

Safety Data Sheet



Section 1: Identification

Product identifier

- Product Name** • Solesta®
- Product Code** • 389114850030; 89114085003

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

- Recommended use** • Solesta is indicated for the treatment of fecal incontinence in patients 18 years and older who have failed conservative therapy.
- Restrictions on use** • Use in accordance with product literature.

Details of the supplier of the safety data sheet

- Manufacturer** • Salix Pharmaceuticals, Inc., a wholly owned subsidiary of Valeant Pharmaceuticals International, Inc.

Bridgewater, NJ 08807
United States
salix.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - US - Infotrac
- Manufacturer** • +1 352-323-3500 - International - Infotrac

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** • Classification criteria not met

Label elements

UN GHS

Other hazards

- UN GHS** • No data available

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	%
Dextranomer	CAS:56087-11-7	5%
Hyaluronic acid (sodium salt)	CAS:9067-32-7	1% TO 2%
Water	CAS:7732-18-5 EINECS:231-791-2	90% TO 95%

The exact percentage of composition has been withheld as a trade secret.

Section 4: First-Aid Measures

Description of first aid measures

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|-------------------|--|
| Inhalation | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention. |
| Skin | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes. |
| Eye | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not irritating to the eye. |
| Ingestion | <ul style="list-style-type: none"> No specific treatment is necessary since this material is not likely to be hazardous by ingestion. If large quantities are accidentally ingested (greater than a tablespoon), get medical attention immediately. |

Most important symptoms and effects, both acute and delayed

- No data available

Indication of any immediate medical attention and special treatment needed

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

Section 5: Fire-Fighting Measures

Extinguishing media

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| Suitable Extinguishing Media | <ul style="list-style-type: none"> Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire. |
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| Unsuitable Extinguishing Media | <ul style="list-style-type: none"> No data available |
|---------------------------------------|---|

Special hazards arising from the substance or mixture

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| Unusual Fire and Explosion Hazards | <ul style="list-style-type: none"> None known - product is not flammable or combustible. |
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| Hazardous Combustion Products | <ul style="list-style-type: none"> No data available |
|--------------------------------------|---|

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

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| Personal Precautions | <ul style="list-style-type: none">• 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. Refer to Section 8. |
| Emergency Procedures | <ul style="list-style-type: none">• No emergency procedures are expected to be necessary when used in accordance with product literature. |

Environmental precautions

- No data available

Methods and material for containment and cleaning up

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|--------------------------------------|--|
| Containment/Clean-up Measures | <ul style="list-style-type: none">• 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. |
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Section 7 - Handling and Storage

Precautions for safe handling

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| Handling | <ul style="list-style-type: none">• No special handling is required. Refer to Section 8. Use only in accordance with product literature. |
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Conditions for safe storage, including any incompatibilities

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| Storage | <ul style="list-style-type: none">• Do not store above 25°C (77°F). Do not freeze. Store in original package in order to protect from light. |
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Section 8 - Exposure Controls/Personal Protection

Control parameters

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| Exposure Limits/Guidelines | <ul style="list-style-type: none">• Refer to the occupational exposure limits / guidelines for the individual product components. |
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Exposure controls

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| Engineering Measures/Controls | <ul style="list-style-type: none">• Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. |
|--------------------------------------|---|

Personal Protective Equipment

- | | |
|--------------------|---|
| Respiratory | <ul style="list-style-type: none">• No respiratory protection required during normal handling. |
| Eye/Face | <ul style="list-style-type: none">• No eye protection is required during normal handling. |
| Hands | <ul style="list-style-type: none">• Wear protective gloves . |
| Skin/Body | <ul style="list-style-type: none">• No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing. |

- | | |
|--|---|
| Environmental Exposure Controls | <ul style="list-style-type: none">• No data available |
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Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Appearance/Description	Grey to whitish turbid gel.
Color	Grey-whitish	Odor	No odor.
Odor Threshold	Not relevant		
General Properties			
Boiling Point	100 °C(212 °F)	Melting Point/Freezing Point	0 °C(32 °F)
Decomposition Temperature	No data available	pH	4.5 to 6.5
Specific Gravity/Relative Density	No data available	Density	1 g/mL
Water Solubility	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	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

Other Material Information • Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

Components		
Dextranomer (5%)	56087-11-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • >5 g/kg; <i>Gastrointestinal:</i> Nausea or vomiting ; <i>Skin and Appendages:</i> Other:Hair
Hyaluronic acid (sodium salt) (1% TO 2%)	9067-32-7	Acute Toxicity: Ingestion/Oral-Rat LD50 • >800 mg/kg; <i>Nutritional and Gross Metabolic:</i> Changes in Chemistry or Temperature:Other changes

GHS Properties	Classification
Acute toxicity	UN GHS • Classification criteria not met
Skin corrosion/Irritation	UN GHS • Classification criteria not met
Serious eye damage/Irritation	UN GHS • Classification criteria not met
Skin sensitization	UN GHS • Classification criteria not met
Respiratory sensitization	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
Toxicity for Reproduction	UN GHS • Classification criteria not met
STOT-SE	UN GHS • Classification criteria not met
STOT-RE	UN GHS • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

Other

- Acute (Immediate)** • Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)** • Under normal conditions of use, no health effects are expected.

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

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

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	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
TDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IMO/IMDG	Not Applicable	Not Regulated	Not Applicable	Not Applicable	
IATA/ICAO	Not Applicable	Not Regulated	Not Applicable	Not Applicable	

Special precautions for user • No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code • 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
Dextranomer	56087-11-7	No
Hyaluronic acid (sodium salt)	9067-32-7	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

- | | | |
|---------------------------------|------------|------------|
| • Hyaluronic acid (sodium salt) | 9067-32-7 | Not Listed |
| • Dextranomer | 56087-11-7 | