	SDS - Safety Data Sheet			
	Product No:	A00XX11	Version:	1.1/EN
	Status:	Effective	Revision date:	Mar/11/2022
	Trade Name:	Furine Medical Skin Wipe		


This Safety Data Sheet contains information concerning the potential risks to those involved in handling, transporting, and working with the material, as well as describing potential risks to the consumer and environment. This information is made available to those who may come into contact with the material or are responsible for the material. This Safety Data Sheet is prepared in accordance with Regulation (EC) N° 1907/2006 modified by regulation (EU) N° 453/2010

1. Identification of the Substance and Supplier

- 1.1 Product Name:** Furine Medical Skin Wipe
- 1.2 Product Use:** Adhesive Remover, prepares skin before application of adhesive.
- 1.2.2 Uses advised against:** Use only as directed in the original product packaging.
- 1.3 Manufacturer/Supplier:** Furine ApS
 Industrivaenget 1
 3320 Skaevinge
 Denmark
- E-mail (competent person):** btn@furine.com
- Information contact:** Telephone +45 2970 9421
- 1.4 Emergency Telephone number:**
- Europe: 112 European emergency phone number, available everywhere in the EU

2. Hazards Identification

- 2.1 Classification of the substance or mixture:**
- Classification according to Regulation (EC) No 1272/2008 [CLP/GHS]:
- Flammable Liquid 2; H225
- Aquatic Acute 1; H400
- Full text of H- and EUH-phrases: see section 16.
- 2.2 Label elements:** The product is a medical device in the EEA and consequently the labelling elements of the CLP provisions do not apply under regulation (EC) No 1272/2008, Title I, Article 1, point 5.

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The pictograms, signal words and hazard statements below are therefore only in this safety data sheet and may not be found in the labelling of the product.

In accordance with Regulation (EC) No 1272/2008:

Hazard components for labelling: hexamethyldisiloxane

Hazard Pictograms:



Flame GHS02



Environment GHS09

Signal word: Danger

Hazard statements:

H225 Highly flammable liquid and vapor

H400 Very toxic to aquatic life

Precautionary statements:

P210 Keep away from heat/sparks/open flames/hot surfaces – No smoking

P233 Keep container tightly closed *(optional)*

P273 Avoid release to the environment

P240 Ground/bond container and receiving equipment *(optional)*

P241 Use explosion-proof electrical/ventilating/light/.../equipment *(optional)*

P242 Use only non-sparking tools *(optional)*

P243 Take precautionary measures against static discharge *(optional)*


2.3 Other hazards

Adverse physicochemical effects: Flammable

3. Composition/Information on Ingredients

3.1 n/a

3.2 Mixtures The liquid includes volatile silicones.

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3.2.2 Hazardous Ingredients This product contains the substances listed below, which are defined as dangerous substances or hazardous chemicals as defined in Regulation (EC) No 1272/2008 and present at concentration > 0.1 %

CAS No.	EC No.	Index No	REACH No.	% [weight]	Name	Classification according to Regulation (EC) No 1272/2008
107-46-0	203-492-7	n/a	01-211949608-31	> 90 %	Hexamethyl-disiloxane	Flam.Liq. 2 Aquatic Acute 1 Aquatic Chronic 1

Note: Classification refers to classifications of raw substances at 100 % and are used as basis for classifying the mixture.

3.3 Additional Information The sachets include < 5 ml liquid.

4. First Aid Measures

4.1 Description of first aid measures


When in doubt or if symptoms are observed, get medical advice.

Inhalation: If the product is accidentally inhaled as vapour or spray, ensure access to fresh air. If signs of discomfort, seek medical advice, showing copy of this data sheet if possible.

Skin contact: If there is accidental contact with skin or clothing, rinse with water. However, the product will evaporate rapidly following contact. Note that the product is intended to be deliberately applied to skin.

Eye contact: If there is accidental eye contact flush eyes immediately with plenty of water. If signs of discomfort, seek medical advice and show copy of this data sheet if possible.

Ingestion: If accidentally swallowed, rinse mouth with small quantity of water or milk. Seek medical advice if signs of discomfort and show copy of this data sheet if possible. Do not induce vomiting.

