

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

1.1 Product Names: Stomahesive® Powder
Orahesive® Powder
Varicare™

1.2 Product Use: Skin protectant

1.3 Manufacturer/Supplier:	ConvaTec Inc. 211 America Ave Greensboro North Carolina 27409 USA	ConvaTec Canada Ltd. 1425 TransCanada Highway, suite 100 Dorval Québec H9P 2V3
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Customer Helpline: Customer Interaction Centre: Canada: 1-800-465-6302

USA: 800-422-8811

Contact (email address): USA: cic@convatec.com

Canada: convatec.canada@convatec.com

1.4 In Case of Emergency Call: CHEMTREC: 800-424-9300
Outside USA: +1 703 527 3887

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture The product is not classified according to the Globally Harmonized System (GHS).

Classification according to Directive 67/548/EEC or Directive 1999/45/EC Not applicable.

Information concerning particular hazards for human and environment: Not applicable.

Additional information:

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.

Label elements

GHS label elements Not applicable

Hazard pictograms Not applicable

Signal word Not applicable

Hazard statements Not applicable

Additional information:

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.

Classification system:

NFPA ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

HMIS ratings (scale 0 - 4)



Health = 0

Fire = 0

Reactivity = 0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical characterization: Mixtures

Description: Class I medical device

Dangerous components: Not applicable

Additional information: All the percentages given are percentages by weight unless stated otherwise.

4. FIRST AID MEASURES

Description of first aid measures

General information: In case of doubt or when symptoms persist, always call a doctor.

After inhalation:

Supply fresh air; consult doctor in case of complaints.

After skin contact:

Remove contaminated clothing and shoes.

Wash with water and soap.

Seek immediate medical advice if symptoms occur.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

Do not rub the eyes. Flush eyes with clean water.

Remove contact lenses.

After swallowing:

Do not induce vomiting; immediately call for medical help.

Rinse mouth with clean water.

Information for doctor:

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

Indication of any immediate medical attention and special treatment needed

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

5. FIRE FIGHTING MEASURES

Extinguishing media

Suitable extinguishing agents:

Not applicable. The product is not flammable.

Use firefighting measures that suit the environment.

For safety reasons unsuitable extinguishing agents: Water with full jet.

Special hazards arising from the substance or mixture No further relevant information available.

Advice for firefighters

Protective equipment: Standard protective clothing for firefighters.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures Not required.

Environmental precautions: No special measures required.

Methods and material for containment and cleaning up:

Shut off leaks if without risk.

If possible dike the spill with inert material.

Dispose contaminated material as waste according to item 13.

Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

7. HANDLING AND STORAGE

Handling:

Precautions for safe handling No special measures required.

Information about protection against explosions and fires: No special measures required.

Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles: Store in a cool, dry, well ventilated place.

Information about storage in one common storage facility: No special measures required.

Further information about storage conditions: Keep receptacle tightly sealed.

Specific end use(s) No further relevant information available.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

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

Control parameters

Components with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

Additional information: The lists that were valid during the creation were used as basis.

Exposure controls

Personal protective equipment:

General protective and hygienic measures: The usual precautionary measures for handling chemicals should be followed.

Breathing equipment: Not required.

Protection of hands: Optional.

Eye protection: Not required.

9. PHYSICAL AND CHEMICAL PROPERTIES

· Information on basic physical and chemical properties	
· General Information	
· Appearance:	
Form:	Powder
Color:	Off white to light tan
· Odor:	Odorless
· Odor threshold:	Not determined.
· pH-value:	Not determined.
· Change in condition	
Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
· Flash point:	Not applicable.
· Flammability (solid, gaseous):	Not applicable.
· Ignition temperature:	
Decomposition temperature:	Not determined.
· Auto igniting:	Product is not self-igniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not determined.
· Density:	Not determined.
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with	
Water:	Miscible.
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not determined.
	Not applicable.
Kinematic:	Not determined.
· Other information	No further relevant information available.

10. STABILITY AND REACTIVITY

Reactivity No further relevant information available.

Chemical stability

Thermal decomposition / conditions to be avoided: No decomposition if used and stored according to specifications.

Possibility of hazardous reactions No dangerous reactions known.

