EUROPEAN COMMISSION

Health & Consumer Protection
Directorate-General

Scientific Committee on Health and Environmental Risks

SCHER

Risk Assessment Report on 2-furaldehyde (furfural) Environmental Part

CAS No.: 98-01-1;
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Scientific Committees
on consumer products
on emerging and newly identified health risks
on health and environmental risks

Opinion adopted by the SCHER during the 21st plenary of 15 January 2008

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 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 furfural has been done using the methodology proposed in the Technical Guidance Document. The compound is mainly used to produce furan derivatives, but also as a selective solvent, mainly in refineries, and in the production of pesticides.

The amount of information on furfural emissions and effects in the scientific literature seems to be very limited. Some effect studies in the aquatic environment were performed around 1980, but information on effects on the terrestrial environment has not been found. Only a few measurements of environmental concentrations have been reported.

A study of furfural toxicity to fish becomes a critical input to this risk assessment. There is always a risk that the concentrations in the tests of volatile compounds are lower than the nominal value. In this test the concentrations were tested and found considerably lower than expected, in the end of the exposure periods it was not even possible to measure the substance. Furthermore the analytical results varied widely between double samples and the NOEC derived from the test can be questioned.

SCHER therefore suggests a new fish test in a dynamic test system to decrease the problems to maintain the furfural concentrations during the test. This will probably result in a lower NOEC and maybe also several PEC/PNEC values over 1.

There is no recommendation for testing of effects in the terrestrial compartment, as "the development of risk reduction measures for the aquatic compartment should take account of the conclusions for the terrestrial for these three scenarios".

SCHER disagrees with this conclusion as there is a risk that the measures involve evaporation of furfural from the water phase, and therefore it is essential to have a reliable PNEC also for the terrestrial environment.

SCHER supports the other conclusions of the RAR. It is also very good that the possible problem connected to emissions of furfural from the pulp and paper industry is highlighted although it is out of the mandate for the work with existing chemicals.

3.2 Specific Comments

3.2.1 Exposure assessment

2-Furaldehyde, probably more known as furfural, is produced at two sites in the EU, but the major amount is imported. There are site specific release data available from the major importer, who uses the major part of the furfural to produce furan derivatives. The reported values are low, 312 kg emitted of the 31 000 tons imported per year, which corresponds to 10 g per ton of a rather volatile compound. This may, however, be explained by the peculiar odour of the substance and emissions to air would be easy to detect. With a few exceptions the emissions from production, processing and formulations at other sites are predicted according to the TGD. A major source seems to be the use in the oil industry. Company data from one refinery show an emission to air of 113 ton of the used 375 tons per year. If the same emission factor would be applicable to all refineries it would correspond to 1 700 tons which is one third of the EU production. Another major source to furfural in the environment may be the sulphite pulping process, which has even been suggested as a commercial source of this compound.

A few measured concentration of furfural in water (none of them in Europe) have been located and none in air or soil. The literature list, however, just contains three references to scientific papers published after 2000.

3.2.2 Effect assessment

Furfural is relatively volatile and it is essential that the actual concentration in the test medium is measured in the aquatic effect tests. The short term values for freshwater fish (LC50 between 1.2 and 32 mg/L) referred to in the RAR were produced up to around 1980 and only one has been produced with a known concentration. The US EPA ECOTOX database (http://cfpub.epa.gov/ecotox/report.cfm?type=short) gives more data than those used for this assessment, but they are all in the same region and also relatively old.

A short term semi-static test with Zebrafish (following the OECD guideline 212 "Fish, Short-term Toxicity Test on Embryo and Sac-fry Stages") has been performed, and as the furfural has a log Kow < 4 it can be interpreted as a long term test. The concentration of the substance decreased however very quickly in the test medium. The nominal concentration of furfural was 0.47 mg/L, but the concentration in the freshly prepared solution ranged between 0.33 and 0.41, between 0.04 and 0.17 after 6 hours and could never be detected after 24 hours of exposure. In vessels without larvae the concentration also decreased but not as much as in the larvae containing vessels. The reported NOEC (0.33 mg/L) was calculated as the geometric mean from concentrations measured in test vessels without any larvae, and obviously the larvae were exposed to lower concentrations.

SCHER has difficulties to understand the rationale for that procedure, and expect the true value to lower than that used in the assessment.

Two short and one long term tests using *Daphnia magna* are reported. The latter seems to be well performed in a flow-through system with measured concentrations and gave a NOEC of 1.9 mg/L. Closed test systems were used to determine the furfural toxicity to aquatic plants and microorganisms, which probably minimize evaporation losses. There are several long term tests on freshwater plants reported and the most sensitive species seems to be *Microsystis aeruginosa* with a NOEC of 2.7 mg/L. The lowest NOEC for microorganisms, 0.59 mg/L, was found for *Entosiphon sulcatum*.

PNEC for the aquatic environment is derived from the NOEC found in the fish test by the use of an assessment factor of 10 based on tests with three different species, but the concentration uncertainty in that test makes this PNEC unreliable. If that study is not used there are results from only two species and an assessment factor of 50 has to be applied to the NOEC for *Daphnia magna*, resulting in a PNEC of 0.038 mg/L for aquatic organisms. As this is higher than what can be expected from the fish study, a new test has to be done. To

avoid the concentration variation this must be dynamic test where fresh test medium is supplied continuously.

There are no studies on sediment-dwelling organisms and no PNEC is derived, which can be accepted as the major part of the furfural will be distributed to the water phase. PNEC for microorganisms is derived from the toxicity found for activated sludge.

There are no data on the toxicity of furfural to the terrestrial environment or the atmosphere which is a serious limitation for a compound with relatively high vapour pressure.

SCHER supports the assessment of the risk for secondary poisoning, especially due to the very low Kow of the substance.

3.2.3 Risk characterisation

The risk characterisation of furfural in the aquatic environment depends on the toxicity in fish. This indicates that several activities locally give PEC/PNEC values above 1. As mentioned above this value is probably too high and with a lower PNEC also emissions from some other activities may cause concern. The possibly high emissions from the pulp and paper industry have to be addressed under some other legislation than the one for existing chemicals.

The absence of a risk assessment of furfural in the sediment can be accepted due to the distribution to the water phase, but SCHER does suggest the production of data to make an assessment of the relatively volatile compound in the terrestrial environment possible.

SCHER supports the conclusion (i)[1] for soil as the assessment based on the partitioning principle gives PEC/PNEC ratios over 1 for some of the scenarios.

The PBT assessment result that furfural is neither P nor B is also supported by SCHER.

4. LIST OF ABBREVIATIONS

LC50 Median lethal concentration
NOEC No observed effect concentration
PEC Predicted environmental concentration
PNEC Predicted no effect concentration
RAR Risk assessment report
TGD Technical Guidance Document

[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.