## SAFETY DATA SHEET

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

A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information under Article 32.
1.1 Product identifier

- Product Name: Wipe Away Adhesive Remover Wipes/ Salts Adhesive Remover
- Product Part Number: WA1
- Product Description: Non-woven swab containing 2 mL solvent sealed in a sachet
1.2 Relevant identified uses of the substance or mixture and uses advised against
- Use of the substance/mixture: Adhesive remover
- Use advised against: No information available
1.3 Details of the supplier of the safety data sheet
- Name of Supplier: Salts Healthcare UK
- Address of Supplier: Richard Street

Aston, Birmingham B7 4AA
United Kingdom

- Telephone: $\quad$ +44 (0) 1213332000
- Fax: $\quad+44$ (0) 1463240950
- Email: hello@salts.co.uk
1.4 Emergency telephone number
- +44(0) 1213332000


## SECTION 2: Hazards identification

Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
2.1 Classification of the substance or mixture

- Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]: Flam. Liq. 3, H226; Asp. Tox. 1, H304; Aquatic Chronic 4, H413; EUH066
- Additional information: For full text of Hazard- and EU Hazard-statements: see section 16


### 2.2 Label elements

- Exempt from labelling requirements under CLP
- This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)
2.3 Other hazards
- Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
- Not a PBT according to REACH Annex XIII
- Not a vPvB according to REACH Annex XIII
- Does not contain any substances with endocrine disrupting properties


## SECTION 3: Composition/information on ingredients

3.1 Substances

- Not applicable
3.2 Mixtures

Revision: 28 November 2022

## SECTION 3: Composition/information on ingredients (....)

- Contains the following hazardous ingredients or ingredients with a workplace exposure limit:

| Chemical Name | Conc. | CAS No. | EC No. | Classification <br> (REGULATION <br> (EC) No <br> 1272/2008) <br> [CLP/GHS] | SCL/ <br> M-Factor/ <br> ATE | REACH <br> Registration <br> Number | WEL/ <br> OEL |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | $50-70 \%$ | - | $918-167-1$ | Flam. Liq. 3, H226 <br> Asp. Tox. 1,H304 <br> Aquatic Chronic 4, <br> H413 <br> EUH066 | M factor <br> (Chronic) <br> $=0$ | - | Yes |
| White mineral oil <br> (petroleum) | $1-10 \%$ | $8042-47-5$ | $232-455-8$ | Not classified | - | - | None |

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

- Rescuers should put on approved personal protective equipment (PPE) before administering first aid

Contact with eyes
If substance has got into eyes, immediately wash out with plenty of water for several minutes Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

## Contact with skin

No hazard expected under normal conditions of use
If skin irritation or rash occurs: wash with plenty of soap and water

## Ingestion

Give plenty of water to drink
Do not induce vomiting because of risk of aspiration into the lungs. If aspiration is suspected obtain immediate medical attention
If vomiting occurs turn patient on side
Get immediate medical advice/attention.

## Inhalation

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.
Keep warm and at rest, in a half upright position. Loosen clothing
Obtain immediate medical attention
4.2 Most important symptoms and effects, both acute and delayed

Contact with eyes
May cause redness and irritation
Contact with skin
Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
Repeated exposure may cause skin dryness or cracking
Ingestion
The ingestion of significant quantities may cause chronic pneumonitis
May cause dizziness, confusion, headache or stupor
May cause gastro-intestinal disturbances
May cause nausea/vomiting
Inhalation

## SECTION 4: First aid measures (....)

Inhalation of solvent vapours may give rise to nausea, headaches and dizziness May cause respiratory irritation May cause shortness of breath
4.3 Indication of any immediate medical attention and special treatment needed

- Treat symptomatically


## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

- Suitable extinguishing media: Sand/earth; water spray; water fog; alcohol resistant foam; dry powder; carbon dioxide
- Unsuitable extinguishing media: High volume water jet
5.2 Special hazards arising from the substance or mixture
- Flammable liquid and vapour.
- Vapours may ignite
- In confined spaces, sewers, etc., the vapours may collect to form explosive mixtures with air
- Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback
- Gives off irritating or toxic fumes (or gases) in a fire.
- Decomposition products may include carbon oxides


