RISK MANAGEMENT OPTION ANALYSIS

CONCLUSION DOCUMENT

for

Nickel Sulphate

EC No 232-104-9

CAS No 7786-81-4

Member State: France

Dated: August 2016

Disclaimer: Please note that this RMOA conclusion was compiled on the basis of available information and may change in the light of new information or further assessment.

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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. 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 other 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

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Nickel sulphate (NiSO4) belongs to the family of nickel compounds including nickel metal, nickel salts, organometallic nickel substances, etc. More than a hundred are classified under the CLP Regulation. At least 26 nickel compounds are registered under REACH, 16 as full dossiers (REACH Article 10), 8 as intermediate dossiers (REACH article 18) and 2 with both full and intermediate dossiers. Additional registrations can also be expected. From those 26 nickel compounds, 6 have been selected by the French Competent Authority for further assessment (nickel sulphate, hydroxycarbonate, dichloride, dinitrate, bis(hydrogen)phosphate and monoxide). Risk management option analyses (RMOA) have been carried out on NiSO4 and NiO as both salts cover substantially the majority of the uses reported for nickel compounds. ***Therefore the conclusion of these two RMOAs is also valid for the other Nickel compounds.***

Classification and labelling

$NiSO_4$ is currently classified under Annex VI of the CLP Regulation (EC No.1272/2008) as follows.

Index No	International Chemical Identification	EC No	CAS No	Classification		Spec. Conc. Limits, M-factors	Notes
				Hazard Class and Category Code(s)	Hazard statement code(s)		
028-009-00-5	Nickel sulphate	232-104-9	7786-81-4	Acute tox. 4 Skin Irrit. 2 Skin Sens. 1 Acute Tox. 4 Resp Sens. 1 Muta. 2 Carc. 1A Repr. 1B STOT RE 1 Aquatic acute 1 Aquatic chronic 1	H302 H315 H317 H332 H334 H341 H350i H360D H372 H400 H410	Skin Sens. 1; H317: C ≥ 0,01% STOT RE 1; H373: C ≥ 1% Skin Irrit. 2; H315: C ≥ 20% STOT RE 2; H373: 0,1% ≤ C < 1% M=1	none

Information on any previous risk assessment, risk reduction strategy and RMO analyses

Previous risk assessment carried out under Council Regulation 793/93

A risk assessment has been carried out in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances for 5 nickel compounds. Indeed nickel metal, nickel sulphate, nickel dichloride, nickel dinitrate and nickel carbonate have been included in the third and the fourth priority lists of substances for assessment under this Regulation due to concerns for human health and the large annual quantities used. The final approved version of the risk assessment report (RAR) is dated May 2009; the chapter 4 (Addendum 2-year inhalation study in rats) has been added in November 2009.

The work assessed the effects and risks:

- on the environment and human exposed indirectly via environment for nickel (metal) and the four nickel salts,

- on the human health for $NiSO_4$ (workers and consumers).

The risk assessment covered the following occupational uses of the 5 compounds (those flagged with * were relevant for $NiSO_4$)

- production of nickel metal* and nickel salts*,
- alloy production including nickel plating* activities and chemical pre-treatments of plated metals,
- battery production,
- catalyst production*,
- production of nickel-containing chemicals*,
- use in coins,
- contact with tools and other nickel-releasing surfaces,
- end-uses of nickel-containing products (batteries, catalysts, welding rods).

The main risks identified by the risk assessment are the occupational inhalation exposure and the skin sensitisation of consumers.

