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	Title:	Esenta Barrier Spray 50 ml		

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

- 1.1 Product Names:** Esenta skin barrier spray 50 ml
- 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](mailto:stoma.webcare@convatec.com)  
Wound Care: [wound.webcare@convatec.com](mailto:wound.webcare@convatec.com)  
Customer Service: [uk.customerservice@convatec.com](mailto: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, GHS04

**Signal word** Danger

**Hazard statements**

- H222 Extremely flammable aerosol
- H229 Pressurised container: may burst if heated
- H280 Contains gas under pressure; may explode if heated

**Precautionary statements**

- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P211 Do not spray on an open flame or other ignition source.
- P251 Do not pierce or burn, even after use.
- P410+P403 Protect from sunlight. Store in a well-ventilated place.
- P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

**Additional labelling according to Directive 75/324/EEC relating to aerosol dispensers**

Extremely flammable. Pressurized container: may burst if heated. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Do not pierce or burn, even after use. Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.

**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

Not relevant (mixture)

#### 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

#### **Remarks**

When put on the market gases have to be classified as 'Gases under pressure', in one of the groups compressed gas, liquefied gas, refrigerated liquefied gas or dissolved gas. The group depends on the physical state in which the gas is packaged and therefore has to be assigned case by case.

### 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.

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**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.

## 5. FIRE FIGHTING MEASURES

### 5.1 Extinguishing media

**Suitable extinguishing agents:** Alcohol resistant foam; Dry extinguishing powder; Carbon dioxide (CO<sub>2</sub>).

**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).

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### Appropriate containment techniques

Use of adsorbent materials.

### Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

### 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.

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- 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.

**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.

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## 10. STABILITY AND REACTIVITY

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### 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..

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## 11. TOXICOLOGICAL INFORMATION

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### 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.


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## 12. ECOLOGICAL INFORMATION

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### 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.

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## 13. DISPOSAL CONSIDERATIONS

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### 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

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### 14.1 UN number or ID number

ADR/RID/ADN /DOT UN 1950

IMDG-Code UN 1950


ICAO-TI UN 1950

### 14.2 UN proper shipping name

ADR/RID/ADN /DOT AEROSOLS

IMDG-Code AEROSOLS

ICAO-TI Aerosols, flammable

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**14.3 Transport hazard class(es)**

ADR/RID/ADN /DOT	2 (2.1)
IMDG-Code	2.1
ICAO-TI	2.1

**14.4 Packing group**

Not assigned

**14.5 Environmental hazards**

Non-environmentally hazardous acc. to the dangerous goods regulations

**14.6 Special precautions for user**

Provisions for dangerous goods (ADR) should be complied within the premises.

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

No data available.

**Information for each of the UN Model Regulations**

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - additional information 49 CFR § 172.101 Hazardous Materials Table (DOT)

Classification code	5F
Danger label(s)	2.1




Special provisions (SP)	190, 327, 344, 625
Excepted quantities (EQ)	E0
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	D

**International Maritime Dangerous Goods Code (IMDG) - additional information**

Marine pollutant	-
Danger label(s)	2.1



Special provisions (SP)	63, 190, 277, 327, 344, 381, 959
Excepted quantities (EQ)	E0
Limited quantities (LQ)	1 L

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EmS F-D, S-U

Stowage category -

#### International Civil Aviation Organization (ICAO-IATA/DGR) - additional information

Danger label(s) 2.1



Special provisions (SP) A145, A167

Excepted quantities (EQ) E0

Limited quantities (LQ) 1 L

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## 15. REGULATORY INFORMATION

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### 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.

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## 16. OTHER INFORMATION

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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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**Disclaimer**

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

The product is classed as a medical device and the information is provided on a voluntary basis.

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### HISTORY PAGE

<b>VERSION:</b>	1.0	<b>CR:</b>	043826	<b>ORIGINATOR:</b>	Tom Hyde	<b>Date:</b>	23 <sup>rd</sup> August 2021
Comments: Original version to support launch of Esenta Sting Free Range							
<b>VERSION:</b>	2.0	<b>CR:</b>	044420	<b>ORIGINATOR:</b>	Jake Cook	<b>Date:</b>	To be completed at next update
Comments: Corrected flash point based on supplier data sheet TR204 SM-078112.							