Institute for Health and Consumer Protection
*Former* Toxicology and Chemical Substance (TCS)
European Chemicals Bureau
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# DIMETHYLDIOCTADECYLAMMONIUM CHLORIDE (DODMAC)

CAS No: 107-64-2

EINECS No: 203-508-2

## Summary Risk Assessment Report

## With addendum 2009

2009 EUR 20397 EN/3

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# DIMETHYLDIOCTADECYLAMMONIUM CHLORIDE

**(DODMAC)**

**Addendum – 2009**

CAS No: 107-64-2

EINECS No: 203-508-2

# SUMMARY RISK ASSESSMENT REPORT

# EXPLANATORY NOTE

This is an addendum to the Summary Risk Assessment Report on dimethyldioctadecylammonium chloride (DODMAC), that has been prepared by Germany in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances and published in 2002 on the European Chemicals Bureau website (Summary Risk Assessment Report , Special Publication I.02.76) [1].

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR).

[1] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.ec.europa.eu/

**Data requirement according to Regulation (EC) 1217/2002**

**DHTDMAC (Cas-No. 61789-80-8)**

**Evaluation of provided information**

According to Art. 12 (2) of Regulation EEC 793/93 industry had to provide information on the yearly consumption volumes of the substance DHTDMAC (quaternary ammonium compounds, bis(hydrogenated tallow alkyl) dimethyl, chlorides) (Cas-No. 61789-80-8) for the year 2000 to 2002. The reason for this requirement was the concern for a significant increase in consumption volumes of the substance which would pose a potential risk for the environment.

Within the frame of an EU risk assessment for the substance DODMAC, which is contained in the technical mixture DHTDMAC with a percentage of 42%, consumption figures for the years 1998 and 1999 have already been available.

Therefore, an evaluation of the consumption figures for DHTDMAC for the years 1998 to 2002 can be performed.

The following data have been provided by industry:

| Year | Organo field bentonites [t/a] | Fabric softener [t/a] | Other uses [t/a] | Σ softener and other uses [t/a] | Total consumption [t/a] |
|---|---|---|---|---|---|
| 1998 | 4,986 | 408 | 276 | 684 | 5,670 |
| 1999 | 3,656 | 333 | 642 | 975 | 4,631 |
| 2000 | 3,116 | 526 | 669 | 1,195 | 4,311 |
| 2001 | 3,594 | 101 | 684 | 785 | 4,379 |
| 2002 | 4,278 | 73 | 603 | 676 | 4,954 |

No clear trend in the consumption of DHTDMAC over these 5 years can be observed. A potential risk for the environment (surface waters and sediment) may occur from the direct use of the substance as fabric softener or in other uses (hair conditioner, car washing…). The amount of DHTDMAC used in these applications (wide dispersive use) increased from 1998 to 2000 from 684 tonnes/annum to 1,195 tonnes/annum but decreased afterwards to 785 and 676 tonnes/annum in 2001 and 2002. It cannot be excluded that the consumption of DODMAC for these applications will increase again in the following years.

The highest consumption volume of DHTDMAC in direct applications in 2000 was by a factor of 1.75 higher than the volume used in the risk assessment of DODMAC for the year 1998. Considering the fact, that the PEC/PNEC ratio for DHTDMAC is by a factor of 2.4 higher than the ratio for DODMAC, as DODMAC is contained in the technical product DHTDMAC with a fraction of 42% gives the following PEC/PNEC ratios for DHTDMAC for the year 2000 (based on the PEC and PNEC derivation in the EU RAR DODMAC):

| | PEC/PNEC ratio |
|---|---|
| Surface water | 0.37 |
| Sediment | 0.53 |

Conclusion

The consumption of DHTDMAC for the years 1998 to 2002 will not result in a risk for the aquatic environment (surface water and sediment). However, an increase by a factor of about 2 compared to the figures for 2000 may result in a risk for the sediment compartment.

# DIMETHYLDIOCTADECYLAMMONIUM CHLORIDE
## (DODMAC)

CAS No: 107-64-2

EINECS No: 203-508-2

# SUMMARY RISK ASSESSMENT REPORT

*2002*

Germany

The Rapporteur for dimethyldioctadecylammonium chloride is the Federal Institute for Occupational Safety and Health.

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| | |
|---|---|
| **Date of Last Literature Search :** | **1995** |
| **Review of report by MS Technical Experts finalised:** | **December 1998** |
| **Final report:** | **2002** |

## PREFACE

This document provides a summary, with conclusions, of the risk assessment report of the substance dimethyldioctadecylammonium chloride that has been prepared by Germany in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and the procedures followed, the underlying data and the literature references, the reader is referred to the original Comprehensive Risk Assessment Report that can be obtained from the European Chemicals Bureau[2]. The present summary report should preferably not be used for citation purposes.

[2] European Chemicals Bureau – Existing Chemicals – http://ecb.jrc.it

# CONTENTS

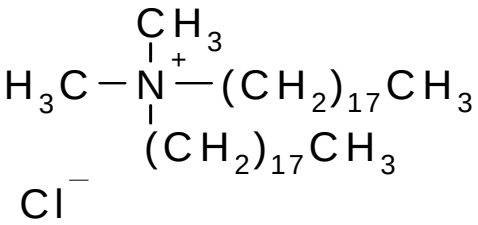


# TABLES

# 1 GENERAL SUBSTANCE INFORMATION

## 1.1 IDENTIFICATION OF THE SUBSTANCE

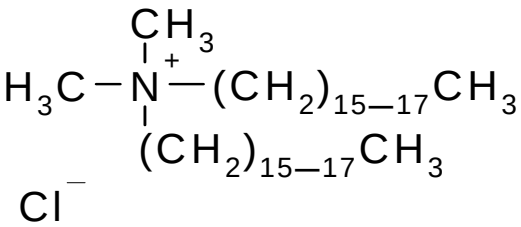
CAS Number: 107-64-2
EINECS Number: 203-508-2
IUPAC Name: Dimethyldioctadecylammonium chloride
Synonyms: DODMAC
Distearyldimethylammonium chloride (DSDMAC)
CA-Index name: 1-Octadecanaminium, N,N-dimethyl-N-octadecyl-, chloride
Empirical formula: $C_{38}H_{80}NCl$
Structural formula:



Molecular weight: 586.52 g/mol

Dimethyldioctadecylammonium chloride (DODMAC) as an isolated substance is not produced or used in a commercial range. But it is one of the active component of the technical product ditallowdimethylammonium chloride (DHTDMAC) which is of commercial interest:

CAS Number: 61789-80-8
EINECS Number: 263-090-2
IUPAC Name: N,N-Dimethyl-N,N-di-n-alkyl(C16-18)-ammoniumchloride
Synonyms: Di(hydrogenated tallow alkyl) dimethylammoniumchlorides
(DHTDMAC)
Empirical formula: approx. $C_{36,4}H_{76,8}NCl$
(related to approx. 65 % $C_{38}H_{80}NCl$, 30 % $C_{34}H_{72}NCl$, 5 % $C_{30}H_{64}NCl$)
Structural formula:



Molecular weight: approx. 567 - 573 g/mol (ECETOC, 1993)

Dimethyldialkyl($C_{16-18}$)ammoniumchloride (DHTDMAC) is a mixture of quaternary ammonium compounds, with DODMAC as the main component, which is produced from hardened, i.e. hydrogenated natural fats. The alkyl chain length distribution related to the total molecule in standard European products with bovine tallow as the most important raw fat (e.g. Praepagen WK, Genamin DSAC) is:

| | | |
|---|---|---|
| $C_{12}$ | max. 2 % | |
| $C_{14}$ | 1 - 5 % | |
| $C_{16}$ | 25 - 35 % | |
| $C_{18}$ | about 65 % | |
| $C_{20}$ | max. 2 % | (Hoechst AG, 1980) |

According to these distributions, DHTDMAC consists of about 65 % of $C_{18}$-chains. Since each molecule contains two alkyl chains, the proportion of DODMAC related to the total content of dimethyldialkylammonium compounds can be estimated as 42 % DODMAC contained in DHTDMAC.

## 1.2 PURITY/IMPURITIES, ADDITIVES

The active content of technical pure DHTDMAC amounts to a w/w ≥ 95 %, of which free amines and hydrochlorides amount to a w/w ≤ 3 % (the active content is defined as the sum of quaternary ammonium compounds inclusively the free amines and hydrochlorides).

Impurities are:

| | |
|---|---|
| Monoalkyl($C_{16-18}$)trimethylammoniumchloride | < 4 % |
| Dialkyl($C_{16-18}$)methylamine, Trialkyl($C_{16-18}$)amine and their hydrochlorides | < 2 % |
| Isopropanol | < 2 % |
| Water | < 4 % |
| Sodium chloride | < 1 % |

Technical pure DHTDMAC is not used as such but as paste-like preparations with an active content of a w/w approx. 77 %, approx. 13 % isopropanol, < 2 % free amines and hydrochlorides and approx. 10 % water (Hoechst AG, 1980).

Concerning DODMAC the exact composition regarding the impurities is not known. Therefore an active content of 100 % for DODMAC is assumed in the following risk assessment.

## 1.3 PHYSICO-CHEMICAL PROPERTIES

DODMAC and DHTDMAC belong to the group of the quaternary ammonium compounds (“quats”) and are cationic tensides.

**Table 1.1** Physico-chemical properties

| | **DODMAC (active content 100 %)** | **DHTDMAC (active content ≥ 95 %)** |
|---|---|---|
| Physical state | solid | solid |
| Melting point | 72-122 °C | 60 - 65 °C |
| Boiling point | decomposition at 135 °C | decomposition at 120 °C |
| Density | 0.84 g/cm³ at 88 °C | 0.86 g/cm³ at 50 °C |
| Vapour pressure | negligible because of the salt character | negligible because of the salt character |
| Surface tension | 11 mN/m at 20 °C<br>(saturated solution; method: film balance) | no data available |
| Water solubility | not soluble, dispersible<br>2.7 mg/l [< 1 pg/l] | not soluble, dispersible |
| Partition coefficient log Kow | 3.80 (measured) | no data available) |
| Flash point | not applicable because substance is solid | not applicable because substance is solid |
| Flammability | not highly flammable;<br>no data available, but the behaviour is assumed to be comparable to DHTDMAC | not highly flammable;<br>A.12 not conducted because of structural reasons |
| Explosive properties | not explosive because of structural reasons | not explosive because of structural reasons |
| Oxidising properties | no oxidizing properties because of structural reasons | no oxidizing properties because of structural reasons |

## 1.4 CLASSIFICATION

Classification of pure DODMAC according to Annex I of Directive 67/548/EC; 28th ATP:

| | | | |
|---|---|---|---|
| Xi | *Irritant* | R 41 | *Risk of serious damage to eyes* |
| N | *Dangerous for the environment* | R 50/53 | *Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment* |

Technical grade DODMAC (77% dimethyldioctadecylammonium chloride, 11.3% isopropanol and 11.7% water) causes corrosion after a 4-hour contact with the skin of rabbits: A test with 6 rabbits (semi-occlusive application of 0.5 ml for 4 hours) resulted in moderate irritation, the effects increased after the day of application till exhibition of severe necrosis after a 14-day observation time. According to these data and the criteria of Directive 93/21/EEC, technical grade "DODMAC" (containing approximately 12% isopropanol) is to be classified "C, corrosive" and labelled "R 34, causes burns".

# 2 GENERAL INFORMATION ON EXPOSURE

Dimethyldioctadecylammonium chloride (DODMAC) as an isolated substance is not produced or used in a commercial range. DODMAC occurs as a major component of the technical product dihydrogenated tallow dimethyl ammonium chloride (DHTDMAC).

DHTDMAC is produced from tallow acids by the following synthesis pathway:

tallow → tallowfatty acid → tallowfatty acid nitrile → dihydrogenated tallow amine → dihydrogenated tallow methyl amine → dihydrogenated tallow dimethyl ammonium chloride (DHTDMAC, containing about 42% DODMAC).

The alkyl chains of this compound consist of 60-70% C18-chains, so the proportion of DODMAC is about 42% related to the total content of dialkyldimethylammonium compounds.

The following exposure assessment is performed for DODMAC in particular. If appropriate, data for DHTDMAC are considered. All figures for DHTDMAC (if not other more stated) are related to the active compound and do not include the solvent content of the technical product.