Risk assessment outcome for workers

Risks were identified for all the following manufacture and use scenarios considered in the risk assessment (those flagged with * were relevant for $NiSO_4$):

1. Production of nickel metal: refining*
2. Production of nickel salts*
3. Production of alloys
   - melting and foundry techniques,
   - powder metallurgy,
   - nickel plating*
   - chemical pre-treatment of metals*
4. Battery production
5. Catalyst production*
6. Production of nickel-containing chemicals*

Based on the information and the classification available at that time (identified uses and exposure levels, hazard characterization and subsequent classification, agreed DNELs, etc.), risks were identified for workers based on inhalation exposure (to nickel salts) and on the following health effects:

- acute inhalational toxicity (short-term peak exposures to nickel salts),
- respiratory sensitisation (occupational asthma following inhalation exposure to nickel salts),
- chronic inhalational toxicity (full-shift exposure),
- inhalational carcinogenicity (for all scenarios except those where the exposure is purely to metallic nickel),
- reproductive toxicity (fertility and developmental toxicity following inhalation).

Note that there were no concern for workers after oral exposure, as it was assumed that this is prevented by personal hygiene measures.

Summary of the RAR conclusion on the occupational risk assessment for $NiSO_4$:

Conclusion	Endpoints of concern	Reasoning
(i) on hold. There is need for further information and/or testing	Effects on fertility and development	There is need for further studies to evaluate the possible effects of nickel sulphate on germ cells, but further testing is not considered practicable

(iii) There is a need for limiting the risks: risk reduction measures which are already being applied shall be taken into account	Acute toxicity, respiratory sensitisation, repeated dose toxicity, carcinogenicity, effects on fertility and development	The risk assessment has shown that a concern with inhalational exposure is expressed for all inhalational exposure scenarios in relation to worst case exposure levels. For typical exposure levels concern is expressed to the majority of the endpoints/exposure scenarios
(ii) There is at present no need for further information and/or testing or for risk reduction measures beyond those which are being applied	Effects on fertility and development, dermal exposures for acute and repeated dose toxicity, irritation, sensitisation, carcinogenicity and reproductive toxicity	The risk assessment has shown that following typical inhalational exposure for some scenarios (effects on fertility and development, and for all scenarios for dermal exposures for acute and repeated dose toxicity, irritation, sensitisation, carcinogenicity and reproductive toxicity) there is no need for limiting the risks taking into account the risk reduction measures that are already being applied

Risk assessment outcome for dermal exposure and skin sensitization

There appeared to be little concern for induction of skin allergy from contact with nickel-containing chemicals in the workforce, or for any other health effects related to dermal exposure. With respect to metallic nickel, whilst release of nickel from the metal or nickel-containing alloys during occupational exposure is possible, skin contact to these materials is unlikely to be prolonged, and therefore the possibility of induction of sensitization is much reduced compared to soluble nickel compounds.
Thus a conclusion (ii) has been considered justified for all workplace scenarios for induction of nickel allergy. The exposure levels were also considered sufficiently low to justify a conclusion (ii) for the elicitation of symptoms of nickel allergy in previously sensitised individuals for workplace exposure.

Risk assessment outcome for welding activities

The risk assessment reflects agreement with the conclusions drawn by IARC (1990) and Cross et al. (1999) that there is a concern for the welding process, although the concern is not specifically associated with the presence of nickel alone in either the materials used for welding or the materials being welded. Several substances potentially hazardous to health are present both as part of the welding materials (rod, core etc.) and as components of the surfaces to be welded. The hazards associated with the process are primarily associated with the fumes generated, exposure to nickel by inhalation cannot be excluded when nickel metal or nickel salts are involved in the welding process. Nevertheless, the composition of these fumes depends on the components of the welding process, as well as on the welding method used. Therefore no targeted risk characterisation has been carried out for the use of nickel in welding.

Risk assessment outcome for consumers

Concerns for consumers are very different than for workers. Consumers are mainly exposed by skin contact (to nickel metal) and oral exposure (to nickel salts). Whilst dermal exposure is to nickel metal, oral exposure is to soluble nickel. There is indeed no significant inhalational exposure to nickel or nickel compounds for consumers. Both the induction of nickel allergy in non-sensitive people and the elicitation of allergic reactions in people already sensitive to nickel have been considered for the risk assessment.
The main concern is related to direct and prolonged skin exposure to nickel(metal)-containing objects such as coins, earrings, clasps of necklaces, zippers, finger rings, medallions, metal identification tags, buttons, wire support of bra cups, buttons on jeans, watchbands, bracelets, spectacle frames etc. as well as to piercing posts used for ear-piercing and piercing of other parts of the body.
Consumers can also be exposed to nickel orally from nickel released to food, nickel released from water heating devices (kettles), nickel released to drinking water, nickel in

