

ROHS Annex II Dossier for Nickel sulphate and Nickel sulfamate. Restriction proposal for substances in electrical and electronic equipment under RoHS

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	Nickel sulfamate: 237-396-1
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	97-0, 10101-98-1
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Table of Contents

List of 1	Tables	5
Abbrevi	ations	6
CONTE	XT and SCOPE of the DOSSIER / substance assessment	8
1.	IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS	10
1.1.1.	Name, other identifiers, and composition of the substance	10
1.1.2.	Physico-chemical properties	11
1.2.	Classification and labelling status	11
1.2.1.	Classification in Annex VI of CLP Regulation	13
1.2.2.	Self-classification(s)	14
1.3.	Legal status and use restrictions	15
1.3.1.	Regulation of the substance under REACH	15
1.3.2.	Other legislative measures	16
1.3.3.	Non-governmental initiatives	17
2.	USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT	18
2.1.	Function of the substance	19
2.2.	Types of applications / types of materials	19
2.3.	Quantities of the substance used	20
2.4.	Potential for impacts of the substance on the environment and on health during the use of EEE	20
3.	HUMAN HEALTH HAZARD PROFILE	21
3.1.	Existing Guidance values (DNELs, OELs)	22
4.	ENVIRONMENTAL HAZARD PROFILE	24
4.1.	Endpoints of concern	24
4.2.	Potential for secondary poisoning and bioaccumulation	24
4.3.	Guidance values (PNECs)	25
5.	WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT	26
6.	EXPOSURE ESTIMATION DURING WEEE TREATMENT	27
7.	IMPACT AND RISK EVALUATION	28
8.	ALTERNATIVES	29

8.1.	Availability of substitutes / alternative technologies	29
8.2.	Hazardous properties of substitutes	31
8.3.	Data basis for alternatives and uncertainties	31
9.	DESCRIPTION OF SOCIO-ECONOMIC IMPACTS	32
9.1.	Approach and assumptions	32
9.2.	Impact on chemicals industry	32
9.3.	Impact on EEE producers	32
9.4.	Impact on EEE users	33
9.5.	Impact on waste management	33
9.6.	Impact on administration	33
9.7.	Total socio-economic impact	33
10.	RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS	35
11.	List of References	36
11.1.	Databases	36
11.2.	Contributions, documents and reports	36
Appendix	I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018	38
Appendix	II: Contributions to stakeholder consultation hold from 26 September 2019 to 07 November 2019	39

List of Tables

Table 1-1:	Substance identity and composition of nickel sulphate and nickel sulfamate	10
Table 1-4:	Overview of physico-chemical properties of nickel sulphate and nickel sulfamate	11
Table 1-6:	Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Regulation (EC) No 1272/2008	13
Table 3-1:	OEL for the respirable fraction of both nickel metal and nickel compounds	22
Table 3-1:	Guidance DNEL values for nickel sulphate and nickel sulfamate according to the registration dossiers	23
Table 4-1:	PNECs values for nickel	25

Abbreviations

ABS	Acrylonitrile Butadiene Styrene
ACSIEL	Alliance Elektronique
BOELV	Binding Occupational Exposure Limit Value
bw	body weight
CAS	Chemical Abstracts Service
ChemSec	International Chemical secretariat
CLP	Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging
CMR	Carcinogenic, Mutagenic, or toxic for Reproduction
DEPA	Danish Environmental Protection Agency
DNEL	Derived No-Effect Level
dw	Dry weight
EC	European Commission
ECHA	European Chemicals Agency
EEE	Electrical and Electronic Equipment
EQS	Environmental Quality Standards
EU RAR	European Risk Assessment Report
IED	Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on Industrial Emissions (integrated pollution prevention and control)
IUPAC	International Union of Pure and Applied Chemistry
MCCP	Medium-Chain Chlorinated Paraffins
OEL	Occupational Exposure Limit
OEM	Original Equipment Manufacturer
Op. cit .	Opus citatum, the work cited
PACT	Public Activities Coordination Tool
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-effect Concentration
PTFE	Polytetrafluoroethylene
RAC	Risk Assessment Committee

REACH	Regulation (EU) No 1907/2006 on the Registration, Evaluation, Authorisation and restriction of Chemical substances
RMOA	Regulatory Management Option Analysis
RoHS	Directive 2011/65/EU (RoHS 2) on the restriction of the use of certain hazardous substances in electrical and electronic equipment
SIN	Substitute It Now
SVHC	Substances of Very High Concern
STOT RE	Specific target organ toxicity (repeated exposure)
SME	Small and Medium-sized Enterprises
TWA	Time Weighted Averages
WEEE	Regulation (EU) No 2012/19 on Waste of Electrical and Electronic Equipment
WFD	Water Framework Directive
vPvB	Very Persistent and very Bioaccumulative

CONTEXT and SCOPE of the DOSSIER / substance assessment

The substance assessment of nickel sulphate and nickel sulfamate is being performed as part of the "Study on the review of the list of restricted substances and to assess a new exemption request under RoHS 2 – Pack 15". With contract No. 07.0201/2017/772070/ENV.B.3 implementing Framework Contract No. ENV.A.2/FRA/2015/0008, a consortium led by Oeko-Institut for Applied Ecology, has been assigned by DG Environment of the European Commission to provide technical and scientific support for the review of the list of restricted substances and to assess a new exemption request under RoHS 2. This study includes an assessment of seven substances / group of substances¹ with a view to the review and amendment of the RoHS Annex II list of restricted substances. The seven substances have been pre-determined by the Commission for this task. The detailed assessment is being carried out for each of the seven substances in line with a uniform methodology which was developed as a part of this study².

According to the terms of references of the study, the scope of the assessment concerns nickel sulphate and nickel sulfamate. For this purpose, the evaluation has compiled relevant background information for understanding whether the two nickel compounds are used in the manufacture of EEE and whether they remain present in final EEE articles placed on the EU market. Such information is the basis for assessing possible impacts on the environment and on health associated with the presence of these compounds in EEE and expected to incur during the use phase and/or during the waste phase (end-of-life). Assessment of possible impacts to arise from the presence of other nickel compounds in EEE to be placed on the EU market is beyond the scope of this assessment.

The specific terms of reference of the study points out that the "grouping of substances (e.g. for cobalt or nickel compounds or for MCCPs) shall be possible by following the approach determined in the updated methodology, once agreed." Though a grouping of "nickel and its compounds" appears in the regulatory context, e.g. in the context of the scientific evaluation of occupational exposure limits for nickel and its compounds, a grouping was not proposed for this assessment for the following reasons:

- The nickel salts under considerations here are solely used in metal surface treatment processes, including electrolytic plating and electroless technologies. It can be understood that these substances are transformed through the surface treatment processes and do not remain in their original form in the final produce, i.e. in relevant EEE and its parts. In the final coating, the nickel salts are understood to be converted into nickel metal or nickel²⁺ ions, depending on the process.
- To this extent, the assessment of "nickel and its compounds" would require an extension of the scope of this study to additional applications of nickel and its compounds, e.g. nickel as a derivative from surface treatment processes. This would go beyond the original scope of the study.

¹ For the sake of better readability hereafter the term substance will be used for single substances as well as for group of substances.

² This methodology includes a dossier template for substance assessment which had been prepared by the Austrian Umweltbundesamt GmbH in the course of a previous study. The methodology for substance assessment has been revised based on various proposals from and discussions with stakeholders. Among others, revisions have been made to clarify when the Article 6(1) criteria are considered to be fulfilled and how the precautionary principle is to be applied. The methodology has also been updated in relation to coherence to REACH and other legislation and publicly available sources of relevance for the collection of information on substances have been updated and added. The methodology is available at https://rohs.exemptions.oeko.info/index.php?id=341

In the course of the substance assessment, the 1st stakeholder consultation was held from 20 April 2018 to 15 June 2018 to collect information and data for the seven substances under assessment. Information on this consultation can be found at the Oeko-Institut's project webpage at: http://rohs.exemptions.oeko.info/index.php?id=289.

For nickel sulphate and nickel sulfamate, a total of eleven contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix I. The contributions can be viewed at

http://rohs.exemptions.oeko.info/index.php?id=295.

Based on stakeholder input and publicly available information and stakeholder input, a second version of the dossier has been prepared, which was subject to a 2nd stakeholder consultation that was held from 26 September 2019 to 07 November 2019. For nickel sulphate and nickel sulfamate, a total of seven contributions were submitted by different stakeholders. An overview of the contributions submitted during this consultation is provided in Appendix II. The contributions can be viewed at: https://rohs.exemptions.oeko.info/index.php?id=337.

Mostly, stakeholders expressed agreement with the recommendation. The Nickel Institute (2019)³ provided some valuable corrections and constructive suggestions for editions that were mostly taken up in this version of the dossier. For the controversial point on a further assessment of "nickel and its compounds", the indications for the recommendation are compiled in section 5.

Based on the input from the 2nd stakeholder consultation, the dossier has been revised and completed to the version 3 at hand which represents the final version.

After the revision of the dossiers and their completion, a final stakeholder meeting shall be held to allow stakeholders to comment on the dossiers and particularly on conclusions and recommendations.

³ Nickel Institute (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user upload/RoHS Pack 15/4th Consultation/Contributions/contribution NI_RoHS15_Comments_dossier_Ni_20191107.pdf, last viewed 30.01.2020

Table 1-1:

1. IDENTIFICATION, CLASSIFICATION AND LABELLING, LEGAL STATUS AND USE RESTRICTIONS

1.1 Identification

1.1.1. Name, other identifiers, and composition of the substance

The following information on the substance identity of nickel sulphate⁴ and nickel sulfamate⁵ are extracted from the ECHA database on substances.

Substance identity and composition of nickel sulphate and nickel

sulfamate				
Chemical name	Nickel sulphate	Nickel sulfamate (Nickel bis(sulphamidate))		
EC number	232-104-9	237-396-1		
CAS number	7786-81-4, 10101-97-0, 10101-98-1	13770-89-3		
IUPAC name	nickel(2+) ion sulfate	nickel(2+) ion disulfamate		
Index number in Annex VI of the CLP Regulation	028-009-00-5	028-018-00-4		
Molecular formula	NiO ₄ S	H ₄ N ₂ NiO ₆ S ₂		
Molecular weight (range)	154.756 g/mol	250.853 g/mol		
Synonyms	Nickel (2+) Sulfate Nickel (ii) sulphate Nickel sulfate Nickel Sulphate Nickel Sulphate (slime) Nickel Sulphate hexahydrate nickel(2+) ion sulfate Nickel(2+) sulfate Nickel(2+);sulfate Nickel(11) sulfate Nickel(11) sulfate heptahydrate nickel(11) sulphate Sulfuric acid, nickel(2+) salt (1:1)	amidosulphuric acid Nickel (2+) Disulfamate nickel bis(sulfamidate) Nickel bis(sulphamidate) Nickel sulfamate Nickel sulphamate nickel(2+) disulfamate nickel(2+) ion disulfamate		
Structural formula	$N^{2*} \qquad O = S = O \\ \downarrow O O$	$N^{2^{*}}$ $O = \begin{cases} 0 & 0 & 0 \\ 0 & 0 & 0 & 0 \\ 0 & 0 & 0 &$		

⁴ ECHA Brief Profile: Entry for Nickel sulphate, https://echa.europa.eu/de/brief-profile/-/briefprofile/100.029.186, last

 ⁵ ECHA Brief Profile: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/brief-profile/-

⁵ ECHA Brief Profile: Entry for Nickel bis(sulphamidate), /briefprofile/100.033.982, last viewed 11.06.2018

1.1.2. Physico-chemical properties

Physico-chemical properties of nickel sulphate and nickel sulfamate are summarised in Table 1-2 below and were extracted from the ECHA Registered Substance Database.⁶

sulfamate			
Property	Nickel sulphate	Nickel sulfamate Solid (crystalline material)	
Physical state at 20°C and 101.3 kPa	Solid (crystalline material)		
Melting/freezing point	53 °C for hexahydrate form; loss of water of crystallisation on heating; 840 °C for anhydrous form, decomposition temperature	decomposes at 141.63 °C	
Boiling point	Not relevant	Not relevant	
Vapour pressure	Not relevant	Not relevant	
Water solubility	> 625 g/l at 0 °C and pH 6 - 8	in the range of 49.9 to 60.0% w/w of solution at $20.0 \pm 0.5^{\circ}$ C,	
Partition coefficient n-octanol/ water (log Kow)	Not relevant	Not relevant	
Dissociation constant	Not relevant	Not relevant	
Relative density	2.07 g/cm ³ at 20 °C for hexahydrate form	2.25 at 20 °C	
	3.68 g/cm ³ at 20 °C for anhydrous form		

Table 1-2:Overview of physico-chemical properties of nickel sulphate and nickel
sulfamate

Source: ECHA Registered Substance Database: Entry for Nickel sulphate and Nickel bis(sulphamidate)

1.2. Classification and labelling status

The Regulation No 1272/2008 on Classification, Labelling and Packaging (CLP)⁷ ensures that the hazards presented by chemicals are clearly communicated to workers and consumers in the EU through classification and labelling of chemicals. Annex VI of this Regulation lists substances where a harmonised classification exists based on e.g. human health concerns.

Annex VI of the CLP Regulation is continuously adapted by Member State Competent Authorities and ECHA when new information becomes available, when existing data are re-evaluated, or due to new scientific or technical developments or changes in the classification criteria.⁸

⁶ ECHA Registered Substance Database: Entry for Nickel sulphate, https://echa.europa.eu/registration-dossier//registered-dossier/15304, last viewed 11.06.2018 ECHA Registered Substance Database: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14782/4/1, last viewed 11.06.2018

⁷ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (REACH).

⁸ For further information, see https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling, last viewed 19.04.2018

Based on the conclusions of the ECHA RAC and the EU RAR the human and environmental hazards are further explained in section 3 and 4.

To summarize the table shown below, it is understood based on the harmonised classification that both nickel sulphate and nickel sulfamate are considered as CMR substances. This means that exposure to these substances above a certain threshold could lead to impacts on human health and/or the health of other species, e.g., cancer, genetic defects and/or impacts on the reproductive system and organs. Given other hazards that have been classified, relevant pathways for such impacts include exposure through the respiratory system and inhalation, through contact with skin and through oral exposure. Both compounds have further been classified for aquatic toxicity, meaning that exposure of aquatic organisms is also of potential concern.

1.2.1. Classification in Annex VI of CLP Regulation

Nickel sulphate and nickel sulfamate, are classified under the CLP regulation as follows: 9

Table 1-3:Classification according to part 3 of Annex VI, Table 3.1 (list of harmonised classification and labelling of hazardous
substances) of Regulation (EC) No 1272/2008

Index No.	International	EC No.	CAS No.	Classification		Labelling			Spec. Conc. Limits, M-	
Chemi	Chemical ID			Hazard Class and Category Code(s)	Hazard statement code(s)	Pictogram, Signal Word Code(s)	Hazard statement code(s)	Suppl. Hazard statement code(s)	factors	
028-009- 00-5	nickel sulfate	232- 104-9	7786-81- 4	Carc. 1A Muta. 2 Repr. 1B Acute Tox. 4 * Acute Tox. 4 * STOT RE 1 Skin Irrit. 2 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D *** H332 H302 H372 ** H315 H334 H317 H400 H410	GHS08 GHS07 GHS09 Dgr	H302 H332 H315 H334 H317 H341 H350i H360D *** H372 ** H410	-	STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Irrit. 2; H315: C ≥ 20 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	
028-018- 00-4	nickel bis(sulfamidat e); nickel sulfamate	237- 396-1	13770- 89-3	Carc. 1A Muta. 2 Repr. 1B STOT RE 1 Resp. Sens. 1 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H350i H341 H360D *** H372 ** H334 H317 H400 H410	GHS08 GHS09 Dgr	H350i H341 H360D *** H372 ** H334 H317 H410	-	STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 % Skin Sens. 1; H317: C ≥ 0,01 % M=1	

Source: Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

⁹ Annex VI Regulation No 1272/2008; https://echa.europa.eu/de/information-on-chemicals/annex-vi-to-clp, last viewed 19.04.2018

1.2.2. Self-classification(s)

In line with the CLP Regulation Article 4 (1), manufacturers, importers or downstream users have to (self-)classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment. If a harmonised classification is available, it should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

However, the majority of suppliers decide independently on the classification of a substance or mixture, which is then referred to as self-classification. Therefore, self-classification might indicate an e.g. additional hazard, which is so far not reflected by the harmonised classification. The following assessment of the self-classification therefore only refers to cases where additional hazards were notified in the self-classification.

According to the ECHA's "classification and labelling" inventory (C&L) that contains classification and labelling information on notified and registered substances received from manufacturers and importers, the total number of notifiers is as follows:

- For nickel sulphate: 1,496 C&L notifications (as of June 2018);¹⁰
- for nickel sulfamate: 105 C&L notifications submitted to ECHA (as of June 2018).¹¹

The higher number of notifications for nickel sulphate might reflect the higher usage amount also indicated by a higher tonnage band for nickel sulphate registered under REACH.

As for **nickel sulphate**, most notifiers follow the harmonised classification (1,407 of 1,496 notifications: 94%). Among them, 1,407 notifiers chose to state the carcinogenicity classification 1B instead of 1A but used the same hazard statement (H350i). Category 1A indicates that the substance is known to have carcinogenic potential for humans and this classification is largely based on human evidence. Category 1B specifies that the substance is presumed to have carcinogenic potential for humans and this classification is largely based on animal evidence. 84 notifiers additionally classify nickel sulphate for the human health hazard Eye irritation 2 (H319 – causes serious eye irritation). A minority of notifiers (5 notifiers) lacks certain classifications such as CMR properties (3 notifiers).

As for **nickel sulfamate**, most notifiers follow the harmonised classification (73 out of 105 notifications: 69%). 30 notifiers additionally classify for Acute Toxicity 4: 23 for H 302-Harmful if swallowed and 7 for H 302 and H332-Harmful if inhaled. A small minority (2 notifiers) lacks the Class and Category codes, only providing Hazard Statement Codes.

To summarise the various self-classifications, most notifiers follow the harmonised classification. In some cases, the level of hazard may differ, or certain hazard types have been omitted, and given that the harmonised classification is assumed to have a higher standard of scrutiny, the differences in the self-classification compared to the harmonised classification are not further considered. Furthermore, the ECHA website indicates that the self-classifications are affected by the presence of impurities or additives in the substance.

¹⁰ ECHA CL Inventory: Entry for Nickel sulphate, https://echa.europa.eu/de/information-on-chemicals/cl-inventorydatabase/-/discli/details/9597, last viewed 11.06.2018

ECHA CL Inventory: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/information-on-chemicals/clinventory-database/-/discli/details/16141, last viewed 11.06.2018

1.3. Legal status and use restrictions

In the following, legal restrictions for nickel sulphate and nickel sulfamate are described. It has to be noted that existing legal restrictions often address nickel and nickel compounds as a group of substances.

1.3.1. Regulation of the substance under REACH

Nickel and its compounds are subject to the restriction listed under entry 27 of REACH Annex XVII, which prohibits the use in post assemblies and articles coming into direct and prolonged contact with the skin.¹²

Entry 28 and entry 30 of REACH Annex XVII each applies to a list of specified substances. Both entries list nickel sulphate and nickel sulfamate. The listing of these substances prohibits the supply to the general public: as a substance, as a mixtures or as a constituent of other mixtures.

Nickel sulphate was subject to further scrutiny under REACH by the means of the so-called risk management option analysis (RMOA¹³). France, as the authority carrying out the RMOA, stated that 6 nickel compounds have been selected for further assessment. These are nickel sulphate, hydroxycarbonate, dichloride, dinitrate, bis(hydrogen)phosphate and monoxide. The RMOA has been carried out for nickel sulphate and nickel oxide because these two nickel salts cover the majority of the uses reported for nickel compounds. The French competent authority concludes that the conclusions of the RMOA are also valid for the other nickel compounds. Based on the RMOA, a binding occupational exposure limit value (BOELV) was proposed by the French authorities at 0.01 mg/m³ for nickel compounds.¹⁴

In the further course of this process, the ECHA Committee for Risk Assessment (ECHA RAC 2018)¹⁵ recommended an occupational exposure limit (OEL) of 0.005 mg/m³ for respirable dust and 0.03 mg/m³ for inhalable dust (for further information see section 3.1). ECHA RAC (2018) defines the substance group as nickel metal and the inorganic nickel compounds.

In the further process, the European Commission is expected to present a legislative proposal setting binding OEL values for nickel compounds and other substances in 2019, under the upcoming 4th revision of Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. The Nickel Institute (2019) noted that the OEL for inorganic nickel compounds (classified as CMR 1A-1B) under the next revision of Directive 2004/37/EC is expected in 2020.

A number of Member States have already set OELs for nickel and nickel compounds.¹⁶ The proposal of ECHA RAC (2018) serves as a preparation for the amendment of the Directive

¹² E.g. earrings, necklaces, bracelets and chains, anklets, finger rings, wrist-watch cases, watch straps and tighteners, rivet buttons, rivets, zippers and metal marks, when these are used in garments restricting the rate of nickel release from those parts of such articles coming into direct and prolonged contact with the skin stating that a release of 0.5 µg/cm²/week for a period of at least two years of normal use of the article shall not be exceeded.

¹³ In the meantime, the wording has been changed into Regulatory Management Option Analysis.

¹⁴ France (2016): Risk management option analysis, Conclusion document for nickel sulphate, August 2016; https://www.echa.europa.eu/documents/10162/770bbde2-29f0-b09c-2682-4c1614f7e12c, last viewed 19.04.2018

¹⁵ ECHA RAC (2018): Committee for Risk Assessment RAC, Opinion on scientific evaluation of occupational exposure limits for Nickel and its compounds, ECHA/RAC/A77-O-0000001412-86-189/F, Adopted 9 March 2018; https://echa.europa.eu/documents/10162/13641/nickel_opinion_en.pdf; last viewed 18.06.2018

¹⁶ See an overview in: https://echa.europa.eu/documents/10162/026d40c4-7b36-4b8d-910c-bd036af685bf, last viewed 19.04.2018

2004/37/EC which constitutes a binding occupational exposure limit value which has to be then transposed by the Member States.

The RMOA documentation includes an analysis on the environmental impact, performed by Denmark. According to the RMOA, additional data for sediment compartment were collected in 2012, on the basis of which chronic effects and hazard for freshwater organisms were identified. Based on this data, the RMOA concluded that present risk management measures are not considered appropriate. The need for community-wide measures is expressed.¹⁷ So far, no further steps were taken according to the publicly available information at the ECHA webpage.

1.3.2. Other legislative measures

Other legislative measures also address nickel and its compounds as a substance group. As this substance group also includes nickel sulphate and nickel sulfamate, these legal restrictions are compiled in the following:

- The IED Directive 2010/75/EU on industrial emissions (integrated pollution prevention and control) sets emission limit values for nickel and its compounds:¹⁸
 - Air emission limit values for waste incineration plants with an average emission limit values of 0,5 mg/Nm³ over a sampling period of a minimum of 30 minutes and a maximum of 8 hours for nickel and its compounds, expressed as nickel (Ni), and
 - Emission limit values for discharges of waste water from the cleaning of waste gases for unfiltered samples at 0,5 mg/l.
 - According to the Nickel Institute (2019), there is an upcoming revision of the "Surface treatment of metals and plastics BREF" under the Industrial Emissions Directive.
- A daughter Directive to the WFD, Directive 2013/39/EU¹⁹, sets environmental quality standards (EQS) for nickel in freshwater at 4 μg/l (bioavailable) and the marine water 8.6 μg/l.
- Directive 98/83/EC on the quality of water for human consumption sets a maximum level of 20 µg/l for nickel in water intended for human consumption.²⁰
- Any nickel-containing compound (including the metals in metallic form, as far as these are classified as dangerous substances) can lead to the classification of hazardous waste according to the Commission Decision 2000/532/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 91/689/EEC on hazardous waste.
- Limit values are specified for nickel by Council Decision establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of and Annex II to Directive

¹⁷ France and Anses (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpement-durable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf, last viewed 22.02.2019

¹⁸ Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control); https://eur-lex.europa.eu/legalcontent/EN/TXT/?uri=celex%3A32010L0075, last viewed 19.04.2018

¹⁹ Directive 2013/39/EU of the European Parliament and of the Council of 12 August 2013 amending Directives 2000/60/EC and 2008/105/EC as regards priority substances in the field of water policy; https://eurlex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32013L0039&from=EN, last viewed 18.06.2018

²⁰ The value applies to a sample of water intended for human consumption obtained by an adequate sampling method at the tap and taken so as to be representative of a weekly average value ingested by consumers. Where appropriate, the sampling and monitoring methods must be applied in a harmonised fashion to be drawn up in accordance with Article 7(4) of that Directive. Member States must take account of the occurrence of peak levels that may cause adverse effects on human health.

1999/31/EC (2003/33/EC).²¹ The leaching limit value for waste that is acceptable at landfills for inert waste is calculated at liquid to solid ratios (L/S) of 2 l/kg and 10 l/kg for total release. For Nickel, leaching limit value is 0,2 mg/kg and 0,4 mg/kg dry substance in of 2 l/kg and 10 l/kg samples respectively. In percolation test, the limit value C₀ is 0,12 mg/l.

 Maximum limit values for airborne emission of Nickel and its compounds are established in the Industrial Emissions Directive (Directive 2010/75/EU).²² The average emission limit value is 0,5 mg/Nm³ over a sampling period of a minimum of 30 minutes and a maximum of 8 hours (Annex VI, part 3). The same legislation stipulates an emission limit value for discharges of Nickel in waste water from the cleaning of waste gases. For Nickel and its compounds, the limit values for Nickel in unfiltered samples is 0,5 mg/I (Annex VI, part 5).

1.3.3. Non-governmental initiatives

The International Chemical Secretariat (ChemSec) has developed and regularly updates the socalled SIN List, which identifies potential substances of concern. The list is a measure for putting pressure on legislators to assess and where relevant address substances identified therein in the future in respect to relevant chemical legislation.²³ ChemSec applies a number of categories for adding substances to the SIN List, including substances that can cause cancer, alter DNA or damage reproductive systems (CMR properties); substances that do not easily break down and accumulate in the food chain (PBT/vPvB substances); and substances of equivalent concern that give rise to an equivalent level of concern in terms of potential damage to health and environment (such as substances with endocrine disrupting properties).

Nickel sulphate²⁴ and nickel sulfamate²⁵ are both listed on the SIN List for the reason that they are *"classified CMR according to Annex VI of Regulation 1272/2008"*.

²¹ Leaching limit values for waste acceptable at landfills for inert waste and limit values for non-hazardous waste.

²² https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2010:334:0017:0119:en:PDF; last viewed 12.09.2019

²³ http://chemsec.org/business-tool/sin-list/about-the-sin-list/, last viewed 24.07.2018

²⁴ http://sinlist.chemsec.org/search/search?query=Nickel+sulphate, last viewed 11.06.2018

²⁵ http://sinlist.chemsec.org/search/search?query=nickel+sulfamate, last viewed 11.06.2018

2. USE IN ELECTRICAL AND ELECTRONIC EQUIPMENT

Description of processes

The EEE specific uses of nickel sulphate and nickel sulfamate are in metal surface treatment in electrolytic plating as well as electroless technologies. Within these plating processes, the use of both nickel salts is explained to be an intermediate use resulting in inclusion into or onto a matrix. The function and applications of the nickel layer is further explained below.

Nickel sulphate and nickel sulfamate are converted into nickel metal during the electrolytic processes in surface treatment. The Nickel Institute²⁶ describes the plating process as follows:

"Nickel sulfate and nickel sulfamate are soluble nickel salts. During the electrolytic process in metal surface treatment, these nickel salts are dissolved in the electrolytic bath into nickel²⁺ions and a salt complex (e.g. $SO_4^{2^-}$). The nickel ions migrate to the cathode where the nickel ions are deposited as nickel metal on the surface of relevant parts that have to be plated. Electroless nickel plating is an auto-catalytic reaction. Similar to electrolytic plating, nickel salts are dissolved and form nickel²⁺ions and a salt complex (e.g. $SO_4^{2^-}$). Unlike the electrolytic process, it is not necessary to pass an electric current through the solution to form a deposit of nickel on the substrate. Electroless nickel plating provides an even deposit regardless of the shape and form of the workpiece. It is used as alternative process especially for non-conductive surfaces."

As for the question on possible residues in the layer, the Carl Zeiss Jena GmbH in its stakeholder contribution²⁷ provided own measurements performed with energy dispersive X-ray spectroscopy, which is used to test for impurities. The data includes measurements of an electroless plated nickel layer, showing no residual nickel sulphate in the deposit, and of an electrolytically plated nickel layer put of nickel sulfamate, also showing no nickel sulfamate in the deposit. The measurements show that no residues remain after the treatment processes.

During the 2^{nd} stakeholder consultation, Lynred (2019),²⁸ a manufacturer of infrared imaging detectors, stated that their suppliers communicate on the concentration of nickel sulfamate on the items that *"probably >0.1% on electroformed nickel screens and < 0,1% on the coatings of the concerned components of cold fingers"*. Lynred (2019) concluded that less than 100 g of nickel sulfamate might be found in final products of a year. Thus, there are uncertainties as to residues in the final product. However, this estimation will not further be taken into account.

²⁶ Nickel Institute (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution _Nickel_Institute_Ni_20180608ROHS_Stakeholder_Consultation_FINAL_Comments.pdf, last viewed 18.06.2018

²⁷ Carl Zeiss Jena GmbH (2018): Contribution submitted on 07.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/RoHS-Pack15_Statement-CZJ_Ni-Compounds_final_signed_01062018.pdf, last viewed 18.06.2018

²⁸ LYNRED (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contributions/contribution _LYNRED_RoHS15_comments_Ni_20191107.pdf, last viewed 30.01.2020

In the following, the term **process chemical** will be used for the applications of nickel sulphate and nickel sulfamate, which means that they are applied in the production process and are chemically converted. The starting substance used in the process is not present in the final product.

The term process chemical rather than "intermediate" is proposed as under REACH, reduced registration requirements apply to intermediates, depending on the conditions of manufacture and use. The REACH Regulation defines an intermediate as a "*substance that is manufactured for and consumed in or used for chemical processing to be transformed into another substance*" (Article 3 (15)). However, ECHA states in its "Guidance on Intermediates" that surface treating agents are not regarded as intermediates.²⁹ As nickel sulphate and nickel sulfamate used as surface treating agents are exempted from intermediates according to ECHA, the full registration requirements under REACH are applicable.

2.1. Function of the substance

The functions of the metallic nickel layer in electronic parts, provided by nickel plating are summarised from the information given in the contribution by stakeholders (e.g. Nickel Institute, Carl Zeiss Jena GmbH, Alliance Elektronique – ACSIEL³⁰, Lynred). According to the contributions, the metallic nickel layer:

- acts as a diffusion barrier. France and Anses (2014) explain that the diffusion barrier prevents gold, tin and copper from diffusing into each other, leading to failure of chips, connections and circuit boards;
- provides corrosion resistance;
- provides wear resistance due to good hardness properties;
- provides strong adhesive properties to the substrate surface and to subsequent coating layers as it may be used as a finish layer or as underlayer;
- builds up homogenously and can be applied in a wide range of layer thicknesses; and
- has electrical conductivity.

The plating of plastic is also applied for decorative applications "where bright or satin coatings are required".³¹

2.2. Types of applications / types of materials

As mentioned before, nickel sulphate as well as nickel sulfamate are applied as process chemicals and do not remain in final components and products. The resulting metallic nickel plating is widely used in EEE products, e.g. for electrical connectors and contacts, microprocessors and other chip assemblies, integrated circuits, and printed circuit boards.

²⁹ ECHA (2010): Guidance on Intermediates, version 2, December 2010; https://echa.europa.eu/documents/10162/13632/intermediates_en.pdf/0386199a-bdc5-4bbc-9548-0d27ac222641, last viewed 19.04.2018

³⁰ Alliance Electronique - ACSIEL (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution _ACSIEL_Nickel_CMG_Ni_Salts_20180615.pdf, last viewed 18.06.2018

³¹ https://www.nickelinstitute.org/about-nickel/plating/, last viewed 19.02.2020

According to the Nickel Institute, the largest application of electroless nickel plating is for hard disc drives for computers.

The use of nickel plating on plastics is applied for ABS plastic mouldings of electronic products (i.e. in plastic housings). The plastic plating is according to the website of the Nickel Institute a recent development. Applications in terms of plastic parts cannot be specified based on the information assessed for the dossier here at hand. As the plating of plastic parts is also performed for decorative reasons, it is understood that this is also applied to "larger"³² plastic parts.

2.3. Quantities of the substance used

According to the Nickel Institute (2018), "for Europe, the total amount of nickel salts used in plating during electrical and electronic equipment manufacturing processes are estimated to be less than 5,000 t. 'Nickel salts' include nickel sulfate and nickel sulfamate, as well as other nickel compounds used for plating. No further information is available with regard to the specific use of nickel sulfate and nickel sulfamate."

Further nickel compounds for surface treatment are nickel chloride, nickel hydroxy carbonate, nickel nitrate, nickel diacetate and nickel hydroxide.

According to France and Anses (2014), there are three water-soluble salts used predominantly in electrolytic (and also electroless) nickel plating: nickel sulphate, nickel chloride and nickel sulfamate. Nickel sulphate is stated to be the most used salt; it is the least expensive nickel source and the related sulphate anion has little effect on the deposit properties contrary to anions from other salts. For surface treatment, France and Anses (2014) indicate an amount for nickel sulphate of 12,000 t/y. However, this includes also electroplating used in other sectors, especially aerospace and automotive. It was not feasible to single out the nickel consumption of the EEE sector since available statistical data are not sector specific in this regard.

2.4. Potential for impacts of the substance on the environment and on health during the use of EEE

Seeing that both nickel sulphate and nickel sulfamate are understood not to be present in EEE, impacts would not be expected in relation to these substances in the use phase of such EEE. It is, however, noted that the application of these substances in plating processes used in the manufacture of EEE components results in the presence of nickel or other nickel compounds in the relevant EEE. It is possible that the presence of these compounds may result in impacts on health and/or the environment during the use phase of such equipment. However, the investigation of the potential for such impacts is beyond the scope of this assessment.³³

³² No definition of large can be given here. In the context of marking of plastic parts to facilitate recycling processes, different ecolabel schemes such es TCO or IEEE relate their requirements for marking to plastic parts with a weight greater than 25 grams

³³ There were additions to this paragraph proposed by Nickel Institute (2019) that concerned the OEL and the BREF which has been added in section 1.3. on legal status and use restrictions. The proposed additions are considered not to be linked to potential impact in the use phase but concern the manufacturing phase.

3. HUMAN HEALTH HAZARD PROFILE

The toxicological summary in the registration dossier provided in the ECHA database³⁴ show the same results for nickel sulphate and nickel sulfamate (the guidance values are given in terms of mg nickel and not as mg substance). It is therefore assumed that the nickel ion is the entity being mostly relevant for the human health hazards. In the regulatory context, it is commonly referred to a group "nickel and its compounds".³⁵

The Nickel Institute in its contribution 2019 pointed out that it should be noted here that nickel metal has a different and lower hazard classification than inorganic nickel compounds.

Nickel metal as nickel (CAS 7440-02-0) has a lower carcinogenic classification of category 2 (Carc. 2 – H351 Suspected of causing cancer) compared to the inorganic compounds such as nickel sulphate and nickel sulfamate being harmonised classified for Carc. 1A (H350 May cause cancer); however, nickel is also classified for specific organ toxicity STOT RE 1 (H372 Causes damage to organs through prolonged or repeated exposure) and skin sensitation (Skin Sens. 1: H317 May cause an allergic skin reaction). Critical endpoint

The opinion of ECHA RAC (ECHA RAC 2018) is the most recent evaluation of the critical endpoints of nickel and its compounds. The following conclusions are relevant for the human health hazard of nickel sulphate and nickel sulfamate:

- The main hazard of nickel compounds is their carcinogenicity in the respiratory tract. Exposures
 to mixed nickel compounds have resulted in increased lung cancer risk. In some studies, cancer
 risk has correlated best with the exposure to soluble nickel. In addition, an increased risk for
 nasal cancer has been demonstrated.
- Differences in lung clearance and local cellular uptake between different nickel species are assumed to explain the variability in their carcinogenic potency.
- In humans, exposure to nickel is often via a mixture of soluble and poorly soluble nickel compounds.
- Nickel compounds are not directly mutagenic but have been shown to induce genotoxic effects via different indirect mechanisms.
- Chronic inflammation in the respiratory tract is also likely to play a significant role in nickelinduced carcinogenicity together with indirect genotoxicity.
- The available information on the mechanisms of genotoxicity and cancer support a mode-ofaction based threshold for carcinogenic effects.
- The proposed OEL therefore relies on a mode of action-based threshold for the carcinogenicity
 of nickel compounds. In addition to the mechanistic data reviewed by RAC, data on the lack of
 genotoxicity in animals at inhalation doses below the levels causing inflammation and
 cytotoxicity support this conclusion.
- At exposures below the proposed limit value, no significant residual cancer risk is expected for workers.

³⁴ Op. cit. ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

³⁵ https://echa.europa.eu/de/substance-information/-/substanceinfo/100.239.198

 Nickel compounds have also been shown to exert reproductive effects (effects on both fertility and developmental) in animal studies. The OELs proposed are also considered to be protective for reproductive effects.

Besides the relevant pathway by exposure through the respiratory system and inhalation, contact with skin and through oral exposure is also of relevance reflected by the harmonised classification and legislative measures as well as derived no effect levels as outlined in the next section.

3.1. Existing Guidance values (DNELs, OELs)

There are legal guidance values for the general population for dermal and oral exposure, which cover the group of nickel and its compounds:

- According to entry 27 of REACH Annex XVII: The direct exposure of consumers to products containing nickel and nickel compounds restricts the rate of nickel release ions in jewellery and other objects with skin contact 0.5 µg/cm²/week for a period of at least two years of normal use of the article coming into direct and prolonged contact with the skin.
- The Drinking Water Directive (98/83/EC sets parametric value for the quality of water intended for human consumption for chemicals, among them for nickel at 20 µg/l.

As for the risk of workers, it has already been mentioned that the ECHA RAC (ECHA RAC 2018)³⁶ concluded in March 2018 on occupational exposure limits (OELs) for nickel and its compounds, which includes metal nickel and nickel powder as well as a wide range of inorganic nickel compounds, including nickel sulphate and nickel sulfamate. This is due to exposure to nickel in occupational settings almost always being a mixture of different nickel species (mixture of soluble and poorly soluble nickel compounds) and therefore it was considered as not practicable to give different values for different nickel compounds.

The OEL proposed by ECHA RAC (2018) is shown in the following table. At exposures below the proposed limit value, it is concluded that workers are protected from nickel-induced carcinogenicity.

Table 3-1: OEL for the respirable fraction of both nickel metal and nickel compounds

	Limit value		
OEL as 8-hour TWA	0.005 mg/m ³ for respirable dust		
	0.03 mg/m ³ for inhalable dust		

Note: Respirable dust is the fraction that can penetrate beyond the terminal bronchioles into the gas-exchange region of the lungs. Inhalable dust is the fraction of a dust cloud that can be breathed into the nose or mouth. Source: ECHA RAC (2018); TWA - Total Weighted Average

The following table presents the guidance values submitted by the industry as part of the REACH registration dossier. These values are not verified by authorities.

³⁶ Op. cit. ECHA RAC (2018)

Table 3-2:	Guidance DNEL values for nickel sulphate and nickel sulfamate according
	to the registration dossiers

Population	Exposure route	Effects	Exposure	DNEL	Most sensitive endpoint
		Systemic	Long term	0.05 mg/m ³	repeated dose toxicity (lung inflammation)
			Acute/short term	104 mg/m³	acute toxicity
Workers	Inhalation		Long term	0.05 mg/m ³	carcinogenicity and repeated toxicity
		Local	Acute/short term	1.6 mg/m ³	repeated dose toxicity (lung inflammation)
	Dermal	Local	Long term	0.44 µg/cm ²	sensitisation (skin)
	Inhalation	Systemic	Long term	60 ng/m³	developmental toxicity / teratogenicity
			Acute/short term	8.8 mg/m³	acute toxicity
General Population	Inhalation	Local	Long term	60 ng/m³	developmental toxicity / teratogenicity
			Acute/short term	0.1 mg/m³	repeated dose toxicity
	Oral	Systemic	Long term	0.011 mg/kg bw/day	developmental toxicity / teratogenicity
	- Oral		Acute/short term	0.37 mg/kg bw/day	acute toxicity

Note: bw=body weight

Source: ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

To conclude on human health, as the two nickel salts are not present in the final EEE, there is not risk arising from these substances. Any potential risk for workers e.g. in shredding processes may result from the presence of nickel or nickel compounds others than the two nickel salts in scope of this assessment.

4. ENVIRONMENTAL HAZARD PROFILE

The 2008 EU RAR on the environment addressed nickel together with other nickel compounds, among them nickel sulphate. The EU RAR (2008) concludes that nickel ion is responsible for the toxic action of nickel in the environment. An environmental assessment of nickel metal, compiled in a DEPA report (DEPA 2015),³⁷ explains that the nickel ion is highly toxic in the environment. The actual toxicity of a nickel compound depends on the solubility of the nickel substance and the bioavailability of nickel ion in the environment.

4.1. Endpoints of concern

Due to the aquatic toxicity of the nickel ion, an environmental quality standard (EQS) for nickel in freshwater is set at 4 μ g Ni/l (bioavailable) and the marine water 8.6 μ g Ni/l, adopted through Directive 2013/39/EU.

The aquatic toxicity is also reflected by the harmonised classification of the CLP Regulation, which classifies nickel sulphate and nickel sulfamate as acute and chronic toxic to the aquatic environment (H400 - Very toxic to aquatic life and H410 - Very toxic to aquatic life with long lasting effects).

According to the background document for the RMOA for nickel sulphate,³⁸ an assessment has been completed in 2012 by DEPA on the chronic effects (and potential risks) on freshwater sediment organisms completing the existing environmental risk assessment for nickel compounds.

DEPA considered no risk management measure to be appropriate under the REACH Regulation, but expressed the need for other community-wide measures, such as:

- the establishment of an environmental quality standard for freshwater sediment under the WFD Directive;
- the need for a revision of the Best Available Techniques (BAT) reference documents (so-called BREF) in relation to nickel plating to protect specifically the freshwater sediment compartment also through the Industrial Emission Directive.

4.2. Potential for secondary poisoning and bioaccumulation

The EU RAR (2008) on nickel and its compounds summarises that nickel does bioaccumulate in aquatic biota but that the bioaccumulation factors are generally low and do not appear to biomagnify. Furthermore, the EU RAR (2008) concludes that the risk for secondary poisoning is considered as being low.

³⁷ Danish Environmental Protection Agency (2015): Survey of nickel metal, Part of the LOUS review, Environmental project No. 1723, 2015; https://www2.mst.dk/Udgiv/publications/2015/06/978-87-93352-36-0.pdf, last viewed 18.06.2018

³⁸ Op. cit. France and Anses (2014)

4.3. Guidance values (PNECs)

The predicted no effect concentration (PNEC) is the concentration below which exposure to a substance is not expected to cause adverse effects on species in the environment.

ECHA's registered substances database provides guidance values on aquatic and terrestrial toxicity for nickel. The following guidance values are based on REACH registration dossiers data available on the ECHA database³⁹. The information provided by the registrants has not been subject to scrutiny by ECHA or any EU expert group, or by the authors of this report.

Fact	Compartment	PNEC values for nickel Registration dossiers
Marine water	8.6 µg/l	
Sewage treatment plant (STP)	0.33 mg/l	
Sediment (freshwater)	109 mg/kg sediment dw	
Sediment (marine water)	109 mg/kg sediment dw	
Hazard for terrestrial organism	Soil	29.9 mg/kg soil dw
Hazard for air	Air	No hazard identified
Hazard for predators	Secondary poisoning	0.12 mg/kg food
Source: ECHA Registered Substance Data	abase: Entries for Nickel sulphate and Nickel b	pis(sulphamidate)

Table 4-1:PNECs values for nickel

To conclude on the environmental hazards, the nickel salts are not expected to remain undissociated in the environment but due to e.g. the water solubility, the nickel ion is the relevant compound in the environment. As the nickel salts are converted during EEE manufacture, a release of nickel as an element may appear in the waste phase. This release does not a result from the nickel salts subject to this study and is therefore beyond the scope of this assessment.

³⁹ Op. cit. ECHA Registered Substance Database: Entries for Nickel sulphate and Nickel bis(sulphamidate)

5. WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT

As discussed above (see section 2), nickel sulphate and nickel sulfamate are used in plating technologies based on electrodeposition und electroless deposition for a broad range of electrical and electronic components, including ABS plastic mouldings. Nickel sulphate and nickel sulfamate are solely used as process chemicals which are converted into nickel metal during the electrolytic surface processes. Thus, the available data indicates that nickel sulphate and nickel sulfamate are not found in electrical and electronic equipment (EEE), not even as an impurity.

Due to the fact that these nickel salts are not present in the final EEE product, an evaluation on their impact on waste treatment processes is not further developed.

The evaluation of the waste stream processes would rather have to be conducted for the substance group "nickel and its compounds". Nickel is generally present in many forms in EEE waste (see EU RAR 2008), mostly as nickel compounds – e.g. nickel oxide or nickel hydroxide. Nickel metal and Ni²⁺ can be expected to be present in almost all EEE and thus in all WEEE categories. Nickel plating of plastics housings can be expected to be more common in consumer products which often have shorter lifetimes and do not need to be as robust as equipment with metal housings.

Already the Swedish Chemicals Agency KEMI concluded in it "Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market" in 2015⁴⁰ that *"nickel compounds are hazardous to human and environment and are found to a great extent in EEE products, it is of interest to analyse them more extensively in order to make an assessment of their risks in EEE products."*

This evaluation is however beyond the scope of this review.

The Nickel Institute (2019) claims in this regard that "*it should be noted, however, that no risks* were identified for shredding processes in the REACH chemical safety assessment of the waste life-cycle stage (documented in the joint Chemical Safety Report), which is based on the Best Available Techniques (BAT) Reference Document (BREF) for Waste Treatment (JRC, 2018). Moreover, it should be acknowledged that nickel metal and inorganic nickel compounds have different hazard classifications."

The Joint Chemical Safety Report is not publicly available but submitted to the ECHA; results are extracted and made available in the ECHA Registered Substance database.⁴¹ Thus, the claim of Nickel Institute cannot be scrutinised here. However, the consideration that nickel-plated plastics end up in waste stream processes where processing and shredding of plastic waste generates dust from decomposing and shredding of EEE plastic supports the conclusion as taken by KEMI (2015). No further information on nickel plated plastics in EEE especially on amounts have been provided by stakeholders. These considerations form the basis for the recommendation to assess the substance groups nickel and its compounds in the future.

⁴⁰ Swedish Chemicals Agency KEMI (2015): Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market; <u>https://www.kemi.se/global/pm/2015/pm-7-15.pdf</u>, last viewed 19.04.2018

⁴¹ E.g. for nickel at: https://echa.europa.eu/de/registration-dossier/-/registered-dossier/15544/1; see there under toxicological information.

6. EXPOSURE ESTIMATION DURING WEEE TREATMENT

As nickel sulphate and nickel sulfamate are process chemicals and do not remain in the final EEE, it is concluded that there is no exposure to either of these substances during WEEE treatment.

7. IMPACT AND RISK EVALUATION

An impact and risk evaluation is not carried out as the available data indicate that nickel sulphate and nickel sulfamate are not present in EEE.

8. ALTERNATIVES

Information on possible alternatives are extracted from the following two reports that already reviewed substitution possibilities:

- Draft analysis of the most appropriate risk management option for nickel sulphate (France and Anses 2014);⁴² and
- Survey of nickel metal, Part of the LOUS review by DEPA (2015).⁴³

Further information from the stakeholder contributions submitted during the 1st stakeholder consultation is taken into consideration in the relevant sections.

8.1. Availability of substitutes / alternative technologies

France and Anses (2014) discussed the following possibilities for substitution:

- 'Drop-in' substances that directly replace nickel sulphate in the same production process without change (except minor changes) with other soluble nickel salts;
- the use of alternative substances; and
- alternative technologies.

According to France and Anses (2014), a **substitution** of nickel sulphate is possible **with other soluble nickel salts** (e.g. nickel chloride) as highly dissociated solution of the divalent nickel cation and the appropriate anion are reached. A number of other nickel salts have been used as intermediates in specialised electroless and electrolytic applications such as nickel acetate, nickel fluoborate, nickel hypophosphite and nickel methanesulphonate. The contribution by Coherent⁴⁴ submitted in the 1st stakeholder consultation in 2018 stated that "*in the future, this may change, as electroless nickel appears to be replacing sulfamate nickel in electronics applications (apparently the reliability data finally exists). This may be what prompted the RoHS proposal [...]'. In electroless nickel plating, nickel acetate and hydroxycarbonate are used.*

However, France and Anses (2014) conclude that the substitution between nickel salts is technically not feasible in all situations, e.g. nickel sulphate has no substitutes for the so called "diamond adhesion phase" which is however understood not to be relevant for EEE production. Additionally, France and Anses (2014) points out that other soluble nickel salts show the same hazard profile and that therefore no risk reduction benefit is reached.

As for **alternative substances**, France and Anses (2014) list that besides nickel, chromium, copper, zinc and tin are commonly electrodeposited commercially in large quantities. Nine other metals have been deposited on a commercial scale, however in much smaller quantities:

⁴² France and Anses (French Mandated National Institute) (2014): Draft analysis of the most appropriate risk management option for nickel sulphate, April 2014; http://www.consultations-publiques.developpementdurable.gouv.fr/IMG/pdf/RMOA_NiSO4_PUBLIC.pdf, last viewed 18.06.2018

⁴³ Danish Environmental Protection Agency DEPA (2015): Survey of nickel metal, Part of the LOUS review; Environmental project No. 1723, 2015; https://www2.mst.dk/Udgiv/publications/2015/06/978-87-93352-36-0.pdf, last viewed 18.06.2018

⁴⁴ Coherent (2018): Contribution submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of re-stricted RoHS substances and to assess а new exemption request under 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contributions/Contribution Coherent Nickel Sulphate Stakeholder Response 20180612.pdf, last viewed 18.06.2018

cadmium, cobalt, iron, lead, manganese, indium, gold, silver and platinum (France and Anses 2014). France and Anses (2014) further note:

- Of these metals, only nickel and copper can be deposited by electroless processes. Iron and tin can in certain specific cases be considered to be potential substitutes, but nickel is always necessary when the above-mentioned technical characteristics, such as durability, hardness, high corrosion resistance and capability to withstand high temperatures are required.
- Alternatives such as chromium, cobalt or cadmium have been ruled out because of their hazard profile. Instead, it is understood that nickel plating processes are applied to replace cadmium and lead. According to France and Anses (2014), "some electrical connector companies are now attempting to eliminate the use of cadmium, and are replacing it with either electroless nickel-PTFE or with zinc-nickel electroplate" and furthermore "the use of nickel diffusion barriers has grown with the advent of lead-free solders because the solders have higher melting points, which greatly increases inter-diffusion between copper and gold during wave soldering".

As for noble metals that are alternatives for some specific uses, DEPA (2015) concluded that these are, however, *"more expensive than nickel and the economic feasibility of thus depends also on the implication the plating cost has to the overall cost of the product."*

The substitution by noble metals is also noted in the contribution by Carl Zeiss Jena GmbH⁴⁵ which mentions the possibility to use layers of silver, gold or tantalum on the base of uncoated substrate. Carl Zeiss Jena GmbH⁴⁶ rules out this option because of more negative environmental impacts due to a higher demand of the critical raw materials silver, tantalum and gold.

Other possibilities mentioned by e.g. Carl Zeiss Jena GmbH⁴⁷ such as layers of nitride (titanium or chromium nitride) are explained not to reach the technical requirements and specifications. This is in line with the conclusion in the report of DEPA (2015) that states "*nickel used for plating can be replaced only in areas where there are no specific technical requirements regarding corrosion, or wear resistance. In functional plating in the car and aerospace industry no alternatives seem to be able to compete with nickel. Only where less stringent requirements are specified e.g. for decorative plating on indoor other surface treatments or technical solutions would be suitable." The conclusion was based on investigations of the Nickel Institute and documented in several reports covering uses of a range of nickel substances, which are however not publicly available.*

Alternative processes/technologies like vacuum surface treatments (e.g. evaporation, spraying or chemical / physical vapour deposition) according to France and Anses (2014) can at this stage, only be implemented by larger companies: "The costs are considered prohibitive for SMEs. In addition, while these processes are considered to be safe in use, clean-up and maintenance must take place in extremely strict conditions because of the fume hazard. These processes are not always appropriate for parts with particularly sophisticated shapes."

⁴⁵ Op. cit. Carl Zeiss Jena GmbH (2018)

⁴⁶ Op. cit. Carl Zeiss Jena GmbH (2018)

⁴⁷ Op. cit. Carl Zeiss Jena GmbH (2018)

8.2. Hazardous properties of substitutes

There are various substitutes that are considered to have various hazardous properties that render their use as substitutes as problematic:

- Cadmium itself is restricted by the RoHS Directive and is thus not understood to be a practical alternative. In the report of France and Anses (2014) alternatives such as chromium, cobalt or cadmium have been ruled out because of their hazard profile.
- The substitution with other soluble nickel salts can be substituted for each other but present the same hazard profile. This would be a regrettable substitution which is not considered to result in a benefit in terms of impacts on health and or environment.
- As for the noble metals, Carl Zeiss Jena GmbH claims that silver, tantalum and gold are associated with a higher environmental impact; however, this statement is not substantiated further.

8.3. Data basis for alternatives and uncertainties

The information specified above regarding alternatives for nickel sulphate and nickel sulfamate originates from various documents generated in the context of the REACH Regulation and the setting for an occupational exposure limit. Such documents are understood to have been subject to scrutiny and to have a relatively high certainty. However, France and Anses (2014) point out that *"the analysis of alternatives […] has been carried out by the Nickel Institute in the framework of a socioeconomic analysis (SEA) based on internal reviews and reports as well as available literature. Again this information has not been peer-reviewed or challenged and shall thus be considered as the Industry point of view; it has been aggregated, interpreted and summarized by Anses."*

9. DESCRIPTION OF SOCIO-ECONOMIC IMPACTS

9.1. Approach and assumptions

The scope of this assessment requires a review of possible socio-economic impacts related to a scenario in which the substances under assessment (nickel sulphate and nickel sulfamate) were to be added to the list of restricted substances specified in Annex II of RoHS 2. This would restrict the presence of these substances in EEE to be placed on the market in the future.

However, as has been specified in the sections above, these compounds are used in plating processes of relevance to the manufacture of EEE, but do not remain in the final products in their compound form. In this sense, it is assumed that a restriction of the two substances would not be effective: RoHS restricts the presence of substances present in EEE placed on the market and thus would not affect substances used in manufacture, assuming these do not remain present in the final product to be placed on the market.

Against this background it is generally assumed that:

- Substitution would not take place, seeing as the applications do not contain these substances and would still be allowed on the market;
- the choice of related EEE available to consumers would not be expected to change, nor the properties and characteristics of such EEE;
- the amount of related EEE reaching end-of-life and subject to waste management would not be expected to change as a result of the restriction;
- potential impacts of substitution on health and or environment during use and or the waste phase would thus not be expected.

9.2. Impact on chemicals industry

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change. In this sense, the chemicals industry would continue manufacture as usual.

9.3. Impact on EEE producers

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change. In this sense, EEE producers and their supply chain would continue manufacture as usual.

The only aspect that might change is related to the administrative burden of the restriction of a new substance and the need to document its possible presence in products in order to comply with legislation. This impact is expected to be short termed, mainly occurring following the introduction of the restriction. Its essence would include the preparation of relevant documentation and in some cases, it can be expected that manufacturers and/or their suppliers would increase possible testing of the presence of the two Ni compounds in final components and products to ensure compliance with the restriction. Such activities may be initiated by suppliers that want to prove to Original Equipment Manufacturers (OEMs) that their materials and components are free from the restricted compounds, by OEMs with the same intention in mind as well as by OEMs as a means of

controlling compliance of suppliers with OEM requirements related to the presence of the compounds.

It is noted that most OEMs have supply chain specifications related to the use and presence of hazardous chemicals in components and products purchased from the supply chain. The consultants are aware of a few OEMs that restrict the presence of Ni and its compounds components and products purchased from the supply chain, meaning that to a limited degree, the preparation of documentation and the performance of testing is already performed⁴⁸.

9.4. Impact on EEE users

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products. A slight increase in prices may occur to support the administrative costs specified in Section 0, but these are only expected to result in a minor impact on prices (if at all).

9.5. Impact on waste management

As the compounds do not remain present in the final product, it is assumed that manufacture could continue without change and thus also the placing on the market of relevant products. The same EEE would reach the waste phase and require treatment and in this sense, any possible impacts in his stage related to the use of the two compounds in plating processes would not be expected to differ.

9.6. Impact on administration

As stated in Section 0, though the restriction is not expected to affect EEE placed on the market, compliance with the restriction would still require provision of documentation and in some cases EEE or its components would be tested to ensure that the two compounds are not present. This would result in an administrative burden for manufacturers and suppliers, and it can also be expected that a certain administrative burden would fall on regulators in the relation to the implementation of the restriction in the RoHS Directive and national legislation and its enforcement. This includes the burden of amending the RoHS Directive, of transposing new provisions into national legislation as well as burdens related to enforcement. Though market surveillance activities can be expected to some degree, the understanding that the compounds do not remain in the EEE would probably mean that market surveillance would occur on a small scale if at all (i.e. focus shall remain on substances for which continued illegal presence is expected).

9.7. Total socio-economic impact

To summarise, a possible restriction can be expected to result in administrative costs for both, industry (e.g. EEE manufacturers, suppliers) and for regulators (e.g. legislators, market surveillance). However, the restriction is not expected to generate benefits for the environment or for health (in the form of prevention of possible impacts tied with nickel sulphate and nickel

⁴⁸ For example, Apple in its Regulated Substances Specification 069-0135-J, effective from 21 March, 2016, restricts nickel and its compounds in "all homogeneous materials used in Apple products, accessories, and packaging". The specification refers the scope of this restriction as "Parts with direct and prolonged skin contact" and specifies "Metal alloys with nickel, plating material, anti-corrosive alloy" as examples. See https://www.apple.com/supplier-responsibility/pdf/Apple-Regulated-Substance-Specification.pdf for further detail.

sulfamate in general and particularly during the use and waste phase of interest for RoHS 2 Article 6(1)). In terms of total socio-economic impacts, this suggests that a restriction of the two substances would not be proportionate, given that its costs are not expected to generate benefits for the environment or for health.

It is noted that a possible restriction of nickel and its compounds can be expected to be more effective in terms of preventing possible impacts on environment and health in the use and waste phase of products, that are related to nickel plating of components using nickel sulphate and nickel sulfamate.⁴⁹ Nonetheless, before such an analysis is to be carried out, an assessment of the use of these compounds in EEE would need to be performed to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases.

An investigation of the socio-economic impacts of such a restriction is however beyond the scope of this review.

⁴⁹ The Nickel Institute (2019) commented here that "this statement is not supported by any evidence or data in the dossier. How can this assumption be made if an analysis has not been performed? There is no information in the draft report on the socio-economic impacts (potential impacts for the European industrial value chain; feasibility; competitiveness of manufacturers and SMEs, etc.) or potential benefits."

However, the next sentence explains that an assessment of the use of these compounds in EEE would need to be performed to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases.

10. RATIONALE FOR INCLUSION OF THE SUBSTANCE IN ANNEX II OF ROHS

The two nickel salts nickel sulphate and nickel sulfamate are used in metal surface treatment processes, including electrolytic plating and electroless technologies. It can be understood that these substances are transformed through the surface treatment processes and do not remain in their original form in the final product, i.e. in relevant EEE and its parts. In the final coating, the nickel salts are understood to be converted into nickel metal. It is therefore expected that a restriction of these compounds in EEE would not necessarily be effective in preventing their use in the processes. It is therefore not recommended to restrict the two substances, as benefits on health and environment would not be expected to incur as a result of such a restriction.

In parallel, the assessment would recommend a future assessment under RoHS of nickel and its compounds in order to clarify the range of expected impacts of nickel metal and nickel²⁺ ions during use and/or waste management to clarify the range and nature of possible impacts related to the presence of Ni and its compounds in EEE in the use and waste phases and whether a RoHS restriction of this group would allow preventing such impacts.⁵⁰

It should be noted in this regard that the Swedish Chemical Agency KEMI (2015)⁵¹ in its assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market concluded that nickel sulphate and nickel sulfamate as process chemicals for electroplating are not relevant for inclusion in RoHS. It should further be noted that during the substance prioritisation that is also performed in one working package of this project, nickel and nickel monoxide have been included in the shortlisted substances.⁵² These indications support the conclusion that a grouping of nickel and its compounds is recommended instead of further assessing single compounds.

⁵⁰ The Nickel Institute (2019) stated on this paragraph that *"this conclusive statement is not supported by any evidence in the draft Report. In addition, it should be acknowledged clearly that nickel metal has a different and lower hazard classification than nickel compounds. This aspect is not mentioned anywhere in the draft Report. It is an important point which should be acknowledged."* The addition on the different hazard classification are made in section 3.

⁵¹ Opt cit. Swedish Chemicals Agency KEMI (2015)

⁵² The entry of nickel and its compounds in REACH Annex XVII based on the classification as skin sensitizer is one reason for this inclusion.

11. List of References

11.1. Databases

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- ECHA Registered Substance Database: Entry for Nickel sulphate, https://echa.europa.eu/registrationdossier/-/registered-dossier/15304, last viewed 11.06.2018
- ECHA Registered Substance Database: Entry for Nickel bis(sulphamidate), https://echa.europa.eu/de/registration-dossier/-/registered-dossier/14782/4/1, last viewed 11.06.2018
- ECHA CL Inventory: Entry for Nickel sulphate, https://echa.europa.eu/de/information-on-chemicals/clinventory-database/-/discli/details/9597, last viewed 11.06.2018
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11.2. Contributions, documents and reports

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- Coherent (2018): Contribution submitted on 12.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contribution_Coherent_Nickel_Sulphate_Stakeholder_Response_20180612.pdf, last viewed 18.06.2018

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- Alliance Elektronique ACSIEL (2018): Contribution submitted on 15.06.2018 during the stakeholder consultation conducted from 20 April 2018 to 15 June 2018 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/1st_Consultation_Contribution_ACSIEL_Nickel_CMG_Ni_Salts_20180615.pdf, last viewed 18.06.2018
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Nickel Institute (2019): Contribution submitted on 07.11.2019 during the stakeholder consultation conducted from 26 September 2019 to 07 November 2019 by Oeko-Institut in the course of the study to support the review of the list of restricted substances and to assess a new exemption request under RoHS 2 (Pack 15); https://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/4th_Consultation/Contrib utions/contribution_NI_RoHS15_Comments_dossier_Ni_20191107.pdf, last viewed 30.01.2020

Swedish Chemicals Agency KEMI (2015): Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market; https://www.kemi.se/global/pm/2015/pm-7-15.pdf, last viewed 19.04.2018

Appendix I: Contribution to stakeholder consultation hold from 20 April 2018 to 15 June 2018

The following non-confidential contributions were submitted during the 1st stakeholder consultation (see also: http://rohs.exemptions.oeko.info/index.php?id=295):

> Contribution of the Carl Zeiss Jena GmbH submitted on 07.06.2018: pdf

> Contribution of the Swedish Chemicals Agency (KEMI) submitted on 11.06.2018:

>> Assessment of the risk reduction potential of hazardous substances in electrical and electronic equipment on the EU market: pdf

- > Contribution of Coherent submitted on 12.06.2018: pdf
- > Contribution of MedTech Europe submitted on 15.06.2018: pdf

> Contribution of the JBCE – Japan Business Council in Europe aisbl submitted on 15.06.2018: pdf

> Contribution of the Test and Measurement Coalition (TMC) submitted on 15.06.2018: pdf

> Contribution of the Nickel Institute submitted on 15.06.2018: pdf

> Contribution of the Association of Equipment Manufacturers (AEM) submitted on 15.06.2018: pdf

> Contribution of the Japanese electric and electronic (E&E) industrial associations submitted on 14.06.2018: pdf

> Contribution of the Alliance Elektronique - ACSIEL submitted on 15.06.2018: pdf

> Contribution of the AeroSpace and Defence Industries Association of Europe (ASD) submitted on 14.06.2018: pdf

Appendix II: Contributions to stakeholder consultation hold from 26 September 2019 to 07 November 2019

The following non-confidential contributions were submitted during the 2nd stakeholder consultation (see also: https://rohs.exemptions.oeko.info/index.php?id=337):

> Contribution of COCIR (European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry), submitted on 22.10.2019: PDF

> Contribution of the Japanese electric and electronic (E&E) industrial associations, submitted on 06.11.2019: PDF

> Contribution of the JBCE – Japan Business Council in Europe aisbl, submitted on 07.11.2019: PDF

> Contribution of the Nickel Institute, submitted on 07.11.2019: PDF

> Contribution of Digital Europe, submitted on 07.11.2019: PDF

> Contribution of The European Semiconductor Industry Association (ESIA), submitted on 07.11.2019: PDF

> Contribution of LYNRED by Sofradir and ULIS, submitted on 07.11.2019: PDF