In the EU, DHTDMAC is produced at six sites. The actual production volume was estimated to 5,004 t in 1996 and 5,651 t in 1997.

The use pattern of DHTDMAC in the EU is:

- Fabric softeners. The consumption amount in the EU decreased from about 65,000 t/a in 1990 to 24,000 t/a in 1993. The consumption dropped to 591 t in 1996, 677 t in 1997 and 408 t in 1998. Data about the spatial distribution of the current use are not available.

- Synthesis of organic clays, which are used as drilling muds in oil industry and rheological additives in paints and lacquers. In Europe, 4,113 t of the DHTDMAC production were used for organofield bentonites in 1996, 4,605 t in 1997 and 4,986 t in 1998. In 1997, 4,137 t DHTDMAC were used in solvent-based paints. The total DHTDMAC amount processed by 5 organofield bentonite producers is 5,221 t.

- Other uses. In 1997, 369 t (1998: 276 t) DHTDMAC were used especially for car washing agents and hair conditioners.

# 3 ENVIRONMENT

## 3.1 ENVIRONMENTAL EXPOSURE

Releases of DODMAC into the environment via wastewater occur during production, during processing to and use of activated bentonites and during use of fabric softeners, car washing agents and hair conditioners.

There is different information about releases into the wastewater during production. While some producers state that under regular conditions no emission occurs, another company submitted analytical data. In the literature, high DHTDMAC concentrations in the wastewater of a producer are reported.

To activate bentonites, the natural cations are replaced by DHTDMAC to improve the swelling properties. The activated bentonites are used for the formulation of laquers (which are especially applied in the automobile industry), as drilling muds in oil production, in plastics and greases. With analytical measurements in the sewage no DODMAC could be detected. Therefore the release factor must be below 1.1%.

During the use of fabric softeners, DHTDMAC is adsorbed nearly quantitatively onto the fibre, but will be removed completely during the next wash. As the substance is chemically stable under washing conditions, the total volume used for softeners will be emitted into the household sewage. The same release path has to be expected for additives in cosmetics and car washing products.

Releases into the terrestrial compartment are expected due to application of sewage sludge from municipal sewage treatment plants as fertilizer.

The environmental behaviour of DODMAC is determined by the following characteristics:

- DODMAC is not readily biodegradable.
- Hydrolysis and photolysis are not expected under environmental conditions.
- Based on the moleculare structure of DODMAC, no volatility is expected
- The $Kp_{sed\ and}$ $Kp_{soil}$ of 10,000 l/kg indicate a relevant adsorption onto both the mineral and the organic fraction of sediment and soil
- The $Kp_{susp}$ of 16,800 l/kg indicates a relevant adsorption onto suspended matter
- In aqueous phase DODMAC is not really dissolved but always occurs in vesicles together with other lipophilic organics.

Relevant bioaccumulation from water and sediment is not expected. In wastewater treatment plants (WWTPs) 95 % of the substance are estimated to be removed, mainly by adsorption onto sludge.

The ecological effects of the substance are strongly dependent on the test medium, differences are caused by adsorption onto suspended matter and complexation with anionics. Therefore the relevant ecotoxicity values are derived from tests in river water. For the aquatic risk assessment, the $PEC_{bulk}$ (which includes the fraction adsorbed onto suspended matter) has to be calculated as the PEC being adequate to the river water tests.

**P**redicted **E**nvironmental **C**oncentrations (PEC) (sum of local and regional concentration) are calculated for the local aquatic environments of the production and processing sites using all site

specific information available. The resulting $PEC_{bulk,local}$ for the production sites range between 0 (no emission into sewage at four sites) and 0.22 µg/l. For the five processing sites the $PEC_{bulk,local}$ range from 0 (no emission into sewage at 1 site) to 0.43 µg/l.

In addition, local PECs are estimated for the use of activated bentonites in paint and laquers and for the emissions via household sewage due to use as fabric softeners, in hair conditioners and car washing agents.

For the use of activated bentonites at a medium/large paint user site with a paint consumption of 10 t/month, a $PEC_{bulk,local}$ of 0.41 µg/l was calculated.

For the emission of DODMAC via household sewage, two scenarios were calculated. The first scenario is based on the DODMAC consumption figures for 1998. Additionally, a scenario based on the fabric softener consumption from 1989/90 is calculated, with the rationale to better compare monitoring data with estimated values and to reflect the decrease of environmental pollution in the last years. The second scenario was not used for the risk characterisation. A $PEC_{bulk,local}$ of 0.54 µg/l was derived based on consumption figures for 1998. With the consumption figures for 1989/90 a $PEC_{bulk,local}$ of 10.5 µg/l was calculated.

PEC estimation for the sediment compartment was performed using the local aquatic $PEC_{water}$ and the $Kp_{sed}$ of 10,000. For the production sites the estimated $PEC_{sed}$ ranged from 0 (no emission into sewage at four sites) to 2.9 mg/kg dw. For the processing sites the $PEC_{sed}$ range from 0 (no emission into sewage at 1 site) to 5.7 mg/kg dw.

For the use of activated bentonites a $PEC_{sed}$ of 1.7 mg/kg dw was calculated.

From the emission via household sewage a $PEC_{sed}$ of 7 mg/kg dw was derived based on the consumption figures for 1998 and a $PEC_{sed}$ of 137 mg/kg dw based on the consumption figures for 1989/90.

Because an extremely low volatility of DODMAC is to be expected, no significant exposure of the atmosphere is assumed.

The elimination of DHTDMAC resp. DODMAC in WWTPs is dependent on adsorption onto sludge to a large extent. During application of sludge as fertilizer, the substance reaches agricultural soils. The concentration of DODMAC in sewage sludge is calculated from the emission into the local treatment plant, the sludge adsorption rate of 55% and the sewage sludge production rate of 710 kg/d to 120 mg/kg dw based on consumption figures for 1998 and to 1,300 mg/kg dw for the consumption figures for 1989/90. The resulting bulk concentration in agricultural soil is 0.49 mg/kg dw for the 1998 consumption figure. For the consumption figures for 1989/90 the respective PEC is 5.3 mg/kg dw.