mineral supplements. With the exception of the use of $NiSO_4$ and $NiCl_2$ as a source of nickel in food supplements, there would appear to be little or no consumer exposure to nickel sulphate, chloride, nitrate or carbonate.
The risk assessment concluded that there is no concern for consumers for systemic effects by dermal exposure. The population at risk of developing symptoms after oral challenge are patients with severe nickel sensitization only.
It was indeed agreed that the main group of people where there is particular concern are those who are already nickel-sensitive, and this is a group especially at risk from both dermal and oral exposure to nickel. However, EU legislation has come into force and has been considered adequate to prevent new cases of nickel allergy as well as to reduce the incidence of elicitation in consumers who are already sensitised to nickel from both objects in direct and prolonged contact with the skin as well as piercing posts.

Note that the risk assessment for humans exposed to the environment has not been completed but it has been suggested that the sources of nickel, should this give rise to concern, would be controlled by any risk reduction measures required for concerns for the environment. Therefore no additional risk for humans from the environment was expected.

Previous risk reduction strategy carried out under Council Regulation 793/93

In order to identify appropriate measures to address the risks to human health raised in the risk assessment report, a risk reduction strategy with respect to human health was prepared by Denmark in 2007 in accordance with Council Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

The report stated that nickel and nickel compounds were already widely regulated under EU legislation. The following risk reduction measures were proposed in relation to the obligations under Community law:

- to set occupational exposure limits for nickel metal and nickel compounds in the form of inhalable dust/aerosols under Directive 98/24/EC (chemicals at work) or Directive 2004/37/EC (carcinogens at work) as appropriate,
- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to establish at Community level an occupational exposure limit or limits for welding fumes, according to Directive 98/24/EC or Directive 2004/37/EC as appropriate, taking into account information in the nickel RAR, as well as other risk assessments on chromium(VI) compounds and zinc,
- to consider the validity of derogations for the use of $NiSO_4$ and NiCl2 under Directive 2002/46/EC on the approximation of the laws of the Member States relating to food supplements.

The following measures were proposed in relation to non-regulatory outcomes:

- practical sector-specific guidance of a non-binding nature should be drawn up by the Commission for uses of nickel identified as a concern in the risk assessment, as foreseen under Article 12(2) of Directive 98/24/EC,
- consideration of an exchange of information organised by the Commission to ensure proper guidance to severely nickel-sensitised individuals through the Community,

- the effects of Directive 94/27/EC (relating to restrictions on the marketing and use of certain dangerous substances and preparations) as amended and the associated EN 1811 standard should be monitored in the wider EU population to ensure that the threshold set in the Directive is adequate to prevent new cases of nickel allergy and is also sufficient to prevent elicitation of symptoms in a significant proportion of nickel-sensitised individuals caused by the release of nickel from objects in direct and prolonged contact with the skin and piercing posts.

Previous RMO analysis carried out on environment by Denmark

A risk assessment for the environment and human exposed via the environment has been conducted by Denmark under Council Regulation 793/93 on nickel (metal) and nickel compounds (nickel sulphate, nickel [hydroxy]carbonate, nickel chloride, nickel dinitrate). This report is dated May 2008.

The work was completed in 2012 on the sediment compartment on the basis of new information that was formerly required in COM Reg. 466/2008 on the chronic effects (and potential risks) to freshwaters sediment organisms. A conclusion of substance evaluation (for those five compounds) drafted the 19th of December 2012 was made available to Member States according to transitional measures described in Article 135, 136 and 48 of the REACH regulation. This conclusion is regarded as a risk management option analysis that completes the existing environmental risk assessment for nickel compounds.

