Safety Data Sheet



Section 1: Identification

Product identifier

Product Name • Theraseal™ Hand Protection

Product Code • 301871660066

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Skin care product.

Restrictions on use• Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer

 Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807 United States

valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer +1 352-323-3500 - International - Infotrac

Consumer product: This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to consumer use of the product.

Section 2: Hazard Identification

UN GHS

According to: UN Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Classification of the substance or mixture

UN GHS • Skin Mild Irritation 3

Label elements

UN GHS

WARNING

Precautionary statements

Prevention • Wear protective gloves .

Response • If skin irritation occurs: Get medical advice/attention.

Storage/Disposal • Store at room temperature 15-30C (59-86F).

Other hazards

UN GHS • No data available

Preparation Date: 09/April/2015

Revision Date: 09/April/2015

Page 1 of 9

Format: GHS Language: English (US)

UN GHS

Section 3 - Composition/Information on Ingredients

Substances

 Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Mixtures

Composition					
Chemical Name	Identifiers	%	Classifications According to Regulation/Directive		
Water	CAS:7732-18-5 EINECS:231-791-2	*	UN GHS: not classified		
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	*	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5		
Imidurea	CAS:39236-46-9 EINECS:254-372-6	*	UN GHS: NDA		
Cyclomethicone	CAS:69430-24-6	*	UN GHS: NDA		
Dimethicone 360	CAS:63148-62-9	1%	UN GHS: NDA		
Cyclomethicone aluminum magnesium hydroxide stearate	NDA	*	UN GHS: NDA		
Cetyl dimethicone copolyol	CAS:145686-34-6	*	UN GHS: NDA		
Polyglyceryl-4-isostearate	CAS:91824-88-3	*	UN GHS: NDA		
Hexyl laurate	CAS:34316-64-8 EINECS:251-932-1	*	UN GHS: NDA		

^{*}Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

 No adverse effects anticipated by breathing small amounts. If large amounts are inhaled, remove to fresh air.

Skin

 IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention.

Eye

 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Ingestion

Call a physician or poison control center.

Most important symptoms and effects, both acute and delayed

No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Carbon dioxide, dry chemical powder, appropriate foam or water fog.

Unsuitable Extinguishing • No data available

Preparation Date: 09/April/2015

Revision Date: 09/April/2015

Page 2 of 9

Format: GHS Language: English (US)

UN GHS

Media

Firefighting Procedures

• As in any fire, wear self-contained breathing apparatus and full protective gear.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion

Hazards

Hazardous Combustion

Products

No data available

No data available

Advice for firefighters

No data available

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

No special controls or personal protection required under conditions of intended use.
 In the event of bulk spills, wear suitable protective eyewear, clothing, protective boots and protective gloves. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8.

Emergency Procedures

• Ventilate area. Contain spilled product. For small spills, add suitable absorbent material. Scoop up and place in an appropriate liquid-tight container equipped with a tight cover for disposal. For large spills, dike spilled material or otherwise contain material to ensure runoff does not reach a waterway. Place spilled material in an appropriate, liquid-tight container equipped with a tight cover for disposal. Minimize contact of spilled material with soils to prevent runoff to surface waterways. Dispose of in accordance with Section 13.

Environmental precautions

 Prevent spilled material from entering storm sewers or drains, waterways, and contact with soil.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

No data available

Section 7 - Handling and Storage

Precautions for safe handling

Handling

 Avoid contact with eyes. Avoid prolonged or repeated exposure to skin or mucous membranes, and breathing mists/vapors. Use in a well ventilated area, away from all sources of ignition. Keep container closed. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities

Storage

Store at room temperature 15-30C (59-86F).

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

 Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure controls

Engineering Measures/Controls

 No special controls are required under conditions of intended use. Local exhaust ventilation should be provided when handling bulk product.

