

## 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: Salts Adhesive Remover Spray

WAP/WAPX - Product Code:

- Product Description: Aerosol Dispenser (50 mL)

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

- Use of the substance/mixture: Used for the removal of adhesive residue from patient's skin.

- 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: +44 (0) 121 333 2000 +44 (0) 146 324 0950 - Fax: - Email: hello@salts.co.uk

1.4 Emergency telephone number

- +44 (0) 121 333 2000

## **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. Aerosol 1, H222 H229; Aquatic Acute 1, H400; Aquatic Chronic 2, H411
  - Additional information: For full text of Hazard and EU Hazard statements: see section 16

## 2.2 Label elements

- Exempt from labelling requirements under CLP
- The following labelling is required under the EU Aerosol Dispensers Directive



- Danger: USE ONLY AS DIRECTED

#### Hazard statements

H222 - Extremely flammable aerosol.

H229 - Pressurised container: May burst if heated.

# Precautionary statements

P102 - Keep out of reach of children.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

# **SECTION 2:** Hazards identification (....)

P211 - Do not spray on an open flame or other ignition source.

P251 - Do not pierce or burn, even after use.

P410+P412 - Protect from sunlight. Do no expose to temperatures exceeding 50°C/122°F.

Supplemental Hazard information (EU)

None

#### 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

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

Chemical Name	Conc.	CAS No.	EC No.	Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]	SCL/ M-Factor/ ATE	REACH Registration Number	WEL/ OEL
Hexamethyldisiloxane	99 - 100%	107-46-0	203-492-7	Flam. Liq. 2, H225 Aquatic Acute 1, H400 Aquatic Chronic 2, H411	-	01-2119496108-31-XXXX	No
Peppermint oil	< 1%	68917-18-0	-	Not Classified	-	-	No

# **SECTION 4:** First aid measures

# 4.1 Description of first aid measures

## 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: gently wash with plenty of soap and water

## Ingestion

Rinse mouth with water (do not swallow)

Do NOT induce vomiting.

Never give anything by mouth to an unconscious person

Get medical advice/attention.

#### Inhalation

If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

IF exposed or concerned: Get medical advice/attention.

4.2 Most important symptoms and effects, both acute and delayed

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

Contact with eyes

Mildly irritating to eyes

Contact with skin

No hazard expected under normal conditions of use

#### Ingestion

The ingestion of significant quantities may cause nausea/vomiting May cause gastro-intestinal irritation

#### Inhalation

In cases of severe exposure, irritation of the respiratory tract may develop

- 4.3 Indication of any immediate medical attention and special treatment needed
  - Treat symptomatically
  - The onset of effects may be delayed, keep affected person under medical observation

# **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

- Extremely Flammable
- In a fire or if heated, a pressure increase will occur and the container may burst
- Vapours may ignite
- 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, nitrogen oxides, silicon oxides, formaldehyde

## 5.3 Advice for firefighters

- In case of fire: Evacuate area. Fight fire remotely due to the risk of explosion.
- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.

# **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: May form explosive vapour/air mixtures; Shut off all ignition sources; Avoid contact with eyes; Avoid breathing vapours, mist or gas; Ventilate the area and wash spill site after material pick-up is complete; Wash thoroughly after dealing with spillage
  - 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)

### 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

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

- Avoid formation of spray/mist/aerosols
- Shut off all ignition sources
- Use non-sparking tools.
- Take action to prevent static discharges.
- Spillage causes slippery surface
- Absorb spillage in suitable inert material
- 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

#### 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
- Do not spray on an open flame or other ignition source.
- Do not expose to temperatures exceeding 50°C/ 122°F.
- Take precautionary measures against static discharges
- Do not eat, drink or smoke when using this product.
- Avoid breathing dust/fume/gas/mist/vapours/spray.

## 7.2 Conditions for safe storage, including any incompatibilities

- Keep locked up and out of reach of children
- Keep in a cool, dry, well ventilated place
- Keep in highly flammable materials store
- Keep away from oxidisers, heat, flames or ignition sources
- Protect from sunlight. Do no expose to temperatures exceeding 50°C/ 122°F.
- Take action to prevent static discharges.
- Equipment should be earthed
- Incompatible with strong oxidising agents, strong acids, strong bases

# 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.

## Hexamethyldisiloxane

WEL (long term) 200 ppm (Supplier)

DNEL (inhalational) 53.4 mg/m³ Industry, Long Term, Systemic Effects

DNEL (dermal) 333 mg/kg (bw/day) Industry, Long Term, Systemic Effects

DNEL (inhalational) 13.3 mg/m³ Consumer, Long Term, Systemic Effects

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

DNEL (dermal) 167 mg/kg (bw/day) Consumer, Long Term, Systemic Effects

DNEL (oral) 270 ug/kg (bw/day) Consumer, Long Term, Systemic Effects

PNEC aqua (freshwater) 2 µg/L

PNEC agua (intermittent releases, freshwater) 3 µg/L

PNEC agua (marine water) 200 ng/L

PNEC (STP) 10 mg/L

PNEC sediment (freshwater) 8.9 mg/kg

PNEC sediment (marine water) 890 µg/kg

PNEC terrestrial (soil) 83 µg/kg

PNEC secondary poisoning (food) 5.3 mg/kg

#### Peppermint oil

No exposure limits have been set for this substance

#### 8.2 Exposure controls

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

Ensure adequate ventilation

Use explosion-proof ventilating and lighting equipment.

