

GuttaFlow bioseal

Coltène/Whaledent GmbH & Co. KG

Version No: 2.2

Safety Data Sheet according to the United Nations GHS (Rev. 10, 2023)

Issue Date: 06/03/2023

Print Date: 16/04/2025

L.REACH.GB.EN

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

1.1. Product Identifier

| | |
|-------------------------------|--|
| Product name | GuttaFlow bioseal |
| Chemical Name | Not Applicable |
| Synonyms | Not Available |
| Proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide) |
| Chemical formula | Not Applicable |
| Other means of identification | Not Available |

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

| | |
|--------------------------|--|
| Relevant identified uses | Medical device, for dental use only Use according to manufacturer's directions. |
| Uses advised against | No specific uses advised against are identified. |

1.3. Details of the manufacturer or supplier of the safety data sheet

| | |
|-------------------------|--|
| Registered company name | Coltène/Whaledent GmbH & Co. KG |
| Address | Raiffeisenstrasse 30 89129 Langenau Germany |
| Telephone | +49 (7345) 805 0 |
| Fax | +49 (7345) 805 201 |
| Website | www.coltene.com |
| Email | msds@coltene.com |

1.4. Emergency telephone number


| | |
|-------------------------------------|-------------------------------------|
| Association / Organisation | CHEMWATCH EMERGENCY RESPONSE (24/7) |
| Emergency telephone number(s) | +44 20 3901 3542 (ID#: 9-895869) |
| Other emergency telephone number(s) | +44 808 164 9592 |

SECTION 2 Hazards identification

2.1. Classification of the substance or mixture

| | |
|--|--|
| Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 ^[1] | H411 - Hazardous to the Aquatic Environment Long-Term Hazard Category 2 |
| Legend: | 1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 |

2.2. Label elements

| | |
|---------------------|---|
| Hazard pictogram(s) |  |
|---------------------|---|

| | |
|-------------|----------------|
| Signal word | Not Applicable |
|-------------|----------------|

Hazard statement(s)

| | |
|------|--|
| H411 | Toxic to aquatic life with long lasting effects. |
|------|--|

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

| | |
|------|-----------------------------------|
| P273 | Avoid release to the environment. |
|------|-----------------------------------|

Precautionary statement(s) Response

| | |
|------|-------------------|
| P391 | Collect spillage. |
|------|-------------------|

Precautionary statement(s) Storage

Not Applicable

Precautionary statement(s) Disposal

| | |
|------|--|
| P501 | Dispose of contents/container to authorised hazardous or special waste collection point in accordance with any local regulation. |
|------|--|

Material does not contain any CLP Article 18 substances.

2.3. Other hazards

REACH - Art.57-59: The mixture does not contain Substances of Very High Concern (SVHC) at the SDS print date.

SECTION 3 Composition / information on ingredients

3.1.Substances

See 'Composition on ingredients' in Section 3.2

3.2.Mixtures

| 1. CAS No 2.EC No 3.Index No 4.REACH No | % [weight] | Name | Classified according to GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567 | SCL / M-Factor | Nanoform Particle Characteristics |
|--|---|-----------------------------|--|---|-----------------------------------|
| 1. 1314-13-2 2.215-222-5 3.030-013-00-7 4.Not Available | 10-15 | <u>zinc</u> <u>oxide</u> | Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H400, H410 [2] | SCL: Not Available Acute M factor: 10 Chronic M factor: 1 | Not Available |
| Legend: | 1. Classified by Chemwatch; 2. Classification drawn from GB-CLP Regulation, UK SI 2019/720 and UK SI 2020/1567; 3. Classification drawn from C&L; * EU IOELVs available; [e] Substance identified as having endocrine disrupting properties | | | | |

SECTION 4 First aid measures

4.1. Description of first aid measures

| | |
|--------------|---|
| Eye Contact | If this product comes in contact with eyes: <ul style="list-style-type: none">▶ Wash out immediately with water.▶ If irritation continues, seek medical attention.▶ Removal of contact lenses after an eye injury should only be undertaken by skilled personnel. |
| Skin Contact | If skin or hair contact occurs: <ul style="list-style-type: none">▶ Flush skin and hair with running water (and soap if available).▶ Seek medical attention in event of irritation. |
| Inhalation | <ul style="list-style-type: none">▶ If fumes, aerosols or combustion products are inhaled remove from contaminated area.▶ Other measures are usually unnecessary. |
| Ingestion | <ul style="list-style-type: none">▶ Immediately give a glass of water.▶ First aid is not generally required. If in doubt, contact a Poisons Information Centre or a doctor. |

4.2 Most important symptoms and effects, both acute and delayed

GuttaFlow bioseal

See Section 11

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

Treat symptomatically.

