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 Flush Away Adhesive Remover Wipe

- Product Code: FAW

- Product Description: Wipe with adhesive remover solution - 3 mL/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

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
- 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:

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

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

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

- Highly flammable liquid and vapour.
- 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

- 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: 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

- 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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Ensure adequate ventilation
- Avoid breathing vapours, mist or gas

SECTION 7: Handling and storage (....)

- 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, 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

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

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 aqua (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 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.

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

- 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

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: Wipe containing 3 mL liquid

Colour: WhiteOdour: Peppermint

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

- Boiling point or initial boiling point and boiling range: 100.5 °C @ 101.3 kPa (Hexamethyldisiloxane)

- Flammability: Highly flammable liquid and vapour.

- 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)

- 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

SECTION 10: Stability and 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 ₅₀ (oral, rat)	LC ₅₀ (inhalation, rat)	LD ₅₀ (dermal, rabbit)
Hexamethyldisiloxane	12 160 mg/kg	(4 h) 15 956 ppm	2 000 mg/kg (rat)
Peppermint oil	2 426 mg/kg	No data available	5 000 mg/kg

- 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



SECTION 11: Toxicological information (....)

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

No evidence of mutagenic effects

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

No evidence of carcinogenic effects

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

No evidence of reproductive effects

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

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	100 mg/kg bw/day	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

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SECTION 11: Toxicological information (....)

- 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 ₅₀ (fish)	EC ₅₀ (aquatic invertebrates)	EC ₅₀ (aquatic algae)
Hexamethyldisiloxane	(4 days) 460 - 3 020 μg/L	No data available	(70 h) 180 - 550 μg/L
Peppermint oil	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

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	No data available

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

- Does not contain any substances with endocrine disrupting properties

12.7 Other adverse effects

SECTION 12: Ecological information (....)

- 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

- 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

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 or ID 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, IMGD and ICOA/IATA due to specific exemptions in those rules

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. (hexamethyldisiloxane)

3175 - ADR UN No.: - ADR Hazard Class: 4.1 - ADR Packing Group: Ш - 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)

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SECTION 14: Transport information (....)

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

IMDG UN No.: 3175IMDG Hazard Class: 4.1IMDG 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. (hexamethyldisiloxane)

ICAO UN No.: 3175ICAO Hazard Class: 4.1ICAO 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
- 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
- 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

Version 1 - Created February 2021 by ChemRegs (UK) Ltd.

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. 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



SECTION 16: Other information (....)

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

- ATE: Acute Toxicity Estimate
- 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
- 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 ---