according to Regulation (EC) No. 1907/2006 (REACH)

Nickel(II) nitrate hexahydrate ROTI®METIC 99,999 % (5N)

article number: 5387 date of compilation: 2017-06-09 Version: **3.0 en** Revision: 2022-04-14

Replaces version of: 2017-06-09

Version: (2)

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

Product identifier 1.1

Identification of the substance Nickel(II) nitrate hexahydrate ROTI®METIC

99,999 % (5N)

Article number 5387

Registration number (REACH) It is not required to list the identified uses be-

cause the substance is not subject to registration

according to REACH (< 1 t/a).

Index number in CLP Annex VI 028-012-00-1 EC number 236-068-5 CAS number 13478-00-7

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

sicherheit@carlroth.de

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

with foodstuffs. Do not use for private purposes

(household).

Details of the supplier of the safety data sheet 1.3

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:

1.4 **Emergency telephone number**

e-mail (competent person):

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

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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
2.14	Oxidising solid	2	Ox. Sol. 2	H272
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
3.3	Serious eye damage/eye irritation	1	Eye Dam. 1	H318
3.4R	Respiratory sensitisation	1	Resp. Sens. 1	H334
3.45	Skin sensitisation	1	Skin Sens. 1	H317
3.5	Germ cell mutagenicity	2	Muta. 2	H341
3.6	Carcinogenicity	1A	Carc. 1A	H350i
3.7	Reproductive toxicity	1B	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)

Signal word Danger

Pictograms

GHS03, GHS05, GHS07, GHS08, GHS09











Hazard statements

May intensify fire; oxidiser
Harmful if swallowed or if inhaled
Causes skin irritation
May cause an allergic skin reaction
Causes serious eye damage
May cause allergy or asthma symptoms or breathing difficulties if inhaled
Suspected of causing genetic defects
May cause cancer by inhalation
May damage the unborn child

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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

P201 Obtain special instructions before use

P220 Keep/store away from clothing/combustible materials

P280 Wear protective gloves/eye protection

Precautionary statements - response

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P308+P313 IF exposed or concerned: Get medical advice/attention

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.

H318 Causes serious eye damage.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H341 Suspected of causing genetic defects.

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.

P201 Obtain special instructions before use. P280 Wear protective gloves/eye protection.

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

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.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance Nickel(II) nitrate hexahydrate

Molecular formula $Ni(NO_3)_2 \cdot 6 H_2O$

Molar mass 290,8 ⁹/_{mol}

CAS No 13478-00-7

EC No 236-068-5

Index No 028-012-00-1

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

Specific Conc. Limits	M-Factors	ATE	Exposure route
Skin Irrit. 2; H315: C ≥ 20 % Skin Sens. 1; H317: C ≥ 0,01 % STOT RE 1; H372: C ≥ 1 % STOT RE 2; H373: 0,1 % ≤ C < 1 %	-	361,9 ^{mg} / _{kg} 1,5 ^{mg} / _l /4h	oral inhalation: dust/ mist

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Avoid exposure - obtain special instructions before use.

Following inhalation

Provide fresh air. In case of allergic symptoms, especially in the breathing area, seek medical advice immediately.

Following skin contact

Rinse skin with water/shower. In case of skin reactions, consult a physician.

Following eye contact

In case of contact with eyes flush immediately with plenty of flowing water for 10 to 15 minutes holding eyelids apart and consult an ophthalmologist.

Following ingestion

Rinse mouth with water (only if the person is conscious). Call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

Dyspnoea, Irritation, Allergic reactions (such as skin rashes, hives, asthma or anaphylactic shock), Cough, Vomiting, Nausea, Risk of serious damage to eyes

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

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5.2 Special hazards arising from the substance or mixture

Oxidising property. Non-combustible.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NOx)

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.

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.

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. Ventilate affected area.

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

Keep away from combustible material.

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.

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Incompatible substances or mixtures

Observe hints for combined storage. Keep/store away from clothing/combustible materials. Take any precaution to avoid mixing with combustibles.

Protect against external exposure, such as

humidity, hygroscopic solid

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.

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 DNE	Ls and other t	hreshold levels		
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	50 μg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
DNEL	104 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
DNEL	50 μg/m³	human, inhalatory	worker (industry)	chronic - local effects
DNEL	1,6 mg/m³	human, inhalatory	worker (industry)	acute - local effects
DNEL	0,44 μg/cm²	human, dermal	worker (industry)	chronic - local effects

Environmental values

Relevant PNECs and other threshold levels

29,9 mg/kg

PNFC

Threshold End-**Organism Environmental com-Exposure time** point level partment **PNEC** $7,1 \, ^{\mu g}/_{l}$ aquatic organisms freshwater short-term (single instance) $8,6 \, ^{\mu g}/_{l}$ **PNEC** aquatic organisms marine water short-term (single instance) **PNEC** 0,33 ^{mg}/₁ aquatic organisms sewage treatment plant short-term (single instance) (STP) 109 mg/kg **PNEC** aquatic organisms freshwater sediment short-term (single instance) **PNEC** 109 mg/kg aquatic organisms marine sediment short-term (single instance)

soil

short-term (single instance)

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terrestrial organisms

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8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection





Use safety goggle with side protection.