SECTION 5 Firefighting measures

5.1. Extinguishing media

- ▶ Water spray or fog.
- ▶ Foam.
- ▶ Dry chemical powder.
- ▶ BCF (where regulations permit).
- ▶ Carbon dioxide.

5.2. Special hazards arising from the substrate or mixture

| | |
|----------------------|-------------|
| Fire Incompatibility | None known. |
|----------------------|-------------|

5.3. Advice for firefighters

| | |
|-----------------------|--|
| Fire Fighting | |
| Fire/Explosion Hazard | <ul style="list-style-type: none">▶ Non combustible.▶ Not considered a significant fire risk, however containers may burn. Decomposition may produce toxic fumes of: , metal oxides |

SECTION 6 Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

See section 8

6.2. Environmental precautions

See section 12

6.3. Methods and material for containment and cleaning up

| | |
|--------------|---|
| Minor Spills | Environmental hazard - contain spillage. <ul style="list-style-type: none">▶ Clean up all spills immediately.▶ Avoid contact with skin and eyes.▶ Wear impervious gloves and safety goggles.▶ Trowel up/scrape up.▶ Place spilled material in clean, dry, sealed container.▶ Flush spill area with water. |
| Major Spills | Environmental hazard - contain spillage. Minor hazard. <ul style="list-style-type: none">▶ Clear area of personnel.▶ Alert Fire Brigade and tell them location and nature of hazard.▶ Control personal contact with the substance, by using protective equipment as required.▶ Prevent spillage from entering drains or water ways.▶ Contain spill with sand, earth or vermiculite.▶ Collect recoverable product into labelled containers for recycling.▶ Absorb remaining product with sand, earth or vermiculite and place in appropriate containers for disposal.▶ Wash area and prevent runoff into drains or waterways.▶ If contamination of drains or waterways occurs, advise emergency services. |

6.4. Reference to other sections

Personal Protective Equipment advice is contained in Section 8 of the SDS.

SECTION 7 Handling and storage

7.1. Precautions for safe handling

| | |
|---------------|--|
| Safe handling | <ul style="list-style-type: none">▶ Limit all unnecessary personal contact.▶ Wear protective clothing when risk of exposure occurs.▶ Use in a well-ventilated area.▶ Avoid contact with incompatible materials.▶ When handling, DO NOT eat, drink or smoke.▶ Keep containers securely sealed when not in use.▶ Avoid physical damage to containers. |
|---------------|--|

| | |
|-------------------------------|---|
| | <div><div>▶ Always wash hands with soap and water after handling.</div><div>▶ Work clothes should be laundered separately.</div><div>▶ Use good occupational work practice.</div></div> |
| Fire and explosion protection | See section 5 |
| Other information | <div><div>▶ Store in original containers.</div><div>▶ Keep containers securely sealed.</div><div>▶ Store in a cool, dry, well-ventilated area.</div><div>▶ Store away from incompatible materials and foodstuff containers.</div><div>▶ Protect containers against physical damage and check regularly for leaks.</div></div> |

7.2. Conditions for safe storage, including any incompatibilities

| | |
|---|---|
| Suitable container | <div>Recommended storage temperature: 18 - 24 °C</div> <div><div>▶ Packing as recommended by manufacturer.</div><div>▶ Check all containers are clearly labelled and free from leaks.</div></div> |
| Hazard categories in accordance with Regulation (EC) No 2012/18/EU (Seveso III) | E2: Hazardous to the Aquatic Environment in Category Chronic 2 |
| Qualifying quantity (tonnes) of dangerous substances as referred to in Article 3(10) for the application of | E2 Lower- / Upper-tier requirements: 200 / 500 |

