
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 Wipes
- Product Code: WAP2
- Product Description: Wipe with adhesive remover solution – 3ml/wipe

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

1.4 Emergency telephone number

- +44 (0) 121 333 2000
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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. 2, H225; 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
- This product is covered by the Medical Devices Regulation (EU) 2017/745 (MDR)

2.3 Other hazards

- Not a PBT according to REACH Annex XIII
 - Not a vPvB according to REACH Annex XIII
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SECTION 3: Composition/information on ingredients**3.1 Substances**

- Not applicable

3.2 Mixtures

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

Chemical Name	Conc.	CAS No.	EC No.	Classification (REGULATION (EC) No 1272/2008) [CLP/GHS]	SCL or M-Factor	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

- 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
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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

SECTION 5: Firefighting measures (....)

- Extremely Flammable
- 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 nitrogen and carbon oxides
- Decomposition products may include silicon oxides
- Decomposition products may include formaldehyde

5.3 Advice for firefighters

- Special protective equipment: Wear self-contained breathing apparatus (SCBA). Wear full protective clothing including chemical protection suit.
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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; 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

- Small spills
Wipe up spillage with damp absorbent cloth or towel
- Large spills
Shut off all ignition sources
Use non-sparking tools.
Take action to prevent static discharges.
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
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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 in a cool, dry, well ventilated place
 - Keep in highly flammable materials store
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SECTION 7: Handling and storage (....)

- Keep away from oxidisers, heat, flames or ignition sources
- Protect from sunlight. Do not expose to temperatures exceeding 50°C/ 122°F.
- Take action to prevent static discharges.
- Equipment should be earthed

7.3 Specific end use(s)

- Adhesive remover
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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 atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) 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 atmospheres - 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
 - 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) 23 ug/l
 - PNEC aqua (intermittent releases, freshwater) 3 ug/l
 - PNEC aqua (marine water) 200 ng/l
 - PNEC (STP) 10 mg/l
 - PNEC sediment (freshwater) 8.9 mg/kg
 - PNEC sediment (marine water) 890 ug/kg
 - PNEC terrestrial (soil) 83 ug/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 containment devices and 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
 - Hygiene measures
 - Use good personal hygiene practices
 - Do not eat, drink or smoke when using this product.
 - Wash thoroughly after handling.
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SECTION 8: Exposure controls/personal protection (....)

- 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

- Appearance: Wipe containing 3 ml liquid
- Odour: Peppermint
- Odour threshold: No information available
- pH: Not applicable
- Melting point/freezing point: -68.2 °C @ 101.3 kPa (Hexamethyldisiloxane)
- Initial boiling point and boiling range: 100.5 °C @ 101.3 kPa (Hexamethyldisiloxane)
- Flashpoint: -6 °C c.c. (Hexamethyldisiloxane)
- Evaporation Rate: No information available
- Flammability (solid,gas): H225 - Highly flammable liquid and vapour.
- Upper/lower flammability or explosive limits: Lower explosive limit: 1.5 % (in air); Upper explosive limit: 14.65 % (in air)
- Vapour Pressure: 43 - 55 hPa @ 20 - 25 °C (Hexamethyldisiloxane)
- Vapour Density: No information available
- Relative Density: 0.764 @ 20 °C (Hexamethyldisiloxane)
- Solubility(ies): 930 µg/L @ 23 °C (Hexamethyldisiloxane)
- Partition Coefficient (n-Octanol/Water): Log Pow: 5.06 - 5.2 @ 20 - 25 °C (Hexamethyldisiloxane)
- Autoignition Temperature: 340 °C @ 101.3 kPa (Hexamethyldisiloxane)
- Decomposition temperature: No information available
- Viscosity: Dynamic viscosity at 20 °C is 0.5 mPa.s (Hexamethyldisiloxane)
- Explosive Properties: May form explosive vapour/air mixtures
- Oxidising Properties: No information available

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

SECTION 10: Stability and reactivity (....)

