

CanalPro™ CHX 2%

Coltène/Whaledent GmbH & Co. KG

Version No: 1.1

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

Issue Date: **12/04/2022**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 | CanalPro™ CHX 2% |
|-------------------------------|------------------|
| Chemical Name | Not Applicable |
| Synonyms | Not Available |
| 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 | Magnum Dental OÜ | |
|-------------------------|---|-------------------------------|--|
| Address | Raiffeisenstrasse 30 89129 Langenau Germany | Aardla 13 Tartu 50112 Estonia | |
| Telephone | +49 (7345) 805 0 | +372 7371647 | |
| Fax | +49 (7345) 805 201 | Not Available | |
| Website | www.coltene.com | Not Available | |
| Email | Email msds@coltene.com dental@magnum.ee | | |

1.4. Emergency telephone number

| Association / Organisation | CHEMWATCH EMERGENCY RESPONSE (24/7) | | |
|-------------------------------------|-------------------------------------|--|--|
| Emergency telephone number(s) | +44 20 3901 3542 (ID#: 9-901942) | | |
| 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 | H319 - Serious Eye Damage/Eye Irritation Category 2, H411 - Hazardous to the Aquatic Environment Long-Term Hazard |
|---|---|
| 2019/720 and UK SI | Category 2 |
| 2020/1567 ^[1] | |
| 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)





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Hazard statement(s)

| H319 | Causes serious eye irritation. | | |
|------|--|--|--|
| H411 | Toxic to aquatic life with long lasting effects. | | |

Supplementary statement(s)

Not Applicable

Precautionary statement(s) Prevention

| P273 | Avoid release to the environment. | | |
|------|--|--|--|
| P280 | Wear protective gloves, protective clothing, eye protection and face protection. | | |
| P264 | Wash all exposed external body areas thoroughly after handling. | | |

Precautionary statement(s) Response

| P305+P351+P338 | IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. | | | |
|----------------|--|--|--|--|
| P337+P313 | If eye irritation persists: Get medical advice/attention. | | | |
| 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 | on. |
|--|-----|
|--|-----|

Material contains chlorhexidine gluconate.

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. 18472-51-0 2.242-354-0 3.Not Available 4.Not Available | 1.7-2.7 | chlorhexidine gluconate | Serious Eye Damage/Eye Irritation Category 1, Hazardous to the Aquatic Environment Acute Hazard Category 1, Hazardous to the Aquatic Environment Long-Term Hazard Category 1; H318, H400, H410 [1] | SCL: Not Available Acute M factor: 100 Chronic M factor: 1 | Not Available |
| Legend: | | • | 2. Classification drawn from GB-CLP Regulation, UK SI 2019 .; * EU IOELVs available; [e] Substance identified as having | | |

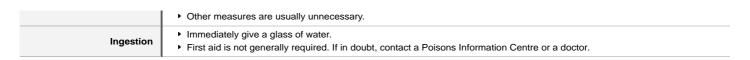
SECTION 4 First aid measures

4.1. Description of first aid measures

| Eye Contact | If this product comes in contact with the eyes: Wash out immediately with fresh running water. Ensure complete irrigation of the eye by keeping eyelids apart and away from eye and moving the eyelids by occasionally lifting the upper and lower lids. Seek medical attention without delay; if pain persists or recurs 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: Flush skin and hair with running water (and soap if available). Seek medical attention in event of irritation. |
| Inhalation | ► If fumes, aerosols or combustion products are inhaled remove from contaminated area. |

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4.2 Most important symptoms and effects, both acute and delayed

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

- ▶ There is no restriction on the type of extinguisher which may be used.
- Use extinguishing media suitable for surrounding area.

Fire Incompatibility None known.

5.2. Special hazards arising from the substrate or mixture

| 5.3. Advice for firefighters | |
|------------------------------|--|
| Fire Fighting | Alert Fire Brigade and tell them location and nature of hazard. Wear breathing apparatus plus protective gloves in the event of a fire. Prevent, by any means available, spillage from entering drains or water courses. Use fire fighting procedures suitable for surrounding area. DO NOT approach containers suspected to be hot. Cool fire exposed containers with water spray from a protected location. If safe to do so, remove containers from path of fire. Equipment should be thoroughly decontaminated after use. |
| Fire/Explosion Hazard | Non combustible. Not considered a significant fire risk, however containers may burn. May emit corrosive fumes. |