Denmark considers that no risk management measure is appropriate under the REACH Regulation but expresses the need for other community-wide measures. It is thus proposed:

- the establishment of an EQS freshwater sediment under the Water Framework Directive (WFD) including potential use of an AVS-based bioavailability normalisation approach,
- that further Guidance is being developed under WFD for refined assessment when initially $EQS_{freshwater\ sediment}$ seems to be exceeded. It is proposed to base such a further development on the refinement approach of the summary report which includes bioavailability normalisation and refinement of the emission/exposure assessment,
- a revision of the BREF note for nickel plating to also protect specifically the freshwater sediment compartment under the Industrial Emission Directive.

Denmark also recommends registrants of nickel to update nickel registration dossiers without undue delay taking into account:

- the new hazard data on freshwater sediment organisms,
- that an assessment factor of 2 is recommended to derive $PNEC_{freshwater\ sediment}$= 47 mg Ni/kg sed. dw,
- the use of the established bioavailability approach i.e. the prescribed use of AVS normalisation models and/or reducing exposure and/or refining emission/exposure assessment if initially calculated $RCR_{freshwater\ sediment}$ >1 to prove safe use (i.e. $RCR_{freshwater\ sediment}$ <1 for refined assessment).

Denmark finally expresses the need for action at national level by Member States Competent Authorities (in future if/when $EQS_{freshwater\ sediment}$ and bioavailability normalisation approach have been adopted under the WFD and employed by registrants under REACH):

- implement BAT in relevant industrial sector,
- monitor if the proposed EQS for freshwater sediment is complied with for all industrial nickel emitting local sites,
- enforce compliance under REACH and the Water Framework Directive.

The French Member State Competent Authority (MSCA FR) agrees with the conclusions of the environmental risk assessment and RMOA conducted by Denmark and considers that no further development of the proposed environmental risk management option is needed.

Therefore the present RMOA has not considered further the environmental risk.

Current legal requirements for nickel and nickel compounds under REACH and other EU legislations

Nickel metal and nickel compounds are existing substances with a long history of production, uses and also hazard and risk characterization. Therefore a number of general and targeted legislative controls are currently in place in the EU. Only those that explicitly cover NiSO4 directly or indirectly are listed below.

EU general legislations on dangerous chemicals covering nickel compounds

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations).

Directive 94/27/EC of 30 June 1994 (amending for the 12th time Directive 76/769/EEC) and Directive 94/60/EC of 20 December 1994 (amending for the 14th time Directive 76/769/EEC) relating to restrictions on the marketing and use of certain dangerous substances and preparations (also called Nickel Directive).

EU workplace legislation regarding occupational health and safety

Directive 90/394/EEC Protection of Workers from Risks to Exposure to Carcinogens at Work and, in its codified version, Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work.

Directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work (informal and binding OELs) and Directive 89/391/EC, Framework Directive (called OSH "Framework directive").

In addition to the OEL legislation and to Directive 2004/37/EC, the risks at the workplace arising from exposure to hazardous substances are controlled at European level by a number of Directives (see below) related to the protection of occupational safety and health. They impose minimum standards for health and safety of workers and provide a framework of directions and safeguards to ensure that the risks in the workplace to health from hazardous substances are managed. Most of them cover indirectly nickel and its compounds regarding to their classification as hazardous substances.

- Directive 2001/58/EC on "Safety Data Sheets" and Directive 1999/45/EC relating to dangerous substances in implementation of Article 27 of Council Directive 67/548/EEC (safety data sheets).
- Directive 89/656/EEC on the use of personal protective equipment (PPE).
- Directive 92/85/EC (pregnant workers directive) on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding (tenth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC).
- Directive 94/33/EC (young workers directive) on the protection of young people at work.

EU legislation regarding consumer protection

The following is provided for information only and not developed further since this RMOA only addresses the occupational risk and not the risk for consumers, considered non-existent for NiSO4 particularly.

