

1. PRODUCT AND COMPANY IDENTIFICATION

Product Identifier

Product Name: Sensi-Care® Protective Barrier

Relevant Identified Uses of the Substance or Mixture and Uses Advised Against

Product Use: For the treatment and prevention of irritation due to incontinence

Details of the Supplier of the Substance or Mixture

Manufacturer: ConvaTec Inc.
211 American Avenue
Greensboro
North Carolina 27409
USA
Customer Interaction Center: 800-422-8811 or 908-904-2432
8:30AM – 8:00PM EST Monday-Thursday
8:30AM – 6:00PM EST Friday
10:00AM – 2:00PM EST Saturday

Emergency Telephone Number

CHEMTREC: 800-424-9300

Outside the US: 703-527-3887

2. HAZARDS IDENTIFICATION

Classification of the Substance or Mixture

GHS Classification: Not Hazardous

Label Elements: No hazard labeling required.

Other Hazards: None identified

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredients

Component	CAS Number	Amount	GHS Classification
White Petrolatum	8009-03-8	30-60	Not Hazardous
Sodium Carboxymethylcellulose	9004-32-4	10-30	Not Hazardous
Zinc Oxide	1314-13-2	10-30	Not Hazardous
Water	7732-18-5	5-10	Not Hazardous
Modified polyether-polysiloxane	144243-3-8	3-7	Not Hazardous
Stearic Acid	57-10-3	1-5	Not Hazardous
Glycerin	56-81-5	1-5	Not Hazardous
Phenoxyethanol	122-99-6	0.5-1.5	Acute Tox Cat 4 (H302), Eye Irrit Cat 2 (H319)

Refer to Section 16 for Full Text of EU/GHS Classes and R Phrases/H Statements

4. FIRST AID MEASURES

Description of First Aid Measures

First Aid

Eyes: If eye contact occurs, flush eyes thoroughly with water. If irritation persists, seek medical attention.

Skin: No first aid should be needed.

Ingestion: If large amount is swallowed, get medical advice.

Inhalation: No first aid should be needed.

See Section 11 for more detailed information on health effects.

Most Important symptoms and effects, both acute and delayed: May cause mild mechanical (abrasive) eye irritation.

Indication of any immediate medical attention and special treatment needed: Immediate medical attention is not required.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use media appropriate for surrounding fire. Avoid direct water or foam on open containers as this may cause frothing.

Special Hazards Arising from the Substance or Mixture: Product will burn under fire conditions. Combustion will release carbon monoxide, carbon dioxide, silicon dioxide, and irritating smoke.

Advice for Fire-Fighters: Wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemical products and all interior fires.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: None required.

Environmental Precautions: Avoid contamination of water supplies and environmental releases. Report spills as required to authorities.

Methods and Material for Containment and Cleaning Up: Mop or scoop up and place in a container for disposal. Clean spill area thoroughly.

Reference to Other Sections:

Refer to Section 13 for disposal information and Section 8 for protective equipment.

7. HANDLING AND STORAGE

Precautions for Safe Handling:

This product is not hazardous. No special handling is required.

Conditions for Safe Storage, Including any Incompatibilities: Store at room temperature. Keep containers closed to protect product integrity.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control Parameters:

Chemical Name	ACGIH TLV	OSHA PEL
White Petrolatum	None Established	5 mg/m ³ TWA (as oil mist, mineral)
Sodium Carboxymethylcellulose	None Established	None Established
Zinc Oxide	2 mg/m ³ (Respirable) TWA 10 mg/m ³ (Respirable) STEL	5 mg/m ³ (Respirable) TWA 15 mg/m ³ (Total Dust) TWA
Water	None Established	None Established
Modified polyether-polysiloxane	None Established	None Established
Steric Acid	None Established	None Established
Glycerin	None Established	5 mg/m ³ (Respirable, Mist) TWA 15 mg/m ³ (Total Dust, Mist) TWA
Phenoxyethanol	None Established	None Established

Exposure Controls:

Appropriate Engineering Controls: No special ventilation is required for normal handling and use.

Personal Protective Measurers

Respiratory Protection: Not necessary if workplace concentrations of hazardous constituents are below recommended limits. If the exposure limit is exceeded, an approved respirator should be worn. Respirator selection and use should be based on contaminant type, form and concentration. Follow local regulations and good Industrial Hygiene practice.

Eye Protection: Follow facility requirements.

Skin Protection: None required.

Other protection: None required.

Document was approved per CR-015944

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic Physical and Chemical Properties:

Appearance and Odor: Smooth, white ointment.

Solubility in Water:	Insoluble	Boiling Point:	Not Applicable
Odor Threshold:	Not Applicable	Partition Coefficient:	Not Applicable
pH:	Not Applicable	Melting Point:	Not Applicable
Specific Gravity:	1.08 @ 21°C	Vapor Density:	Not Applicable
Evaporation Rate:	Not Applicable	Vapor Pressure:	Not Applicable
Flammability(solid/gas):	Not Applicable	Flash Point:	>200°F (93.3°C)
Explosive Limits:	Not Applicable	Autoignition Temperature:	Not determined
Decomposition Temperature:	Not Applicable	Viscosity:	Not determined
Explosive Properties:	Not explosive	Oxidizing Properties:	Not an oxidizer

10. STABILITY AND REACTIVITY

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

Chemical Stability: Stable.