7.3. Specific end use(s)

See section 1.2

SECTION 8 Exposure controls / personal protection

8.1. Control parameters

| Ingredient | DNELs Exposure Pattern Worker | PNECs Compartment |
|------------|--|--|
| zinc oxide | Dermal 0.112 mg/kg bw/day (Systemic, Chronic) Inhalation 0.005 mg/m³ (Systemic, Chronic) Inhalation 0.004 mg/m³ (Local, Chronic) Inhalation 2 mg/m³ (Systemic, Acute) <i>Dermal 0.112 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 0.001 mg/m³ (Systemic, Chronic) *</i> <i>Oral 0.001 mg/kg bw/day (Systemic, Chronic) *</i> <i>Inhalation 1 mg/m³ (Systemic, Acute) *</i> | 0.00019 mg/L (Water (Fresh)) 0.0012 mg/L (Water - Intermittent release) 0.00114 mg/L (Water (Marine)) 18 mg/kg sediment dw (Sediment (Fresh Water)) 6.4 mg/kg sediment dw (Sediment (Marine)) 0.7 mg/kg soil dw (Soil) 0.02 mg/L (STP) 0.16 mg/kg food (Oral) |

* Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

| Source | Ingredient | Material name | TWA | STEL | Peak | Notes |
|---------------|---------------|---------------|---------------|---------------|---------------|---------------|
| Not Available | Not Available | Not Available | Not Available | Not Available | Not Available | Not Available |

Not Applicable

| Ingredient | Original IDLH | Revised IDLH |
|------------|---------------|---------------|
| zinc oxide | 500 mg/m3 | Not Available |


MATERIAL DATA

for zinc oxide:

Zinc oxide intoxication (intoxication zincale) is characterised by general depression, shivering, headache, thirst, colic and diarrhoea. Exposure to the fume may produce metal fume fever characterised by chills, muscular pain, nausea and vomiting. Short-term studies with guinea pigs show pulmonary function changes and morphologic evidence of small airway inflammation. A no-observed-adverse-effect level (NOAEL) in guinea pigs was 2.7 mg/m3 zinc oxide. Based on present data, the current TLV-TWA may be inadequate to protect exposed workers although known physiological differences in the guinea pig make it more susceptible to functional impairment of the airways than humans. The concentration of dust, for application of respirable dust limits, is to be determined from the fraction that penetrates a separator whose size collection efficiency is described by a cumulative log-normal function with a median aerodynamic diameter of 4.0 µm (+-) 0.3 µm and with a geometric standard deviation of 1.5 µm (+-) 0.1 µm, i.e..generally less than 5 µm.