A lot of monitoring data are available for DHTDMAC. For the interpretation of the aquatic monitoring data, it has to be considered that the figures stand for total concentrations, i.e. no distinction has been made between the “dissolved” (in reality: included in vesicles) and the adsorbed fractions. In surface waters concentrations up to 92 µg/l were measured in the 1980ies.

The examination of the pollution of suspended particles in the river Rhine showed that the DHTDMAC concentrations decreased from about 200 mg/kg in 1982 to 25-50 mg/kg in 1994. In the same period the German DHTDMAC consumption for softeners had dropped by more than 90%. More recent data reflecting the actual exposure situation are not available.

For the assessment of **regional exposure** only the emissions during use as fabric softeners, car washing agents and hair conditioners are considered. The releases during production, processing to activated bentonites and use of the bentonites by lacquers are relatively small and can be neglected. The resulting values are:

**Table 3.1** PECs for the use as fabric softeners, hair conditioners and car washing products

| | 1989/90 | 1998 |
|---|---|---|
| PECwater,bulk [µg/l] | 6.3 | 0.14 |
| PECwaterphase [µg/l] | 5.1 | 0.11 |
| PECsediment [mg/kg dw] | 80 | 1.7 |
| PECagr.soil [mg/kg dw] | 0.29 | 0.0067 |

## 3.2 EFFECTS ASSESSMENT

The toxicity of DODMAC is influenced by adsorption onto surfaces, complexation, water quality, usage of solvents and concentration of by-products. Because the database for the pure DODMAC (> 95% purity, $C_{18}$-chain length) would be too small to reveal all these parameters, it is necessary to use ecotoxicological test results for the commercial product DHTDMAC (71-78% active ingredient = quaternary ammonia, different chain lengths) for the effects assessment as well.

Short- and long-term tests are available with fish, invertebrates and algae using both laboratory water and river water. As it is assumed that tests with river water are more relevant these values are used for the environmental hazard assessment.

The most sensitive aquatic species to DODMAC/DHTDMAC is the algae *Selenastrum capricornutum*: in river water tests, a 5d-NOEC = 62 µg/l was determined, while in laboratory water, the 96h-NOEC was 6 µg/l. From a long-term test with *Daphnia magna* a 21d-NOEC for reproduction of 380 µg/l in river water was derived. In an embryo-larval test with *Pimephales promelas* a 33d-NOEC of 230 µg/l in river water was found. With an assessment factor of 10 a **P**redicted **N**o **E**ffect **C**oncentration for riverwater ($PNEC_{riverwater}$) of 6.2 µg/l was derived from the NOEC for *Selenastrum capricornutum*.

For the derivation of a $PNEC_{sediment}$ the result from whole-sediment long-term tests with benthic organisms were used. In a test with the epibenthic midge larva *Chironomus riparius*, a 24d-NOEC for midge emergence of 876 mg/kg dw was obtained. For the endobenthic oligochaete *Lumbriculus variegatus* a 28d-NOEC of 5000 mg/kg dw was derived for survival, reproduction and growth. For the same endpoints a 28d-NOEC of 1,515 mg/kg dw was obtained for *Tubifex tubifex*. A 28d-$EC_{10}$ of 550 mg/kg dw was derived for this endobenthic species. In a further test with the bacterivorous nematode *Caenorhabiditis elegans* a 72h-NOEC of 1350 mg/kg dw was found. Test endpoints were growth, egg production and fertility.

The $PNEC_{sediment}$ was derived from the lowest available effect value, the $EC_{10}$ of 550 mg/kg obtained for *Tubifex tubifex*. An assessment factor of 10 was applied to this value as long-term tests with benthic species representing 3 different living and feeding conditions are available. Therefore, the $PNEC_{sediment}$ is 55 mg/kg dw.

The derivation of a PNEC for microorganisms is based on results from four tests on growth inhibition, respiration inhibition and nitrification inhibition with bacteria using DHTDMAC as test substance. Nitrifying bacteria were found to be the most sensitive microorganisms with the lowest $EC_{50}$ of 2.1 mg/l. With an assessment factor of 10 a $PNEC_{microorganisms}$ of 0.21 mg/l was derived.

Concerning the terrestrial compartment, effect values are available for plants, earthworm and microorganisms. In a plant toxicity study the influence of DHTDMAC on the emergence of plant seedlings and the early growth stages of *Sorghum bicolor* and *Helianthus annuus* were investigated. After 28 days the $EC_{50}$ for fresh weight reduction of the seedlings was 2,530 mg/kg for *Sorghum bicolor* and 2,930 mg/kg for *Helianthus annuus*. 1,000 mg/kg was the highest test concentration with no growth effect. In a test with the earthworm *Eisenia fetida* no significant reduction in body weight nor any behavioural effects were observed after 14 days at the only test concentration of 1,000 mg/kg dw DHTDMAC.

Concerning the toxicity of DHTDMAC to soil microorganisms two studies are available. Soil respiration was measured with soil samples amended with 12.3 g activated sludge and 365 mg DHTDMAC per kg standard soil. After 28 days no depression of oxygen uptake could be measured. In a further study two different soils containing 400 mg DHTDMAC/kg produced 96 and 119% carbon dioxide compared to the controls over 14 weeks.

Assuming that two trophic levels are covered with long-term data for plants and microorganisms, an assessment factor of 50 could be applied and a $PNEC_{soil}$ of 20 mg/kg is calculated.

## 3.3 RISK CHARACTERISATION

### 3.3.1 Aquatic compartment

For the six production sites the PEC/PNEC ratios are below one for wastewater treatment plants, aquatic compartment and sediment compartment. Therefore, no risk is to be expected for the environment from this life-cycle step (**conclusion ii**).

For the life-cycle step processing to activated bentonites a comparison between PEC and PNEC gives PEC/PNEC ratios below one for the aquatic and benthic compartment. Therefore, no risk is to be expected for the environment from this life-cycle step (**conclusion ii**).

For use of activated bentonites also the PEC/PNEC ratios for the aquatic and sediment compartment are below one and no risk is to be expected for the environment from this life-cycle step (**conclusion ii**).