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Notes for the doctor: hexamethyldisiloxane (CAS 107-46-0) is the major component of the mixture.

5. Fire-Fighting Measures

5.1 Extinguishing media: Suitable extinguishing media: Alcohol resistant foam. Carbon dioxide (CO₂), Extinguishing powder. Water mist.

Unsuitable extinguishing media: Do not use a direct water jet on the burning product.

5.2 Special exposure hazards (from the material or its combustion products):

Normal combustion products are considered to be carbon dioxide, although incomplete combustion may lead to the formation of organic decomposition products. However, due to the nature of the product, there is considered to be a low risk of adverse effects to health.

5.3 Special precautions for fire fighters:

No special precautions, although breathing apparatus and protective clothing should be worn due to possible danger of asphyxiation.


6. Accidental Release Measures

6.1 Personal precautions: For personnel other than rescue personnel: move away from the direction of the wind/keep your distance from the source. Smoking and open flames prohibited.

For rescue personnel: In addition to the above: Normal protective clothing corresponding to EN 469 is recommended.

6.2 Environmental precautions:

Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused

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environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Convey/collect waste for possible recycling or placement in suitable waste containers.

6.4. Reference to other sections:

For exposure control and personal protection measures, see section 8. For considerations of waste disposal, see section 13.

7.1 Handling and storage

7.1 Precautions for safe handling:

Protective measures: Keep away from heat sources or direct sunlight.

Fire Preventions: Keep away from ignition sources. Smoking prohibited.

Protect from electrostatic discharges.

7.2 Conditions for safe storage, including any incompatibilities:


Requirements to be met for storage facilities and containers: Store in a cool, dry and well-ventilated place. Follow national guidelines.

Information on storage in common storage facilities: No special precautions required.

Additional information on storage conditions: Store in tightly closed containers.

8. Exposure Controls / Personal Protection

8.1 Control parameters: Substances with limit values to be monitored: The product does not contain

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sufficient quantities of some ingredients with limit values to be monitored at workplace.

DNEL/PEC-values: Hexamethyldisiloxane: 890 mg/m³

8.2 Exposure controls:

Personal protective equipment:

General protective and hygienic measures: the usual precautions must be followed for handling chemicals.

Respiratory protection: Not required.

Hand protection: Optional.

Eye protection: Not required.

9. Physical and Chemical Properties

9.1 Information on basic physical and chemical properties:

Appearance:


Physical state: Textile wipe impregnated with transparent liquid

Colour: None

Odour: characteristic

Safety relevant basic data:

Parameter	Value	Remark
pH	-	no water in the blend
Melting point/range (°C)	ca -68	Hexamethyldisiloxane
Initial boiling point/range (°C, 1013 kPa)	ca 100	Hexamethyldisiloxane
Flash point (°C)	ca -6	Hexamethyldisiloxane
Vapour pressure (kPa, 20°C)	ca 44	Hexamethyldisiloxane
Ignition temperature (°C)	ca 340	Hexamethyldisiloxane

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Density (g/cm ³ , 25°C)	0.76	Hexamethyldisiloxane
Water solubility	Insoluble	Hexamethyldisiloxane
Partition coefficient n-Octanol/Water (log Po/w)	>4	Hexamethyldisiloxane
Viscosity, dynamic (mPas, 25°C)	0,5	Hexamethyldisiloxane

9.2 Physical hazards:

Explosives: Not applicable

Flammable gases: Not applicable

Flammable aerosols: Not applicable

Oxidizing gases: Not applicable

Gases under pressure: Not applicable

Flammable liquids: Flammable liquid and vapor.