Regulation (EC) No 552/2009 amending the REACH Regulation (EC) No 1907/2006 as regards to Annex XVII: restrictions concerning substances classified Carc. 1A/1B, Muta. 1A/1B and/or repr. 1A/1B under Annex VI of the CLP which shall not be placed on the market, or used, as substances, as constituents of other substances, or, in mixtures, for supply to the general public.

Regarding NiSO4 specifically, Annex XVII of REACH as amended by Commission regulation 552/2009 provides that nickel and its compounds shall not be used:

- in any post assemblies which are inserted into pierced ears and other pierced parts of the human body unless the rate of nickel release from such post assemblies is less than 0.2 µg/cm2/week (migration limit),
- in articles intended to come into direct and prolonged contact with the skin such as: earrings, necklaces, bracelets and chains, anklets, finger rings, wrist, watch cases, watch straps and tighteners, rivet buttons, tighteners, rivets, zippers and metal marks, when these are used, in garments, if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0.5 µg/cm2 / week,
- in articles referred to in point (b) where these have a nickel-free coating unless such coating is sufficient to ensure that the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin will not exceed 0.5 µg/cm2 / week for a period of at least two years of normal use of the article.

This restriction has been amended recently in order to ban the placing on the market for consumers Do-It-Yourself (DYI) nickel electroplating hobby kits containing NiSO4.

Regulation (EC) No 1223/2009 on cosmetic products that came into force on 11 July 2013 strengthens the safety of cosmetic products and streamlines the framework for all operators in the sector (Nickel and nickel compounds - including NiSO4, entries 455 to 460 of the Annex- are included in the Annex II "List of substances prohibited in cosmetic products").

Directive 2009/48/EC on toys' safety: chemicals that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under the CLP Regulation No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

EU legislation regarding protection of the environment and/or covering human health safety through environmental exposure

The following is provided for information only and not developed further since this document only covers the human health risk and not the risk for the environment that is considered already framed by the Danish RMOA.

As NiSO4 is classified as dangerous for the environment (aquatic chronic 1) under Annex VI of the CLP, Industry must comply with the requirements of the following environmental legislations:

- Directive 2010/75/EC on industrial emissions (IED) replacing Directive 96/61/EC on Integrated Pollution Prevention and Control (IPPC).
- Directive 96/82/EC on the control of major accident hazards involving dangerous substances (Seveso II Directive).

- Directive 2004/107/EC relating to arsenic, cadmium, mercury, nickel and polycyclic aromatic hydrocarbons in ambient air (4th Daughter Directive).
- Council Directive 98/83/EC on the quality of water intended for human consumption (Drinking water).
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive).
- Directive 2006/118/EC on the protection of groundwater against pollution and deterioration (Ground water Directive).
- Directive 2008/105/EC on environmental quality standards in the field of water policy (EQS or Priority Substances Directive).
- Council Directive 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture.
- Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC (Batteries Directive).
- Directive 2008/103/EC amending Directive 2006/66/EC on batteries and accumulators and waste batteries and accumulators as regards placing batteries and accumulators on the market.

Focus on current instruments setting occupational exposure limit values

- *SCOEL recommendation for nickels' occupational exposure limit values (OELs)*

The Scientific Committee on Occupational Exposure Limits (SCOEL) adopted in June 2001 the following recommendation on indicative OELs for nickel and inorganic nickel compounds.

Exposure to nickel compounds is associated with an increased cancer risk in the lung and nasal cavity, as well as with inflammatory responses/fibrosis in the lung. Since mechanistic data indicate an indirect genotoxic mode of action, nickel is considered as a carcinogen with a practical threshold. The proposed OELs are based on protection from inflammatory effects in the lung, but according to available evidence, it should also protect against carcinogenic effects.

Based on available long-term inhalation studies in rats showing severe lung damage (fibrosis and inflammation) and taking into account the differences between rats and humans with respect to particle deposition in the alveolar region (higher deposition in humans as compared in rats due to potential toxicodynamic differences) an OEL of 0.005 mg/m3 is proposed for the respirable fraction (<10 µm).