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.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state solid

Form crystalline Colour green

Odour like: Nitric acid

Melting point/freezing point 56,7 °C (ECHA)

Boiling point or initial boiling point and boiling 136,7 °C (ECHA)

range

Flammability non-combustible

Lower and upper explosion limit 0 vol% (LEL) - 0 vol% (UEL)

Flash point not applicable
Auto-ignition temperature not determined

Decomposition temperature >137 °C

pH (value) 5 (in aqueous solution: 50 ^g/_l, 20 °C)

Kinematic viscosity not relevant

Solubility(ies)

Water solubility \sim 940 $^{9}/_{1}$ at 20 $^{\circ}$ C

Partition coefficient

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

Vapour pressure <0,003 Pa at 25 °C

Density and/or relative density

Density $2,05 \, {}^{9}/_{cm^3}$ at $0 \, {}^{\circ}\text{C}$ (ECHA)

Relative vapour density information on this property is not available

Bulk density $\sim 800 \, \mathrm{kg/m^3}$

Particle characteristics No data available.

Other safety parameters

Oxidising properties oxidiser

9.2 Other information

Information with regard to physical hazard There is no additional information.

classes:

Other safety characteristics: There is no additional information.

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SECTION 10: Stability and reactivity

10.1 Reactivity

It's a reactive substance. Oxidising property.

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: Acid, Combustible materials, Reducing agents

10.4 Conditions to avoid

Keep away from heat. Decompostion takes place from temperatures above: >137 °C. Protect from moisture.

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.

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-					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	361,9 ^{mg} / _{kg}	rat		ECHA

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation

Causes serious eye damage.

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).

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Specific target organ toxicity - repeated exposure

Causes damage to organs through prolonged or repeated exposure.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

If swallowed

Data are not available.

• If in eyes

Causes serious eye damage, risk of blindness

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

none

11.2 Endocrine disrupting properties

Not listed.

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 (acı	ute)			
Endpoint	Value	Species	Source	Exposure time
LC50	15,3 ^{mg} / _l	fish	ECHA	96 h
EC50	406 ^{µg} / _l	aquatic invertebrates	ECHA	24 h
ErC50	≤1.120 ^{µg} /	algae	ECHA	72 h

Aquatic toxicity (chronic) Exposure time **Endpoint Value Species Source** ErC50 8.363 ^{µg}/_I fish **ECHA** 40 d ≤144 ^{µg}/_I LC50 aquatic invertebrates **ECHA** 21 d ≤108 ^{µg}/_I **ECHA** 21 d EC50 aquatic invertebrates EbC50 6,2 ^{µg}/_I ECHA 30 d aquatic invertebrates

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Biodegradation

The methods for determining the biological degradability are not applicable to inorganic substances.

12.2 Process of degradability

Data are not available.

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

BCF	45 (ECHA)
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12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Not listed.

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.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

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.

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SECTION 14: Transport information

14.1 UN number or ID number

ADRRID UN 2725 IMDG-Code UN 2725 ICAO-TI UN 2725

14.2 UN proper shipping name

ADRRID NICKEL NITRATE

IMDG-Code NICKEL NITRATE

ICAO-TI Nickel nitrate

14.3 Transport hazard class(es)

ADRRID 5.1 IMDG-Code 5.1 ICAO-TI 5.1

14.4 Packing group

ADRRID 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

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Proper shipping name NICKEL NITRATE

Particulars in the transport document UN2725, NICKEL NITRATE, 5.1, III, (E), environ-

mentally hazardous

Classification code O2

Danger label(s) 5.1, "Fish and tree"





Environmental hazards yes (hazardous to the aquatic environment)

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
Transport category (TC) 3

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Tunnel restriction code (TRC) E
Hazard identification No 50
Emergency Action Code 1Z

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID)Additional

information

Classification code 5.1

Danger label(s) 5.1

Fish and tree





Environmental hazards Yes

Hazardous to water

Excepted quantities (EQ) E1
Limited quantities (LQ) 5 kg
Transport category (TC) 3
Hazard identification No 50

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name NICKEL NITRATE

Particulars in the shipper's declaration UN2725, NICKEL NITRATE, 5.1, III, MARINE POL-

LUTANT

Marine pollutant yes (hazardous to the aquatic environment)

Danger label(s) 5.1, "Fish and tree"





Special provisions (SP)

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

Stowage category A

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

Proper shipping name Nickel nitrate

Particulars in the shipper's declaration UN2725, Nickel nitrate, 5.1, III

Environmental hazards yes (hazardous to the aquatic environment)

Danger label(s) 5.1



Excepted quantities (EQ) E1
Limited quantities (LQ) 10 kg

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SECTION 15: Regulatory information

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) nitrate hexahydrate	nickel compounds		R27	27
Nickel(II) nitrate hexahydrate	carcinogenic		R28-30	28
Nickel(II) nitrate hexahydrate	toxic for reproduction		R28-30	30
Nickel(II) nitrate hexahydrate	substances in tattoo inks and permanent make-up		R75	75

Legend

R27

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); (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 require-

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.

