

article number: **1776** Version: **3.0 en** Replaces version of: 2020-10-21 Version: (2)

date of compilation: 2018-10-16 Revision: 2021-11-26

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

#### 1.1 Product identifier

| Identification of the substance          | <b>Zirconium(IV) oxide</b> ROTI®nanoMETIC 3 nm, hy-<br>drophobic  |
|--|---|
| Article number                           | 1776  |
| Registration number (REACH)              | It is not required to list the identified uses be-<br>cause the substance is not subject to registration<br>according to REACH (< 1 t/a). |
| EC number                                | 215-227-2   |
| CAS number                               | 1314-23-4   |
| Form                                     | Nanoform  |
| Dolovant identified uses of the substant | so or mixturo and usos advisod against  |

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

Relevant identified uses:

Uses advised against:

Laboratory chemical Laboratory and analytical use

Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

#### **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

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

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



#### Zirconium(IV) oxide ROTI®nanoMETIC 3 nm, hydrophobic

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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-<br>egory | Hazard class and category | Hazard<br>statement |
|---------|--|---------------|---------------------------|---------------------|
| 3.2     | Skin corrosion/irritation                          | 2             | Skin Irrit. 2             | H315                |
| 3.3     | Serious eye damage/eye irritation                  | 1             | Eye Dam. 1                | H318                |
| 3.9     | Specific target organ toxicity - repeated exposure | 1             | STOT RE 1                 | H372                |

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.

#### 2.2 Label elements

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

Signal word Danger

#### **Pictograms**

GHS05, GHS08



#### **Hazard statements**

| H315 | Causes skin irritation  |
|------|---|
| H318 | Causes serious eye damage   |
| H372 | Causes damage to organs (lung) through prolonged or repeated exposure |

#### **Precautionary statements**

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

| P260 | Do not breathe dust   |
|------|---|
| P280 | Wear protective gloves/protective clothing/eye protection/face protection |

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

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

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

Signal word: Danger

Symbol(s)



H318 H372 Causes serious eye damage. Causes damage to organs (lung) through prolonged or repeated exposure. according to Regulation (EC) No. 1907/2006 (REACH)



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| P260           | Do not breathe dust.   |
|----------------|--|
| P280           | Wear protective gloves/protective clothing/eye protection/face protection.   |
| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |

#### 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 | Zirconium(IV) oxide                 |
|-------------------|-------------------------------------|
| Molecular formula | ZrO <sub>2</sub>                    |
| Molar mass        | 123,2 <sup>g</sup> / <sub>mol</sub> |
| CAS No            | 1314-23-4                           |
| EC No             | 215-227-2                           |
| Form              | Nanoform                            |

#### To stabilise:

| Name of substance | Identifier               | Wt%  |
|-------------------|--------------------------|------|
| Benzoic acid      | CAS No<br>65-85-0        | ≤ 30 |
|                   | EC No<br>200-618-2       |      |
|                   | Index No<br>607-705-00-8 |      |

For full text of abbreviations: see SECTION 16 Contains: Nanomaterial

### **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. In case of skin irritation, 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.



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#### **Following ingestion**

Rinse mouth. Call a doctor if you feel unwell.

- **4.2 Most important symptoms and effects, both acute and delayed** Risk of blindness, Risk of serious damage to eyes, Irritation
- **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

None.

#### 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. 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.

#### 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.

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



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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**

Avoid dust formation.

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

Removal of dust deposits.

#### 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

Use local and general ventilation.

