according to Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

# ROTH

#### Nickel(II) sulfate hexahydrate ≥98 %, extra pure

article number: **7322**Version: **3.0 en**date of compilation: 05.04.2016

Revision: 04.03.2024

Replaces version of: 18.02.2021

Version: (2)

## SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Identification of the substance Nickel(II) sulfate hexahydrate ≥98 %, extra

pure

Article number 7322

Registration number (REACH) 01-2119439361-44-xxxx

EC number 600-152-3 CAS number 10101-97-0

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

#### 1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

**Telephone:**+49 (0) 721 - 56 06 0 **Telefax:** +49 (0) 721 - 56 06 149 **e-mail:** sicherheit@carlroth.de **Website:** www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment

sheet:

e-mail (competent person): sicherheit@carlroth.de

## 1.4 Emergency telephone number

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

#### Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.10	Acute toxicity (oral)	4	Acute Tox. 4	H302
3.1I	Acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.2	Skin corrosion/irritation	2	Skin Irrit. 2	H315
3.4R	Respiratory sensitisation	1	Resp. Sens. 1	H334
3.45	Skin sensitisation	1	Skin Sens. 1	H317

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Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.5	Germ cell mutagenicity	2	Muta. 2	H341
3.6	Carcinogenicity	1A	Carc. 1A	H350i
3.7	Reproductive toxicity		Repr. 1B	H360D
3.9	Specific target organ toxicity - repeated exposure	1	STOT RE 1	H372
4.1A	Hazardous to the aquatic environment - acute hazard	1	Aquatic Acute 1	H400
4.1C	Hazardous to the aquatic environment - chronic hazard	1	Aquatic Chronic 1	H410

For full text of abbreviations: see SECTION 16

## The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire water can cause pollution of watercourses.

#### 2.2 Label elements

#### Labelling according to Regulation (EC) No 1272/2008 (CLP)

#### **Pictograms**

GHS07, GHS08, GHS09







#### **Hazard statements**

H302+H332	Harmful if swallowed or if inhaled
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled
H341	Suspected of causing genetic defects
H350i	May cause cancer by inhalation
H360D	May damage the unborn child
H372	Causes damage to organs through prolonged or repeated exposure
H410	Very toxic to aquatic life with long lasting effects

#### **Precautionary statements**

#### **Precautionary statements - prevention**

P260 Do not breathe dust/fume/gas/mist/vapours/spray

P280 Wear protective gloves/protective clothing/eye protection/face protection/hear-

ing protection/...

#### **Precautionary statements - response**

P302+P352	IF ON SKIN: Wash with plenty of soap and water
P312	Call a POISON CENTRE/doctor if you feel unwell

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor

P391 Collect spillage

## **Precautionary statements - disposal**

P501 Dispose of contents/container to industrial combustion plant

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For professional users only

#### Labelling of packages where the contents do not exceed 125 ml

Signal word: Danger

Symbol(s)







H317 May cause an allergic skin reaction.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H341 Suspected of causing genetic defects. H350i May cause cancer by inhalation. H360D May damage the unborn child.

H372 Causes damage to organs through prolonged or repeated exposure.

P260 Do not breathe dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....

P302+P352 IF ON SKIN: Wash with plenty of soap and water.

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/doctor. P501 Dispose of contents/container to industrial combustion plant.

#### 2.3 Other hazards

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0.1\%$ .

## SECTION 3: Composition/information on ingredients

#### 3.1 Substances

Name of substance Nickel(II) sulfate hexahydrate

Molecular formula  $\text{NiSO}_4 * 6 \text{ H}_2\text{O}$  Molar mass  $262,9 \text{ g/}_{\text{mol}}$ 

REACH Reg. No 01-2119439361-44-xxxx

CAS No 10101-97-0 EC No 600-152-3

#### Substance, Specific Conc. Limits, M-factors, ATE

Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	>300 <sup>mg</sup> / <sub>kg</sub> 2,48 <sup>mg</sup> / <sub>l</sub> /4h	oral inhalation: dust/ mist

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#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

## **Following inhalation**

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

#### **Following skin contact**

Rinse skin with water/shower. After contact with skin, wash immediately with plenty of water. In case of skin reactions, consult a physician. In case of skin irritation, consult a physician.

#### Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

#### Following ingestion

Rinse mouth with water (only if the person is conscious). In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

#### 4.2 Most important symptoms and effects, both acute and delayed

Vomiting, Irritation, Allergic reactions, Cough, Dyspnoea

#### 4.3 Indication of any immediate medical attention and special treatment needed

none

## **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media



#### Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

#### 5.2 Special hazards arising from the substance or mixture

Non-combustible.

#### **Hazardous combustion products**

In case of fire may be liberated: Sulphur oxides (SOx)

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Do not allow firefighting water to enter drains or water courses. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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#### **SECTION 6: Accidental release measures**

#### 6.1 Personal precautions, protective equipment and emergency procedures



#### For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

#### 6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it. If substance has entered a water course or sewer, inform the responsible authority.

#### 6.3 Methods and material for containment and cleaning up

#### Advice on how to contain a spill

Covering of drains. Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

## **SECTION 7: Handling and storage**

#### 7.1 Precautions for safe handling

Use extractor hood (laboratory). Provision of sufficient ventilation. Avoid exposure. Avoid dust formation.

#### Measures to prevent fire as well as aerosol and dust generation

Removal of dust deposits.

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep container tightly closed.

#### **Incompatible substances or mixtures**

Observe hints for combined storage.

#### **Consideration of other advice:**

## **Ventilation requirements**

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

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Specific designs for storage rooms or vessels

Recommended storage temperature: 15 - 25 °C

#### 7.3 Specific end use(s)

No information available.

## **SECTION 8: Exposure controls/personal protection**

#### 8.1 Control parameters

**National limit values** 

**Occupational exposure limit values (Workplace Exposure Limits)** 

This information is not available.

#### **Human health values**

Relevant DNELs and other threshold levels						
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time		
DNEL	0,05 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects		
DNEL	104 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects		
DNEL	0,05 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects		
DNEL	1,6 mg/m³	human, inhalatory	worker (industry)	acute - local effects		

#### **Environmental values**

Relevant PNECs and other threshold levels					
End- point	Threshold level	Organism	Environmental com- partment	Exposure time	
PNEC	7,1 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)	
PNEC	8,6 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	marine water	short-term (single instance)	
PNEC	0,33 <sup>mg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)	
PNEC	109 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	freshwater sediment	short-term (single instance)	
PNEC	109 <sup>mg</sup> / <sub>kg</sub>	aquatic organisms	marine sediment	short-term (single instance)	
PNEC	29,9 <sup>mg</sup> / <sub>kg</sub>	terrestrial organisms	soil	short-term (single instance)	

#### 8.2 Exposure controls

**Individual protection measures (personal protective equipment)** 

**Eye/face protection** 



Use safety goggle with side protection.

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#### Skin protection



#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

#### • type of material

NBR (Nitrile rubber)

#### material thickness

>0,11 mm

#### breakthrough times of the glove material

>480 minutes (permeation: level 6)

#### other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

#### **Respiratory protection**





Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

#### **Environmental exposure controls**

Keep away from drains, surface and ground water.

## SECTION 9: Physical and chemical properties

## 9.1 Information on basic physical and chemical properties

Physical state solid
Form crystals

Colour greenish-blue

Odour odourless

Melting point/freezing point ≥53 °C (Release of crystal water) (ECHA)

Boiling point or initial boiling point and boiling

range

not determined

Flammability non-combustible Lower and upper explosion limit not determined

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Flash point not applicable

Auto-ignition temperature not determined

Decomposition temperature 848 °C (anhydrous) (ECHA)

pH (value) not applicable
Kinematic viscosity not relevant

Solubility(ies)

Water solubility  $\geq 625 \, ^{9}/_{1}$  at 0 °C (ECHA)

Partition coefficient

Partition coefficient n-octanol/water (log value): not relevant (inorganic)

Vapour pressure not determined

Density and/or relative density

Density  $2,07 \, {}^{9}/{}_{\text{cm}^{3}}$  at 20 °C (ECHA)

Relative vapour density Information on this property is not available.

Bulk density  $\sim 1.000 \, ^{\mathrm{kg}} /_{\mathrm{m}^3}$ 

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard hazard classes acc. to GHS

classes: (physical hazards): not relevant

Other safety characteristics: There is no additional information.

## **SECTION 10: Stability and reactivity**

#### 10.1 Reactivity

This material is not reactive under normal ambient conditions.

#### 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

#### 10.4 Conditions to avoid

Keep away from heat. Decompostion takes place from temperatures above: 848 °C.

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#### 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

## **SECTION 11: Toxicological information**

#### 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

#### Classification according to GHS (1272/2008/EC, CLP)

#### **Acute toxicity**

Harmful if swallowed. Harmful if inhaled.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
inhalation: dust/ mist	LC50	2,48 <sup>mg</sup> / <sub>l</sub> /4h	rat	anhydrous	ECHA

#### Skin corrosion/irritation

Causes skin irritation.

#### Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

#### Respiratory or skin sensitisation

May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

#### Germ cell mutagenicity

Suspected of causing genetic defects.

#### Carcinogenicity

May cause cancer by inhalation.

#### **Reproductive toxicity**

May damage the unborn child.

#### Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

#### Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Hazard category	Target organ	Exposure route
1	several organs	if exposed

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

#### Symptoms related to the physical, chemical and toxicological characteristics

#### If swallowed

gastrointestinal complaints

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#### • If in eyes

Data are not available.

#### • If inhaled

May produce an allergic reaction, cough, Dyspnoea

#### • If on skin

causes skin irritation, May produce an allergic reaction, pruritis, localised redness

#### Other information

Other adverse effects: Irreversible damage to internal organs, Central nervous system, Cardiovascular system

#### 11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### 11.3 Information on other hazards

There is no additional information.

## **SECTION 12: Ecological information**

#### 12.1 Toxicity

Very toxic to aquatic life with long lasting effects.

Aquatic toxicity (acute)						
Endpoint	Value	Species	Source	Exposure time		
LC50	15,3 <sup>mg</sup> / <sub>l</sub>	fish	ECHA	96 h		
EC50	685,8 <sup>μg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	48 h		
ErC50	237 <sup>µg</sup> /ı	algae	ECHA	72 h		

Aquatic toxicity (chronic)						
Endpoint	Value	Species	Source	Exposure time		
ErC50	8.363 <sup>µg</sup> / <sub>l</sub>	fish	ECHA	40 d		
LC50	≤144 <sup>µg</sup> / <sub>I</sub>	aquatic invertebrates	ECHA	21 d		
EC50	≤108 <sup>µg</sup> / <sub>I</sub>	aquatic invertebrates	ECHA	21 d		
EbC50	6,2 <sup>µg</sup> / <sub>l</sub>	aquatic invertebrates	ECHA	30 d		

#### 12.2 Persistence and degradability

Data are not available.

## 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

	BCF	45 (ECHA)
- 1		

### 12.4 Mobility in soil

Data are not available.

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#### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### 12.6 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0.1\%$ .

#### 12.7 Other adverse effects

Data are not available.

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

#### Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

#### Relevant provisions relating to waste 13.2

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process.

#### Properties of waste which render it hazardous

- **HP 4** irritant - skin irritation and eye damage
- HP 5 specific target organ toxicity (STOT)/aspiration toxicity
- **HP 6** acute toxicity
- HP 7 carcinogenić
- HP 10 toxic for reproduction
- **HP 11** mutagenic
- sensitising
- HP 13 HP 14 ecotoxic

#### 13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions. Non-contaminated packages may be recycled.

## **SECTION 14: Transport information**

#### 14.1 UN number or ID number

**ADR UN 3077 IMDG-Code UN 3077** ICAO-TI UN 3077

#### 14.2 UN proper shipping name

**ADR** ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.

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IMDG-Code ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

ICAO-TI Environmentally hazardous substance, solid,

n.o.s.

Technical name Nickel(II) sulfate hexahydrate

14.3 Transport hazard class(es)

9 **ADR IMDG-Code** 9 ICAO-TI 9

14.4 Packing group

**ADR** III **IMDG-Code** III ICAO-TI III

14.5 Environmental hazards hazardous to the aquatic environment

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

#### 14.8 Information for each of the UN Model Regulations

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)Additional information

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, Proper shipping name

SOLID, N.O.S.

UN3077, ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S., (Nickel(II) sulfate hexahydrate), 9, III, (-) Particulars in the transport document

Classification code

9, "Fish and tree" Danger label(s)



**Environmental hazards YES** (hazardous to the aquatic environment)

Special provisions (SP) 274, 335, 375, 601

Excepted quantities (EQ) E1 Limited quantities (LQ) 5 kg Transport category (TC) 3 Tunnel restriction code (TRC)

Hazard identification No 90

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International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE,

SOLID, N.O.S.

Particulars in the shipper's declaration UN3077, ENVIRONMENTALLY HAZARDOUS SUB-

STANCE, SOLID, N.O.S., (Nickel(II) sulfate hexahy-

drate), 9, III

Marine pollutant Yes (hazardous to the aquatic environment), (Nickel(II) sulfate

hexahydrate)

Danger label(s) 9, "Fish and tree"

**\*** 

Special provisions (SP) 274, 335, 966, 967, 969

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
EmS F-A, S-F

Stowage category A

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name Environmentally hazardous substance, solid,

n.o.s.

Particulars in the shipper's declaration UN3077, Environmentally hazardous substance,

solid, n.o.s., (Nickel(II) sulfate hexahydrate), 9, IİI

Environmental hazards yes (hazardous to the aquatic environment)

Danger label(s) 9, "Fish and tree"



Special provisions (SP) A97, A158, A179, A197, A215

Excepted quantities (EQ) E1
Limited quantities (LQ) 30 kg

## **SECTION 15: Regulatory information**

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

## Dangerous substances with restrictions (REACH, Annex XVII)

Name of substance	Name acc. to inventory	CAS No	Restriction	No
Nickel(II) sulfate hexahydrate	nickel compounds		R27	27
Nickel(II) sulfate hexahydrate	substances in tattoo inks and perman- ent make-up		R75	75

Legend

R27 1. Shall not be used

(a) 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);

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- (b) in articles intended to come into direct and prolonged contact with the skin such as:
- 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.

  (c) in articles referred to in point (b) where these have a non-nickel 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.

  2. Articles which are the subject of paragraph 1 shall not be placed on the market unless they conform to the requirements of the property of the propert
- ments set out in that paragraph.

  3. The standards adopted by the European Committee for Standardisation (CEN) shall be used as the test methods for demonstrating the conformity of articles to paragraphs 1 and 2.

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#### Legend

**R75** 

1. Shall not be placed on the market in mixtures for use for tattooing purposes, and mixtures containing any such substances shall not be used for tattooing purposes, after 4 January 2022 if the substance or substances in question is or are present in the following circumstances:

(a) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as carcinogen category

1A, 1B or 2, or germ cell mutagen category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight; (b) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as reproductive toxicant category 1A, 1B or 2, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by

(c) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin sensitiser category 1, 1A or 1B, the substance is present in the mixture in a concentration equal to or greater than 0,001 % by weight;

(d) in the case of a substance classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as skin corrosive category 1, 1A, 1B or 1C or skin irritant category 2, or as serious eye damage category 1 or eye irritant category 2, the substance is present in the mixture in a concentration equal to or greater than:

(i) 0,1 % by weight, if the substance is used solely as a pH regulator

(ií) 0,01 % by weight, in all other cases;

(e) in the case of a substance listed in Annex II to Regulation (EC) No 1223/2009 (\*1), the substance is present in the

mixture in a concentration equal to or greater than 0,00005 % by weight;

(f) in the case of a substance for which a condition of one or more of the following kinds is specified in column g (Product type, Body parts) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration equal to or greater than 0,00005 % by weight:

(i) "Rinse-off products";
(ii) "Not to be used in products applied on mucous membranes";
(iii) "Not to be used in eye products";

(g) in the case of a substance for which a condition is specified in column h (Maximum concentration in ready for use preparation) or column i (Other) of the table in Annex IV to Regulation (EC) No 1223/2009, the substance is present in the mixture in a concentration, or in some other way, that does not accord with the condition specified in that column; (h) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concen-

(n) in the case of a substance listed in Appendix 13 to this Annex, the substance is present in the mixture in a concentration equal to or greater than the concentration limit specified for that substance in that Appendix.

2. For the purposes of this entry use of a mixture "for tattooing purposes" means injection or introduction of the mixture into a person's skin, mucous membrane or eyeball, by any process or procedure (including procedures commonly referred to as permanent make-up, cosmetic tattooing, micro-blading and micro-pigmentation), with the aim of making a mark or design on his or her body.

3. If a substance not listed in Appendix 13 falls within more than one of points (a) to (g) of paragraph 1, the strictest concentration limit laid down in the points in question shall apply to that substance. If a substance listed in Appendix 13 also falls within one or more of points (a) to (g) of paragraph 1, the concentration limit laid down in point (h) of paragraph 1 shall apply to that substance.

as also falls within one of more of points (a) to (g) of paragraph 1, the concentration limit faid down in point (ii) of paragraph 1 shall apply to that substance.

4. By way of derogation, paragraph 1 shall not apply to the following substances until 4 January 2023:
(a) Pigment Blue 15:3 (CI 74160, EC No 205-685-1, CAS No 147-14-8);
(b) Pigment Green 7 (CI 74260, EC No 215-524-7, CAS No 1328-53-6).

5. If Part 3 of Annex VI to Regulation (EC) No 1272/2008 is amended after 4 January 2021 to classify or re-classify a substance such that the substance then becomes caught by point (a), (b), (c) or (d) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the date of application of that now or revised classification in fifty the date referred to in paragraph 1 or as the case may be paragraph. plication of that new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect on the date of application of that new or revised classification.

6. If Annex II or Annex IV to Regulation (EC) No 1223/2009 is amended after 4 January 2021 to list or change the listing of a substance such that the substance then becomes caught by point (e), (f) or (g) of paragraph 1 of this entry, or such that it then falls within a different one of those points from the one within which it fell previously, and the

amendment takes effect after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, that amendment shall, for the purposes of applying this entry to that substance, be treated as taking effect from the date falling 18 months after entry into force of the act by which that amendment was made.

7. Suppliers placing a mixture on the market for use for tattooing purposes shall ensure that, after 4 January 2022, the mixture is marked with the following information:

(a) the statement "Mixture for use in tattoos or permanent make-up";

(a) the statement "Mixture for use in tattoos or permanent make-up";
(b) a reference number to uniquely identify the batch;
(c) the list of ingredients in accordance with the nomenclature established in the glossary of common ingredient names pursuant to Article 33 of Regulation (EC) No 1223/2009, or in the absence of a common ingredient name, the IUPAC name. In the absence of a common ingredient name or IUPAC name, the CAS and EC number. Ingredients shall be listed in descending order by weight or volume of the ingredients at the time of formulation. "Ingredient" means any substance added during the process of formulation and present in the mixture for use for tattooing purposes. Impurities shall not be regarded as ingredients. If the name of a substance, used as ingredient within the meaning of this entry, is already required to be stated on the label in accordance with Regulation (EC) No 1272/2008, that ingredient does not need to be marked in accordance with this Regulation;
(d) the additional statement "pH regulator" for substances falling under point (d)(i) of paragraph 1;
(e) the statement "Contains nickel. Can cause allergic reactions." if the mixture contains nickel below the concentration limit specified in Appendix 13;

tion limit specified in Appendix 13

(f) the statement "Contains chromium (VI). Can cause allergic reactions." if the mixture contains chromium (VI) below

the concentration limit specified in Appendix 13; (g) safety instructions for use insofar as they are not already required to be stated on the label by Regulation (EC) No 1272/2008.

The information shall be clearly visible, easily legible and marked in a way that is indelible.

The information shall be written in the official language(s) of the Member State(s) where the mixture is placed on the market, unless the Member State(s) concerned provide(s) otherwise.

Where necessary because of the size of the package, the information listed in the first subparagraph, except for point (a), shall be included instead in the instructions for use.

Before using a mixture for tattooing purposes, the person using the mixture shall provide the person undergoing the procedure with the information marked on the package or included in the instructions for use pursuant to this paragraph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

tattooing purposes.

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9. This entry does not apply to substances that are gases at temperature of 20  $^{\circ}$ C and pressure of 101,3 kPa, or generate a vapour pressure of more than 300 kPa at temperature of 50  $^{\circ}$ C, with the exception of formaldehyde (CAS No 50-00-0, EC No 200-001-8).

10. This entry does not apply to the placing on the market of a mixture for use for tattooing purposes, or to the use of a mixture for tattooing purposes, when placed on the market exclusively as a medical device or an accessory to a medical device, within the meaning of Regulation (EU) 2017/745, or when used exclusively as a medical device or an accessory to a medical device, within the same meaning. Where the placing on the market or use may not be exclusively as a medical device or an accessory to a medical device, the requirements of Regulation (EU) 2017/745 and of this Regulation shall apply cumulatively.

#### List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

#### **Seveso Directive**

2012/	2012/18/EU (Seveso III)					
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes			
E1	environmental hazards (hazardous to the aquatic environment, cat. 1)	100 200	56)			

#### Notation

56) Hazardous to the Aquatic Environment in category Acute 1 or Chronic 1

#### **Deco-Paint Directive**

VOC content	0 %
VOC content	0 <sup>g</sup> / <sub>l</sub>

#### **Industrial Emissions Directive (IED)**

VOC content	0 %
VOC content	0 <sup>g</sup> / <sub>l</sub>

## Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

## Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

#### Water Framework Directive (WFD)

#### List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Nickel(II) sulfate hexahydrate	nickel compounds		b)	
Nickel(II) sulfate hexahydrate	nickel compounds	7440-02-0	c)	

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#### List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Nickel(II) sulfate hexahydrate	Substances and preparations, or the breakdown products of such, which have been proved to pos- sess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrine- related functions in or via the aquatic environment		a)	
Nickel(II) sulfate hexahydrate	Metals and their compounds		a)	

#### Legend

Indicative list of the main pollutants a) b)

List of priority substances in the field of water policy

Environmental Quality Standards for Priority Substances and certain other pollutants

#### Regulation on the marketing and use of explosives precursors

not listed

#### **Regulation on drug precursors**

not listed

#### Regulation on substances that deplete the ozone layer (ODS)

not listed

#### Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

#### Regulation on persistent organic pollutants (POP)

not listed

#### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

#### **National inventories**

Country	Inventory	Status
CN	IECSC	substance is listed
JP	CSCL-ENCS	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed
VN	NCI	substance is listed

Legend

CSCL-ENCS

List of Existing and New Chemical Substances (CSCL-ENCS)
Inventory of Existing Chemical Substances Produced or Imported in China
National Chemical Inventory
New Zealand Inventory of Chemicals
Philippine Inventory of Chemicals and Chemical Substances (PICCS)
Taiwan Chemical Substance Inventory IECSC

NZIoC

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#### 15.2 Chemical safety assessment

According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.

## **SECTION 16: Other information**

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
1.1	Index No: 028-009-00-5		yes
1.1		EC number: 600-152-3	yes
1.1	EC number: 232-104-9	CAS number: 10101-97-0	yes
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-state- ments: see SECTION 16.		yes
2.1		The most important adverse physicochemical, human health and environmental effects: Delayed or immediate effects can be expected after short or long-term exposure. Spillage and fire water can cause pollution of watercourses.	yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Precautionary statements - prevention: change in the listing (table)	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2		Precautionary statements - disposal	yes
2.2		Precautionary statements - disposal: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes
2.3		Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	yes
2.3		Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes
3.1	Index No: 028-009-00-5		yes
11.1		Acute toxicity: change in the listing (table)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
14.1	UN number: 3077	UN number or ID number	yes
14.1		ADR: UN 3077	yes
14.1		IMDG-Code: UN 3077	yes
14.1		ICAO-TI: UN 3077	yes
14.2	UN proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	UN proper shipping name	yes
14.2		ADR: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	yes
14.2		IMDG-Code: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S.	yes
14.2		ICAO-TI: Environmentally hazardous substance, solid, n.o.s.	yes
14.3	Class: 9 (miscellaneous dangerous substances and articles) (environmentally hazardous)		yes
14.3		ADR: 9	yes
14.3		IMDG-Code: 9	yes
14.3		ICAO-TI: 9	yes
14.4	Packing group: III (substance presenting low danger)	Packing group	yes
14.4		ADR: III	yes
14.4		IMDG-Code: III	yes
14.4		ICAO-TI: III	yes
14.8	UN number: 3077		yes
14.8	Class: 9		yes
14.8	Packing group: III		yes
14.8	UN number: 3077		yes
14.8	Class: 9		yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
14.8	Marine pollutant: yes (hazardous to the aquatic environment)	Marine pollutant: yes (hazardous to the aquatic environment), (Nickel(II) sulfate hexahydrate)	yes
14.8	Packing group: III		yes
14.8	UN number: 3077		yes
14.8	Class:		yes
14.8	Packing group: III9 + "fish and tree"		yes
14.8		Packing group: change in the listing (table)	yes
14.8		Danger label(s): 9, "Fish and tree"	yes
14.8		Danger label(s): change in the listing (table)	yes
14.8	Special provisions (SP): A97, A158, A179, A197, 274	Special provisions (SP): A97, A158, A179, A197, A215	yes
15.1	• Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC):  Not listed.		yes
15.1	Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS): Not listed.		yes
15.1	Regulation 850/2004/EC on persistent organic pollutants (POP):     Not listed.		yes
15.1		Restrictions according to REACH, Annex XVII	yes
15.1		Dangerous substances with restrictions (REACH, Annex XVII): change in the listing (table)	yes
15.1		Deco-Paint Directive	yes
15.1		VOC content: 0 %	yes
15.1		VOC content: 0 <sup>g</sup> / <sub>I</sub>	yes
15.1		Industrial Emissions Directive (IED)	yes
15.1		VOC content: 0 %	yes
15.1		VOC content: 0 <sup>9</sup> / <sub>I</sub>	yes
15.1	Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD): not listed	Water Framework Directive (WFD)	yes

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Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
15.1	National inventories: Substance is listed in the following national inventories: - EINECS/ELINCS/NLP (Europe) - REACH (Europe)		yes
15.1		List of pollutants (WFD): change in the listing (table)	yes
15.1		Regulation on the marketing and use of explosives precursors: not listed	yes
15.1		Regulation on drug precursors: not listed	yes
15.1		Regulation on substances that deplete the ozone layer (ODS): not listed	yes
15.1		Regulation concerning the export and import of hazardous chemicals (PIC): not listed	yes
15.1		Regulation on persistent organic pollutants (POP): not listed	yes
15.1		Other information: Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.	yes
15.1		National inventories	yes
15.1		National inventories: change in the listing (table)	yes
15.2	Chemical Safety Assessment: No Chemical Safety Assessment has been car- ried out for this substance.	Chemical safety assessment: According to REACH, Article 14 (1) a chemical safety assessment has been carried out for this substance or components of this mixture when the substance has been registered in quantities of 10 tonnes or more per year per registrant.	yes

## Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EbC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control

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Abbr.	Descriptions of used abbreviations
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

#### Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

#### List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H332	Harmful if inhaled.

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Code	Text
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341	Suspected of causing genetic defects.
H350i	May cause cancer by inhalation.
H360D	May damage the unborn child.
H372	Causes damage to organs through prolonged or repeated exposure.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

#### Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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