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

1.1 Product Names: Esenta skin barrier wipe – 3ml

1.2 Product Use: The product is intended for professional use
Medical application
Professional use

1.3 Manufacturer/Supplier:

USA
Convatec Inc.
7815 National Service Road Suite 600
Greensboro
North Carolina 27409
USA

Customer Helpline:
Customer Interaction Centre: 800-422-8811
Contact (email address): cic@convatec.com
ConvaTec Canada Ltd.

Canada

1425 TransCanada Highway, Suite 100
Dorval
Quebec H9P 2V3
Canada

Customer Helpline:
Customer Interaction Centre: 1-800-465-6302
Contact (email address): convatec.canada@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

USA

According to 29CFR1910.1200(b)6(vii) for "Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first aid supplies); 29CFR1910.1200 is not applicable.


Canada

Medical devices within the meaning of the FOOD AND DRUGS ACT (R.S.C., 1985, c. F-27) are not subject to the WHMIS supplier label and MSDS requirements of the Hazard Products Act.

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

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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.

The product is classed as a medical device and the information is provided on a voluntary basis. This information is based upon the present state of our knowledge. The information provided in this Product Information Document (PID) has been compiled and is solely intended for this product. This PID is not a Safety Data Sheet (SDS) but follows the main headings of an SDS, and as such does not need to be revised with SDS specific revisions under the REACH Regulation. This document may not contain all the necessary information needed within an SDS.

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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not relevant (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.

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:

Not Applicable

After skin contact:

Not Applicable – product is intended for application

After eye contact:

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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.

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: Not Applicable

Hazardous combustion products

None

5.3 Advice for fire-fighters

Protective equipment:

Fight fire with normal pre- cautions from a reasonable distance.

Special protective equipment for firefighters

Not Required

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

No special precautions needed.

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

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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.

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.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

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.

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

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No data available.

Additional information:

The lists valid during the making of this Product Information Document 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

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 miscible
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

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.

10.5 Incompatible materials: None Known.

10.6 Hazardous decomposition products: None Known.

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

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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 (carcinogenicity, mutagenicity and toxicity for reproduction)

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

12. ECOLOGICAL INFORMATION

12.1 Toxicity

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.

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

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.


14. TRANSPORT INFORMATION

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

IMDG shipped under special provision 216

ADR shipped under the special provision 216

ICAO shipped under special provision A46

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15. REGULATORY INFORMATION


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

There is no additional information.

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

16. OTHER INFORMATION

None

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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.

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

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1. History Page

Version:	1.0	CR:	050526	Originator:	Julian Fairhurst	Date:	Complete in subsequent version
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Comments:

1. New Product Information Document