### 5.3 Advice for firefighters

- Shut off all ignition sources
- Collect contaminated fire extinguishing water separately. This MUST not be discharged into drains. Prevent fire extinguishing water from contaminating surface or ground water.
- Wear chemical protection suit and positive-pressure breathing apparatus


## SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

- No action shall be taken involving any personal risk or without suitable training
- Only trained and authorised personnel should carry out emergency response
- Personal precautions for non-emergency personnel: Avoid contact with eyes; Avoid breathing vapours, mist or gas; Wear protective clothing as per section 8 ; Wash thoroughly after handling.
- Personal precautions for emergency responders: Evacuate the area and keep personnel upwind; Shut off all ignition sources; Wear chemical protection suit; Wear self-contained breathing apparatus (SCBA); Ventilate the area and wash spill site after material pick-up is complete; Wash thoroughly after dealing with spillage


### 6.2 Environmental precautions

- Do not allow to enter public sewers and watercourses
- Avoid release to the environment.
6.3 Methods and material for containment and cleaning up
- Small spills

Wipe up spillage with damp absorbent cloth or towel

- Large spills

Shut off all ignition sources
Use non-sparking tools.
Absorb spillage in earth or sand
Place in appropriate container
Remove contaminated material to safe location for subsequent disposal
Ventilate the area and wash spill site after material pick-up is complete

## SECTION 6: Accidental release measures (....)

Seek expert advice for removal and disposal of all contaminated materials and wastes
6.4 Reference to other sections

- See section(s): 7, 8 \& 13


## SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Ensure adequate ventilation
- Avoid breathing vapours, mist or gas
- Keep away from oxidisers, heat, flames or ignition sources
- Do not eat, drink or smoke when using this product.
- Avoid contact with eyes
7.2 Conditions for safe storage, including any incompatibilities
- Keep locked up and out of reach of children
- Keep only in original packaging.
- Keep in a cool, dry, well ventilated place
- Keep in highly flammable materials store
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Take action to prevent static discharges.
- Equipment should be earthed
- Incompatible with strong oxidising agents, strong acids


### 7.3 Specific end use(s)

- Adhesive remover


## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

- If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.
Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace exposure - Measurement of exposure by inhalation to chemical agents - Strategy for testing compliance with occupational exposure limit values). European Standard EN 14042 (Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents). European Standard EN 482 (Workplace exposure. General requirements for the performance of procedures for the measurement of chemical agents). Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

Hydrocarbons, C11-C12, isoalkanes, $<2 \%$ aromatics
WEL (long term) $1200 \mathrm{mg} / \mathrm{m}^{3}$ (Supplier, reciprocal calculation procedure - RCP)
WEL (short term) 177 ppm (Supplier, reciprocal calculation procedure - RCP)
White mineral oil (petroleum)
DNEL (inhalational) $164.56 \mathrm{mg} / \mathrm{m}^{3}$ Industry, Long Term, Systemic Effects
DNEL (dermal) $217.05 \mathrm{mg} / \mathrm{kg}$ bw/day Industry, Long Term, Systemic Effects
DNEL (inhalational) $34.78 \mathrm{mg} / \mathrm{m}^{3}$ Consumer, Long Term, Systemic Effects
DNEL (dermal) $93.02 \mathrm{mg} / \mathrm{kg}$ bw/day Consumer, Long Term, Systemic Effects
DNEL (oral) $25 \mathrm{mg} / \mathrm{kg}$ bw/day Consumer, Long Term, Systemic Effects
8.2 Exposure controls

- Selection and use of personal protective equipment should be based on a risk assessment of exposure potential


## SECTION 8: Exposure controls/personal protection (....)

- Engineering controls

Ensure adequate ventilation

- Respiratory protection

No respiratory protection is needed during normal handling
Respiratory protection may be required under exceptional circumstances when excessive air contamination exists and the OEL/WEL limits are exceeded

- Skin protection

None required for normal handling of product

- Eye/face protection

None required for normal handling of product

- Thermal hazards Not applicable
- Hygiene measures Use good personal hygiene practices Do not eat, drink or smoke when using this product. Wash thoroughly after handling.
- Environmental exposure controls Do not empty into drains Do not allow to penetrate the ground/soil.


## SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

- Physical state: Non-woven swab containing solvent sealed in a sachet
- Colour: No information available
- Odour: Lavender
- Melting point/freezing point: No information available
- Boiling point or initial boiling point and boiling range: 179-191 ${ }^{\circ} \mathrm{C} @ 101.325 \mathrm{kPa}$ (Hydrocarbons, C11-C12, isoalkanes, <2\% aromatics)
- Flammability: Flammable liquid and vapour.
- Lower and upper explosion limit: No data available
- Flash point: $\quad 59^{\circ} \mathrm{C}$ @ 101.325 kPa (Hydrocarbons, C11-C12, isoalkanes, <2\% aromatics)
- Auto-ignition temperature: $\quad 200^{\circ} \mathrm{C} @ 101.325 \mathrm{kPa}$ (Hydrocarbons, C11-C12, isoalkanes, $<2 \%$ aromatics)
- Decomposition temperature:

Not determined

- pH :

Not applicable

- Kinematic viscosity: $\quad 1.57 \mathrm{~mm}^{2} / \mathrm{s}$ (Hydrocarbons, C11-C12, isoalkanes, $<2 \%$ aromatics)
- Solubility: Insoluble in water
- Partition coefficient n-octanol/water (log value): 1.99-6.73 @ $20^{\circ} \mathrm{C}$ and pH 7 (Hydrocarbons, C11C12, isoalkanes, <2\% aromatics)
- Vapour Pressure: $\quad 70 \mathrm{~Pa} @ 20^{\circ} \mathrm{C}$ (Hydrocarbons, C11-C12, isoalkanes, $<2 \%$ aromatics)
- Density and/or relative density: $0.76 \mathrm{~g} / \mathrm{cm}^{3} @ 15^{\circ} \mathrm{C}$ (Hydrocarbons, C11-C12, isoalkanes, $<2 \%$ aromatics)
- Relative vapour density:

No data available

- Particle characteristics:

Not applicable
9.2 Other information

## SECTION 9: Physical and chemical properties (....)

- Volatile Organic Compounds (VOC): No information available


## SECTION 10: Stability and reactivity

### 10.1 Reactivity

- No information available
10.2 Chemical stability
- Considered stable under normal conditions
10.3 Possibility of hazardous reactions
- May form explosive vapour/air mixtures
- Vapours are heavier than air and may travel considerable distances to a source of ignition and flashback
10.4 Conditions to avoid
- Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- Keep away from static electricity
10.5 Incompatible materials
- Incompatible with strong oxidising agents, strong acids
10.6 Hazardous decomposition products
- Decomposition products may include carbon oxides


## SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

- Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices
- Acute Toxicity

Based on available data, the classification criteria are not met
Substances

| Chemical Name | LD $_{50}$ <br> (oral, rat) | LC $_{50}$ <br> (inhalation, rat) | LD $_{50}$ <br> (dermal, rabbit) |
| :--- | :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | $5000-15000 \mathrm{mg} / \mathrm{kg}$ | $(4 \mathrm{~h}) 4.951-9.3 \mathrm{mg} / \mathrm{L}$ | $2200-2500 \mathrm{mg} / \mathrm{kg}$ |
| White mineral oil <br> (petroleum) | $5000 \mathrm{mg} / \mathrm{kg}$ | $(4 \mathrm{~h}) 5 \mathrm{mg} / \mathrm{L}$ | $2000 \mathrm{mg} / \mathrm{kg}$ |