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

| Clean up all spills immediately. |
|---|
| Avoid breathing vapours and contact with skin and eyes. |
| Control personal contact with the substance, by using protective equipment. |
| Contain and absorb spill with sand, earth, inert material or vermiculite. |
| ▶ Wipe up. |
| ▶ Place in a suitable, labelled container for waste disposal. |
| Environmental hazard - contain spillage. |
| Moderate hazard. |
| ▶ Clear area of personnel and move upwind. |
| Alert Fire Brigade and tell them location and nature of hazard. |
| Wear breathing apparatus plus protective gloves. |
| Prevent, by any means available, spillage from entering drains or water course. |
| ▶ Stop leak if safe to do so. |
| ► Contain spill with sand, earth or vermiculite. |
| Neutralise/decontaminate residue (see Section 13 for specific agent). |
| Collect solid residues and seal in labelled drums for disposal. |
| Wash area and prevent runoff into drains. |
| ▶ After clean up operations, decontaminate and launder all protective clothing and equipment before storing and re-using. |
| 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

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7.1. Precautions for safe handling

| Titi Toodationo for caro ii | |
|-------------------------------|---|
| Safe handling | Avoid all personal contact, including inhalation. Wear protective clothing when risk of exposure occurs. Use in a well-ventilated area. Avoid contact with moisture. 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. Always wash hands with soap and water after handling. Work clothes should be laundered separately. Launder contaminated clothing before re-use. Use good occupational work practice. |
| Fire and explosion protection | See section 5 |
| Other information | |

7.2. Conditions for safe storage, including any incompatibilities

| Suitable container | Recommended storage temperature: 15 - 25 °C Packing as recommended by manufacturer. |
|---|--|
| Storage incompatibility | None known |
| 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 |
|-------------------------|---|---|
| chlorhexidine gluconate | Dermal 6 mg/kg bw/day (Systemic, Chronic) Inhalation 0.36 mg/m³ (Systemic, Chronic) Dermal 3 mg/kg bw/day (Systemic, Chronic) * Inhalation 0.00009 mg/m³ (Systemic, Chronic) * Oral 0.03 mg/kg bw/day (Systemic, Chronic) * Oral 2 mg/kg bw/day (Systemic, Acute) * | 0.001 mg/L (Water (Fresh)) 0.001 mg/L (Water - Intermittent release) 0 mg/L (Water (Marine)) 0.866 mg/kg sediment dw (Sediment (Fresh Water)) 0.087 mg/kg sediment dw (Sediment (Marine)) 5.26 mg/kg soil dw (Soil) 0.25 mg/L (STP) |

^{*} Values for General Population

Occupational Exposure Limits (OEL)

INGREDIENT DATA

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

Not Applicable

| Ingredient | Original IDLH | Revised IDLH |
|-------------------------|---------------|---------------|
| chlorhexidine gluconate | Not Available | Not Available |

MATERIAL DATA

Sensory irritants are chemicals that produce temporary and undesirable side-effects on the eyes, nose or throat. Historically occupational exposure standards for these irritants have been based on observation of workers' responses to various airborne concentrations. Present day expectations require that nearly every individual should be protected against even minor sensory irritation and exposure standards are established using uncertainty factors or safety factors of 5 to 10 or more. On occasion animal no-observable-effect-levels (NOEL) are used to determine these limits where human results are unavailable. An additional approach. typically used by the TLV committee (USA) in determining respiratory standards for this group of chemicals, has been to assign ceiling values (TLV C) to rapidly acting irritants and to assign short-term exposure limits (TLV STELs) when the weight of evidence from irritation, bioaccumulation and other endpoints combine to warrant such a limit. In contrast the MAK Commission (Germany) uses a five-category system based on intensive odour, local irritation, and elimination half-life.

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However this system is being replaced to be consistent with the European Union (EU) Scientific Committee for Occupational Exposure Limits (SCOEL); this is more closely allied to that of the USA.

OSHA (USA) concluded that exposure to sensory irritants can:

- cause inflammation
- cause increased susceptibility to other irritants and infectious agents
- lead to permanent injury or dysfunction
- permit greater absorption of hazardous substances and
- acclimate the worker to the irritant warning properties of these substances thus increasing the risk of overexposure.

8.2. Exposure controls

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.

The basic types of engineering controls are:

Process controls which involve changing the way a job activity or process is done to reduce the risk.

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.

General exhaust is adequate under normal operating conditions. Local exhaust ventilation may be required in specific circumstances. If risk of overexposure exists, wear 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.