In addition to chronic inflammation of the lung, the proposed OEL also needs to protect from nickel-induced carcinogenicity. Since epidemiological evidence suggests not only the induction of lung tumours, which may be provoked by respirable particle sizes, but also of nasal tumours, and particles at the workplace are not limited to the respirable fraction, exposure towards inhalable nickel particles needs to be limited for carcinogenic nickel species as well. Based on the available epidemiological studies, an OEL of 0.01 mg Ni/m3 is proposed for the inhalable fraction (<100 µm) of water soluble as well as poorly water soluble nickel compounds (metallic nickel is excluded) in order to protect from nickel-induced carcinogenicity.

- *Indicative occupational exposure limit values (IOELVs) or binding occupational exposure limit values (BOELVs)*

An EU framework for the setting of Indicative Occupational Exposure Limit Values (IOELVs) is defined, *inter alia*, in Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work. Binding

Occupational Exposure Limit Values (BOELVs) are developed when socio-economic and technical feasibility factors are taken into account and may be then set under the Carcinogens Directive (2004/37/EC).

Any chemical agent for which an IOEL value is set at European level, Member States must establish a national exposure limit value, taking into account the Community indicative limit value, determining its nature in accordance with national legislation and practice.

Any chemical agent for which a BOELV value is established at European level, Member States must establish an corresponding national binding OEL value which can be stricter, but cannot exceed the Community limit value.

There are currently no IOELV nor BOELV for nickel and its compounds. However, a number of Member States have already set formal national OELs for nickel and nickel compounds. Those in force national OELs generally group the nickel compounds for which OELs apply as either water-insoluble inorganic nickel compounds or as water-soluble nickel species. Since they are part of national legislation, there may be differences across European countries in relation to the legal or advisory framework which affects the way the limit is interpreted and applied. In addition, the legal duties imposed may vary.

Those national OELs, even close, are not harmonized between Member States and are over the SCOEL recommendation of 0.01 mg Ni/ m3, except for the nickel carbonyl species and except for Denmark, such as shown below.

Country	OEL (mg Ni/m³) as Ni	Comments
France	1.0	Nickel carbonate, Nickel dihydroxyde, Nickel subsulfide, Nickel oxide, Nickel sulfide, Nickel trioxyde: 8-h time weighted average exposure limit value
	0.1	Nickel sulphate
	0.12	Nickel carbonyle
Germany[1]	0.5	Metallic nickel, nickel carbonate
	0.5	Nickel dioxide, nickel sulphide and sulphidic ores
	0.05	Nickel compounds as inhalable droplets (e.g. nickel sulphate, nickel chloride, nickel acetate).
Sweden	0.5	Metallic nickel
	0.1 ppm total dust	Nickel compounds
	0.007	Nickel carbonyl (equivalent to 0.001 ppm)
	0.1 ppm total dust	Trinickel disulfide
Poland	0.25	Nickel and its compounds
Belgium	1	Nickel metal
	0.2	Insoluble nickel compounds
	0.12 (0.05 ppm)	Nickel carbonyl
	0.1	Nickel subsulfide
	1	Nickel sulfide (dust and smoke)
Norway	0.007 (0.001 ppm)	Nickel carbonyl and nickel tetracarbonyl
	0.05	Nickel metal and other nickel compounds
Finland	1	Nickel metal
	0.1	Other nickel compounds (except nickel carbonyl)
	0.007 (0.01 ppm)	Nickel carbonyl (8 h)
	0.021 (0.003 ppm)	Nickel carbonyl (15 min)
United Kingdom	0.5	Nickel metal and water- insoluble nickel compounds
	0.1	Water- soluble nickel compounds
	0.24	Nickel carbonyl
The Netherlands	1.0	Metallic nickel
	0.1	Nickel oxide, nickel carbonate
	0.1	Soluble nickel compounds
	0.12	Nickel carbonyl

[1] Reported values were in force until 2006 but are no more valid; new threshold values are currently discussed

