according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
Product name: Take 1 Advanced Bite Registration - Base

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

Relevant identified uses
Main use category: Professional use
Use of the substance/mixture: Preparation intended for dental medical use

Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier: KERRHAWE S.A.
Via Strecce n°4
6934 Bioggio (Switzerland)
T +41916100505

Manufacturer: Kerr Corporation
1717 West Collins Avenue
92867 Orange – CALIFORNIA (U.S.A.)
T +41916100505

Contact person : safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number

Emergency number: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

Country | Organisation/Company | Address | Emergency number |
---|---|---|---|
Gibraltar | GHA Call Centre Zone 2, Level3, St Bernard’s Hospital | Harbour Views Road | +350 200 79700 +350 200 72266 |
Ireland | National Poisons Information Centre Beaumont Hospital | PO Box 1297 Beaumont Road 9 Dublin | +353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7) |
Malta | Medicines & Poisons Info Office | Mater Dei Hospital MSD Msida | +356 2545 6504 |
United Kingdom | National Poisons Information Service (Newcastle Unit) | Claremont Place Newcastle-upon-Tyne, Newcastle | +44 191 2606182/+44 191 2606190 24H |

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]
STOT RE 2 H373

Full text of H statements : see section 16

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP): 

Signal word (CLP): Warning

Hazardous ingredients: Quartz (SiO2)
Hazard statements (CLP): H373 - May cause damage to organs through prolonged or repeated exposure.

Precautionary statements (CLP): P260 - Do not breathe dust. P314 - Get medical advice/attention if you feel unwell. P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Extra phrases: The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

2.3. Other hazards
Other hazards not contributing to the classification: None under normal conditions.

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII
This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances
Not applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quartz (SiO2)</td>
<td>(CAS-No.) 14808-60-7 (EC-No.) 238-878-4 (REACH-no) N/A</td>
<td>&lt; 100</td>
<td>STOT RE 2, H373</td>
</tr>
<tr>
<td>Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica substance with a Community workplace exposure limit substance with national workplace exposure limit(s) (GB, IE)</td>
<td>(CAS-No.) 68909-20-6 (EC-No.) 272-697-1 (REACH-no) n/a</td>
<td>&lt; 50</td>
<td>Not classified</td>
</tr>
</tbody>
</table>

Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

First-aid measures general: If medical advice is needed, have product container or label at hand. Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation: Assure fresh air breathing. Allow the victim to rest. Get medical advice/attention if you feel unwell.

First-aid measures after skin contact: Gently wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

First-aid measures after eye contact: Rinse immediately with plenty of water. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion: If swallowed, rinse mouth with water (only if the person is conscious). Call a POISON CENTER/doctor if you feel unwell. Do NOT induce vomiting.

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

Symptoms/effects: In all cases of doubt, or when symptoms persist, seek medical attention. Causes damage to organs (lungs) (Inhalation).

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

No specific measures identified.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media


Unsuitable extinguishing media: Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard: Non flammable.

Explosion hazard: Product is not explosive.

Hazardous decomposition products in case of fire: Carbon dioxide. Carbon monoxide. fume.
5.3. Advice for firefighters

Firefighting instructions: Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.

Protection during firefighting: Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

General measures: Ensure adequate ventilation, especially in confined areas. Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8.

For non-emergency personnel

Protective equipment: See Heading 8.

Emergency procedures: Evacuate unnecessary personnel.

For emergency responders

Emergency procedures: Ventilate area.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up: Sweep or shovel into suitable containers. Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections

For further information refer to section 13. See Heading 8. Exposure controls and personal protection.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Precautions for safe handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing dust.

7.2. Conditions for safe storage, including any incompatibilities


Incompatible products: Strong oxidizers.

Incompatible materials: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)

No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

<table>
<thead>
<tr>
<th>Silanamine, 1,1,1-trimethyl-N-(trimethylsilyl)-, hydrolysis products with silica (68909-20-6)</th>
<th>EU</th>
<th>Local name</th>
<th>Respirable crystalline silica dust</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>IOELV TWA (mg/m³)</td>
<td>0.1 mg/m³ Respirable fraction</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>Local name</td>
<td>Silica, amorphous respirable dust</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>OEL (8 hours ref) (mg/m³)</td>
<td>2.4 mg/m³</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Local name</td>
<td>Silica, amorphous</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL TWA (mg/m³)</td>
<td>2.4 mg/m³ respirable dust 6 mg/m³ inhalable dust</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quartz (SiO2) (14808-60-7)</th>
<th>EU</th>
<th>Local name</th>
<th>Silica crystaline (Quartz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU</td>
<td>Notes</td>
<td>(Year of adoption 2003)</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>Local name</td>
<td>Quartz, respirable dust, (see Silica, crystalline)</td>
<td></td>
</tr>
<tr>
<td>Ireland</td>
<td>OEL (8 hours ref) (mg/m³)</td>
<td>0.1 mg/m³</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>Local name</td>
<td>Silica</td>
<td></td>
</tr>
<tr>
<td>United Kingdom</td>
<td>WEL TWA (mg/m³)</td>
<td>0.1 mg/m³ respirable crystalline</td>
<td></td>
</tr>
</tbody>
</table>

8.2. Exposure controls

Appropriate engineering controls: Ensure good ventilation of the work station. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.
Personal protective equipment: Gloves. Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Avoid all unnecessary exposure.