For emission of DODMAC via household sewage due to the use as fabric softeners, car washing agents and hair conditioners, the following PEC/PNEC ratios were calculated:

**Table 3.2** PEC/PNEC ratios for the use as fabric softeners, car washing agents and hair conditioners

| PEC/PNEC ratios | 1989/90 | 1998 |
|---|---|---|
| $PEC_{local,bulk}/PNEC_{river\ water}$ | 10.5 / 6.2 = 1.7 | 0.54 / 6.2 = 0.087 |
| $C_{eff}/PNEC_{wwtp}$ | 42 / 210 = 0.2 | 4.0 / 210 = 0.019 |
| $PEC_{local,sed}/PNEC_{sed}$ | 137 / 55= 2.5 | 7.0 / 55= 0.12 |

The risk assessment based on consumption figures for the former use (period 1989/90) indicates that even if the household sewage is purified in a municipal wwtp, a risk to both aquatic and benthic organisms is expected. For the aquatic and sediment compartment an improvement of effect data is not possible as there are data from 3 trophic levels already available. Also the exposure data can not be improved to lead to a PEC/PNEC ratio of < 1. It has to be concluded that the former use of DHTDMAC as fabric softener led to a risk for the aquatic environment. However, the risk assessment is performed on the basis of recent emission data, and no conclusion is drawn from this scenario. The risk assessment based on the consumption figures from 1998 (uses as fabric softener, car washing agents, hair conditioners) does not indicate a risk for aquatic and sediment organisms (**conclusion ii**).

However, it should be considered that the present risk assessment is based on DODMAC only which is the major component of the technical product DHTDMAC. A risk assessment of DHTDMAC would lead to PECs which are higher by a factor of 2.4, while the PNECs are identical (as the toxicity of both substances is equal).

The DHTDMAC emissions via household sewage decreased substantially in the last decade, since the substance was largely replaced in fabric softeners. The consumption figures for the period 1996 to 1998 show no clear tendency. It has to be ensured that the use of DHTDMAC in fabric softeners, car washing agents and hair conditioners should not increase in the future.

Because an extremely low volatility of DODMAC is to be expected, no significant exposure of the atmosphere is assumed.

### 3.3.2 Terrestrial compartment

The $PEC_{local,soil}/PNEC_{soil}$ ratio due to the emissions via household sewage is below one both for the scenario based on consumption figures for 1989/90 and 1998.

The risk assessment indicates that a risk to soil organisms due to the uses of DHTDMAC in fabric softeners, car washing agents and hair conditioners is not to be expected (**conclusion ii)**.

### 3.3.3 Non compartment specific effects relevant to the food chain

The bioconcentration of DODMAC in fish is only low. Thus biomagnification via the route fish $\rightarrow$ fish-eating mammal or bird can be excluded.

In addition, bioaccumulation tests with the endobenthic species *Lumbriculus variegatus* and *Tubifex tubifex* also show a low bioaccumulation potential. Therefore, bioaccumulation via the food chain is not to be expected for DODMAC (**conclusion ii**).

# 4 HUMAN HEALTH

## 4.1 EXPOSURE ASSESSMENT

### 4.1.1 Occupational exposure

DODMAC is not produced or used as an isolated product but is applied exclusively as the main component in DHTDMAC (42% DODMAC). Therefore the occupational exposure is described for the manufacture and use of DHTDMAC whereas the exposure assessment is performed for the component DODMAC.

DHTDMAC is marketed in the form of a paste-like preparation containing 75% DHTDMAC (32% DODMAC). In addition, an aqueous emulsion containing 16% DHTDMAC (7% DODMAC) as well as a powdery form of DHTDMAC (purity 95%, 40% DODMAC) are placed on the market.

As a chemical intermediate DHTDMAC is used for the production of organic clays (organophilic bentonites). The majority of the produced organic clays are applied in drilling muds (DHTDMAC concentration < 1%) in the oil industry. DHTDMAC is also used in the laundry/cleaning products industry (fabric softeners, car-cleaning products), in the chemico-technical and the cosmetic industries (e.g. hair cosmetics).

Occupational exposure limit values for DODMAC are not established.

Dermal and inhalation exposure is estimated for the following occupational exposure scenarios:

- manufacture of preparations (containing 16% / 7%, 75% / 32% or 95% / 40% DHTDMAC / DODMAC),
- production of personal care products, fabric softeners, car cleaning agents and organic clays; - use of hair care and car cleaning products.

The exposure assessment is based on expert judgement and estimations according to the EASE model. Measured data on the level, duration and frequency of exposure are not available.

On account of the physico-chemical properties of the substance (ionic substance, low vapour pressure) inhalation exposure to vapours is assumed to be negligible but exposure to dusts at the workplace during the handling of the powdery preparations must be considered.

The assessment of dermal exposure is made in consideration of the corrosive effect of DHTDMAC (DODMAC). Because worker avoid daily repeated contacts with corrosive substances, daily dermal exposure is assessed as low if paste or liquid preparations containing 75% DHTDMAC (32% DODMAC) or 16% DHTDMAC (7% DODMAC) are used. Since dermal exposure cannot be completely excluded, occasional dermal exposure is assessed in addition for the same scenarios. For the manufacture and use of the powdery preparation with 95% DHTDMAC (40% DODMAC) in the large scale chemical industry, dermal exposure is assessed as low because the regular use of gloves can be presupposed. For the case that gloves are not used, dermal exposure is assessed with the EASE model.

The results for the different scenarios are summarised in **Table 4.1**.

