



TARGETED RISK ASSESSMENT REPORT ON
SODIUM HYDROXIDE (NAOH)
HUMAN HEALTH PART

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

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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 health part of the document is of good quality, it is comprehensive and the exposure and effects assessment follows the TGD within the limits defined for targeted risk assessments.

The human health risk assessment is targeted solely on respiratory, dermal and ocular irritation which the report considers the major endpoints for an assessment of sodium hydroxide health risks.

The SCHER agrees with this approach.

4.2 Specific Comments

4.2.1 Exposure assessment

Human exposure to sodium hydroxide may occur during occupational handling by inhalation and skin contact; consumer exposure may be caused by skin contact and accidental ingestion. Ocular corrosion during handling of sodium hydroxide solutions without adequate eye protection may also occur.

The RAR uses measured data, physico-chemical properties of sodium hydroxide, and information on production processes and consumer uses in combination with model predictions (EASE) for exposure assessment.

A number of scenarios for occupational exposures are evaluated for risk characterisation. Inhalation exposure is estimated based on measured data, extent of skin contact and dermal uptake is modelled.

Regarding direct consumer exposure, several used scenarios were developed. Indirect exposure via the environment is not considered relevant since the major toxicities of sodium hydroxide are caused by the high pH of aqueous solutions.

This approach is supported by the SCHER.

4.2.2 Effect assessment

The SCHER agrees that skin, eye and respiratory irritation/corrosion are the major hazards during use of sodium hydroxide. As correctly outlined in the RAR, systemic effects are not considered relevant due to the massive local toxicities and the buffer capacity of the blood.

Absence of mutagenicity in bacteria suggests that sodium hydroxide is unlikely to cause cancer by genotoxic mechanisms.

The SCHER also agrees that sodium hydroxide solutions should not be considered as skin or respiratory sensitizers.

4.2.3 Risk characterisation

4.2.3.1 Workers

A NOEL of 1 mg sodium hydroxide per m³ regarding respiratory irritation is derived and several of the developed occupational exposure scenarios give exposures above this NOEL. The SCHER agrees with these conclusions. However, the use of MOS values in the assessment is questioned since the effects assessment is based on a human study with a large number of individuals.

Potentially vulnerable groups regarding occupational exposures would have been detected and therefore the MOS approach may not be appropriate. However, the measured inhalation exposures are often based on 8 h TWAs and higher peak exposures may occur during shifts.

Therefore conclusion iii)¹ is acceptable. It has to be assumed that adequate skin and eye protection is used when handling sodium hydroxide solutions and the endpoints skin and eye irritation/corrosion therefore are not included in the occupational risk assessment.

4.2.3.2 Consumers

Regarding consumer exposure, the RAR justifies conclusion iii) based on the many reported accidental intoxications with sodium hydroxide. However, the SCHER would propose to apply conclusion iii) (as for irritation and corrosivity) also to the endpoints acute toxicity and eye irritation because corrosion has to be considered an acute toxic effect and eye damage is also reported in the surveys from the poison centres.

Conclusion ii) regarding skin and respiratory tract sensitization and the other endpoints regarding systemic toxicity is supported by SCHER.

5. LIST OF ABBREVIATIONS

EASE	Estimation and Assessment of Substance Exposure Physico-chemical properties
MOS	Margin of Safety
NOEL	No Effect Level
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.*