Eye protection: Not required

Skin and body protection: Not required

Respiratory protection: Not required. Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Extra personal protection: P2 filter respirator for harmful particles. Standard EN 143.

Other information: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Appearance: Paste.
Colour: Various.
Odour: slight, Fruity.
Odour threshold: Not determined
pH: Not determined
Relative evaporation rate (butylacetate=1): Not determined
Melting point: Not determined
Freezing point: Not determined
Boiling point: Not determined
Flash point: Not determined
Auto-ignition temperature: Not determined
Decomposition temperature: Not determined
Flammability (solid, gas): Not applicable, Non flammable.
Vapour pressure: Not determined
Relative vapour density at 20 °C: Not determined
Relative density: ≈ 1.25
Solubility: Insoluble in water.
Log Pow: Not determined
Viscosity, kinematic: Not determined
Viscosity, dynamic: Not determined
Explosive properties: Product is not explosive.
Oxidising properties: Non flammable.
Explosive limits: Not determined

9.2. Other information

No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
None to our knowledge.

10.2. Chemical stability
Stable under normal conditions.

10.3. Possibility of hazardous reactions
No polymerization.

10.4. Conditions to avoid
Direct sunlight. Extremely high or low temperatures.
10.5. Incompatible materials
oxidizing materials.

10.6. Hazardous decomposition products
No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Classification</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Skin corrosion/irritation</td>
<td>Not classified</td>
<td>Repeated exposure may cause skin dryness or cracking. Based on available data, the classification criteria are not met pH: Not determined</td>
</tr>
<tr>
<td>Serious eye damage/irritation</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met      pH: Not determined</td>
</tr>
<tr>
<td>Respiratory or skin sensitisation</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Germ cell mutagenicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>STOT-single exposure</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>STOT-repeated exposure</td>
<td>May cause damage to organs through prolonged or repeated exposure.</td>
<td></td>
</tr>
<tr>
<td>Aspiration hazard</td>
<td>Not classified</td>
<td>Based on available data, the classification criteria are not met</td>
</tr>
<tr>
<td>Potential adverse human health effects and symptoms</td>
<td>Based on available data, the classification criteria are not met</td>
<td></td>
</tr>
</tbody>
</table>

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity
No additional information available

12.2. Persistence and degradability

<table>
<thead>
<tr>
<th>Effect</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistence and degradability</td>
<td>Not established.</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

<table>
<thead>
<tr>
<th>Effect</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Log Pow</td>
<td>Not determined</td>
</tr>
<tr>
<td>Bioaccumulative potential</td>
<td>Not established.</td>
</tr>
</tbody>
</table>

12.4. Mobility in soil

<table>
<thead>
<tr>
<th>Effect</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ecology - soil</td>
<td>Insoluble in water.</td>
</tr>
</tbody>
</table>

12.5. Results of PBT and vPvB assessment

<table>
<thead>
<tr>
<th>Effect</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII</td>
<td></td>
</tr>
<tr>
<td>This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII</td>
<td></td>
</tr>
</tbody>
</table>

12.6. Other adverse effects

<table>
<thead>
<tr>
<th>Effect</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other adverse effects</td>
<td>None to our knowledge.</td>
</tr>
<tr>
<td>Additional information</td>
<td>Avoid release to the environment.</td>
</tr>
</tbody>
</table>
SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods
Regional legislation (waste) : Dispose of contents/container in accordance with licensed collector’s sorting instructions.
Waste treatment methods : Do not discharge into drains.
Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
Ecology - waste materials : Avoid release to the environment.
European List of Waste (LoW) code : 18 01 07 - chemicals other than those mentioned in 18 01 06

SECTION 14: TRANSPORT INFORMATION

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number
Not regulated for transport

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards
No supplementary information available

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code
Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
EU-Regulations
Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

National regulations

15.2. Chemical safety assessment
No chemical safety assessment has been carried out

SECTION 16: OTHER INFORMATION

Other information : None.
Date of issue : 30/03/2018
Revision date : 30/03/2018
Date of total revision : 30/03/2018
Version : 1.0
Signature : A. Åsebø Murel

Full text of H- and EUH-statements:
STOT RE 2 Specific target organ toxicity — Repeated exposure, Category 2
H373 May cause damage to organs through prolonged or repeated exposure.
The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.