8.2. Exposure controls

GuttaFlow bioseal

| <p>8.2.1. Appropriate engineering controls</p> | <p>Engineering controls are used to remove a hazard or place a barrier between the worker and the hazard. Well-designed engineering controls can be highly effective in protecting workers and will typically be independent of worker interactions to provide this high level of protection.</p> <p>The basic types of engineering controls are:</p> <p>Process controls which involve changing the way a job activity or process is done to reduce the risk.</p> <p>Enclosure and/or isolation of emission source which keeps a selected hazard "physically" away from the worker and ventilation that strategically "adds" and "removes" air in the work environment. Ventilation can remove or dilute an air contaminant if designed properly. The design of a ventilation system must match the particular process and chemical or contaminant in use. Employers may need to use multiple types of controls to prevent employee overexposure.</p> <p>General exhaust is adequate under normal operating conditions. If risk of overexposure exists, wear SAA approved respirator. Correct fit is essential to obtain adequate protection. Provide adequate ventilation in warehouse or closed storage areas. Air contaminants generated in the workplace possess varying "escape" velocities which, in turn, determine the "capture velocities" of fresh circulating air required to effectively remove the contaminant.</p> <table border="1"> <thead> <tr> <th>Type of Contaminant:</th><th>Air Speed:</th></tr> </thead> <tbody> <tr> <td>solvent, vapours, degreasing etc., evaporating from tank (in still air)</td><td>0.25-0.5 m/s (50-100 f/min)</td></tr> <tr> <td>aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation)</td><td>0.5-1 m/s (100-200 f/min.)</td></tr> <tr> <td>direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion)</td><td>1-2.5 m/s (200-500 f/min)</td></tr> <tr> <td>grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion).</td><td>2.5-10 m/s (500-2000 f/min.)</td></tr> </tbody> </table> <p>Within each range the appropriate value depends on:</p> <table border="1"> <thead> <tr> <th>Lower end of the range</th><th>Upper end of the range</th></tr> </thead> <tbody> <tr> <td>1: Room air currents minimal or favourable to capture</td><td>1: Disturbing room air currents</td></tr> <tr> <td>2: Contaminants of low toxicity or of nuisance value only</td><td>2: Contaminants of high toxicity</td></tr> <tr> <td>3: Intermittent, low production.</td><td>3: High production, heavy use</td></tr> <tr> <td>4: Large hood or large air mass in motion</td><td>4: Small hood - local control only</td></tr> </tbody> </table> <p>Simple theory shows that air velocity falls rapidly with distance away from the opening of a simple extraction pipe. Velocity generally decreases with the square of distance from the extraction point (in simple cases). Therefore the air speed at the extraction point should be adjusted, accordingly, after reference to distance from the contaminating source. The air velocity at the extraction fan, for example, should be a minimum of 1-2 m/s (200-400 f/min.) for extraction of solvents generated in a tank 2 meters distant from the extraction point. Other mechanical considerations, producing performance deficits within the extraction apparatus, make it essential that theoretical air velocities are multiplied by factors of 10 or more when extraction systems are installed or used.</p> | Type of Contaminant: | Air Speed: | solvent, vapours, degreasing etc., evaporating from tank (in still air) | 0.25-0.5 m/s (50-100 f/min) | aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.) | direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min) | grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). | 2.5-10 m/s (500-2000 f/min.) | Lower end of the range | Upper end of the range | 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents | 2: Contaminants of low toxicity or of nuisance value only | 2: Contaminants of high toxicity | 3: Intermittent, low production. | 3: High production, heavy use | 4: Large hood or large air mass in motion | 4: Small hood - local control only |
|---|---|----------------------|------------|---|-----------------------------|---|----------------------------|--|---------------------------|--|------------------------------|------------------------|------------------------|---|---------------------------------|---|----------------------------------|----------------------------------|-------------------------------|---|------------------------------------|
| Type of Contaminant: | Air Speed: | | | | | | | | | | | | | | | | | | | | |
| solvent, vapours, degreasing etc., evaporating from tank (in still air) | 0.25-0.5 m/s (50-100 f/min) | | | | | | | | | | | | | | | | | | | | |
| aerosols, fumes from pouring operations, intermittent container filling, low speed conveyer transfers, welding, spray drift, plating acid fumes, pickling (released at low velocity into zone of active generation) | 0.5-1 m/s (100-200 f/min.) | | | | | | | | | | | | | | | | | | | | |
| direct spray, spray painting in shallow booths, drum filling, conveyer loading, crusher dusts, gas discharge (active generation into zone of rapid air motion) | 1-2.5 m/s (200-500 f/min) | | | | | | | | | | | | | | | | | | | | |
| grinding, abrasive blasting, tumbling, high speed wheel generated dusts (released at high initial velocity into zone of very high rapid air motion). | 2.5-10 m/s (500-2000 f/min.) | | | | | | | | | | | | | | | | | | | | |
| Lower end of the range | Upper end of the range | | | | | | | | | | | | | | | | | | | | |
| 1: Room air currents minimal or favourable to capture | 1: Disturbing room air currents | | | | | | | | | | | | | | | | | | | | |
| 2: Contaminants of low toxicity or of nuisance value only | 2: Contaminants of high toxicity | | | | | | | | | | | | | | | | | | | | |
| 3: Intermittent, low production. | 3: High production, heavy use | | | | | | | | | | | | | | | | | | | | |
| 4: Large hood or large air mass in motion | 4: Small hood - local control only | | | | | | | | | | | | | | | | | | | | |
| <p>8.2.2. Individual protection measures, such as personal protective equipment</p> |  | | | | | | | | | | | | | | | | | | | | |
| <p>Eye and face protection</p> | <ul style="list-style-type: none"> ▶ Safety glasses with side shields ▶ Chemical goggles. [AS/NZS 1337.1, EN166 or national equivalent] ▶ Contact lenses may pose a special hazard; soft contact lenses may absorb and concentrate irritants. A written policy document, describing the wearing of lenses or restrictions on use, should be created for each workplace or task. This should include a review of lens absorption and adsorption for the class of chemicals in use and an account of injury experience. Medical and first-aid personnel should be trained in their removal and suitable equipment should be readily available. In the event of chemical exposure, begin eye irrigation immediately and remove contact lens as soon as practicable. Lens should be removed at the first signs of eye redness or irritation - lens should be removed in a clean environment only after workers have washed hands thoroughly. [CDC NIOSH Current Intelligence Bulletin 59]. | | | | | | | | | | | | | | | | | | | | |
| <p>Skin protection</p> | <p>See Hand protection below</p> | | | | | | | | | | | | | | | | | | | | |
| <p>Hands/feet protection</p> | <ul style="list-style-type: none"> ▶ Wear general protective gloves, eg. light weight rubber gloves. | | | | | | | | | | | | | | | | | | | | |
| <p>Body protection</p> | <p>See Other protection below</p> | | | | | | | | | | | | | | | | | | | | |
| <p>Other protection</p> | <p>No special equipment needed when handling small quantities.</p> <p>OTHERWISE:</p> <ul style="list-style-type: none"> ▶ Overalls. ▶ Barrier cream. ▶ Eyewash unit. | | | | | | | | | | | | | | | | | | | | |