#### 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<br>try | Name of agent | CAS No | Identifi-<br>er | TWA<br>[mg/<br>m³] | STEL<br>[mg/<br>m³] | Ceil-<br>ing-C<br>[mg/<br>m <sup>3</sup> ] | Nota-<br>tion | Source    |
|-------------|---------------|--------|-----------------|--------------------|---------------------|--|---------------|-----------|
| GB          | dust          |        | WEL             | 10                 |                     |  | i             | EH40/2005 |
| GB          | dust          |        | WEL             | 4                  |                     |  | r             | EH40/2005 |

Notation

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

Respirable fraction

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) 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) TWA

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



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| Relevant DNELs of components of the mixture |         |               |                       |  |                   |                               |  |  |
|---|---------|---------------|-----------------------|--|-------------------|-------------------------------|--|--|
| Name of sub-<br>stance                      | CAS No  | End-<br>point | Threshol<br>d level   | Protection<br>goal, route of<br>exposure | Used in           | Exposure time                 |  |  |
| Benzoic acid                                | 65-85-0 | DNEL          | 3 mg/m <sup>3</sup>   | human, inhalat-<br>ory                   | worker (industry) | chronic - systemic<br>effects |  |  |
| Benzoic acid                                | 65-85-0 | DNEL          | 0,1 mg/m <sup>3</sup> | human, inhalat-<br>ory                   | worker (industry) | chronic - local ef-<br>fects  |  |  |
| Benzoic acid                                | 65-85-0 | DNEL          | 62,5 mg/kg<br>bw/day  | human, dermal                            | worker (industry) | chronic - systemic<br>effects |  |  |

#### **Relevant PNECs of components of the mixture**

|                        | •       |               |  |                            |                                 |                                 |
|------------------------|---------|---------------|--|----------------------------|---------------------------------|---------------------------------|
| Name of sub-<br>stance | CAS No  | End-<br>point | Threshol<br>d level                    | Organism                   | Environmental compartment       | Exposure time                   |
| Benzoic acid           | 65-85-0 | PNEC          | 0,331 <sup>mg</sup> / <sub>l</sub>     | aquatic organ-<br>isms     | water                           | intermittent re-<br>lease       |
| Benzoic acid           | 65-85-0 | PNEC          | 0,34 <sup>mg</sup> / <sub>l</sub>      | aquatic organ-<br>isms     | freshwater                      | short-term (single<br>instance) |
| Benzoic acid           | 65-85-0 | PNEC          | 0,034 <sup>mg</sup> / <sub>l</sub>     | aquatic organ-<br>isms     | marine water                    | short-term (single<br>instance) |
| Benzoic acid           | 65-85-0 | PNEC          | 100 <sup>mg</sup> / <sub>l</sub>       | aquatic organ-<br>isms     | sewage treatment<br>plant (STP) | short-term (single<br>instance) |
| Benzoic acid           | 65-85-0 | PNEC          | 1,75 <sup>mg</sup> / <sub>kg</sub>     | aquatic organ-<br>isms     | freshwater sedi-<br>ment        | short-term (single<br>instance) |
| Benzoic acid           | 65-85-0 | PNEC          | 0,175 <sup>mg</sup> /<br><sub>kg</sub> | aquatic organ-<br>isms     | marine sediment                 | short-term (single<br>instance) |
| Benzoic acid           | 65-85-0 | PNEC          | 0,151 <sup>mg</sup> /<br>kg            | terrestrial organ-<br>isms | soil                            | short-term (single<br>instance) |

#### 8.2 Exposure controls

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

#### Eye/face protection



Use safety goggle with side protection.

#### Skin protection





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#### 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 consider-able 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). P1 (filters at least 80 % 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   | nanoparticle  |
| Colour   | white   |
| Odour  | odourless   |
| Melting point/freezing point                             | 2.700 °C  |
| Boiling point or initial boiling point and boiling range | 5.000 °C  |
| Flammability   | this material is combustible, but will not ignite readily |
| Lower and upper explosion limit                          | not determined  |
| Flash point  | not applicable  |
| Auto-ignition temperature                                | not determined  |
| Decomposition temperature                                | not relevant  |
|  |   |

