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

### Nickel(II)-oxide ROTI®METIC 99,999 % (5N)

article number: 5388 date of compilation: 2016-08-11 Version: 3.0 en Revision: 2024-03-03

Replaces version of: 2022-01-14

Version: (2)

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

#### **Product identifier** 1.1

Identification of the substance Nickel(II)-oxide ROTI®METIC 99,999 % (5N)

Article number 5388

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 028-003-00-2 EC number 215-215-7 CAS number 1313-99-1

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

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). 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

e-mail (competent person):

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

sheet:

1.4

# **Emergency telephone number**

Street **Telephone** Website **Name Postal** code/city **National Poisons Information** Dublin 9 Beaumont Road +353 1 809 2166 https:// www.poisons.ie/ Centre Beaumont Hospital

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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
3.45	Skin sensitisation	1	Skin Sens. 1	H317
3.6	Carcinogenicity	1A	Carc. 1A	H350i
3.9	Specific target organ toxicity - repeated exposure		STOT RE 1	H372
4.1C	Hazardous to the aquatic environment - chronic hazard	4	Aquatic Chronic 4	H413

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**

GHS07, GHS08





## **Hazard statements**

H317	May cause an allergic skin reaction
H350i	May cause cancer by inhalation

H372 Causes damage to organs through prolonged or repeated exposure

H413 May cause long lasting harmful effects to aquatic life

## **Precautionary statements**

# **Precautionary statements - prevention**

P260 Do not breathe dust

P280 Wear protective gloves/eye protection

# **Precautionary statements - response**

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

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

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#### Symbol(s)



H317 May cause an allergic skin reaction. H350i May cause cancer by inhalation.

H372 Causes damage to organs through prolonged or repeated exposure.

H413 May cause long lasting harmful effects to aquatic life.

P260 Do not breathe dust.

P280 Wear protective gloves/eye protection. P302+P352 IF ON SKIN: Wash with plenty of water.

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

#### 2.3 Other hazards

#### **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)-oxide

Molecular formula NiO

Molar mass 74,69 g/<sub>mol</sub>
CAS No 1313-99-1
EC No 215-215-7
Index No 028-003-00-2

# **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**

After contact with skin, wash immediately with plenty of water. In case of skin reactions, 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

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible).

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

Allergic reactions

## 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, dry extinguishing powder, ABC-powder

#### Unsuitable extinguishing media

water jet

## 5.2 Special hazards arising from the substance or mixture

Non-combustible.

### 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. 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.

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#### 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). Avoid exposure. Avoid dust formation.

## 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.

## **Incompatible substances or mixtures**

Observe hints for combined storage.

**Consideration of other advice:** 

#### 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)**

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
EU	nickel compounds	1313-99-1	IOELV	0,1			i	2022/431/ EU
IE	nickel, inorganic com- pounds, insoluble	1313-99-1	OELV	0,5			Ni	S.I. No. 619 of 2001

#### **Notation**

Ceiling value is a limit value above which exposure should not occur Inhalable fraction Ceiling-C

Calculated as Ni (nickel)

Ni STEL Short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-

minute period (unless otherwise specified)

**TWA** Time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8

hours time-weighted average (unless otherwise specified)

#### **Human health values**

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Relevant DNELs and other threshold levels					
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time	
DNEL	0,05 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects	
DNEL	0,05 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - local effects	
DNEL	18,9 mg/m³	human, inhalatory	worker (industry)	acute - local effects	

#### **Environmental values**

Relevant	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.

#### 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)

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#### 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 powder, crystalline

Colour dark grey
Odour odourless

Melting point/freezing point 1.955 °C (ECHA) Boiling point or initial boiling point and boiling not determined

range

Flammability non-combustible

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

Flash point not applicable
Auto-ignition temperature >400 °C (ECHA)
Decomposition temperature not relevant
pH (value) not applicable
Kinematic viscosity not relevant

Solubility(ies)

Water solubility 0 <sup>9</sup>/<sub>l</sub> at 20 °C (practically insoluble) (ECHA)

Partition coefficient

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

Vapour pressure not determined

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Density and/or relative density

Density  $6,72 \, \mathrm{g}/_{\mathrm{cm}^3}$ 

Relative vapour density Information on this property is not available.

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard

classes:

hazard classes acc. to GHS (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, Fluorine, Iodine, Hydrogen peroxide

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

#### 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**

Shall not be classified as acutely toxic.

