EUROPEAN COMMISSION
DIRECTORATE-GENERAL HEALTH AND CONSUMER PROTECTION
Directorate C - Scientific Opinions
Unit C2 – Management of Scientific Committees; scientific co-operation and networks

Scientific Committee on Toxicity, Ecotoxicity and the Environment

Brussels, C2/JCD/csteeop/**DodmacENV09012002**/D(02)

SCIENTIFIC COMMITTEE ON TOXICITY, ECOTOXICITY AND THE ENVIRONMENT (CSTEE)

Opinion on the results of the Risk Assessment of:

Dimethyldioctadecylammonium chloride (DODMAC)

CAS No.: 107-64-2
EINECS No.: 203-508-2

REPORT VERSION (Environment)

Draft of 16.07.2001

Carried out in the framework of Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances[1]

Opinion expressed at the 29th CSTEE plenary meeting

Brussels, 09 January 2002

[1] Regulation 793/93 provides a systematic framework for the evaluation of the risks to human health and the environment of those substances if they are produced or imported into the Community in volumes above 10 tonnes per year. The methods for carrying out an in-depth Risk Assessment at Community level are laid down in Commission Regulation (EC) 1488/94, which is supported by a technical guidance document.

Terms of reference

In the context of Regulation 793/93 (Existing Substances Regulation), and on the basis of the examination of the Risk Assessment Report the CSTEE is invited to examine the following issues:

Does the CSTEE agree with the conclusions of the Risk Assessment Report?

2. If the CSTEE disagrees with such conclusions, the CSTEE is invited to elaborate on the reasons for this divergence of opinion.

INTRODUCTION

Production

DODMAC is an isolated substance, which is not produced or used commercially. DODMAC occurs as a major component of the technical product DHTDMAC (dihydrogenated tallow dimethyl ammonium chloride). DHTDMAC is produced from tallow acids. The proportion of DODMAC is about 42% related to the total content of dialkyldimethylammonium compounds. Data from 6 European producers are included in IUCLID.

Use of DHTDMAC

DHTDMAC is mainly used in fabric softeners (400 t in 1998) and in the synthesis of organic clays used as drilling muds (5,221 t/year; year unclear) and rheological additives in paints and lacquers. Other uses mentioned in literature (but not accounted for in ERA) include use as conditioning agent in personal care products, car washing agents, sugar refining, antistatic agents, corrosion inhibitors, foam depressants, flotation chemicals, asphalt and petroleum additives (276 t in 1998). Especially the use of fabric softener has decreased from 65000 t/a in 1990 to approximately 400 t/a in 1997 and 1998.

GENERAL COMMENTS

Complications in the risk assessment with DODMAC

The risk assessment of DODMAC, a quaternary ammonium compound, is extremely complicated because:

- DODMAC is not produced or used as an isolated compound but it is the active component of a technical product, DHTDMAC.
- DHTDMAC is a mixture.
- Impurities and additives are present in this technical mixture.
- The quartenary ammonium compounds are hardly/not soluble in water.
- These chemicals have very high adsorption coefficients.
- The adsorption coefficients vary, probably according to the variation in the composition of the chemical, the mixture or the impurities and/or the variation in the nature of the solid

fraction in soil, sediment, suspended solids in surface water and sewage. These and perhaps (many) other factors contribute to the complexity of the exposure of species living in the water column, in sediment or in the terrestrial environment and therefore contribute to the complexity of the effects assessment for the aquatic and terrestrial environment.

Adequate monitoring and environmental data

Despite some clear complexities in the risk assessment of DODMAC, there are two major advantages with this chemical:

- A lot of environmental research has been carried out which contributes to our understanding of the complexity of the exposure and effects of DODMAC. This allows for a proper estimation of the PNECs in soil, sediment and water.
- Much monitoring has been carried out which allows for a validation of the exposure predictions.

General comments regarding the presentation of the risk assessment

Because of the complexities in the exposure and effects assessment of DODMAC and the variation in the environment (*e.g.* the composition and the nature of suspended solids and sediment), the CSTEE would have preferred ranges in PECs rather than fixed values where natural variation and uncertainty seems to be absent. The same holds for the PNECs. Quite a number of NOECs are available. The CSTEE would like to see the application of statistical extrapolation techniques as another way to derive PNECs. Such an approach - a more liberal interpretation of the TGD - provides a better insight into the uncertainties in the risk assessment in general, whereas the standard approach only provides fixed values which can easily be interpreted as "absolute truth".

Conclusions from the risk assessment

The CSTEE endorses the conclusion ii) in the risk assessment report regarding the environment.