- Skin corrosion/irritation

Based on available data, the classification criteria are not met
Substances

| Chemical Name | Irritation/corrosion |
| :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | Adverse effect observed (irritating) |
| White mineral oil <br> (petroleum) | No adverse effect observed (not irritating) |

- Serious eye damage/irritation

Based on available data, the classification criteria are not met

## SECTION 11: Toxicological information (....)

# Substances 

| Chemical Name | Irritation/corrosion |
| :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | No adverse effect observed (not irritating) |
| White mineral oil <br> (petroleum) | No adverse effect observed (not irritating) |

- Respiratory or skin sensitisation

Based on available data, the classification criteria are not met
Substances

| Chemical Name | Skin sensitisation | Respiratory <br> sensitisation |
| :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | No adverse effect observed (not sensitising) | No study available |
| White mineral oil <br> (petroleum) | No adverse effect observed (not sensitising) | No data available |

- Germ cell mutagenicity

No evidence of mutagenic effects
Substances

| Chemical Name | Toxicity - In Vitro | Toxicity - In Vivo |
| :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | No adverse effect observed (negative) | No adverse effect observed (negative) |
| White mineral oil <br> (petroleum) | No data available | No data available |

- Carcinogenicity

Based on available data, the classification criteria are not met
Substances

| Chemical Name | NOAEL <br> (oral, rat) | NOAEC <br> (inhalation, rat) | NOAEL <br> (dermal, rat) |
| :--- | :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | No data available | No data available | No data available |
| White mineral oil <br> (petroleum) | $1200 \mathrm{mg} / \mathrm{kg}$ bw/day | No data available | No data available |

- Reproductive toxicity

Based on available data, the classification criteria are not met
Substances

| Chemical Name | NOAEL <br> (oral, rat) | NOAEC <br> (inhalation, rat) | NOAEL <br> (dermal, rat) |
| :--- | :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | No data available | No data available | No data available |
| White mineral oil <br> (petroleum) | $1000 \mathrm{mg} / \mathrm{kg}$ bw/day <br> (Effect on fertility) | No data available | No data available |

- Specific target organ toxicity (STOT) - single exposure Based on available data, the classification criteria are not met

Substances

| Chemical Name | Route | Remarks |
| :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | Respiratory | No study available |

## SECTION 11: Toxicological information (....)

| White mineral oil <br> (petroleum) | Respiratory | No study available |
| :--- | :--- | :--- |

- Specific target organ toxicity (STOT) - repeated exposure Based on available data, the classification criteria are not met

| Substances |  |  |  |
| :--- | :--- | :--- | :--- |
| Chemical Name | NOAEL <br> (oral,rat) | NOAEL <br> (inhalation, <br> rat) | NOAEL <br> (dermal, rat) |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | $1000 \mathrm{mg} / \mathrm{kg}$ bw/day | $10400 \mathrm{mg} / \mathrm{m}^{3}$ | No data available |
| White mineral oil <br> (petroleum) | $1200 \mathrm{mg} / \mathrm{kg}$ bw/day | $50 \mathrm{mg} / \mathrm{m}^{3}$ | $125-2000 \mathrm{mg} / \mathrm{kg}$ bw/day |

- Aspiration hazard May be fatal if swallowed and enters airways. Classification based on calculation and concentration thresholds
- Contact with eyes May cause redness and irritation
- Contact with skin

Prolonged skin contact will result in defatting of the skin, leading to irritation, and in some cases, dermatitis
Repeated exposure may cause skin dryness or cracking.