Possibility of Hazardous Reactions: None known.

Conditions to Avoid: None known.

Incompatible Materials: None known.

Hazardous Decomposition Products: Products of combustion include carbon dioxide, carbon monoxide, silicon dioxide and irritating smoke.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Hazards

Inhalation: None expected.

Skin Contact: None expected.

Eye Contact: May cause slight irritation.

Ingestion: Not expected to be acutely toxic.

Chronic Health Effects: None known.

Acute Toxicity Values: Oral rat LD50: > 2000 mg/kg
Dermal rabbit LD50: >2000 mg/kg

Skin corrosion/irritation: No irritation is expected.

Eye damage/ irritation: No irritation is expected.

Respiratory Irritation: No irritation is expected.

Skin Sensitization: No adverse effects expected. Components are not sensitizers.

Respiratory Sensitization: No adverse effects expected. Components are not sensitizers.

Germ Cell Mutagenicity: 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.

Developmental / Reproductive Toxicity: This product is not expected to present a risk of adverse reproductive or developmental toxicity.

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.

12. ECOLOGICAL INFORMATION

Toxicity: Zinc Oxide: Zebrafish LC50: 1.793 mg/L/96 hr; Daphnia EC50: 1.7 mg/L/48 hr

Persistence and degradability: Product contains zinc oxide which is not rapidly biodegradable.

Bioaccumulative Potential: No data available.

Mobility in Soil: No data available.

Results of PVT and vPvB assessment: None required.

Other Adverse Effects: None known.

13. DISPOSAL CONSIDERATIONS

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

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(es)	14.4 Packing Group	14.5 Environmental Hazards
US DOT	None	Not Regulated	None	None	
CANADIAN TDG	None	Not Regulated	None	None	
EU ADR/RID	None	Not Regulated	None	None	
IMDG	None	Not Regulated	None	None	
IATA/ICAO	None	Not Regulated	None	None	

14.6 Special Precautions for User: None identified

14.7 Transport in Bulk According to Annex III MARPOL 73/78 and the IBC Code: Not applicable. Transported in packaged form only.

15. REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

United States Regulations

EPA SARA Regulations:

SARA 311/312 Hazard Categories:

- N – Fire Hazard
- N – Sudden Release of Pressure
- N – Reactivity
- N – Acute Health
- N – Chronic Health

SARA 313: This contains the following chemicals above de minimus concentrations subject to the notification or reporting requirements of SARA 313: None

CERCLA Section 103: This product is not subject to release notification. However, states and local authorities may have more stringent requirements. Report releases as required by all local and national authorities.

California Proposition 65: This product is not known to contain chemicals regulated under California Proposition 65.

Canada Regulations

WHMIS: This product is not hazardous.

INTERNATIONAL INVENTORIES

TSCA Status: All of the ingredients of this product are listed on TSCA.

Document was approved per CR-015944

Canadian Environmental Protection Act: All of the ingredients of this product are listed on the DSL.

16. OTHER INFORMATION

Full text of Classification abbreviations used in Section 2 and 3:

Acute Tox Cat 4 - Acute Toxicity Category 4

Eye Irrit Cat 2 - Eye Irritation Category 2

H302 - Harmful if swallowed.

H319 - Causes serious eye irritation.

This information is furnished without warranty, expressed or implied. It is accurate to the best knowledge of ConvaTec. The data on this sheet is related only to the specific product designated herein. ConvaTec assumes no legal responsibility for the use or reliance upon these data.

HISTORY PAGE

VERSION:	1.0	DCR:	006045	ORIGINATOR:	Donn Hirschmann
COMMENTS: THIS IS AN ORIGINAL SAFETY DATA SHEET.					
VERSION:	2.0	DCR:	007571	ORIGINATOR:	A. Agrawal
COMMENTS: THIS IS PART OF AN UMBRELLA DCR (SDS12-016-PA, SDS13-044-NA, SDS13-045-NA, SDS13-064-NA, SDS13-065-NA, SDS13-067-EU, SDS13-069-NA, SDS13-070-NA). THROUGHOUT DOCUMENT, REMOVED BMS REFERENCES. THERE ARE NO TECHNICAL CHANGES TO THE DOCUMENT; CONVA TEC IS NO LONGER A BMS COMPANY.					
VERSION:	3.0	CR:	015944	ORIGINATOR:	D. Miles
COMMENTS: MANUFACTURER'S DETAILS WAS UPDATED IN SECTION 1. THE SAFETY DATA SHEET WAS UPDATED TO COMPLY WITH THE GLOBAL HARMONISED SYSTEM REQUIREMENTS.					

Document was approved per CR-015944