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



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|--------|---|--|
|        | pH (value)  | not applicable   |
|        | Kinematic viscosity                                 | not relevant   |
|        | Solubility(ies)                                     |  |
|        | Water solubility                                    | (practically insoluble)  |
|        | Partition coefficient                               |  |
|        | Partition coefficient n-octanol/water (log value):  | not relevant (inorganic)                                       |
|        | Vapour pressure                                     | not determined   |
|        | Density and/or relative density                     |  |
|        | Density   | 5,77 – 5,9 <sup>g</sup> / <sub>cm³</sub> at 20 °C              |
|        | Relative vapour density                             | information on this property is not available                  |
|        | Particle characteristics                            |  |
|        | Particle characteristics                            | contains: Nanoform   |
|        | Particle size                                       | 3 nm   |
|        | Other safety parameters                             |  |
|        | Oxidising properties                                | none   |
| 9.2    | Other information                                   |  |
|        | Information with regard to physical hazard classes: | hazard classes acc. to GHS<br>(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

No known hazardous reactions.

#### 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.

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



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### **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     | >5.000 <sup>mg</sup> / <sub>kg</sub> | rat     |        | ECHA   |

#### Acute toxicity of components of the mixture

| Name of substance | CAS No  | Exposure<br>route        | Endpoint | Value  | Species |
|-------------------|---------|--------------------------|----------|--|---------|
| Benzoic acid      | 65-85-0 | oral                     | LD50     | 2.360 <sup>mg</sup> / <sub>kg</sub>          | rat     |
| Benzoic acid      | 65-85-0 | inhalation:<br>dust/mist | LC50     | >12.200 <sup>mg</sup> /<br><sub>m³</sub> /4h | rat     |
| Benzoic acid      | 65-85-0 | dermal                   | LD50     | >2.000 <sup>mg</sup> / <sub>kg</sub>         | rabbit  |

#### Skin corrosion/irritation

Causes skin irritation.

#### Serious eye damage/eye irritation

Causes serious eye damage.

#### Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

#### **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 (lung) through prolonged or repeated exposure.

| Hazard category | Target organ | Exposure route |
|-----------------|--------------|----------------|
| 1               | lung         | if exposed     |

#### Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

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



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#### 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

Inhalation of dust may cause irritation of the respiratory system, cough, Dyspnoea

#### • If on skin

causes skin irritation

#### 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

Shall not be classified as hazardous to the aquatic environment.

| Aquatic toxicity (acute) |                                   |            |        |                  |  |  |
|--------------------------|-----------------------------------|------------|--------|------------------|--|--|
| Endpoint                 | Value                             | Species    | Source | Exposure<br>time |  |  |
| LC50                     | >100 <sup>mg</sup> / <sub>l</sub> | zebra fish | ECHA   | 96 h             |  |  |

| Aquatic toxicity (acute) of components of the mixture |         |          |                                    |                             |                  |  |  |  |
|---|---------|----------|------------------------------------|-----------------------------|------------------|--|--|--|
| Name of sub-<br>stance                                | CAS No  | Endpoint | Value                              | Species                     | Exposure<br>time |  |  |  |
| Benzoic acid  | 65-85-0 | EC50     | 252 <sup>mg</sup> / <sub>l</sub>   | Tetrahymena pyri-<br>formis | 48 h             |  |  |  |
| Benzoic acid  | 65-85-0 | LC50     | 44,6 <sup>mg</sup> / <sub>l</sub>  | bluegill                    | 96 h             |  |  |  |
| Benzoic acid  | 65-85-0 | ErC50    | >33,1 <sup>mg</sup> / <sub>l</sub> | algae                       | 72 h             |  |  |  |

| Aquatic toxicity (chronic) of components of the mixture        |         |      |                                   |  |      |  |  |
|--|---------|------|-----------------------------------|--|------|--|--|
| Name of sub-<br>stanceCAS NoEndpointValueSpeciesExpose<br>time |         |      |                                   |  |      |  |  |
| Benzoic acid   | 65-85-0 | EC50 | >120 <sup>mg</sup> / <sub>l</sub> | rainbow trout (Onco-<br>rhynchus mykiss) | 28 d |  |  |
| Benzoic acid   | 65-85-0 | EC50 | >25 <sup>mg</sup> / <sub>l</sub>  | daphnia magna                            | 21 d |  |  |



