TARGETED RISK ASSESSMENT REPORT ON SODIUM HYDROXIDE (NAOH) ENVIRONMENTAL PART

CAS No.: 1310-73-2; EINECS No.: 215-185-5

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ACKNOWLEDGEMENTS

The rapporteur is acknowledged for his valuable contribution to this opinion:

Prof. M. Vighi, Professor of Ecology and Applied Ecology, Department of Environmental Sciences, University of Milano Bicocca, Italy.

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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. TARGETED RISK ASSESSMENTS

In order to accelerate the EU risk assessment process for existing substances, the European Commission has clearly expressed a wish to perform so-called 'targeted risk assessments' (TRA) for the 4th Priority-list substances, which include NaOH. In this context 'targeted' means that not all endpoints, as defined in the Technical Guidance Documents (TGD), are addressed thoroughly in the risk assessment. In a TRA one deviates therefore from the standard comprehensive risk assessment that covers all possible exposure routes of the chemical and all protection goals. Arguments and requirements for performing a TRA within EC Regulation 793/93 are discussed in the Competent Authority discussion paper 'Use of Targeted Risk Assessments in the EU' (DOC ENV/D/900718/01).

3. 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.

4. OPINION

4.1 General Comments

The environmental risk assessment is targeted solely on the effects on pH in the aquatic environment. Considering the characteristics of the substance, its environmental fate and its character of natural compound (Na is an essential nutrient for living organisms) of common and wide occurrence, the SCHER agrees with this approach.

The report conclusion is that no additional information is needed for the environmental risk assessment and no additional measures, besides a proper pH control of waste waters, are needed.

The SCHER finds this conclusion appropriate.

4.2 Specific Comments

4.2.1 Exposure assessment

NaOH is a very high production volume compound (estimated world-wide demand about 44 million tonnes), used for several industrial and domestic purposes.

Due to emission patterns, chemical properties (high solubility, low vapour pressure), environmental fate properties (rapid neutralisation and wash-out in the atmosphere, neutralisation in soil) it is expected to be present in significant amounts only in water, where it is ionised in Na^+ and OH^-.

Experimental measurements in the aquatic environment can be performed indirectly, by determining OH^- concentration trough pH measurement. Sodium measurements can also be performed.

4.2.2 Effect assessment

4.2.2.1 Aquatic compartment

It has been assumed that adverse effects are only due to OH^-, being expected environmental Na concentrations unlikely to produce any adverse effect.

It must be taken into account that the potential effects are strictly depending on the buffer capacity of the water.

Moreover, besides direct effects of pH on aquatic organisms, indirect effects should be taken into account (bioavailability of metals, dissociation of ionisable compounds, etc).

All eco-toxicological data available have been judged as non valid for the derivation of a PNEC due to insufficient information on the methodology and on experimental conditions (pH, buffer capacity, etc.).

Nevertheless, it is pointed out in the report that there is no need for additional acute toxicity data since they cannot be used to derive a PNEC for sodium hydroxide, because:

- the natural pH of aquatic ecosystems can vary significantly between aquatic ecosystems; optimum conditions for aquatic organisms are ranging from 6 up to 9;
- the sensitivity of aquatic organisms to pH changes can vary significantly among aquatic ecosystems;
- the change in pH due to an anthropogenic NaOH addition is influenced significantly by the buffer capacity of the receiving water;
- the effects of pH on aquatic ecosystems are well documented in the literature.

This position is supported by the SCHER.

Therefore effect assessment has been based on the possibility for a pH increase above 9, assumed as a threshold for optimal conditions, in waters with different buffering capacity. It follows a NaOH concentration of 1.0 and 6.1 mg/L for water with low (20 mg/L bicarbonate concentration) or high (195 mg/L bicarbonate concentration) buffer capacity respectively.

These concentrations correspond to Na concentrations of 0.6 and 3.5 mg/L respectively, lower than usual background concentrations. This confirms the irrelevance of sodium effects.

This approach is considered acceptable by the SCHER.

4.2.2.2 Terrestrial compartment

Toxicity data on terrestrial organisms are not available, but the report suggests that there is no need for testing due to the low exposure expected.

This position is supported by the SCHER.

4.2.3 Risk characterisation

Being effects of NaOH expected to be exclusively produced by pH changes, the control of pH is assumed as a sufficient measure for controlling NaOH risk for the aquatic environment.

Being pH one of the basic traditional parameters to be regularly measured in waste waters, and being the control of pH a relatively easy measure, the report suggests that no additional information is needed for the environmental risk assessment and no additional measures, besides a proper pH control, are needed.

The SCHER supports this conclusion.

5. LIST OF ABBREVIATIONS

PNEC	Predicted No Effect Concentration
TGD	Technical Guidance Document
TRA	Targeted Risk Assessment