Flammable solids: Not applicable

Self-reactive substances and mixtures: Not applicable

Pyrophoric liquids Pyrophoric solids: Not applicable

Self-heating substances and mixtures: Not applicable

Substances or mixtures which, in contact with water emit flammable

gases: Not applicable

Oxidizing liquids: Not applicable


Oxidizing solids: Not applicable

Organic peroxides: Not applicable

Metal corrosion: Not applicable

9.3 Other safety information:

Properties of explosive atmospheres (mixtures): Gases and vapors:

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lower 0,7 %, upper 26 %

Physical-chemical properties of nanoparticles: Not applicable

Limiting oxygen concentration: Not applicable

Bulk density: 0.76 g/cm³

Solubility in different media: Insoluble in water

Stability in organic solvents and identity of relevant degradation

products: No data available

Evaporation rate: 1.7 (butyl acetate = 1)

Conductivity: No data available

Surface tension: No data available

Dissociation constant in water (pKa): Insoluble in water

Oxidation-reduction Potential: No data available

Fat solubility (solvent – oil to be specified): No data available

10. Stability and Reactivity

10.1 Reactivity: Not reactive under normal conditions of use and storage.

10.2 Chemical stability: Stable.

10.3 Possibility of hazardous reactions:
No information available.


10.4 Conditions to avoid: Avoid all possible sources of ignition (spark or flame).

10.5 Incompatible materials: Exothermic reaction with: Oxidizing Materials. Strong Acids. Strong Alkalis.

10.6 Hazardous decomposition products:
Decomposition with: Carbon dioxide (CO₂). Carbon monoxide. Nitrogen oxides (NO_x).

11. Toxicological Information

This product is a medical device and has been evaluated in accordance with Directive 93/42/EEC concerning medical devices.

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Acute toxicity

	Effect Dose	Species	Remark
Acute oral toxicity	LD50: >5000 mg/kg	Rat	Hexamethyldisiloxane
Acute dermal toxicity	LD50: >2000 mg/kg	Rabbit	
Acute inhalation toxicity	LC50: c. 106 mg/l (4 hours)	Rat	Hexamethyldisiloxane

Potential Health Hazards:

Inhalation: Inhalation of vapors may be slightly irritating.

Skin Contact: None expected. Non-irritating to skin.

Eye Contact: None expected. Non-irritating to eyes.

Ingestion: No adverse effects are expected.

Chronic Health Effects: No adverse effects are expected.

Acute Toxicity Values: This product is not expected to be acutely toxic based on an evaluation of the component materials. Hexamethyldisiloxane: LD50 oral rat >16 ml/kg; LD50 dermal rat >2000 mg/kg; LC50 inhalation rat 106 mg/L/4 hr HFC 134a (1,1,1,2-tetrafluoroethane): LD50 >=567,000 ppm/4 hr.

Skin corrosion/irritation: Non-irritating to rabbit skin.

Serious eye damage/irritation: Non-irritating to rabbit eyes.

Irritation to respiratory tract: No irritation is expected.


Respiratory or skin sensitization: No adverse effects expected.

Components are not sensitizers.

CMR effects (carcinogenity, mutagenicity and Toxicity for reproduction)

This product is not expected to present a risk of genetic damage.

Carcinogenicity: None of the components is listed as a potential carcinogen by IARC, NTP, ACGIH or the EU CLP.

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Developmental / Reproductive Toxicity: This product is not expected to present a risk of adverse reproductive or developmental toxicity. Studies with hexamethyldisiloxane did not show effects on fertility or development.

Specific Target Organ Toxicity (Single Exposure): No adverse effects of exposure are expected from normal use. Specific Target Organ Toxicity (Repeated Exposure): No adverse effects of exposure are expected from normal use.

Other information: This product should never be ingested. Keep away from food and drink.

12. Ecological Information

12.1 Toxicity: Hexamethyldisiloxane, NOEC

Chronic (long term) toxicity to daphnia magna (Big water flea) – Effective dose 0,08 mg/L – 504 h

Acute (short term) toxicity to algae – daphnia magna (Big water flea) > 0,37 mg/L – 48 h

Chronic (long term) toxicity to algae – Cyprinus carpio (Common Carp) >= 0,04 mg/L

12.2 Persistence and degradability:

Analytical method, Degree of elimination: Degradation rate 2%, 672 h;

Evaluation: Poorly biodegradable


12.3 Bioaccumulative potential:

Hexamethyldisiloxane has experimentally derived BCFs of 776-2410 and a log Kow of 5.06 indicating that bioaccumulation is possible.

