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	Artifact Name:	SDS - Safety Data Sheet	Name:	SDS21-057-EU
	Title:	Esenta Skin Barrier Foam Applicators - 1ml and 3ml		

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

- 1.1 Product Names:** Esenta skin barrier foam applicator 1ml
Esenta skin barrier foam applicator 3ml
- 1.2 Product Use:** The product is intended for professional use
Medical application
Professional use
- 1.3 Manufacturer/Supplier:** ConvaTec Limited
First Avenue
Deeside Industrial Park

Deeside, Flintshire

CH5 2NU
United Kingdom
- Customer Helpline:** Clinical Helpline number(s)
Stoma Care UK: 0800 282 254 or Republic of Ireland: 1800 721 721
Wound Care UK: 0800 289 738 or Republic of Ireland: 1800 946 938
Customer Service: +44 (0) 1244 284 882
- Contact (E-Mail address):** Clinical Helpline:
Stoma Care: stoma.webcare@convatec.com
Wound Care: wound.webcare@convatec.com
Customer Service: uk.customerservice@convatec.com
- 1.4 In Case of Emergency Call:** **US: 1-866-968-6376 (Hours - Monday - Friday 8:30 till 7pm EST)**
Canada: 1-800-465-6302 (Hours - Monday - Friday 8:00 till 6pm EST)
UK: +44(0)1244 284 882 (Hours - Monday - Friday 8:30 till 4pm GMT)
AUS: +61(0)3 9239 2700 (Hours - Monday - Friday 8:00 till 5pm Sydney time)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture Classification according to Regulation (EC) No 1272/2008

Additional information:

According to Regulation EU 1272/2008;

Article 1.5 a; Medicinal products for human use, as defined in Directive 2001/83/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation


Article 1.5 b; Medicinal products for veterinary use, as defined in Directive 2001/82/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.

Article 1.5 d; Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC, are exempted for both classification and labelling according to this Regulation.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 The product is classified and labelled according to the CLP regulation.

Hazard pictograms

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GHS02

Signal word Danger

Hazard statements

H225 Flammable liquid and vapour.

Precautionary statements

- P101 If medical advice is needed, have product container and label at hand.
- P102 Keep out of reach of children
- P103 Read label before use
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P280 Wear Protective gloves/protective clothing/eye protection/face protection
- P240 Ground/bond container and receiving equipment.
- P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P403+P235 Store in a well-ventilated place, keep cool.
- P501 Dispose of contents/container in accordance with local/regional/national/international regulations

Additional information:

According to Regulation EU 1272/2008;

Article 1.5 a; Medicinal products for human use, as defined in Directive 2001/83/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.

Article 1.5 b; Medicinal products for veterinary use, as defined in Directive 2001/82/EC in their final state and intended for the final user, are exempted for both classification and labelling according to this Regulation.

Article 1.5 d; Medical devices as defined in Directives 90/385/EEC and 93/42/EEC, which are invasive or used in direct physical contact with the human body, and in Directive 98/79/EC, are exempted for both classification and labelling according to this Regulation.

2.3 Other hazards

Physical / chemical hazards: THE PRODUCT IS FLAMMABLE!


Results of PBT and vPvB assessment

PBT:

Does not meet specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a PBT.

vPvB:

Does not meet specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a vPvB.

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Mixture of siloxanes

3.2 Mixtures

Description : Medical device

The product does not contain any other ingredients which are classified according to present knowledge of the supplier and contribute to the classification of the product and hence require reporting in this section.

Dangerous components: Not applicable.

Additional information:

All the percentages given are percentages by weight unless stated otherwise.

For the wording of the listed risk phrases refer to section 16

4. FIRST AID MEASURES

4.1 Description of first aid measures

General information: Do not leave affected person unattended. Remove victim out of the danger area. In case of unconsciousness place person in the recovery position. Never give anything by mouth. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice

After inhalation:

Provide fresh air. If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. In case of respiratory tract irritation, consult a physician.

After skin contact:

Remove contaminated clothing and shoes.

Wash with water and soap.

Seek immediate medical advice if symptoms occur.

After eye contact:

Irrigate copiously with clean, fresh water for at least 15 minutes, holding the eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

After swallowing:


Do not induce vomiting; call for medical help immediately.

Rinse mouth with clean water.

4.2 Most important symptoms and effects, both acute and delayed No further relevant information available.

4.3 Indication of any immediate medical attention and special treatment needed

For specialist advice physicians should contact the anti- poison control centre.

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5. FIRE FIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents: Alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO₂).

For safety reasons unsuitable extinguishing agents: Water with full jet

5.2 Special hazards arising from the substance or mixture: In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

During fire hazardous fumes/smoke could be produced.

5.3 Advice for fire-fighters

Protective equipment:

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

Special protective equipment for firefighters

Self-contained breathing apparatus (EN 133). Standard protective clothing for firefighters.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel

Remove persons to safety. Ventilate affected area.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases. Use personal protective equipment as required.