8.2.1. Appropriate engineering controls

| 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.) |

Within each range the appropriate value depends on:

| 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 |

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

8.2.2. Individual protection measures, such as personal protective equipment









Eye and face protection

- 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.

Skin protection

See Hand protection below

Hands/feet protection

- ▶ Wear chemical protective gloves, e.g. PVC.
- Wear safety footwear or safety gumboots, e.g. Rubber

Body protection

See Other protection below

Other protection

- Overalls.
- P.V.C apron. ▶ Barrier cream.
 - Skin cleansing cream.
 - Eye wash unit.

8.2.3. Environmental exposure controls

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See section 12

SECTION 9 Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Appearance | Colourless | | |
|---|----------------|---|---------------|
| | | | |
| Physical state | Liquid | Relative density (Water = 1) | 0.990-1.100 |
| Odour | Not Available | Partition coefficient n- octanol / water | Not Available |
| Odour threshold | Not Available | Auto-ignition temperature (°C) | Not Available |
| pH (as supplied) | 5.0-7.0 | Decomposition temperature (°C) | Not Available |
| Melting point / freezing point (°C) | 0 | Viscosity (cSt) | Not Available |
| Initial boiling point and boiling range (°C) | 100 | 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 | Miscible | 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 | Unstable in the presence of incompatible materials. Product is considered stable. Hazardous polymerisation will not occur. |
| 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

| 11.1. Illiorination on toxico | nogical 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 | There is sufficient evidence to classify this material as eye damaging or irritating |

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| d) Respiratory or Skin sensitisation 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. 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. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Inhaled Ingestion | | | | |
|---|---|--|--|--|
| f) Carcinogenicity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. | | | | |
| g) Reproductivity Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. i) STOT - Repeated Exposure Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. | Based on available data, the classification criteria are not met. | | | |
| h) STOT - Single Exposure i) STOT - Repeated Exposure Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Inhaled | Based on available data, the classification criteria are not met. | | | |
| i) STOT - Repeated Exposure Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. Inhaled | Based on available data, the classification criteria are not met. | | | |
| Exposure j) Aspiration Hazard Based on available data, the classification criteria are not met. Based on available data, the classification criteria are not met. | Based on available data, the classification criteria are not met. | | | |
| Inhaled | Based on available data, the classification criteria are not met. | | | |
| | | | | |
| | | | | |
| Ingestion | | | | |
| | | | | |
| Skin Contact | | | | |
| Eye | | | | |
| Chronic | | | | |
| TOXICITY IRRITATION | | | | |
| CanalPro™ CHX 2% Not Available Not Available | | | | |
| TOXICITY IRRITATION | | | | |
| Intravenous (rat) LD50: 24.2 mg/kg ^[2] Eye: adverse effect observed (irreverse) | sible damage) ^[1] | | | |
| Chlorhexidine gluconate Oral (Rat) LD50: 2000 mg/kg ^[2] Skin (Human - child): 0.5%/2D | | | | |
| Subcutaneous (rat) LD50: 3320 mg/kg ^[2] Skin: no adverse effect observed (not | | | | |
| Legend: 1. Value obtained from Europe ECHA Registered Substances - Acute toxicity 2. Value obtained from ma | : irritating) ^[1] | | | |

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

Unless otherwise specified data extracted from RTECS - Register of Toxic Effect of chemical Substances

Legend: ★ - Data either not available or does not fill the criteria for 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

| 12.11. Toxicity | | | | | |
|-------------------------|------------------|--------------------|-------------------------------|------------------|------------------|
| CanalPro™ CHX 2% | Endpoint | Test Duration (hr) | Species | Value | Source |
| | Not Available | Not Available | Not Available | Not Available | Not Available |
| | Endpoint | Test Duration (hr) | Species | Value | Source |
| | EC50 | 48h | Crustacea | 0.045mg/L | 2 |
| chlorhexidine gluconate | EC50 | 72h | Algae or other aquatic plants | 0.01mg/l | 2 |
| | EC10(ECx) | 72h | Algae or other aquatic plants | 0.003mg/l | 2 |
| | LC50 | 96h | Fish | 0.804mg/L | 2 |
| | | | | | |

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

12.4. Mobility in soil

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

12.5. Results of PBT and vPvB assessment

| | P | В | Т |
|-------------------------|---------------|---------------|---------------|
| 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