Type A-P Filter of sufficient capacity. (AS/NZS 1716 & 1715, EN 143:2000 & 149:2001, ANSI Z88 or national equivalent)

8.2.3. Environmental exposure controls

See section 12

SECTION 9 Physical and chemical properties

GuttaFlow bioseal

9.1. Information on basic physical and chemical properties

| | | | |
|---|-----------------|--|---------------|
| Appearance | Not Available | | |
| Physical state | Non Slump Paste | Relative density (Water = 1) | 1.8 - 2.0 |
| Odour | Not Available | Partition coefficient n-octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | Not Available | Decomposition temperature (°C) | Not Available |
| Melting point / freezing point (°C) | Not Available | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | >150 | Molecular weight (g/mol) | Not Available |
| Flash point (°C) | Not Available | Taste | Not Available |
| Evaporation rate | Not Available | Explosive properties | Not Available |
| Flammability | Not Applicable | Oxidising properties | Not Available |
| Upper Explosive Limit (%) | Not Available | Surface Tension (dyn/cm or mN/m) | Not Available |
| Lower Explosive Limit (%) | Not Available | Volatile Component (%vol) | Not Available |
| Vapour pressure (kPa) | Not Available | Gas group | Not Available |
| Solubility in water | Immiscible | pH as a solution (1%) | Not Available |
| Vapour density (Air = 1) | Not Available | VOC g/L | Not Available |
| Heat of Combustion (kJ/g) | Not Available | Ignition Distance (cm) | Not Available |
| Flame Height (cm) | Not Available | Flame Duration (s) | Not Available |
| Enclosed Space Ignition Time Equivalent (s/m3) | Not Available | Enclosed Space Ignition Deflagration Density (g/m3) | Not Available |
| Nanoform Solubility | Not Available | Nanoform Particle Characteristics | Not Available |
| Particle Size | Not Available | | |

9.2. Other information

Not Available

SECTION 10 Stability and reactivity

| | |
|---|-----------------|
| 10.1.Reactivity | See section 7.2 |
| 10.2. Chemical stability | |
| 10.3. Possibility of hazardous reactions | See section 7.2 |
| 10.4. Conditions to avoid | See section 7.2 |
| 10.5. Incompatible materials | See section 7.2 |
| 10.6. Hazardous decomposition products | See section 5.3 |

SECTION 11 Toxicological information

11.1. Information on toxicological effects

| | |
|---|---|
| a) Acute Toxicity | Based on available data, the classification criteria are not met. |
| b) Skin Irritation/Corrosion | Based on available data, the classification criteria are not met. |
| c) Serious Eye Damage/Irritation | Based on available data, the classification criteria are not met. |
| d) Respiratory or Skin sensitisation | Based on available data, the classification criteria are not met. |
| e) Mutagenicity | Based on available data, the classification criteria are not met. |
| f) Carcinogenicity | Based on available data, the classification criteria are not met. |
| g) Reproductivity | Based on available data, the classification criteria are not met. |