Personal Protective Equipment

Preparation Date: 09/April/2015

Revision Date: 09/April/2015

Page 3 of 9

Format: GHS Language: English (US)

UN GHS

Pictograms



Respiratory

• In the event of a bulk spill, and where risk assessment shows that air-purifying respirators are appropriate, a NIOSH (US) or CEN (EU) -certified air-purifying respirator equipped with organic vapor cartridges may be permissible under certain circumstances where airborne concentrations are expected to exceed exposure limits, when adequate oxygen is present and as a backup to engineering controls. Use a positive pressure air-supplied respirator if there is any potential for an uncontrolled release or any other circumstances where air purifying respirators may not provide adequate protection.

Eye/Face

Wear eye/face protection , .

Hands

Wear protective gloves .

Skin/Body

No special personal protection required under conditions of intended use. In the event
of a bulk spill, wear appropriate protective clothing.

General Industrial Hygiene Considerations

Handle in accordance with good industrial hygiene and safety practice.

Environmental Exposure Controls

No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid Cream	Color	White
Odor	Not relevant	Odor Threshold	Not relevant
General Properties		-	
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	Not relevant	рН	No data available
Specific Gravity/Relative Density	No data available	Water Solubility	Slightly water soluble
Viscosity	No data available		
Volatility		-	
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	Not relevant		
Flammability		-	
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Flammability (solid, gas)	Not relevant		
Environmental			
Octanol/Water Partition coefficient	Not relevant		

Section 10: Stability and Reactivity

Reactivity

Stable under normal temperatures and pressures.

Chemical stability

Stable under normal temperatures and pressures.

Possibility of hazardous reactions

Preparation Date: 09/April/2015

Revision Date: 09/April/2015

Page 4 of 9

Format: GHS Language: English (US)

UN GHS

No data available

Conditions to avoid

Excessive heat above 90°F for prolonged periods.

Incompatible materials

No data available

Hazardous decomposition products

No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Dimethicone 360 (1%)	163148-62-9	Acute Toxicity: Ingestion/Oral-Rat LDLo • >5 g/kg; Irritation: Skin-Rabbit • 500 μL 24 Hour(s) • Mild irritation

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Aspiration Hazard	UN GHS • Classification criteria not met
Carcinogenicity	UN GHS • Classification criteria not met
Germ Cell Mutagenicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Skin Mild Irritation 3
Skin sensitization	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
Toxicity for Reproduction	UN GHS • Classification criteria not met
Respiratory sensitization	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

Acute (Immediate)

Chronic (Delayed)

Under normal conditions of use, no health effects are expected.

Under normal conditions of use, no health effects are expected.

May cause mild irritation.

Chronic (Delayed)

Acute (Immediate)

May cause skin irritation.

Skin

Acute (Immediate)

Chronic (Delayed)

Under normal conditions of use, no health effects are expected.

Under normal conditions of use, no health effects are expected.

Ingestion

Acute (Immediate)

May be harmful if swallowed.

Chronic (Delayed)

Under normal conditions of use, no health effects are expected.

Preparation Date: 09/April/2015 Revision Date: 09/April/2015

Section 12 - Ecological Information

Toxicity

• This material has not been tested for environmental effects.

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in Soil

No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Packaging waste

 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

	UN number	UN proper shipping name	Transport hazard class (es)	Packing group	Environmental hazards
DOT	NDA	Not regulated	NDA	NDA	NDA
TDG	NDA	Not regulated	NDA	NDA	NDA
IMO/IMDG	NDA	Not regulated	NDA	NDA	NDA
IATA/ICAO	NDA	Not regulated	NDA	NDA	NDA

Special precautions for user

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

No data available

Section 15 - Regulatory Information

Safety, health and environmental regulations/legislation specific for the substance or mixture SARA Hazard Classifications • No data available

Inventory					
Component	CAS	Canada DSL	Canada NDSL	EU EINECS	TSCA
Cetyl dimethicone copolyol	145686-34- 6	No	No	No	No
Cyclomethicone	69430-24-6	Yes	No	No	Yes
Dimethicone 360	63148-62-9	Yes	No	No	Yes