**Table 4.1** Summary of exposure data

| Exposure scenario | Duration and frequency | Inhalation exposure<br>Shift average [mg/m³] | Dermal exposure<br>Shift average [mg/p/day] |
|---|---|---|---|
| **Chemical industry (inclusive cosmetic industry)** | | | |
| Manufacturing of a preparation containing 75% / 32% DHTDMAC / DODMAC (paste) | shift length, daily single contacts | negligible [1, 3] | low [1, 4]<br>0 – 13 [2, 4] |
| Manufacturing of a preparation containing 16% / 7% DHTDMAC / DODMAC (emulsion) | shift length, daily single contacts | negligible [1, 3] | low [1, 4]<br>0 – 3 [2, 4] |
| Manufacturing of a preparation containing 95% / 40% DHTDMAC / DODMAC (powder) | shift length, not daily | 0.8 – 2.0 [2] | low [1, 5]<br>(with PPE)<br>17 – 170 [2]<br>(without PPE) |
| Production of personal care products (use of the powder containing 95% / 40% DHTDMAC / DODMAC) | 2 hours, daily | 0.2 – 0.5 [2]<br>(with LEV) | low [1, 5]<br>(with PPE)<br>17 – 170 [2]<br>(without PPE) |
| **Industrial area** | | | |
| Production of fabric softeners (use of the paste containing 75% / 32% DHTDMAC / DODMAC) | 2 hours, daily single contacts | negligible [1, 3] | low [1, 4]<br>0 – 13 [2] |
| Production of car cleaning agents (use of the paste containing 75% / 32% DHTDMAC / DODMAC) | 2 hours, daily single contacts | negligible [1, 3] | low [1, 4]<br>0 – 13 [2] |
| Production of organic clays (use of emulsions containing 16% / 7% DHTDMAC / DODMAC) | 2 hours, daily single contacts | negligible [1, 3] | low [1, 4]<br>0 – 3 [2] |
| **Skilled trade** | | | |
| Use of hair-care products containing 2% / 1% DHTDMAC / DODMAC | 5 hours, daily | negligible [1, 3] | 34 – 110 [2] |
| Use of car polishing and car cleaning products containing 4% / 2% DHTDMAC / DODMAC [6] | shift length, daily | negligible [1, 3] | 26 – 105 [2] |

LEV – local exhaust ventilation; PPE – personal protective equipment (here gloves)

[1] Exposure assessment based on expert judgement
[2] Exposure assessment based on model estimates (EASE model)
[3] On account of the very low vapour pressure (estimated to $10^{-15}$ Pa)
[4] Corrosive effect of the 75 % resp. 16 % preparation
[5] High acceptance of using PPE (here gloves) in the large-scale chemical industry (see text)
[6] Spray application of car polishing or cleaning products cannot be estimated yet. It is assumed to be not critical.

### 4.1.2 Consumer exposure

DHTDMAC is used as a fabric softener in hand laundering products. Textiles may also contain the substance after washing. Moreover, DHTDMAC is used by consumers in the form of cosmetic products (hair care products) and is a constituent of paints. Inhalation exposure through dust can be neglected in private application.

Exposure to softeners in hand laundering

For dermal exposure to DHTDMAC during hand laundering it is assumed that 30 g of a product containing 10% of DHTDMAC are used in a volume of 5,000 ml of water (DHTDMAC concentration 0.6 mg/ml). The acute dermal exposure amounts about 50 µg/kg bw per event. Assuming a twice-weekly use an exposure of ~14 µg DHTDMAC (6 µg DODMAC)/kg bw/d results as yearly average for this application.

Exposure to DHTDMAC by wearing softened fabrics

The calculation of the total amount for dermal exposure via wearing of softened fabrics results to about 34 mg of DHTDMAC. This amount corresponds to a dermal exposure of ~550 µg DHTDMAC (230 µg DODMAC)/kg bw/d.

Exposure via cosmetics

Hair care products contain a maximum of 1-2% DHTDMAC (up to 0.8% DODMAC). Such products can be used as products which are rinsed off (e.g. hair conditioner) or as products which remain in the hair. A daily single amount of 12 g of a hair care product which will be rinsed off (rinse-off product) will result in a consumer exposure of 40 µg DHTDMAC (~17 µg DODMAC)/kg bw/d taking into consideration of a rinse-off coefficient of 10% and a partition coefficient of 10% (Scientific Committee for Cosmetology, 1994).

Assuming a daily use of a single amount of 12 g of a non-rinse hair care product and a partition coefficient of 10%, a dermal exposure of the consumer to ~400 µg DHTDMAC (~170 µg DODMAC)/kg bw/d will result.

Combined dermal exposure

Assuming that a consumer will use hair cosmetics and will perform a hand wash laundry and wears a cloth which is washed with DHTDMAC (DODMAC) containing softener, a person will be exposed to DODMAC in the upper microgram/kg bw and day range (up to 500 µg/kg bw/d) when the products are used as intended.

### 4.1.3 Indirect Exposure via the Environment

Man can be exposed indirectly to DODMAC via emissions into the hydrosphere and the terrestrial compartment. Just as the environmental exposure, two scenarios are calculated: based on the consumption figures of DHTDMAC as fabric softener in 1989/90 reflecting the former use and the figures from 1998 reflecting the actual situation where the consumption has been decreased substantially.

The main contribution to the intake at local scale are plants with fractions of about 90 % (consumption figures from1989/90) and about 95 % (1998 consumption figures), respectively, to the total daily dose. In addition, intake occurs via drinking water and fish. The total daily dose is estimated to 0.27 µg/kg bw/d for the consumption figures for 1998 and 3 µg/kg bw/d for the consumption figures for 1989/90.

Indirect exposure via the environment is calculated using data for intake via drinking water, fish and plants. As a worst case approach, the concentration in drinking water was calculated for the production from surface water. With a consumption of 2 l drinking water per day and a body

weight of 70 kg the daily intake amounts 0.003 µg/kg bw/d. The daily intake via fish was calculated to be 0.012 µg/kg bw/d.

For the intake via plants a daily consumption of 1.2 kg leaf crops and 384 g root crops was assumed resulting in a maximum intake of 0.25 µg/kg bw/d.

On the basis of these data, a total daily dose of 0.27 µg/kg bw/d is calculated. The risk assessment which is based on the local concentrations (representing a worst case approach) leads to the conclusion of "no concern", thus, an estimation of the average intake (which should be derived from regional environmental concentrations) has not been performed.

## 4.2 EFFECTS ASSESSMENT

From studies with dermal administration of dimethyldioctadecylammonium chloride (DODMAC) it can be assumed that the dermal absorption and the concentration of the substance in the skin will be very low. No data are available on toxicokinetics and metabolism of DODMAC using the oral or inhalation routes of exposure.

Human data on the acute toxicity of DODMAC are not available. In rats, the substance exhibited only low acute toxicity with oral $LD_{50}$ > 2,000 mg/kg bw, dermal $LD_{50}$ > 2,000 mg/kg bw and inhalation $LC_{50}$ > 180 mg/l/1 hour. According to the acute toxicity data DODMAC is not to be classified.

