baua:
Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
Federal Institute for Occupational
Safety and Health

Risk Management Option Analysis Conclusion Document

Substance Name:	**Nickel sulphide and trinickel disulphide**
EC Number:	**240-841-2 and 234-829-6**
CAS Number:	**16812-54-7 and 12035-72-2**
Authority:	**German and Hungarian CA**
Date:	**30 March 2017**

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority (aMSCA). In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Regulation (EC) No 1907/2006:

NiS and Ni_3S_2 are regulated by two entries in Annex XVII (Entry 27 & 28). Entry 27 does not specifically refer to NiS or Ni_3S_2 but to nickel and its compounds in piercings and other articles which come into direct contact with the skin. Entry 28 applies to all category 1 carcinogens which are listed in Appendix 1 of the REACH Regulation. Both substances are listed in this Appendix. Both entries in Annex XVII, however, do not affect the exposure and therefore the risk for workers in the industrial catalyst sector.

Directive 2004/37/EC:

Both sulphides are carcinogens; therefore the provisions of Directive 2004/37/EC apply. This includes substitution by less dangerous substances if technically possible. If substitution is technically not possible, manufacturing and use of the substance shall apply in closed systems. If closed systems are not possible the exposure of workers must be reduced to a level as low as technically possible:

- Limitation of the quantities of a carcinogen or mutagen at the place of work;
- Keeping as low as possible the number of workers exposed or likely to be exposed;
- Design of work process and engineering control measures so as to avoid or minimise the release of carcinogens or mutagen into the place of work;
- Use of existing appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an unforeseeable event or an accident;
- Collective protection measures and/or, where exposure cannot be avoided by other means, individual protection measures;

Regulation (EC) No 1223/2009:

Both sulphides are listed in Annex II of Regulation (EC) No 1223/2009 and are therefore prohibited in cosmetic products.

Regulation (EC) No 1272/2008:

Both sulphides are listed Annex VI and therefore have a harmonised classification as Skin Sens. 1, Muta. 2, Carc. 1A, STOT RE 1, Aquatic Acute 1 and Aquatic Chronic 1. In addition, for each substance a CLH proposal has been submitted. The hazard classes which are proposed for harmonisation are Acute Toxicity 4, H332 and STOT RE 1 (target organ specification: lungs) in case of NiS and Acute Toxicity 4, H332, Aquatic Acute 1, M-factor=1, Aquatic Chronic 1, M-factor=1 in case of Ni_3S_2.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	x

3. Need for follow-up regulatory action at EU level

3.1 Harmonised classification and labelling

NiS and Ni_3S_2 already have harmonised classifications and CLH proposals were submitted by Finland and industry. At the moment, there are no further indications for the revision of the corresponding classifications. Therefore, submission of a CLH dossier is not considered as an option to be pursued.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

In principle, NiS and Ni_3S_2 fulfil the criteria to be identified as SVHC according to Article 57(a). Inclusion of substances in the candidate list leads to additional information obligations for the companies dealing with these substances, these substances in mixtures or in articles. However, since NiS and Ni_3S_2 are solely used at industrial sites – in most cases in closed systems – these obligations alone would not generate any additional information and would not reduce the exposure or the risk at the workplace.

The inclusion of SVHCs in the Candidate List is the first step of the authorisation procedure. Authorisation is intended to assure that the risks from SVHCs are properly controlled and that these substances are progressively replaced by less hazardous or safer substances. All uses of a substance are covered by the authorisation obligation, except uses considered as intermediates, and in case there are grounds for specific exemptions.
Only very few and well-defined uses have been identified for the nickel sulphides, mainly in the catalyst sector. Given the exposure data at hand for these uses, risks can be considered as minimized by the implemented RMMs. Thus this RMO is not considered appropriate.

3.3 Restriction under REACH

The use of NiS and Ni_3S_2 is mainly limited to the catalyst sector. In comparison to the nickel industry in total, the use of these sulphides in catalysts is only a niche application. The nickel industry is a large industrial sector with many employees potentially exposed

to nickel and its compounds. Hence, a restriction which would ban NiS and Ni_3S_2 in catalysts would not yield a great influence on the amount of workers exposed to nickel ions. Furthermore, substitution costs would be high, and thus cannot be considered as proportional compared to the risks which are already adequately controlled by the RMMs implemented at the workplaces.

4. No action needed at this time

The use of NiS and Ni_3S_2 is focussed on the application of catalysts and can be considered as a niche application. Compared to the number of workers in the overall nickel industry the number of workers possibly exposed to NiS and Ni_3S_2 is small. In addition, the rather long lifetimes of the catalysts containing nickel sulphides minimize the number of events where exposure to workers can occur. The exchange of the catalysts is conducted by specialized employees of catalyst exchange companies. Data provided by industry shows that these employees are adequately trained and supervised and use appropriate personal protective equipment.

In addition, it was shown that authorisation and restriction cannot be considered as proportional RMOs according to the low remaining risks.

As already stated both sulphides are carcinogenic. Directive 2004/37/EC on the protection of workers from the risks related to exposures to carcinogens or mutagen applies without prejudice to the REACH regulation. Therefore exposure to NiS and Ni_3S_2 must already be minimised as far as possible. This Directive provides further that limit values should be established for all those carcinogens or mutagens for which the available information, including scientific and technical data, makes this possible. The aMSCA acknowledges that a European wide limit value (BOEL) for NiS and Ni_3S_2 may contribute to the reduction of exposure and risks at the workplace.

Based on the analysis of available exposure data and the operational conditions including personal protective measures descripted no unacceptable risk which needs to be addressed by a ban on a Union-wide basis was identified. In addition, no feasible alternatives are available and the benefits of continued use of NiS and Ni_3S_2 for catalyst applications are high. Therefore, aMSCA currently does not see a need for further action.