6.2 Environmental precautions:

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up:

Advice on how to contain a spill

Covering of drains.

Advice on how to clean up a spill


Wipe up with absorbent material (e.g. cloth, fleece).

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

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6.4 Reference to other sections:

Hazardous combustion products: see section 5.
 Personal protective equipment: see section 8.
 Incompatible materials: see section 10.
 Disposal considerations: see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling Keep away from heat and direct sunlight.

Recommendations

Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

Explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

Incompatible substances or mixtures

Keep away from alkalis, oxidising substances, acids.

Control of effects

Protect against external exposure, such as

- High temperatures. UV-radiation/sunlight.

Consideration of other advice


Store in a well-ventilated place. Keep container tightly closed.

- ventilation requirements

Use local and general ventilation. Ground/bond container and receiving equipment.

Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

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7.3 Specific end use(s):

The product is intended for professional use. Medical application.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Additional information about design of technical facilities: No further data; see item 7.

8.1 Control parameters

No information available.

Relevant DNELs/DMELs/PNECs and other threshold levels

No data available.

Additional information:

The lists valid during the making of this safety data sheet were used as basis to compile the above information.

8.2 Exposure controls


Appropriate engineering controls

General ventilation.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

General Information

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Physical state	acc. to product description
Colour	acc. to product description
Odour	acc. to product description
Melting point/freezing point	not determined
Boiling point or initial boiling point and boiling range	not determined
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	LEL: UEL: not determined
Flash point	-6 °C
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Water solubility	Not micible
Partition coefficient n-octanol/water (log value)	this information is not available
Vapour pressure	not determined
Density	not determined
Particle characteristics	not relevant (liquid)

9.2 Other information

No further relevant information available.

10. STABILITY AND REACTIVITY

10.1 Reactivity

The mixture contains reactive substance(s). Risk of ignition.

If heated: Risk of ignition.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.


10.3 Possibility of hazardous reactions

No dangerous reactions known.

10.4 Conditions to avoid

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

Hints to prevent fire or explosion

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Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials: Oxidisers.

10.6 Hazardous decomposition products: Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5..

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Health effects are not known.

Acute toxicity

Shall not be classified as acutely toxic.

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard


Shall not be classified as presenting an aspiration hazard..

CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)

Product is not considered to be carcinogenic, mutagenic or reprotoxic.

12. ECOLOGICAL INFORMATION

12.1 Toxicity

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Aquatic toxicity: No further relevant information available.

12.2 Persistence and degradability: No further relevant information available.

12.3 Bioaccumulative potential: No further relevant information available.

12.4 Mobility in soil: No further relevant information available.

Additional ecological information:

General notes: Generally not hazardous for water

12.5 Results of PBT and vPvB assessment

PBT:

Does not meet the specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a PBT.

vPvB:

Does not meet the specific criteria detailed in Annex XIII of Regulation 1907/2006 and the substance is not considered as a vPvB.

12.6 Other adverse effects No further relevant information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal - relevant information


Do not empty into drains. Avoid release to the environment.

Waste treatment of containers/packaging

Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

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14. TRANSPORT INFORMATION

Transport as a consumer sachet product, fill volume of up to 3ml per sachet.

	ADR	IMDG	ICAO
14.1 UN Number	UN3175	UN3175	UN3175
14.2 UN Proper shipping name	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.	SOLIDS CONTAINING FLAMMABLE LIQUID, N.O.S.
14.3 Transport hazard class(es)	4.1	4.1	4.1
14.4 Packing group	II	II	II
14.5 Environmental hazards	Yes	Yes	Yes
14.6 Special Provisions	Special Provision 216 (Not subject to the requirements of ADR)	Special Provision 216 (Not subject to the requirements of IMDG)	Exempted by Special Provision A46
14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable	Not transported in bulk	Not applicable

15. REGULATORY INFORMATION

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

European regulations: No further relevant information available.


Cosmetic Products; EC Regulation 1223/2009:

According to this Regulation a safety assessment is carried out and is available for relevant authorities.

15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

16. OTHER INFORMATION

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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Abbreviations and acronyms:

Abbr	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	European Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
DGR	Dangerous Goods Regulations (see IATA/DGR)
DMEL	Derived Minimal Effect Level
DNEL	Derived No-Effect Level
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LEL	Lower explosion limit (LEL)
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concern- ing the International carriage of Dangerous goods by Rail)
UEL	Upper explosion limit (UEL)
vPvB	Very Persistent and very Bioaccumulative

Key literature references and sources for data


Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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HISTORY PAGE

VERSION:	1.0	CR:	044124	ORIGINATOR:	Tom Hyde	Date:	22 September 2021
Comments: Original version to support launch of Esenta Sting Free Range							
VERSION:	2.0	CR:	045524	ORIGINATOR:	Jake Cook	Date:	To be completed at next update
Comments: Revised section 3.1 to state "mixture of siloxanes".							