GuttaFlow bioseal

| | |
|-----------------------------|---|
| h) STOT - Single Exposure | Based on available data, the classification criteria are not met. |
| i) STOT - Repeated Exposure | Based on available data, the classification criteria are not met. |
| j) Aspiration Hazard | Based on available data, the classification criteria are not met. |

| | | |
|-------------------|---|--|
| GuttaFlow bioseal | TOXICITY | IRRITATION |
| | Not Available | Not Available |
| zinc oxide | TOXICITY | IRRITATION |
| | dermal (rat) LD50: >2000 mg/kg ^[1] | Eye (Rodent - rabbit): 500mg/24H - Mild |
| | Inhalation (Rat) LC50: >1.79 mg/l4h ^[1] | Eye: no adverse effect observed (not irritating) ^[1] |
| | Oral (Rat) LD50: >5000 mg/kg ^[1] | Skin (Human): 300ug/3D (intermittent) - Mild |
| | | Skin (Rodent - rabbit): 500mg/24H - Mild |
| | | Skin: no adverse effect observed (not irritating) ^[1] |
| Legend: | 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from manufacturer's SDS. Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances | |

| | | | |
|-----------------------------------|---|--------------------------|---|
| Acute Toxicity | ✗ | Carcinogenicity | ✗ |
| Skin Irritation/Corrosion | ✗ | Reproductivity | ✗ |
| Serious Eye Damage/Irritation | ✗ | STOT - Single Exposure | ✗ |
| Respiratory or Skin sensitisation | ✗ | STOT - Repeated Exposure | ✗ |
| Mutagenicity | ✗ | Aspiration Hazard | ✗ |

Legend: ✗ – Data either not available or does not fill the criteria for classification
✔ – Data available to make classification

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

11.2.2. Other information

See Section 11.1

SECTION 12 Ecological information

12.1. Toxicity

| | | | | | |
|-------------------|--|--------------------|-------------------------------|---------------|---------------|
| GuttaFlow bioseal | Endpoint | Test Duration (hr) | Species | Value | Source |
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| zinc oxide | Endpoint | Test Duration (hr) | Species | Value | Source |
| | BCF | 1344h | Fish | 19-110 | 7 |
| | EC50 | 48h | Crustacea | 0.105mg/L | 2 |
| | EC50 | 72h | Algae or other aquatic plants | 0.022mg/L | 2 |
| | ErC50 | 72h | Algae or other aquatic plants | 0.62mg/l | 2 |
| | EC50 | 96h | Algae or other aquatic plants | 0.042mg/L | 2 |
| | EC10(ECx) | 168h | Algae or other aquatic plants | 0.003mg/L | 2 |
| | LC50 | 96h | Fish | 0.102mg/L | 2 |
| Legend: | Extracted from 1. IUCLID Toxicity Data 2. Europe ECHA Registered Substances - Ecotoxicological Information - Aquatic Toxicity 4. US EPA, Ecotox database - Aquatic Toxicity Data 5. ECETOC Aquatic Hazard Assessment Data 6. NITE (Japan) - Bioconcentration Data 7. METI (Japan) - Bioconcentration Data 8. Vendor Data | | | | |

Toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

12.2. Persistence and degradability

| Ingredient | Persistence: Water/Soil | Persistence: Air |
|------------|---------------------------------------|---------------------------------------|
| | No Data available for all ingredients | No Data available for all ingredients |

12.3. Bioaccumulative potential

| Ingredient | Bioaccumulation |
|------------|-----------------|
| zinc oxide | LOW (BCF = 217) |

12.4. Mobility in soil

| Ingredient | Mobility |
|------------|---------------------------------------|
| | No Data available for all ingredients |

12.5. Results of PBT and vPvB assessment

| | P | B | T |
|-------------------------|---------------|---------------|---------------|
| Relevant available data | Not Available | Not Available | Not Available |
| PBT | ✗ | ✗ | ✗ |
| vPvB | ✗ | ✗ | ✗ |
| PBT Criteria fulfilled? | No | | |
| vPvB | No | | |

12.6. Endocrine disrupting properties

No evidence of endocrine disrupting properties were found in the current literature.

12.7. Other adverse effects

No evidence of ozone depleting properties were found in the current literature.