- Ingestion

The ingestion of significant quantities may cause chronic pneumonitis
May cause dizziness, confusion, headache or stupor
May cause gastro-intestinal disturbances
May cause nausea/vomiting

- Inhalation

Inhalation of solvent vapours may give rise to nausea, headaches and dizziness
May cause respiratory irritation.
May cause shortness of breath
11.2 Information on other hazards

- Does not contain any substances with endocrine disrupting properties


## SECTION 12: Ecological information

### 12.1 Toxicity

- May cause long lasting harmful effects to aquatic life.
- Classification based on calculation and concentration thresholds

Substances

| Chemical Name | LC $_{50}$ (fish) | EC $_{50}$ (aquatic <br> invertebrates) | EC $_{50}$ (aquatic <br> algae) |
| :--- | :--- | :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | EC $_{50}$ (4 days) $76.8 \mathrm{~g} / \mathrm{L}$ | $\mathrm{LL}_{50}$ (4 days) $1 \mathrm{~g} / \mathrm{L}$ | (72 h) $100 \mathrm{mg} / \mathrm{L}$ |
| White mineral oil <br> (petroleum) | LL550 (4 days) $100-10000 \mathrm{mg} / \mathrm{L}$ | $\mathrm{LL}_{50}(48 \mathrm{~h}) 100 \mathrm{mg} / \mathrm{L}$ | No data available |

12.2 Persistence and degradability

- Some ingredients are biodegradable


## Revision: 28 November 2022

## SECTION 12: Ecological information (....)

Substances

| Chemical Name | Biodegradation |
| :--- | :--- |
| Hydrocarbons, <br> C11-C12, isoalkanes, <2\% <br> aromatics | Readily biodegradable (100\%) |
| White mineral oil <br> (petroleum) | Substance is a hydrocarbon UVCB. <br> Inherently biodegradable, but not readily biodegradable <br> moderately persistent, particularly in anaerobic conditions |

### 12.3 Bioaccumulative potential

- Bioaccumulation is not expected

| Substances |  |  |
| :--- | :--- | :--- |
| Chemical Name | Bioconcentration Factor (BCF) | Log Kow |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | Substance is a hydrocarbon UVCB. <br> The estimated BCF for this substance ranges from 6.91-3625.07 L/kg | (Log Pow) $1.99-6.73 @ 20^{\circ} \mathrm{C}$ and <br> pH 7 |
| White mineral oil <br> (petroleum) | Substance is a hydrocarbon UVCB. <br> Being poorly soluble in water, its bio-availability <br> to aquatic organisms is minimal and bioaccumulation is unlikely | Calculated log Pow for <br> constituents of this substance <br> range between 4.3 and 18.02 |

12.4 Mobility in soil

- No data available

| Substances |  |
| :--- | :--- |
| Chemical Name | Adsorption/desorption |
| Hydrocarbons, <br> C11-C12, isoalkanes, $<2 \%$ <br> aromatics | Koc $51.56-356204.99 \mathrm{~L} / \mathrm{kg}$ |
| White mineral oil <br> (petroleum) | Poorly soluble in water |

12.5 Results of PBT and vPvB assessment

- Not a PBT according to REACH Annex XIII
- Not a vPvB according to REACH Annex XIII
12.6 Endocrine disrupting properties
- Does not contain any substances with endocrine disrupting properties
12.7 Other adverse effects
- No information available


## SECTION 13: Disposal considerations

13.1 Waste treatment methods

- Avoid release to the environment.
- Do not pierce or burn container, even after use
- Empty containers may contain flammable vapours
- Disposal should be in accordance with local, state or national legislation


### 13.2 Classification

- The waste must be identified according to the List of Wastes (2000/532/EC)
- Hazardous Property Code(s): HP 3 Flammable; HP 5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity; HP 14 Ecotoxic


## SECTION 14: Transport information

Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed

## SECTION 14: Transport information (....)

into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.
14.1 UN number or ID number

- UN No.: 3175
14.2 UN proper shipping name
- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hydrocarbons)
14.3 Transport hazard class(es)
- Hazard Class: 4.1


### 14.4 Packing group

- Packing Group: II
14.5 Environmental hazards
- Not classified
14.6 Special precautions for user
- Protect from heat
14.7 Maritime transport in bulk according to IMO instruments
- Not applicable


