-986-9	731-27-1	Soft fouling (fungi, algae)
Dichlofluanid	214-118-7 0	1085-98-9 0	Soft fouling (bacteria, fungi, algae)
Copper thiocyanate	214-183-1	1111-67-7	Hard fouling (barnacles, mussels) (CAEP, 2012)
Dicopper oxide	215-270-7	1317-39-1	Hard fouling (barnacles, mussels) (CAEP, 2012)
Copper	231-159-6	7440-50-8	Hard fouling (barnacles, mussels) (CAEP, 2012)
Zineb	235-180-1	12122-67-7	Soft fouling (bacteria, fungi, algae) Hard fouling (barnacles) (Ireland, 2011)
Zinc pyrithione	236-671-3	13463-41-7	Soft fouling (bacteria, fungi, algae) (ARCH, 2008)
Copper pyrithione	238-984-0	14915-37-8	Soft fouling (bacteria, fungi, algae) (ARCH, 2008)
Cybutryne	248-872-3	28159-98-0	Soft fouling (algae) (Netherlands, 2011)
DCOIT	264-843-8	64359-81-5	Soft fouling (bacteria, fungi, algae) Hard fouling (barnacles) (Norway, 2010)

7.2 Non-biocidal alternatives

There have been research and development projects trying to find effective and usable non-biocidal solutions against fouling organisms (DEPA, 2004; DEPA 2007; DEPA, 2008; DEPA, 2012_a; DEPA, 2012_b). The best alternative is to apply costly siliconized epoxy coating to the submerged surface. This results in a very smooth and slippery surface that can prevent foulants from settling permanently on the surface. This solution is commercially available and applicable on transport ships, ferries or speed boats that sail with a high speed (>15 knots). For slower boats (<15 knots) this solution is not feasible as the lower sailing speed allows the foulants to settle. Apart from this solution, there are currently no effective non-biocidal alternatives available that can replace the chemical antifouling products.

7.3 Summary

Antifoulant agents are important for the maneuverability of the ships, the prevention of transfer of invasive species and the decrease in energy consumption and CO₂ emission. Because of the negative effects on the environment from many antifoulants, several projects have been initiated with the aim of developing alternatives to Cybutryne and antifouling paints in general. There are currently 6 biocidal active substances on the market in the EU that, like Cybutryne, are effective against algae. Apart from siliconized coatings, there are currently no effective non-biocidal alternatives available.

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List of abbreviations

Abbreviation	Description
AF	Assessment factor
AOEL	Acceptable operator exposure level
as	Active substance
BCF	Bioconcentration factor
BPD	Biocidal Products Directive
BPR	Biocidal Products Regulation
bw	Body weight
°C	Degrees Celsius (centigrade)
CA	Competent Authority
CLP	EU Classification, Labelling and Packing regulation
EEA	European Economic Area
EINECS	European inventory of existing commercial substances
K_{oc}	Organic carbon adsorption coefficient
kPa	Kilopascal(s)
LOAEL	Lowest observable adverse effect level
NOAEL	No observed adverse effect level
NOEC	No observed effect concentration
PBT	Persistent, Bioaccumulative, Toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PPE	Personal protective equipment
PT	Product type
vPvB	Very persistent, very bioaccumulative

Survey of cybutryne

This survey is part of the Danish EPA's review of the substances on the List of Undesirable Substances (LOUS). The report defines the substance and present information on the use and occurrence of cybutryne 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 substances.

Kortlægning af cybutryne

Denne kortlægning er et led i Miljøstyrelsens kortlægninger af stofferne på Listen Over Uønskede Stoffer (LOUS). Rapporten definerer stoffet og indeholder blandt andet en beskrivelse af brugen og forekomsten af cybutryne 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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