EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 2,2-bis(chloromethyl)trimethylene bis[bis(2-chloroethyl)phosphate] (V6)

Environmental Part

CAS No.: 38051-10-4;
EINECS No.: 253-760-2

Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

Opinion adopted by the SCHER during the 20th plenary of 29 November 2007

About the Scientific Committees

Three independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems which may pose an actual or potential threat.

They are: the Scientific Committee on Consumer Products (SCCP), the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) and are made up of external experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Evaluation Agency (EMEA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

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Questions relating to examinations of the toxicity and ecotoxicity of chemicals, biochemicals and biological compound whose use may have harmful consequences for human health and the environment.

In particular, the Committee addresses questions related to new and existing chemicals, the restriction and marketing of dangerous substances, biocides, waste, environmental contaminants, plastic and other materials used for water pipe work (e.g. new organics substances), drinking water, indoor and ambient air quality. It addresses questions relating to human exposure to mixtures of chemicals, sensitisation and identification of endocrine disrupters.

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http://ec.europa.eu/health/ph_risk/risk_en.htm

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1. BACKGROUND

Council Regulation 793/93 provides the framework for the evaluation and control of the risk of existing substances. Member States prepare Risk Assessment Reports on priority substances. The Reports are then examined by the Technical Committee under the Regulation and, when appropriate, the Commission invites the Scientific Committee on Health and Environmental Risks (SCHER) to give its opinion.

2. TERMS OF REFERENCE

The SCHER on the basis of the examination of the Targeted Risk Assessment Report is invited to examine the following issues:

1. Does the SCHER find the conclusions of the targeted risk assessment appropriate?
2. If the SCHER finds any conclusion not appropriate, the SCHER is invited to elaborate on the reasons for this divergence of opinion.
3. If the SCHER finds any specific approaches or methods used to assess the risks inappropriate, the SCHER is invited to suggest possible alternative approaches or methods meeting the same objectives.

3. OPINION

3.1 General Comments

The environmental part of the risk assessment of 2,2-bis(chloromethyl)trimethylene-bis[bis(2-chloroethyl) phosphate] (V6) has been done mainly using the methodology proposed in the Technical Guidance Document. The compound is a flame retardant mainly used for polyurethane foams used in automotive industry. The risk assessment results in conclusion (ii)[1] for the environment.

The exposure assessment is partly based on industry data regarding emissions from production, but there are no measurements of emissions from the use or disposal of V6. The assessor is therefore estimating V6 emissions from flame retarded polyurethane foam using data measured for other phosphate based flame retardants, which SCHER expects give a high uncertainty. Those tests were furthermore static, while a larger emission can be expected from a car seat where the inner air of the material frequently is pressed out. Also data predicted with OECD emission scenario documents will be uncertain as the area of polyurethane foam is much larger than a solid polymer. Most of the flame retarded foam is disposed of in landfills, but there is no estimate of the emissions from those in the assessment.

SCHER recommends conclusion i) for the exposure and dynamic measurements of emissions of the right substance from both use and disposal.

A study referred to in the RAR reported vapour emissions that seems to correspond to TCPP partial pressures much higher than saturation pressure for that compound. This study is used to assume that only 10% of the compound in the foam is "available".

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[1] *According to the Technical Guidance Document on Risk Assessment – European Communities 2003:*

- conclusion i): There is a need for further information and/or testing;

- 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;

- conclusion iii): There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

SCHER cannot support this assumption and suggests that the exposure estimates are recalculated assuming that all V6 can leave the matrix.

The effect assessment is mainly based on good toxicity studies, but for higher plants results for other compounds have to be used. Plants seem to be particularly sensitive to these substances, and this information has not been considered in the derivation of the PNECsoil.

The SCHER considers that an additional study on terrestrial plants should be conducted. The result is not expected to modify the conclusion of low risk in most cases, but there is a specific site with a PEC/PNEC relatively close to 1 which should be reassessed.

3.2 Specific Comments

3.2.1 Exposure assessment

2,2-bis(chloromethyl)trimethylenebis[bis(2-chloroethyl) phosphate], with the trivial name V6, is used as an additive flame retardant mainly in polyurethane foam. The main use of this foam is in the automotive industry. Less than 2500 tonnes were used in the EU in the year 2000, while less than 5000 tonnes were produced in the union.

There is only one producer of V6 in the EU, which means that some information has to remain classified. This makes it difficult to review the assessment as not only volumes and measured data but also some of the applications are unknown to the reviewer.

The assessor use measured data for the emissions from the producer. It would have been useful to try to predict this emission as well to support the measurements, especially as the PEC_{local} in water for production is ten times higher than the measured concentrations.

There are no measurements of V6 emissions from flame retarded foam, but another flame retardant (TCPP) with similar structure has been studied. That study, as it is described in Annex II of the RAR, is difficult to interpret. Foam (30 g) containing 14.3% TCPP was placed in a room of 63 m^3 with an estimated air exchange of one time per day. After one day the mean concentration in the foam was 10% and as maximum 126 m^3 has passed the sample that volume would have contained 34 mg TCPP per m^3. This corresponds to a vapor pressure of more than hundred times the saturation pressure for TCPP. There may be adsorption of the compound on other surfaces of the room, a process which is rather slow and hardly of a major importance over one day.

The SCHER does not believe the results from that study can be used to assume that only 40% of the TCPP in the foam is "available". The TCPP results are then used to derive corresponding data for V6 and with the argument that V6 "is a more adsorbing, higher molecular weight molecule containing an additional phosphate group and proportionately more chlorine" and thus must be less available. The result is that the assessor regards the available fraction of V6 is 10% at most.

SCHER considers this process very uncertain. First a dynamic test procedure needs to be applied, and there is no obvious reason why a fraction of the phosphates should be unavailable. There is no solid base for the transformation of the TCPP results to V6. A ten times higher availability would have given some PEC/PNEC values over 1.

The in-service losses may also have been underestimated in the RAR. The ESD estimates are valid for a solid plastic surface, but the polyurethane foam used for furniture has a much larger area, and furthermore in the furniture applications it is squeezed frequently and thus also emissions from inner surfaces may be reaching the environment.

Most of the V6 will follow the foam to landfills and those may be the major sources of the substance in the environment. SCHER does not understand how the argument that V6 is less than 5% of the equivalent tonnage of TCPP in the landfills can make its emission negligible. V6 may be emitted from the landfills as vapour or in the leachate, but also in fine foam particles.

3.2.2 Effect assessment

There are good studies available for V6 toxicity in fish, *Daphnia*, algae and microorganisms. The RAR presents comparisons of measured data and QSAR estimations; nevertheless a conservative approach is employed for calculating the PNEC value for aquatic organisms, applying a factor of 50 as chronic information on fish is not available.

For the terrestrial compartment there is a test done on earthworms, but for higher plants and soil microorganisms the assessor is using data for other phosphate flame retardants which SCHER has difficulties to accept. The arguments for this read-across are similarities in physical properties and chemical structures and that toxicity for freshwater algae are similar, but SCHER recommends tests of the right substance, especially as similar flame retardants have been found in pine needles. This is particular relevant as plants seems to be the most sensitive taxonomic group for soil exposures

There is no effect study reported on marine organisms and an assessment factor of 500 is used on the PNEC for fresh water. The SCHER considers that the direct addition of a factor of 10 for the derivation of PNEC for marine organisms is not supported by scientific knowledge and that a proper estimation of the expected differences in bioavailability and toxicity between freshwater and marine environments should be considered.

For the PBT assessment the only data to be used for the P parameter is that V6 is not ready biodegradable. There are no data available for bioconcentration, but the octanol/water partitioning (log K_{ow}=2.83) does not indicate that V6 is a B compound and the available NOECs does not indicate that it is a T compound, and SCHER supports the conclusion V6 is not a PBT substance.

3.2.3 Risk characterisation

The PEC/PNEC ratios for both aquatic and terrestrial environments are below 1 resulting in conclusion (ii) in the RAR, as well as the same conclusion for secondary poisoning. The highest value is 0.126 for "flexible foam – furniture – foaming" and would thus have been slightly above 1 if the V6 had been regarded as 100% available. It is more difficult to predict how much the large surface area and the dynamic effect can increase the emissions. SCHER would therefore recommends a conclusion (i) regarding the exposure assessment and a call for dynamic emission tests with V6; as well as terrestrial plan study.

The risks calculated for the marine environment and secondary poisoning are lower and a ten-fold higher exposure would still give ratios below 1.

4. LIST OF ABBREVIATIONS

OECD	Organisation for Economic Co-operation and Development
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
RAR	Risk assessment report
TCPP	Tris(2-chloro-1-methylethyl) phosphate
V6	2,2-Bis(chloromethyl)trimethylenebis[bis(2-chloroethyl)phosphate]