HAZCHEM

Not Applicable

Land transport (ADR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number or ID number | Not Applicable | | |
|----------------------------------|----------------|----------------|--|
| 14.2. UN proper shipping name | Not Applicable | | |
| 14.3. Transport hazard class(es) | Class | Not Applicable | |

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| | Subsidiary Hazard Not Appli | cable | |
|------------------------------------|--------------------------------|----------------|--|
| 14.4. Packing group | Not Applicable | | |
| 14.5. Environmental hazard | Not Applicable | | |
| | Hazard identification (Kemler) | Not Applicable | |
| | Classification code | Not Applicable | |
| | Hazard Label | Not Applicable | |
| 14.6. Special precautions for user | Special provisions | Not Applicable | |
| 101 4001 | Limited quantity | Not Applicable | |
| | Transport Category | Not Applicable | |
| | Tunnel Restriction Code | Not Applicable | |

Air transport (ICAO-IATA / DGR): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number | Not Applicable | | | |
|------------------------------------|---|--|----------------|--|
| 14.2. UN proper shipping name | Not Applicable | | | |
| | ICAO/IATA Class | Not Applicable | | |
| 14.3. Transport hazard class(es) | ICAO / IATA Subsidiary Hazard | Not Applicable | | |
| 01400(00) | ERG Code | Not Applicable | | |
| 14.4. Packing group | Not Applicable | Not Applicable | | |
| 14.5. Environmental hazard | Not Applicable | | | |
| | Special provisions | | Not Applicable | |
| | Cargo Only Packing Instructions | | Not Applicable | |
| | Cargo Only Maximum Qty / Pack | | Not Applicable | |
| 14.6. Special precautions for user | Passenger and Cargo Packing In | Passenger and Cargo Packing Instructions | | |
| | Passenger and Cargo Maximum Qty / Pack | | Not Applicable | |
| | Passenger and Cargo Limited Quantity Packing Instructions | | Net Applicable | |
| | Passenger and Cargo Limited Qu | uantity Packing Instructions | Not Applicable | |

Sea transport (IMDG-Code / GGVSee): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number | Not Applicable | | |
|------------------------------------|---------------------|---------------------------------------|--|
| 14.2. UN proper shipping name | Not Applicable | Not Applicable | |
| 14.3. Transport hazard | IMDG Class | Not Applicable | |
| class(es) | IMDG Subsidiary Haz | IMDG Subsidiary Hazard Not Applicable | |
| 14.4. Packing group | Not Applicable | | |
| 14.5 Environmental hazard | Not Applicable | | |
| | EMS Number | Not Applicable | |
| 14.6. Special precautions for user | Special provisions | Not Applicable | |
| | Limited Quantities | Not Applicable | |
| | | | |

Inland waterways transport (ADN): NOT REGULATED FOR TRANSPORT OF DANGEROUS GOODS

| 14.1. UN number | Not Applicable |
|------------------------------------|------------------------------------|
| 14.2. UN proper shipping name | Not Applicable |
| 14.3. Transport hazard class(es) | Not Applicable Not Applicable |
| 14.4. Packing group | Not Applicable |
| 14.5. Environmental hazard | Not Applicable |
| 14.6. Special precautions for user | Classification code Not Applicable |

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| Special provisions | Not Applicable |
|--------------------|----------------|
| Limited quantity | Not Applicable |
| Equipment required | Not Applicable |
| Fire cones number | Not Applicable |

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 |
|-------------------------|---------------|
| chlorhexidine gluconate | Not Available |

14.7.3. Transport in bulk in accordance with the IGC Code

| Product name | Ship Type |
|-------------------------|---------------|
| chlorhexidine gluconate | Not Available |

SECTION 15 Regulatory information

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

chlorhexidine gluconate is found on the following regulatory lists

Great Britain GB Biocidal Active Substances

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 | No (chlorhexidine gluconate) |
| China - IECSC | Yes |
| Europe - EINEC / ELINCS / NLP | Yes |
| Japan - ENCS | Yes |
| Korea - KECI | Yes |
| New Zealand - NZIoC | Yes |
| Philippines - PICCS | No (chlorhexidine gluconate) |
| 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. |

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SECTION 16 Other information

| Revision Date | 12/04/2022 |
|---------------|------------|
| Initial Date | 14/02/2022 |

Full text Risk and Hazard codes

| H318 | Causes serious eye damage. |
|------|---|
| H400 | Very toxic to aquatic life. |
| H410 | Very toxic to aquatic life with long lasting effects. |

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

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