SECTION 13 Disposal considerations

13.1. Waste treatment methods

| | |
|------------------------------|--|
| Product / Packaging disposal | Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.) |
| Waste treatment options | Not Available |
| Sewage disposal options | Not Available |

SECTION 14 Transport information

Labels Required

| | |
|------------------|---|
| |  |
| Marine Pollutant |  |
| HAZCHEM | 2Z |

Land transport (ADR-RID)

| | |
|----------------------------------|--|
| 14.1. UN number or ID number | 3077 |
| 14.2. UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide) |
| 14.3. Transport hazard class(es) | Class 9 Subsidiary Hazard Not Applicable |
| 14.4. Packing group | III |
| | Environmentally hazardous |

GuttaFlow bioseal

| | | |
|------------------------------------|--------------------------------|-----------------|
| 14.5. Environmental hazard | | |
| 14.6. Special precautions for user | Hazard identification (Kemler) | 90 |
| | Classification code | M7 |
| | Hazard Label | 9 |
| | Special provisions | 274 335 375 601 |
| | Limited quantity | 5 kg |
| | Transport Category | 3 |
| | Tunnel Restriction Code | Not Applicable |

Air transport (ICAO-IATA / DGR)

| | | |
|------------------------------------|--|-------------------------|
| 14.1. UN number | 3077 | |
| 14.2. UN proper shipping name | Environmentally hazardous substance, solid, n.o.s. (contains zinc oxide) | |
| 14.3. Transport hazard class(es) | ICAO/IATA Class | 9 |
| | ICAO / IATA Subsidiary Hazard | Not Applicable |
| | ERG Code | 9L |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Environmentally hazardous | |
| 14.6. Special precautions for user | Special provisions | A97 A158 A179 A197 A215 |
| | Cargo Only Packing Instructions | 956 |
| | Cargo Only Maximum Qty / Pack | 400 kg |
| | Passenger and Cargo Packing Instructions | 956 |
| | Passenger and Cargo Maximum Qty / Pack | 400 kg |
| | Passenger and Cargo Limited Quantity Packing Instructions | Y956 |
| | Passenger and Cargo Limited Maximum Qty / Pack | 30 kg G |

Sea transport (IMDG-Code / GGVSee)

| | | |
|------------------------------------|--|---------------------|
| 14.1. UN number | 3077 | |
| 14.2. UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide) | |
| 14.3. Transport hazard class(es) | IMDG Class | 9 |
| | IMDG Subsidiary Hazard | Not Applicable |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Marine Pollutant | |
| 14.6. Special precautions for user | EMS Number | F-A , S-F |
| | Special provisions | 274 335 966 967 969 |
| | Limited Quantities | 5 kg |

Inland waterways transport (ADN)

| | | |
|------------------------------------|--|--------------------|
| 14.1. UN number | 3077 | |
| 14.2. UN proper shipping name | ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains zinc oxide) | |
| 14.3. Transport hazard class(es) | 9 | Not Applicable |
| 14.4. Packing group | III | |
| 14.5. Environmental hazard | Environmentally hazardous | |
| 14.6. Special precautions for user | Classification code | M7 |
| | Special provisions | 274; 335; 375; 601 |
| | Limited quantity | 5 kg |
| | Equipment required | PP, A*** |

Fire cones number

0

14.7. Maritime transport in bulk according to IMO instruments

14.7.1. Transport in bulk according to Annex II of MARPOL and the IBC code

Not Applicable

14.7.2. Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

| Product name | Group |
|--------------|---------------|
| zinc oxide | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|--------------|---------------|
| zinc oxide | Not Available |

SECTION 15 Regulatory information

15.1. Safety, health and environmental regulations / legislation specific for the substance or mixture

zinc oxide is found on the following regulatory lists

- Great Britain GB Biocidal Active Substances
- Great Britain GB mandatory classification and labelling list (GB MCL)
- International WHO List of Proposed Occupational Exposure Limit (OEL) Values for Manufactured Nanomaterials (MNMS)

Additional Regulatory Information

Not Applicable

This safety data sheet is in compliance with the following EU legislation and its adaptations - as far as applicable - : Directives 98/24/EC, - 92/85/EEC, - 94/33/EC, - 2008/98/EC, - 2010/75/EU; Commission Regulation (EU) 2020/878; Regulation (EC) No 1272/2008 as updated through ATPs.