R28-30

1. Shall not be placed on the market, or used,

- as substance

- as constituents of other substances, or,

- in mixtures

for supply to the general public when the individual concentration in the substance or mixture is equal to or greater

- either the relevant specific concentration limit specified in Part 3 of Annex VI to Regulation (EC) No 1272/2008, or, - the relevant concentration specified in Directive 1999/45/EC where no specific concentration limit is set out in Part 3 of Annex VI to Regulation (EC) No 1272/2008.

Without prejudice to the implementation of other Community provisions relating to the classification, packaging and labelling of substances and mixtures, suppliers shall ensure before the placing on the market that the packaging of such substances and mixtures is marked visibly, legibly and indelibly as follows: 'Restricted to professional users'.

2. By way of derogation, paragraph 1 shall not apply to:
(a) medicinal or veterinary products as defined by Directive 2001/82/EC and Directive 2001/83/EC;
(b) cosmetic products as defined by Directive 76/768/EEC;

(c) the following fuels and oil products:
- motor fuels which are covered by Directive 98/70/EC,
- mineral oil products intended for use as fuel in mobile or fixed combustion plants,

- fuels sold in closed systems (e.g. liquid gas bottles); (d) artists' paints covered by Directive 1999/45/EC;

(e) the substances listed in Appendix 11, column 1, for the applications or uses listed in Appendix 11, column 2. Where a date is specified in column 2 of Appendix 11, the derogation shall apply until the said date; (f) devices covered by Regulation (EU) 2017/745.

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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 weight:

(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.

according to Regulation (EC) No. 1907/2006 (REACH)



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Legend

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/	18/EU (Seveso III)			
No	Dangerous substance/hazard categories	Qualifying quantity plication of lower quire	(tonnes) for the ap- and upper-tier re- ments	Notes
P8	oxidising liquids and solids	50	200	55)

Notation

55) Oxidising liquids, category 1, 2 or 3, or oxidising solids, category 1, 2 or 3

Deco-Paint Directive

VOC content 0 %	VOC content
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Industrial Emissions Directive (IED)

VOC content	0 %	

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) nitrate hexahydrate	nickel compounds		b)	
Nickel(II) nitrate hexahydrate	nickel compounds	7440-02-0	c)	
Nickel(II) nitrate hexahydrate	Substances which contribute to eutrophication (in particular, nitrates and phosphates)		a)	
Nickel(II) nitrate hexahydrate	Substances and preparations, or the breakdown products of such, which have been proved to possess carcinogenic or mutagenic properties or properties which may affect steroidogenic, thyroid, reproduction or other endocrinerelated functions in or via the aquatic environment		a)	

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List of pollutants (WFD)

Name of substance	Name acc. to inventory	CAS No	Listed in	Remarks
Nickel(II) nitrate hexahydrate	Metals and their compounds		a)	

Legend

A) B) C)

Indicative list of the main pollutants 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
AU	AICS	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
KR	KECI	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TW	TCSI	substance is listed

Legend

AICS ECSI

Australian Inventory of Chemical Substances EC Substance Inventory (EINECS, ELINCS, NLP) Inventory of Existing Chemical Substances Produced or Imported in China Korea Existing Chemicals Inventory New Zealand Inventory of Chemicals Philippine Inventory of Chemicals and Chemical Substances (PICCS) Taiwan Chemical Substance Inventory **IECSC**

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

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ROTH

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SECTION 16: Other information

Indication of changes (revised safety data sheet)

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

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	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		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

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de naviga tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Ir land Waterways)
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 substance
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 eithe growth (EbC50) or growth rate (ErC50) relative to the control
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causin 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 iden fier of substances commercially available within the EU (European Union)

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Abbr.	Descriptions of used abbreviations
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
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
LEL	Lower explosion limit (LEL)
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regula- tions concerning the International carriage of Dangerous goods by Rail)
SVHC	Substance of Very High Concern
UEL	Upper explosion limit (UEL)
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). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

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

Code	Text
H272	May intensify fire; oxidiser.
H302	Harmful if swallowed.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H318	Causes serious eye damage.
H332	Harmful if inhaled.
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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