- Respiratory protection

None required for normal handling of product

In case of insufficient ventilation, wear suitable respiratory equipment

- 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: Pressurized aerosol containerColour: No information available

- Odour: Peppermint

- Melting point/freezing point: -68.2 °C @ 101.3 kPa (Hexamethyldisiloxane)

- Boiling point or initial boiling point and boiling range: -68.2 °C @ 101.3 kPa (Hexamethyldisiloxane)

- Flammability: H222 - Extremely flammable aerosol.

- Lower and upper explosion limit: Lower explosive limit: (Hexamethyldisiloxane) 1.5% (in air); Upper

explosive limit: (Hexamethyldisiloxane) 14.65% (in air)

- Flash point: -6 °C c.c. (Hexamethyldisiloxane)

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

- Auto-ignition temperature: 340 °C @ 101.3 kPa (Hexamethyldisiloxane)

- Decomposition temperature: No information available

- pH: Not applicable

- Kinematic viscosity: No information available

- Solubility: 930 µg/L @ 23 °C (Hexamethyldisiloxane)

- Partition coefficient n-octanol/water (log value): Log Pow: 5.06 - 5.2 @ 20 - 25 °C

(Hexamethyldisiloxane)

- Vapour pressure: 43 - 55 hPa @ 20 - 25 °C (Hexamethyldisiloxane)

- Density and/or relative density: 0.764 @ 20 °C (Hexamethyldisiloxane)

- Relative vapour density: No information available

- Particle characteristics: Not applicable

#### 9.2 Other information

- No information available

# **SECTION 10:** Stability and reactivity

#### 10.1 Reactivity

- Vapours may ignite

#### 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

- Avoid overheating
- Keep away from heat and sources of ignition
- Keep away from direct sunlight
- Keep away from static electricity

# 10.5 Incompatible materials

- Incompatible with strong oxidising agents, strong acids, strong bases

# 10.6 Hazardous decomposition products

- Decomposition products may include carbon oxides, nitrogen oxides, silicon oxides, formaldehyde

# **SECTION 11: Toxicological information**

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

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

- Acute Toxicity

Based on available data, the classification criteria are not met

#### Substances

Chemical Name	LD <sub>50</sub> (oral, rat)	LC <sub>50</sub> (inhalation, rat)	LD <sub>50</sub> (dermal, rabbit)
Hexamethyldisiloxane	12 160 mg/kg	(4h) 15 956 ppm	2 000 mg/kg (rat)
Peppermint oil	2 426 mg/kg	No data available	5 000 mg/kg

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

- Skin corrosion/irritation

Based on available data, the classification criteria are not met

#### Substances

Chemical Name	Irritation/corrosion	
Hexamethyldisiloxane	No adverse effect observed (not irritating)	
Peppermint oil	No adverse effect observed (not irritating)	

- Serious eye damage/irritation

Based on available data, the classification criteria are not met

#### Substances

Chemical Name	Irritation/corrosion
Hexamethyldisiloxane	No adverse effect observed (not irritating)
Peppermint oil	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 sensitisation
Hexamethyldisiloxane	No adverse effect observed (not sensitising)	No data available
Peppermint oil	No adverse effect observed (not sensitising)	No data available

- Germ cell mutagenicity

Based on available data, the classification criteria are not met

#### Substances

Chemical Name	Toxicity - In Vitro	Toxicity - In Vivo
Hexamethyldisiloxane	No study available	No adverse effect observed (negative)
Peppermint oil	No adverse effect observed (negative)	No data available

- Carcinogenicity

Based on available data, the classification criteria are not met

## Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Hexamethyldisiloxane	No data available	33 200 mg/m³	No data available
Peppermint oil	No data available	No data available	No data available

- Reproductive toxicity

Based on available data, the classification criteria are not met

## Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Hexamethyldisiloxane	No data available	33 200 mg/m³ (Effect on fertility) 19 924 mg/m³ (Effect on developmental toxicity)	No data available
Peppermint oil	No data available	No data available	No data available

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

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

#### Substances

Chemical Name	Route	Remarks
Hexamethyldisiloxane	Respiratory	No study available
Peppermint oil	Respiratory	No data available

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

#### Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Hexamethyldisiloxane	160 mg/kg bw/day	400 ppm	1 000 mg/kg bw/day
Peppermint oil	No data available	No data available	No data available