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#### Biodegradation

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

#### 12.2 Process of degradability

| Degradability of components of the mixture |         |                              |                       |      |        |        |
|--|---------|------------------------------|-----------------------|------|--------|--------|
| Name of<br>substance                       | CAS No  | Process                      | Degrada-<br>tion rate | Time | Method | Source |
| Benzoic acid                               | 65-85-0 | biotic/abiotic               | >70 %                 | 5 d  |        |        |
| Benzoic acid                               | 65-85-0 | carbon dioxide<br>generation | 89,5 %                | 35 d |        | ECHA   |

#### 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

| BCF  |         | 0,188 | 0,188 (ECHA) |  |  |
|--|---------|-------|--------------|--|--|
| Bioaccumulative potential of components of the mixture                     |         |       |              |  |  |
| Name of substance         CAS No         BCF         Log KOW         BOD5/ |         |       |              |  |  |
| Benzoic acid   | 65-85-0 |       | 1,88         |  |  |

#### 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.

#### 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.

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



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### **SECTION 14: Transport information**

- 14.1 UN number or ID number
- 14.2 UN proper shipping name
- 14.3 Transport hazard class(es)
- 14.4 Packing group
- 14.5 Environmental hazards

#### not subject to transport regulations

not assigned

none

not assigned

non-environmentally hazardous acc. to the dangerous 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

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

Not subject to ADR, RID and ADN.

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 |  |  |
| Zirconium(IV) oxide  | substances in tattoo inks and perman-<br>ent make-up |        | R75         | 75 |  |  |

Legend

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

(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

(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:

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; (ii) 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

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



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#### Legend

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

(ii) "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 concentration limit specified for that substance in that Appendix.

tration equal to or greater than the concentration limit specified for that substance in that Appendix.
 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.
 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 falls within one or more of points (a) to (g) of paragraph 1, the strictest in Appendix 13 falls within one or more of points (a) to (g) of paragraph 1, the substance listed in Appendix 13 falls within specified for that substance. If a substance listed in Appendix 13 falls of the paragraph 1, the concentration limit laid down in points (h) of paragraph 1, the substance

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.
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 new or revised classification is after the date referred to in paragraph 1 or, as the case may be, paragraph 4 of this entry, to that amendment shall for the nurnoses of applying this entry to that substance he treated as

graph 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 entry of the state of the marked in accordance with the Regulation." ent 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

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

graph. 8. Mixtures that do not contain the statement "Mixture for use in tattoos or permanent make-up" shall not be used for

9. This entry does not apply to substances that are gases at temperature of 20 °C and pressure of 101,3 kPa, or gener-ate a vapour pressure of more than 300 kPa at temperature of 50 °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, within the same meaning. ively 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.



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



#### Zirconium(IV) oxide ROTI®nanoMETIC 3 nm, hydrophobic

#### article number: 1776

| Seveso                  | Seveso Directive                      |   |       |  |  |  |  |  |
|-------------------------|---------------------------------------|---|-------|--|--|--|--|--|
| 2012/18/EU (Seveso III) |                                       |   |       |  |  |  |  |  |
| Νο                      | Dangerous substance/hazard categories | Qualifying quantity (tonnes) for the ap-<br>plication of lower and upper-tier re-<br>quirements | Notes |  |  |  |  |  |
|                         | not assigned                          |   |       |  |  |  |  |  |

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

| <b>VOC content</b> $0\%$ | VOC content |  |
|--------------------------|-------------|--|
|--------------------------|-------------|--|

#### Industrial Emissions Directive (IED)

| VOC content | 0 %   |
|-------------|-------|
| VOC content | 0 g/l |

# 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 |
| Zirconium(IV) oxide      | Metals and their compounds |        | A)        |         |

#### Legend

A) Indicative list of the main 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.