12.4 Mobility in soil: No data available

12.5 Results of PBT and vPvB assessment:

Hexamethyldisiloxane: The substance does not meet the PBT/vPvB criteria

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of REACH, annex XIII

12.6 Other adverse effects: Hexamethyldisiloxane: Very toxic to aquatic life. The evaluation was carried out according to the calculation method of the preparation directive.

13. Disposal Considerations

13.1 Waste treatment methods:

Dispose in accordance with all local, state and national regulations. Local regulations may be more stringent than regional and national requirements. It is the responsibility of the waste generator to determine the toxicity and physical characteristics of the material to determine the proper waste identification and disposal in compliance with applicable regulations.

14. Transport Information

Furine Medical Skin Wipes are individually packed in letters. Each letter contains <10 ml of flammable liquid absorbed in a solid material. The product meets SP216 (ADR/IMDG) and A46 (IATA) and does **not** need to be transported as fully regulated dangerous goods (see section 14.5).

14.1 Land Transport (ADR/RID/GGVSE):

UN-No: 3175 **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**


Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID,
N.O.S. (hexamethyldisiloxan)

Name according to bill of freight: Solids containing flammable liquid, n.o.s.
(hexamethyldisiloxan)

Transport Class(es): 4.1 Flammable solids **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

Risk Code: 40 **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

Packing group: II **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

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Hazard label(s): Flammable **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

14.2 Sea transport (IMDG-Code/GGVSee):

UN No: 3175 **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID,
N.O.S. (hexamethyldisiloxan)

IMDG Class(es): 4.1 Flammable solids **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

Packing group: II **WITH RULES OF EXEMPTION. SEE SECTION 14.5.**

14.3 Air transport (ICAO-IATA/DGR) :

UN No: 3175

Proper shipping name: SOLIDS CONTAINING FLAMMABLE LIQUID,
N.O.S. (hexamethyldisiloxan)

ICAO/IATA Class(es): 4.1 Flammable solids

Packing group: II


Special provision(s): Flammable

14.4 Environmental Hazards: Land transport (ADR/RID): Yes

Sea transport (IMDG): Yes (P)

14.5 Additional information: ADR/RID chapter 3.3 Special rule 216

Mixtures of solids which are not subjected to the requirements of ADR and flammable liquids may be carried under this entry without first applying the classification criteria of Class 4.1, provided there is no free liquid visible at the time the packaging, vehicle or container is closed. 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 provided there is no free liquid in the packet or article.

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IMDG Code chapter 3.3 special rule 216

Mixtures of solids which are not subject to the provisions of this Code and flammable liquids may be transported under this entry without first applying the classification criteria of class 4.1, provided there is no free liquid visible at the time the substance is loaded or at the time the packaging or cargo transport unit is closed. Each cargo transport unit shall be leak proof when used as a bulk container. 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 the provisions of this Code provided there is no free liquid in the packet or article.

15. Regulatory Information

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

EU regulations

Water hazard class (WGK) Class: 1 (Slightly hazardous to water)

Classification according to WvWvS


Information according 1999/13/EC about limitation of emissions of volatile organic compounds (VOC-guideline): This information is not available.

15.2 Chemical Safety Assessment:

Chemical safety assessment for substances has not been carried out.

16. Other Information

The above information is correct to the best of our knowledge, information and understanding at the time of publication. The information is intended as a guide to safe handling, use, processing, storage, transport, disposal and release and should not be considered a guarantee or indication of quality. The information

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relates only to the specific material indicated and does not apply to these materials in combination with other materials or for use in other processes, unless expressly stated in the text. Document produced and managed by means of computer. Valid without signature.

16.1 Indication of changes: First release September 2020

Revision dates: see header.

16.2 Abbreviations and acronyms:

none

16.3 Key literature references and sources for data:

REACH registration information

Supplier Material Data Sheet (SDS)

16.4 Classification for mixtures and used evaluation method according to regulation (EC) 1207/2008 [CLP]:

Calculation method based on the classification of hazardous components.

16.5 Relevant H- and EUH-phrases (number and full text):

H225 Highly flammable liquid and vapor

H400 Very toxic to aquatic life

H410 Very toxic to aquatic life with long lasting effects