- Aspiration hazard

Based on available data, the classification criteria are not met

Contact with eyes
 Mildly irritating to eyes

- Contact with skin

No hazard expected under normal conditions of use

- Ingestion

The ingestion of significant quantities may cause nausea/vomiting May cause gastro-intestinal irritation

- Inhalation

In cases of severe exposure, irritation of the respiratory tract may develop

- 11.2 Information on other hazards
  - Does not contain any substances with endocrine disrupting properties

# **SECTION 12:** Ecological information

## 12.1 Toxicity

- Very toxic to aquatic life with long lasting effects.
- Classification based on calculation and concentration thresholds

## Substances

Chemical Name	LC <sub>50</sub> (fish)	EC <sub>50</sub> (aquatic invertebrates)	EC <sub>50</sub> (aquatic algae)
Hexamethyldisiloxane	(4 days) 460 - 3 020 μg/L	No data available	(70 h) 180 - 550 μg/L
Hexamethyldisiloxane	No data available	No data available	No data available

## 12.2 Persistence and degradability

- Not readily biodegradable

## Substances

Chemical Name	Biodegradation	
Hexamethyldisiloxane	Biodegradation in water screening tests: 2% biodegradation in 28 days (O2 consumption) (OECD 301C)	
Peppermint oil	No data available	

## 12.3 Bioaccumulative potential

- Potential bioaccumulation



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

#### Substances

Chemical Name	Bioconcentration Factor (BCF)	Log Kow
Hexamethyldisiloxane	1 971 L/kg ww	(Log Pow) 5.06 @ 20 °C
Peppermint oil	No data available	Not applicable, inorganic

## 12.4 Mobility in soil

- Insoluble in water

## Substances

Chemical Name	Adsorption/desorption
Hexamethyldisiloxane	Koc 1 000 @ 20°C
Peppermint oil	No data available

## 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

- No information available

#### 12.7 Other adverse effects

- No information available

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

- This material and/or its container must be disposed of as hazardous waste
- Do not pierce or burn container, even after use
- Empty containers may contain flammable vapours
- Avoid release to the environment.
- 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 14 Ecotoxic

# **SECTION 14: Transport information**



## 14.1 UN number or ID number

- UN No.: 1950

# 14.2 UN proper shipping name

- Proper Shipping Name: AEROSOLS

## 14.3 Transport hazard class(es)

- Hazard Class: 2

# 14.4 Packing group

- Packing Group: N/A

### 14.5 Environmental hazards

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

- Marine pollutant

#### 14.6 Special precautions for user

- Ensure valve protection device (where provided) is correctly fitted.

### 14.7 Maritime transport in bulk according to IMO instruments

- Not applicable

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

Proper Shipping Name: AEROSOLSADR UN No.: 1950ADR Hazard Class: 2

- ADR Packing Group: Not applicable

- Tunnel Code: D - LQ: 1L

- Special Provision(s): 190, 327, 344, 625

## 14.9 Sea (IMDG)

Proper Shipping Name: AEROSOLS
IMDG UN No.: 1950
IMDG Hazard Class: 2

- IMDG Packing Group: Not applicable

- LQ: 1L

- Special Provision(s): 63. 190, 277, 327, 344, 381, 959

#### 14.10 Air (ICAO/IATA)

- Proper Shipping Name: AEROSOLS, FLAMMABLE

- ICAO UN No.: 1950 - ICAO Hazard Class: 2.1

- ICAO Packing Group: Not applicable

## **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 Aerosol Dispensers Directive (2008/47/EC)
  - 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.

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

Sources of data: Information from published literature and supplier safety data sheets

Version 1.0.0. Created February 2021 by ChemRegs (UK) Ltd.

Revision No. 1.1.0. Revised April 2017.

Changes made: Minor amendments to sub-section 6.1 and typographical errors corrected

Revision No. 2.0.0. Revised March 2020.

Changes made: Updates to section 2.2 for labelling and minor changes to all sections

Revision No. 3.0.0. 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. Aerosol 1, H222 - H229: Classification based on calculation and concentration thresholds
 Aquatic Acute 1, H400: Classification based on calculation and concentration thresholds
 Aquatic Chronic 2, H411: Classification based on calculation and concentration thresholds

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

- H222: Extremely flammable aerosol
- H225: Highly flammable liquid and vapour.
- H229: Pressurised container: May burst if heated
- H400: Very toxic to aquatic life
- H411: Toxic to aquatic life with long lasting effects

## 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<sub>50</sub>: Lethal Concentration, 50%
- LD50: Lethal Dose, 50%
- 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
- SVHC: Substances of Very High Concern
- STOT RE: Specific Target Organ Toxicity Repeated Exposure
- STOT SE: Specific Target Organ Toxicity Single Exposure
- vPvB: very Persistent and very Bioaccumulative
- WEL: Workplace Exposure Limit

--- end of safety datasheet ---