Human data on local irritation/corrosion caused by DODMAC are not available. Pure DODMAC causes severe effects to the eyes, but exhibits only moderate skin irritation in rabbits, while the technical grade substance (containing 12% isopropanol) demonstrated severe corrosive properties. The relevance of such data for the assessment of the skin irritant properties of pure DODMAC is questionable. However, the local corrosivity of technical grade DODMAC is crucial for the evaluation of results of toxicological testing performed in order to assess acute effects after application of DODMAC. Based on the reported data, pure DODMAC is classified "Xi, irritant" and labelled "R 41, risk of serious damage to eyes", while technical grade "DODMAC" (containing approximately 12% isopropanol) is to be classified "C, corrosive" and labelled "R 34, causes burns". Data on respiratory irritation are not available.

DODMAC is used in hair cosmetics (as a nearly 100% pure substance, proven to cause only moderate skin irritation) and in detergents (normally in the form of a mixture of approximately 75% of DODMAC dissolved in 25% isopropanol/water, proven to cause skin corrosion). Slightly irritant effects are only elicited with minimal concentrations of technical grade DODMAC, while pure DODMAC needs much higher concentrations in order to cause similar effects. Based on human patch tests and on tests with guinea pigs, it can be concluded that DODMAC does not induce skin sensitization in humans. DODMAC is reported to enhance significantly skin allergy to chemical substances in tests with guinea pigs and mice. However, there is no need for labelling according to EU regulations.

There is no information on health effects in humans following repeated exposure to DODMAC via any route. Following repeated oral administration of 500 mg/kg bw/d to rats degeneration of adrenal cortex was induced. Comparable lesions in the adrenals were also seen after 500 mg/kg bw/d DHTDMAC, additional effects were reticuloendothelial hyperplasia and accumulation of foamy macrophages of mesenteric lymph nodes and increased incidence of chronic liver inflammation. No adverse effects were reported up to 100 mg DODMAC/kg bw/d in subacute oral studies (NOAEL). After repeated dermal application to rabbits, local irritation but no

systemic toxic effects were observed up to 40 mg/kg bw/d (NOAEL). A systemic LOAEL was not determined. There is no information on the effects after prolonged inhalation exposure to rodents.

DODMAC showed negative results in bacterial mutation tests with Salmonella strains and E. coli WP2uvrA and in an in vitro chromosomal aberration test with V79 cells (with and without metabolic activation). There is no evidence of a genotoxic potential of the substance.

There are no experimental animal data on cancerogenicity of DODMAC or DHTDMAC. There are no data from mutagenicity studies which give concern regarding cancerogenic properties of the substances.

There are no human data available on the reproductive toxicity of DODMAC. The potential to adversely affect reproduction and development was investigated in a study according to OECD-Guideline 421 with oral administration to rats. During this study clear signs of general toxicity were observed after repeated administration of 500 mg/kg bw/d in both sexes, a dosage which also led to impaired reproductive performance. From this study a NOAEL for reproductive toxicity of 125 mg/kg/d can be estimated based on the reduced mating, fertility and gestation indices in the 500 mg/kg dose group.

## 4.3 RISK CHARACTERISATION

### 4.3.1 Workplace

For the purpose of risk characterisation, it is assumed that inhalation of dust and skin contact are the main routes of exposure. For risk characterisation exposure estimates for the component DODMAC are used. Oral exposure is not considered to be a significant route of exposure under normal working practices.

There was no lethality in rats at extremely high exposure levels (180,000 $mg^3$ for 1 hour). During normal use of DODMAC occupational exposure at this extreme level can be excluded. Therefore acute inhalation risks are not considered of concern **(conclusion ii)**. Acute dermal toxicity is considered to be very low as well. There was no lethality at the dose level of 2,000 mg/kg. Percutaneous absorption is known to be very low. The highest value for dermal exposure was calculated to be 170 mg/person/d. Comparison of this level of exposure with acute dermal toxicity data shows, that acute dermal risks are not considered of concern **(conclusion ii)**.

Pure DODMAC (97 %) showed mild to moderate skin irritation in rabbits; the degree of local effects is not considered sufficient for classification. Technical grade DODMAC however was corrosive in rabbits. There are no experimental data concerning the acute irritating effect of dilutions of technical grade DODMAC. For preliminary assessment of solutions of technical grade DODMAC it is proposed (with reference to the preparations directive) to consider dilutions greater than 10 % of technical grade DODMAC as corrosive, and those between 5 % and 10 % as irritating to the skin. Based on the occupational exposure assessment, there is either handling of corrosive preparations (using personal protective equipment) or handling of dilutions which are not considered irritating to the skin **(conclusion ii)**. Pure DODMAC caused serious damage to the eyes of rabbits. Applying the same rationale as for skin irritation, **conclusion ii** is reached for eye irritation as well. Based on the toxicological information that acute irritation potency due to inhalation exposure does not seem to be severe, relevant acute respiratory tract irritation at the exposure levels reported is not suspected to occur **(conclusion ii)**.

Based on animal and human data, DODMAC itself is not considered to be a skin sensitizer. However, DODMAC is reported to enhance skin allergy response to known sensitizers. For preparations that are classified with R 43 this extra risk of combined exposures (DODMAC and known sensitizer) is considered to be effectively covered **(conclusion ii)**. Asthmatic reactions following inhalation exposure to DODMAC so far have not been reported **(conclusion ii)**.

The experimental NOAEL of 100 mg/kg/d of the subacute oral rat study is used for the assessment of repeated dose toxicity by inhalation and by dermal contact. The experimental NOAEL of 100 mg/kg/d will correspond to a human NAEL of 7,000 mg/person/d. Assuming that a worker of 70 kg inhales 10 $m^3$ air per working day and that an adjustment factor for inhalatory uptake is not necessary, a systemic NAEC of 700 $mg/m^3$ will result. Assuming the necessity of duration adjustment and metabolic rate scaling, and comparing the toxicological data with the highest chronic exposure level of 0.5 $mg/m^3$, systemic health risks due to chronic inhalation exposure are not expected **(conclusion ii for repeated dose toxicity by inhalation)**. Based on limited data on low respiratory tract irritation in acute inhalation testing and based on the available inhalation exposure data, especially the lack of relevant chronic dust exposure in the skilled trade area, **conclusion ii was drawn for chronic respiratory tract irritation as well**.