SPECIFIC COMMENTS

Release, exposure and fate

- Some comments made by industry refer to the conservative assumptions made in the estimation of environmental exposure. The CSTEE is of the opinion that given the efforts made by industry to develop georeferenced exposure models, the enormous reduction in the wide-dispersive use as fabric softener and the extensive monitoring data that are available, preference should be given to these higher-tier levels of information. Should however major changes in the use and production of these chemicals appear in future, the exposure assessment has to be updated.
- The adsorption coefficients vary, probably according to the variation in the composition of the chemical, the mixture or the impurities and/or the variation in the nature of the solid

fraction in soil, sediment, suspended solids in surface water and sewage. *E.g.* the Kp_{sed} and Kp_{soil} are 10,000 l/kg and the Kp_{susp} is 16,800 l/kg. Other sorption coefficients (measured in laboratory tests) have been published. These were in the range of 3000 l/kg. These few data already demonstrate a high variation in adsorption.

Aquatic effects, incl. Sediments

PNECs for water and sediment can also be derived from tests with laboratory water and the application of EP (equilibrium partitioning) when standard suspended solids percentages for surface water and the appropriate adsorption coefficients for suspended solids and sediment are used. This would contribute to our understanding of the variation in PNECs and their uncertainties as described in the general comments section. An example is given below.

In order to verify the PNEC for sediment based on sediment-dwelling organisms, the PNEC for sediment can also be derived from the PNEC for water (laboratory water) and not from river water (page 48). In this case the PNEC based on tests with reconstituted water would be based on the test with *Selenastrum capricornutum* (NOEC = 0.006 mg/L= 6 µg/L) and would thus lead to a PNEC for water of 0.6 µg/L. The PNEC for sediment would then become (eqn 54 in the TGD on page 335): 4.6 mg/kg dw. But this does not change the conclusion.

Tubbing and Admiraal (1991) have shown the inhibition of metabolic activity of bacterial and phytoplankton in the lower Rhine by DTDMAC. From thymidine incorporation studies it appeared that a total concentration of DTDMAC in Rhine water of 10 µg/L reduced this incorporation with 10%. They concluded that a total concentration of 10 µg/L is likely to have biological consequences. The rapporteur did not include this study in the RAR of DODMAC. (Tubbing and Admiraal, 1991. Appl. Environ. Microbiol. 51, 356-361). This value supports the PNEC for river water as calculated by the rapporteur.

On page 48 the *rapporteur* proposes to apply an additional factor of 10 in order to derive a PNEC for sediment. Although these chemicals strongly adsorb to sediment, it is not certain that the uptake of this chemical will increase as a result of ingestion of sediments. Moreover, the rapporteur states that relevant bioaccumulation from water and sediment is not expected.

Despite the advantages of using ECx values in stead of NOECs, the CSTEE prefers the use of NOECs in the case of deriving a PNEC for sediment. In fact, there are 4 sediment tests available and for only one test an EC10 has been derived, in a manner which is at least debatable. The CSTEE prefers the use of NOECs in this case. This would lead to the use of the NOEC of *Chironomus riparius* of 876 mg/kg and would lead to a PNEC for sediment of 876/10 = 88 mg/kg.

Secondary poisoning

The CSTEE agrees with conclusion ii).

Atmosphere

No information is available. Physicochemical behaviour suggests that this compartment is of low relevance. Therefore conclusion ii) can be accepted.

Soil

No data on the toxicity of DODMAC to soil organisms are available. The RAR proposes to use the available information on DHTDMAC (a mixture containing about 42% of DODMAC). PNECsoil organisms is estimated from the data on plants, earthworms and soil micro-organisms (respiration). An assessment factor of 50 on the lowest NOEC (soil microorganisms) is proposed considering the availability of a growth test on plants. The toxicity of DHTDMAC is considered similar to DOCMAC. Considering the low toxicity and the available data the CSTEE supports these assessments

Risk characterisation

The CSTEE endorses the conclusion ii) in the risk assessment report regarding the environment. Although this is the most favourable outcome of a risk assessment, it has been noted that the substance has been under debate, not only a decade ago, when the use of this type of fabric softener was very high, but also recently. This is based on some comments from industry (see references) , which were distributed to the members of the CSTEE.

REFERENCES

Koch, V (2001). Issues “risk assessment of sediment compartment”and “overly conservative assumptions on release, exposure and fate”. Request on evaluation by rapporteur and CSTEE. Clariant GmbH, Regulatory Affairs, Environmental Risk Assessment. Sulzbach.