- Incompatible with strong acids
- Incompatible with alkalis (strong bases)
- Incompatible with oxidizing substances

10.6 Hazardous decomposition products

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

SECTION 11: Toxicological information

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

11.1 Information on toxicological effects

- Acute Toxicity
Based on available data, the classification criteria are not met

Substances

Chemical Name	LD50 (oral, rat)	LC50 (inhalation, rat)	LD50 (dermal, rabbit)
Hexamethyldisiloxane	12 160 mg/kg	15 956 ppm (4hr)	2 000 mg/kg (rat)
Peppermint oil	2 426 mg/kg	No data available	No data available

- Skin corrosion/irritation
Based on available data, the classification criteria are not met
- Serious eye damage/irritation
Based on available data, the classification criteria are not met
- Respiratory or skin sensitisation
Based on available data, the classification criteria are not met
- Germ cell mutagenicity
No evidence of mutagenic effects
- Carcinogenicity
No evidence of carcinogenic effects

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Hexamethyldisiloxane	No data available	33 200 mg/m ³	No data available
Peppermint oil	No data available	No data available	No data available

- Reproductive toxicity
No evidence of reproductive effects

Substances

Chemical Name	NOAEL (oral, rat)	NOAEC (inhalation, rat)	NOAEL (dermal, rat)
Hexamethyldisiloxane	No data available	33 200 mg/m ³ (Effect on fertility) 19 923.93 mg/m ³ (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
- Specific target organ toxicity (STOT) - repeated exposure
Based on available data, the classification criteria are not met

SECTION 11: Toxicological information (....)

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

SECTION 12: Ecological information

12.1 Toxicity

- Very toxic to aquatic life with long lasting effects.
- Classification based on calculation and concentration thresholds
- Hexamethyldisiloxane
LC50 (fish) 460 - 3 020 ug/l (4 days)
EC50 (aquatic algae) 180 - 550 ug/l (70 hr)
- Peppermint oil
No data available

12.2 Persistence and degradability

- Not readily biodegradable

12.3 Bioaccumulative potential

- Hexamethyldisiloxane
BCF: 1 971 L/kg ww

12.4 Mobility in soil

- Insoluble 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 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
- Avoid release to the environment.
- Disposal should be in accordance with local, state or national legislation

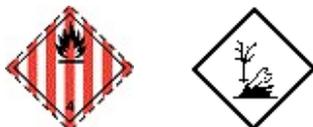
13.2 Classification

SECTION 13: Disposal considerations (....)

- The waste must be identified according to the List of Wastes (2000/532/EC)
 - Hazardous Property Code(s): HP 3 Flammable; HP 14 Ecotoxic
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SECTION 14: Transport information

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.



14.1 UN number

- UN No.: 3175

14.2 UN proper shipping name

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hexamethyldisiloxane)

14.3 Transport hazard class(es)

- Hazard Class: 4.1

14.4 Packing group

- Packing Group: II

14.5 Environmental hazards

- Marine pollutant

14.6 Special precautions for user

- This material is classified as dangerous for transport under the UN model regulations but is not subject to ADR/RID, IMDG and ICOA/IATA due to specific exemptions in those rules

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

- Not applicable

14.8 Road/Rail (ADR/RID)

- Proper Shipping Name: SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S. (hexamethyldisiloxane)
- 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. (hexamethyldisiloxane)
- IMDG UN No.: 3175
- IMDG Hazard Class: 4.1
- IMDG Pack 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. (hexamethyldisiloxane)

SECTION 14: Transport information (....)

- 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.
- Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation) applies in Europe
- 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.
- 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 published literature and supplier safety data sheets

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

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

- Flam. Liq. 2, H225: 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:

- H225: Highly flammable liquid and vapour.
- H400: Very toxic to aquatic life
- H411: Toxic to aquatic life with long lasting effects

Acronyms

- CAS: Chemical Abstracts Service
- DNEL: Derived No-Effect Level
- EC: European Community
- EC50: Effective Concentration, 50%
- GHS: Globally Harmonised System
- LC50: Lethal Concentration, 50%
- LD50: Lethal Dose, 50%
- NOAEC: No observed adverse effect concentration
- NOAEL: No observed adverse effect level

SECTION 16: Other information (....)

- 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
- vPvB: very Persistent and very Bioaccumulative
- WEL: Workplace Exposure Limit

--- end of safety datasheet ---
