



Scientific Committee on Health and Environmental Risks

SCHER

Opinion on

Risk Assessment Report on Nickel; Nickel carbonate; Nickel chloride; Nickel dinitrate; Nickel sulphate

Indirect exposure

CAS No: 7440-02-0; 3333-67-3; 7718-54-9; 13138-45-9;
7786-81-4

EINECS No: 231-111-4; 222-068-2; 231-743-0; 236-068-5;
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The SCHER adopted this opinion at its 24th plenary on 15 July 2008

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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.

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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

On the basis of the examination of the Risk Assessment Report the SCHER is invited to examine the following issues:

- (1) Does the SCHER agree with the conclusions of the Risk Assessment Report?
- (2) If the SCHER disagrees with such conclusions, it is invited to elaborate on the reasons.
- (3) If the SCHER disagrees with the approaches or methods used to assess the risks, it is invited to suggest possible alternatives.

3. OPINION

3.1 General comments

The indirect exposure part of the document is of good quality, it is comprehensive and transparent, and the exposure assessment follows the TGD. The document assesses indirect human exposures to elemental nickel and some water-soluble nickel salts.

3.2 Specific comments

3.2.1 Exposure assessment

The RAR contains a detailed assessment of the environmental exposures on a local and regional scale. Average and reasonable worst-case exposures are defined for a number of scenarios with a very detailed documentation. The delineated exposures often are based on measured data on nickel content in food, water, and environmental media. In cases when assumptions are used as the basis for the assessment, the basis for these assumptions are justified in detail and conclusions can therefore easily be followed.

3.2.3 Risk characterisation

In the risk assessment part, the estimated exposures are put into relation to relevant health effects of nickel and nickel salts as defined in the RAR for nickel and nickel salts, human health part. The risk characterisation uses the MOE approach as outlined in the TGD.

SCHER support conclusion ii)¹ for the regional scenarios as indicated in the document. Conclusion iii) is supported due to a high dietary intake of nickel as a potential risk for exacerbation of allergic symptoms in highly nickel sensitized individuals. Conclusion iii), as derived in the RAR for some other scenarios regarded repeated dose toxicity endpoints, is also supported.

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.*

4. LIST OF ABBREVIATIONS

MOE	Margin of Exposure
RAR	Risk Assessment Report
TGD	Technical Guidance Document