Conditions to avoid No further relevant information available.

Incompatible materials: No further relevant information available.

Hazardous decomposition products: Formation of toxic gases is possible during heating or in case of fire.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity:

Available data: Based on available data acute toxic effects are not expected.

Primary irritant effect:

on the skin: No irritant effect.

on the eye: No irritating effect.

Respiratory tract: Not applicable.

Ingestion: Not applicable.

Sensitization: No sensitizing effects known.

Additional toxicological information:

Carcinogenic categories

IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

NTP (National Toxicology Program)

None of the ingredients is listed.

OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

CMR effects (carcinogenicity, mutagenicity, toxicity for reproduction):

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

12. ECOLOGICAL INFORMATION

Toxicity

Aquatic toxicity: No further relevant information available.

Persistence and degradability No further relevant information available.

Behavior in environmental systems:

Bioaccumulative potential No further relevant information available.

Mobility in soil No further relevant information available.

Additional ecological information:

General notes: Generally not hazardous for water

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.

Other adverse effects No further relevant information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Recommendation: Disposal must be made according to official regulations.

Uncleaned packagings:

Recommendation: Disposal must be made according to official regulations.

14. TRANSPORT INFORMATION

· UN-Number	
· DOT, ADR, RID, ADN, IMDG, IATA	Not applicable
· UN proper shipping name	
· DOT, ADR, RID, ADN, IMDG, IATA	Not applicable
· Transport hazard class(es)	
· DOT, ADR, RID, ADN, IMDG, IATA	
· Class	Not applicable
· Packing group	
· DOT, ADR, RID, ADN, IMDG, IATA	Not applicable
· Environmental hazards:	
· Marine pollutant:	No
· Special precautions for user	Not applicable.
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· UN "Model Regulation":	Not applicable

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15. REGULATORY INFORMATION

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

Sara

Section 355 (extremely hazardous substances):
None of the ingredient is listed.
Section 313 (Specific toxic chemical listings):
None of the ingredients is listed.
TSCA (Toxic Substances Control Act):
All ingredients are listed.

Proposition 65

Chemicals known to cause cancer:
None of the ingredients is listed.
Chemicals known to cause reproductive toxicity for females:
None of the ingredients is listed.

Chemicals known to cause reproductive toxicity for males:
None of the ingredients is listed.
Chemicals known to cause developmental toxicity:
None of the ingredients is listed.

Carcinogenic categories

EPA (Environmental Protection Agency)
None of the ingredients is listed.
TLV (Threshold Limit Value established by ACGIH)
None of the ingredients is listed.
NIOSH-Ca (National Institute for Occupational Safety and Health)
None of the ingredients is listed.

GHS label elements Not applicable

Hazard pictograms Not applicable

Signal word Not applicable

Hazard statements Not applicable

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

16. OTHER INFORMATION

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

Abbreviations and acronyms:

NOEC: No Observed Effect Concentration

IC50: Inhibition Concentration, 50 percent

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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HISTORY PAGE

VERSION:	1.0	CR:	018236	ORIGINATOR:	Desiree Miles		
COMMENTS: This is the first version of this document. This product safety data sheet was written according to Global Harmonized System							
VERSION:	2.0	CR:	019137	ORIGINATOR:	D. Miles		
COMMENTS: Updated Section 1.0 to correct the customer helpline number for the USA to 800-422-8811. Section 2, included exception statement for Canada.							
VERSION:	3.0	CR:	020644	ORIGINATOR:	Julian Fairhurst Jackie Collings	Date:	To be completed at next update
COMMENTS: This is an umbrella CR, other document's affected SDS13-044-NAE, SDS13-040-NAE, SDS13-045-NAE, SDS13-060-NAE, SDS13-070-NAE, SDS12-027-NAE and SDS12-034-NAE. Section 1.3 updated the customer helpline phone number and address for Canada.							

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SIGNATURE PAGE

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Version:	3.0,Effective,CURRENT

Signed by	Justification	Date & Time
Jackie Collings	Author Approval	5/3/2016 7:49:47 AM
Nathalie Ayotte	Quality Approval	4/28/2016 10:40:42 AM
Sara J Peers	Change Control Approval	4/26/2016 3:34:30 AM