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



#### Zirconium(IV) oxide ROTI®nanoMETIC 3 nm, hydrophobic

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#### **National inventories**

| Country | Inventory  | Status              |
|---------|------------|---------------------|
| AU      | AICS       | 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 |

#### Legend

| Legena     |   |
|------------|---|
| AICS       | Australian Inventory of Chemical Substances   |
| CICR       | Chemical Inventory and Control Regulation   |
| CSCL-ENCS  | List of Existing and New Chemical Substances (CSCL-ENCS)  |
| DSL        | Domestic Substances List (DSL)  |
| ECSI       | EC Substance Inventory (EINECS, ELINCS, NLP)  |
| IECSC      | Inventory of Existing Chemical Substances Produced or Imported in China                                   |
| INSQ       | National Inventory of Chemical Substances   |
| KECI       | Korea Existing Chemicals 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   |
|            | AICS<br>CICR<br>CSCL-ENCS<br>DSL<br>ECSI<br>IECSC<br>INSQ<br>KECI<br>NZIOC<br>PICCS<br>REACH Reg.<br>TCSI |

#### 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)

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

| Section | Former entry (text/value)                            | Actual entry (text/value)  | Safety-<br>relev-<br>ant |
|---------|--|--|--------------------------|
| 2.1     |  | Classification according to Regulation (EC) No<br>1272/2008 (CLP):<br>change in the listing (table)  | yes                      |
| 2.1     |  | The most important adverse physicochemical,<br>human health and environmental effects:<br>Delayed or immediate effects can be expected<br>after short or long-term exposure. | yes                      |
| 2.2     | Hazardous ingredients for labelling:<br>Benzoic acid |  | yes                      |

#### Restructuring: section 9, section 14

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



### Zirconium(IV) oxide ROTI®nanoMETIC 3 nm, hydrophobic

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| Section | Former entry (text/value)                             | Actual entry (text/value)  | Safety-<br>relev-<br>ant |
|---------|---|--|--------------------------|
| 2.2     | contains:<br>Benzoic acid                             |  | yes                      |
| 2.3     | Other hazards:<br>There is no additional information. | Other hazards  | yes                      |
| 2.3     |   | Results of PBT and vPvB assessment:<br>According to the results of its assessment, this<br>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<br>tion intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Ir<br>land Waterways) |
| ADR       | Accord relatif au transport international des marchandises dangereuses par route (Agreement concern<br>ing the International Carriage of Dangerous Goods by Road)   |
| BCF       | Bioconcentration factor   |
| BOD       | Biochemical Oxygen Demand   |
| 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  |
| COD       | Chemical oxygen demand  |
| DGR       | Dangerous Goods Regulations (see IATA/DGR)  |
| DNEL      | Derived No-Effect Level   |
| 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 iden fier of substances commercially available within the EU (European Union)  |
| EH40/2005 | EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-li-<br>cence/)  |
| EINECS    | European Inventory of Existing Commercial Chemical Substances   |
| ELINCS    | European List of Notified Chemical Substances   |
| 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 Na<br>tions   |
| 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   |
| 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  |

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



### Zirconium(IV) oxide ROTI®nanoMETIC 3 nm, hydrophobic

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| Abbr.   | Descriptions of used abbreviations   |  |
|---------|--|--|
| LC50    | Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50<br>lethality during a specified time interval                           |  |
| LD50    | Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during specified time interval   |  |
| log KOW | n-Octanol/water  |  |
| 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-<br>tions concerning the International carriage of Dangerous goods by Rail) |  |
| STEL    | Short-term exposure limit  |  |
| SVHC    | Substance of Very High Concern   |  |
| TWA     | Time-weighted average  |  |
| VOC     | Volatile Organic Compounds   |  |
| vPvB    | Very Persistent and very Bioaccumulative   |  |
| WEL     | Workplace exposure limit   |  |

#### 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.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). 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   |  |
|------|--|--|
| H315 | Causes skin irritation.  |  |
| H318 | Causes serious eye damage.   |  |
| H372 | Causes damage to organs (lung) through prolonged or repeated exposure. |  |

#### Disclaimer

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