Denmark	0.05	Metallic nickel
	0.05	Insoluble nickel compounds
	0.01	Soluble nickel compounds
	0.007	Nickel carbonyl
Austria	0.05	Nickel metal and alloys, nickel sulphide, sulphidic ores, oxidic nickel and nickel carbonates in inhalable dust, as well as any nickel compound in the form of inhalable droplets
	0.05	Soluble nickel compounds
Ireland	1.0	Insoluble Ni compounds
	0.1	Soluble Ni compounds
	0.12	Nickel carbonyl
Italy	1.5	Ni metal
	0.2	Insoluble Ni compounds
	0.1	Nickel subsulfide
Luxembourg		Cf. German OELs
Portugal	1.0	Insoluble Ni compounds
Spain	1.0	Insoluble Ni compounds
	0.1	Soluble Ni compounds
	0.12	Nickel carbonyl

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	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restrictions	
Other EU-wide measures	X
No need for regulatory follow-up action	

3. FOLLOW-UP AT EU LEVEL

3.1 Need for follow-up regulatory action at EU level

3.1.1 Harmonised classification and labelling

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

At the date of the RMOA this option is considered as not appropriate. However, this option should be re-assessed in the future for further consideration, taking into account the progress regarding the implementation of the other measure (binding inhalable occupational exposure limits of 0.01 mg and 0.005 Ni/m3 respectively for the inhalable and respirable fractions) or when new data will be available.

3.1.3 Restriction

3.1.4 Other Union-wide regulatory risk management measures

Nickel sulphate is manufactured by three different routes (from copper refining, from solvent extraction of $NiSO_4$ leachate and from crystallisation of a purified $NiSO_4$ leachate) and used in 5 main uses: metal surface treatment (covering 4 specific applications), batteries manufacturing, production of other nickel salts / nickel metal powder and manufacturing of micronutrient additives for biogas production.

For the purpose of the RMOA, a level of risk has been estimated. Based on the considered appropriate DNEL by MSCA-FR (0.01 mg NiO/m^3) which differs from the registrants' DNEL (0.05 mg NiO/m^3), the risk might be not controlled for all the 11 GES. A risk management action is needed and the objective of a risk reduction strategy (RRS) would be to formally set a binding inhalable occupational exposure limit of 0.01 mg NiO/m^3 and to keep exposure below this limit at the workplace.

In conclusion, from the currently identified legislation covering directly or indirectly the risk from the manufacturing and uses of $NiSO_4$, a risk management option considered relevant for further processing is a binding OEL under Directive 2004/37/EC at 0.01 mg Ni SO_4/m^3.

As said previously, Risk management option analyses have been carried out on NiSO4 and NiO as both salts cover substantially the majority of the uses reported for Ni compounds. ***Therefore the conclusion of these two RMOA is also valid for the other Nickel compounds.***

The French authorities consider that a binding OEL under Directive 2004/37/EC at 0.01 mg/m³ for nickel compounds is today the adequate risk management options to address the risk identified.

By legally enforcing BOELVs for nickel compounds around 2017, Directive 2004/37/EC could be seen as a relevant preliminary measure, where the risk can be technically managed by lowering or if possible preventing exposure. Obligations imposed to operators are clear and could in theory be technically achievable.

It is also considered proportionate as :

- uses/processes for which the risk is considered already managed by a relevant exposure control will be maintained,
- Industry will have to implement without delay significant technical adaptations of processes for at least part of exposure scenarios that are currently seen at risk because of high and uncontrolled exposure,
- a more drastic measure will be decided later on if needed, based on results from on-site surveys and national controls.

The implementation of a BOEL will also require registrants to revise and update their registration dossiers under REACH with a relevant chemical safety assessment showing that risks are adequately controlled; responsibility under REACH is therefore still kept on the operators.

4. CURRENTLY NO FOLLOW-UP FORESEEN AT EU LEVEL

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier should be made via the Registry of Intentions.

Follow-up action	Date for intention	Actor
BOEL for all nickel compounds classified as CMR 1A-1B at 0.01 and 0.005 mg/m3 respectively for the inhalable and respirable fractions.	2017	COMMISSION