### 14.8 Road/Rail (ADR/RID)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hydrocarbons)
- ADR UN No.: 3175
- ADR Hazard Class: 4.1
- ADR Packing Group: II
- Tunnel Code: (E)
- Special Provision(s):

216; Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.
14.9 Sea (IMDG)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hydrocarbons)
- IMDG UN No.: 3175
- IMDG Hazard Class: 4.1
- IMDG Packing Group: II
- Special Provision(s): 216; Sealed packets and articles containing less than 10 ml of a packing group II or III flammable liquid absorbed into a solid material are not subject to ADR/IMDG/IATA provided there is no free liquid in the packet or article.
14.10 Air (ICAO/IATA)
- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hydrocarbons)
- ICAO UN No.: 3175
- ICAO Hazard Class: 4.1
- ICAO Packing Group: II
- Special Provision(s): A46; Small inner packagings consisting of sealed packets or articles containing less than 10 mL of a Packing Group II or III flammable liquid absorbed into a solid material are not subject to these Regulations provided there is no free liquid in the packet or article.


## SECTION 15: Regulatory information

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

- A safety data sheet is not required for this product under Article 31 of REACH. This safety data sheet has been created on a voluntary basis to communicate relevant information under Article 32.
- This safety data sheet is provided in compliance with REACH Regulation (EC) No 1907/2006 (as amended by Regulation (EU) 2020/878) and UK REACH
- Exempt from the requirements of CLP as product is regulated as a medical device or an accessory to a medical device. Information is provided to inform users of the hazards associated with the use of the product.
- The GB Classification, Labelling and Packaging Regulation (GB CLP) applies in Great Britain
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)
- Reviewed in accordance with ISO 10993-1:2018 Biological Evaluation of Medical Devices
15.2 Chemical safety assessment
- A REACH chemical safety assessment has not been carried out


## SECTION 16: Other information

This information is intended to cover potential hazards at the place of work and does not detail medical uses, indications, contra-indications and precautions for the treatment of patients.

Sources of data: Information from company data, published literature and supplier safety data sheets
Created by ChemRegs (UK) Ltd April 2017
Revision No. 2.0.0.. Revised November 2022.
Changes made: Updated to conform to the latest version of REACH Annex II and the Medical Devices
Regulation (EU) 2017/745 (MDR)

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

- Flam. Liq. 3, H226: Classification based on calculation and concentration thresholds
- Asp. Tox. 1, H304: Classification based on calculation and concentration thresholds
- Aquatic Chronic 4, H413: Classification based on calculation and concentration thresholds

Text not given with phrase codes where they are used elsewhere in this safety data sheet:

- H226: Flammable liquid and vapour
- H304: May be fatal if swallowed and enters airways
- H413: May cause long lasting harmful effects to aquatic life
- EUH066: Repeated exposure may cause skin dryness or cracking


## Acronyms

- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstracts Service
- DNEL: Derived No-Effect Level
- EC: European Community
- EC50: Effective Concentration, 50\%
- GHS: Globally Harmonised System
- LC ${ }_{50}$ : Lethal Concentration, 50\%
- LD ${ }_{50}$ : Lethal Dose, $50 \%$
- LL50: Lethal Loading Rate resulting in $50 \%$ effect.
- LOAEC: Lowest Observed Adverse Effect Concentration
- LOAEL: Lowest Observed Adverse Effect Level


## SECTION 16: Other information (....)

- NOAEC: No Observed Adverse Effect Concentration
- NOAEL: No Observed Adverse Effect Level
- OEL: Occupational Exposure Limit
- PBT: Persistent, Bioaccumulative and Toxic
- PNEC: Predicted No-Effect Concentration
- REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals
- SCL: Specific Concentration Limit
- STOT RE: Specific Target Organ Toxicity Repeated Exposure
- STOT SE: Specific Target Organ Toxicity Single Exposure
- SVHC: Substances of Very High Concern
- vPvB: very Persistent and very Bioaccumulative
- WEL: Workplace Exposure Limit
--- end of safety datasheet ---