Preparation Date: 09/April/2015 Revision Date: 09/April/2015 Format: GHS Language: English (US)
UN GHS

Hexyl laurate	34316-64-8	Yes	No	Yes	Yes
Polyglyceryl-4- isostearate	91824-88-3	No	No	No	No
Sodium chloride	7647-14-5	Yes	No	Yes	Yes
Imidurea	39236-46-9	Yes	No	Yes	Yes
Water	7732-18-5	Yes	No	Yes	Yes

Canada

Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Canada - WHMIS - Classifications of Substances		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
Imidurea	39236-46-9	Not Listed
		Uncontrolled product
Water	7732-18-5	according to WHMIS classification criteria
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
Canada - WHMIS - Ingredient Disclosure List		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed

Environment		
Canada - DWQ (Drinking Water Quality) - IMACs		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
• Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed

Preparation Date: 09/April/2015 Revision Date: 09/April/2015

United States

Environment		
U.S CERCLA/SARA - Hazardous Substances and their Reportable Quan		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
• Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
U.S RCRA (Resource Conservation & Recovery Act) - Basis for Listing	- Appendix VII	
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
U.S RCRA (Resource Conservation & Recovery Act) - D Series Wastes	- Max Conc of Contamina	nts for the Tox
Characteristic		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
Imidurea	39236-46-9	Not Listed
• Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed

United States - California

Environment U.S California - Proposition 65 - Carcinogens List			
Cyclomethicone	69430-24-6	Not Listed	
Sodium chloride	7647-14-5	Not Listed	
Imidurea	39236-46-9	Not Listed	
Water	7732-18-5	Not Listed	
Dimethicone 360	63148-62-9	Not Listed	
Cetyl dimethicone copolyol	145686-34-6	Not Listed	
Polyglyceryl-4-isostearate	91824-88-3	Not Listed	
Hexyl laurate	34316-64-8	Not Listed	
U.S California - Proposition 65 - Developmental Toxicity			
Cyclomethicone	69430-24-6	Not Listed	
Sodium chloride	7647-14-5	Not Listed	
Imidurea	39236-46-9	Not Listed	
• Water	7732-18-5	Not Listed	
Dimethicone 360	63148-62-9	Not Listed	
Cetyl dimethicone copolyol	145686-34-6	Not Listed	

Preparation Date: 09/April/2015 Revision Date: 09/April/2015 Format: GHS Language: English (US)
UN GHS

Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Female		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
• Imidurea	39236-46-9	Not Listed
• Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed
U.S California - Proposition 65 - Reproductive Toxicity - Male		
Cyclomethicone	69430-24-6	Not Listed
Sodium chloride	7647-14-5	Not Listed
• Imidurea	39236-46-9	Not Listed
• Water	7732-18-5	Not Listed
Dimethicone 360	63148-62-9	Not Listed
Cetyl dimethicone copolyol	145686-34-6	Not Listed
Polyglyceryl-4-isostearate	91824-88-3	Not Listed
Hexyl laurate	34316-64-8	Not Listed

Section 16 - Other Information

Last Revision Date Preparation Date Disclaimer/Statement of Liability

- 09/April/2015
- 09/April/2015
- The above information and recommendations contained in the Safety Data Sheet have been compiled from sources believed to be accurate and reliable and to represent the most reasonable current opinion on the subject as of the date the SDS was prepared. No warranty, guaranty, or representation is made as to the correctness or sufficiency of the information. Such data are offered solely for consideration, investigation, and verification but do not purport to be all inclusive and should be used only as a guide. The user of this product must decide what safety measures are necessary to safely use this product, either alone or in combination with other products, and determine its environmental regulatory compliance obligations under any applicable federal or state laws.

Preparation Date: 09/April/2015 Revision Date: 09/April/2015