The exposure scenarios with relevant repeated dermal exposure are the “use of hair-care products” (skilled trade) and the “use of car polishing and car cleaning products” (skilled trade). The exposure assessment for these 2 scenarios (highest value of 110 mg/p/d) is solely based on EASE calculations without use of personal protective equipment. Taking into account that percutaneous absorption of DODMAC is considered to be lower than oral absorption, MOS values calculated are considered to be of no concern **(conclusion ii for repeated dose toxicity by dermal contact)**. Concerning combined exposure, there is no concern for repeated dose toxicity.

There are no carcinogenicity data available. Based on negative mutagenicity test results, DODMAC is not suspected to be a carcinogen. Corresponding risks at the workplace are not anticipated to occur **(conclusion ii for mutagenicity and carcinogenicity)**.

For reproductive toxicity a NOAEL of 125 mg/kg/d was derived from an oral screening study in rats. At a higher dose, impaired reproductive performance was accompanied by signs of maternal toxicity. Comparing the dose of 8,750 mg/person/d (70 x 125) with the highest acute dermal exposure level (170 mg/person/d) a lowest MOS value of 51 is calculated. Based on metabolic rate scaling and assuming a reduced systemic availability following dermal exposure, no concern is derived **(conclusion ii for fertility impairment and developmental toxicity following dermal contact)**. Comparison of the highest acute inhalation exposure of 2 $mg/m^3$ with the calculated NAEC of 875 $mg/m^3$ ($125 \times 70 \times 10^{-1}$) yields a lowest MOS value of 440. Assuming an equivalent inhalatory and oral uptake and metabolic rate scaling, calculated MOS values are considered high enough in order to derive no concern **(conclusion ii for both types of reproductive toxicity for inhalation exposure)**.

### 4.3.2 Consumers

Consumer exposure may occur as a result of using hair cosmetics and softeners containing DHTDMAC (DODMAC). The total amount available for potential uptake by the skin is estimated to amount up to 0.5 mg DODMAC/kg bw/d. Other exposure routes are of minor importance.

Repeated dose toxicity

Studies in rats have shown that no relevant treatment-related effects associated with repeated oral administration were observed at dosages of 100 mg/kg bw/d (NOAEL). Following the exposure assessment consumers may be exposed dermal to the substance. The estimated external body burden in the range of 100 - 500 µg/kg bw/d is compared with a NOAEL from oral 28-day studies on rats. The margin of safety is judged to be sufficient, even if route-to-route extrapolation is taken into consideration. Because of the poor dermal absorption of the substance, the internal exposure will be much lower **(conclusion ii)**.

Reproductive toxicity

Data from a study according to OECD Guideline 421 with oral administration to rats did not give evidence for adverse effects up to doses of 125 mg/kg bw/d (NOAEL). Following the exposure assessment, the consumer may be dermal exposed. The estimated external body burden in the range of 100 - 500 µg/kg bw/d is compared with an oral NOAEL from the OECD-Guideline 421 study assuming an absorption of 100%. There are no reasons to assume that special concern can be derived neither from this procedure nor from the available toxicokinetic information. Taking into account the estimated low exposure it can be concluded that there is no concern **(conclusion ii)**.

### 4.3.3 Humans exposed via the environment

Indirect exposure via the environment is calculated using data for oral intake via drinking water, fish and plants (local concentrations, worst case approach). On the basis of these data, a total daily dose of 0.00027 mg/kg bw/d is calculated. The main route of exposure is via consumption of plants (94%).

Repeated dose toxicity

In a repeated dose toxicity study (rat, oral, 28 day study) the NOAEL for substance-related toxic effects was 100 mg/kg bw/d. The margin of safety expressed by the magnitude between the calculated exposure value resulting from a worst case approach and the NOAEL is considered to be sufficient. Thus, the substance is of no concern in relation to indirect exposure via the environment **(conclusion ii)**.

Reproductive toxicity

From the results of an OECD-Guideline 421 study with oral application to rats a NOAEL for reproductive toxicity of 125 mg/kg bw/d was estimated. Taking into account that the calculated low local concentrations represent a worst case approach it can be concluded that the margin of safety for a local scenario is considered to be sufficient. Thus, there is no concern in relation to indirect exposure via the environment **(conclusion ii)**.

# 5 RESULTS

## 5.1 ENVIRONMENT

**Conclusion (ii)** There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

The risk assessment shows that the production of DODMAC, the processing and use of activated bentonites as well as the use as fabric softeners, car washing agents and hair conditioners does not indicate a risk to the environment. However, it should be considered that the present risk assessment is based on DODMAC only which is the major component of the technical product DHTDMAC. A risk assessment of DHTDMAC would lead to higher PEC/PNEC ratios.

The DHTDMAC consumption figures for the period 1996 to 1998 show no clear tendency. It has to be ensured that the use of DHTDMAC in fabric softeners, car washing agents and hair conditioners should not increase in the future.

## 5.2 HUMAN HEALTH

Workers

**Conclusion (ii)** There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

Consumers

**Conclusion (ii)** There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

In the occupational risk assessment of DODMAC health risks of workers are evaluated for dermal and inhalation exposure. Overall no concern **(conclusion ii)** is derived for all toxicological endpoints.

Humans exposed via the environment

**Conclusion (ii)** There is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.

European Commission

**EUR 20397 EN/3 – European Union Summary Risk Assessment Report**
**Dimethyldioctadecylammonium chloride (DODMAC),**
**Volume 14 published in 2002 with Addendum 2009**

*Editors: K. Aschberger, O. Cosgrove, S. Pakalin, A. Paya-Perez, S. Vegro.*

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The report provides the comprehensive risk assessment of the substance dimethyldioctadecylammonium chloride (DODMAC). It has been prepared by Germany in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to man and the environment, laid down in Commission Regulation (EC) No. 1488/94.

The evaluation considers the emissions and the resulting exposure to the environment and the human populations in all life cycle steps. Following the exposure assessment, the environmental risk characterisation for each protection goal in the aquatic, terrestrial and atmospheric compartment has been determined. For human health the scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks have been identified.

The risk assessment for dimethyldioctadecylammonium chloride concludes that there is at present no concern for the environment or for human health. There is at present no need for further information and/or testing or for risk reduction measures beyond those that are being applied already.