Information according to 2012/18/EU (Seveso III):

| Seveso Category | E2 |
|-----------------|----|
|-----------------|----|

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

National Inventory Status

| National Inventory | Status |
|---|---|
| Australia - AIIC / Australia Non-Industrial Use | Yes |
| Canada - DSL | Yes |
| Canada - NDSL | Yes |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | Yes |
| USA - TSCA | All chemical substances in this product have been designated as TSCA Inventory 'Active' |
| Taiwan - TCSI | Yes |
| Mexico - INSQ | Yes |
| Vietnam - NCI | Yes |
| Russia - FBEPH | Yes |
| Legend: | Yes = All CAS declared ingredients are on the inventory No = One or more of the CAS listed ingredients are not on the inventory. These ingredients may be exempt or will require registration. |

SECTION 16 Other information

GuttaFlow bioseal

| | |
|---------------|------------|
| Revision Date | 06/03/2023 |
| Initial Date | 05/01/2022 |

Full text Risk and Hazard codes

| | |
|------|---|
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |

SDS Version Summary

| Version | Date of Update | Sections Updated |
|---------|----------------|---|
| 1.2 | 06/03/2023 | Firefighting measures - Fire Fighter (extinguishing media), Composition / information on ingredients - Ingredients, Stability and reactivity - Instability Condition, Transport Information |

Other information

The SDS is a Hazard Communication tool and should be used to assist in the Risk Assessment. Many factors determine whether the reported Hazards are Risks in the workplace or other settings. Risks may be determined by reference to Exposures Scenarios. Scale of use, frequency of use and current or available engineering controls must be considered.

For detailed advice on Personal Protective Equipment, refer to the following EU CEN Standards:

EN 166 Personal eye-protection

EN 340 Protective clothing

EN 374 Protective gloves against chemicals and micro-organisms

EN 13832 Footwear protecting against chemicals

EN 133 Respiratory protective devices

Definitions and abbreviations

- PC - TWA: Permissible Concentration-Time Weighted Average
- PC - STEL: Permissible Concentration-Short Term Exposure Limit
- IARC: International Agency for Research on Cancer
- ACGIH: American Conference of Governmental Industrial Hygienists
- STEL: Short Term Exposure Limit
- TEEL: Temporary Emergency Exposure Limit,
- IDLH: Immediately Dangerous to Life or Health Concentrations
- ES: Exposure Standard
- OSF: Odour Safety Factor
- NOAEL: No Observed Adverse Effect Level
- LOAEL: Lowest Observed Adverse Effect Level
- TLV: Threshold Limit Value
- LOD: Limit Of Detection
- OTV: Odour Threshold Value
- BCF: BioConcentration Factors
- BEI: Biological Exposure Index
- DNEL: Derived No-Effect Level
- PNEC: Predicted no-effect concentration
- MARPOL: International Convention for the Prevention of Pollution from Ships
- IMSBC: International Maritime Solid Bulk Cargoes Code
- IGC: International Gas Carrier Code
- IBC: International Bulk Chemical Code
- AIIC: Australian Inventory of Industrial Chemicals
- DSL: Domestic Substances List
- NDSL: Non-Domestic Substances List
- IECSC: Inventory of Existing Chemical Substance in China
- EINECS: European INventory of Existing Commercial chemical Substances
- ELINCS: European List of Notified Chemical Substances
- NLP: No-Longer Polymers
- ENCS: Existing and New Chemical Substances Inventory
- KECI: Korea Existing Chemicals Inventory
- NZIoC: New Zealand Inventory of Chemicals
- PICCS: Philippine Inventory of Chemicals and Chemical Substances
- TSCA: Toxic Substances Control Act
- TCSI: Taiwan Chemical Substance Inventory
- INSQ: Inventario Nacional de Sustancias Químicas
- NCI: National Chemical Inventory
- FBEPH: Russian Register of Potentially Hazardous Chemical and Biological Substances

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]

| | |
|---|--------------------------|
| Classification according to regulation (EC) No 1272/2008 [CLP] and amendments | Classification Procedure |
| Hazardous to the Aquatic Environment Long-Term Hazard Category 2, H411 | Calculation method |