Acute toxicity						
Exposure route	Endpoint	Value	Species	Method	Source	
oral	LD50	8.796 <sup>mg</sup> / <sub>kg</sub>	rat		ECHA	
inhalation: dust/ mist	LC50	>5,08 <sup>mg</sup> / <sub>l</sub> /4h	rat		ECHA	

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#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

## Serious eye damage/eye irritation

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

#### Respiratory or skin sensitisation

May cause an allergic skin reaction.

## **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

## Carcinogenicity

May cause cancer by inhalation.

## **Reproductive toxicity**

Shall not be classified as a reproductive toxicant.

#### 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.

#### **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

Data are not available.

#### • If inhaled

Data are not available.

#### • If on skin

May produce an allergic reaction, pruritis, localised redness

#### Other information

none

## 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.

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# **SECTION 12: Ecological information**

#### 12.1 Toxicity

May cause long lasting harmful effects to aquatic life.

## 12.2 Persistence and 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

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

Handle contaminated packages in the same way as the substance itself. Completely emptied packages can be recycled.

# 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.

# Properties of waste which render it hazardous

**HP 5** specific target organ toxicity (STOT)/aspiration toxicity

**HP7** carcinogenic

**HP 13** sensitising

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.

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# **SECTION 14: Transport information**

**14.1 UN number or ID number** not subject to transport regulations

**14.2 UN proper shipping name** not assigned

**14.3 Transport hazard class(es)** none

**14.4 Packing group** not assigned

**14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous goods regulations

14.6 Special precautions for user

There is no additional information.

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

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

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

Not subject to ICAO-IATA.

# **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)-oxide	nickel compounds		R27	27
Nickel(II)-oxide	carcinogenic		R28-30	28
Nickel(II)-oxide	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);
 (b) in articles intended to come into direct and prolonged contact with the skin such as:

- earrings,

- necklaces, bracelets and chains, anklets, finger rings,

- wrist-watch cases, watch straps and tighteners,

- rivet buttons, tighteners, rivets, zippers and metal marks, when these are used in garments,

if the rate of nickel release from the parts of these articles coming into direct and prolonged contact with the skin is greater than 0,5 μg/cm2/week.

(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-

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.

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#### Legend

R28-30 1. Shall not be placed on the market, or used,

- as substances,
- as constituents of other substances, or,

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 generic concentration limit specified in Part 3 of Annex I of 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;

- (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 Regulation (EC) No 1272/2008;
  (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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**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

(f) in the case of a substance is the invalid in the legislation (EC) No 1223/2009 (17), 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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#### 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/	2012/18/EU (Seveso III)					
No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements	Notes			
11	nickel compounds in inhalable powder form	1				

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

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

VOC content	0 %
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### 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)-oxide nickel compounds b) Nickel(II)-oxide nickel compounds 7440-02-0 c) Nickel(II)-oxide Substances and preparations, or a) 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 Nickel(II)-oxide 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 c)

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## 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)

#### 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	AIIC	substance is listed
CA	DSL	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	CSCL-ENCS	substance is listed
KR	KECI	substance is listed
MX	INSQ	substance is listed
NZ	NZIoC	substance is listed
PH	PICCS	substance is listed
TR	CICR	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

Australian Inventory of Industrial Chemicals Chemical Inventory and Control Regulation List of Existing and New Chemical Substances (CSCL-ENCS) AIIC CICR CSCL-ENCS DSL ECSI

Domestic Substances List (DSL)
EC Substance Inventory (EINECS, ELINCS, NLP)
Inventory of Existing Chemical Substances Produced or Imported in China National Inventory of Chemical Substances
Korea Existing Chemicals Inventory **IECSC** 

NCI National Chemical Inventory
NZIOC New Zealand Inventory of Chemicals
PICCS Philippine Inventory of Chemicals and Chemical Substances (PICCS)
REACH Reg. REACH registered substances
TCSI Taiwan Chemical Substance Inventory

**TSCA** Toxic Substance Control Act

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# 15.2 Chemical safety assessment

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

# **SECTION 16: Other information**

# Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
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
14.8	Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information:  Not subject to ADR, RID and ADN.		yes
15.1		National inventories: change in the listing (table)	yes

# **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
2022/431/EU	Directive (EU) 2022/431 of the European Parliament and of the Council of 9 March 2022 amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
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
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
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
IMDG	International Maritime Dangerous Goods Code

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Abbr.	Descriptions of used abbreviations
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
IOELV	Indicative occupational exposure limit value
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)
S.I. No. 619 of 2001	Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
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).

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

Code	Text
H317	May cause an allergic skin reaction.
H350i	May cause cancer by inhalation.
H372	Causes damage to organs through prolonged or repeated exposure.
H413	May cause long lasting harmful effects to aquatic life.

#### **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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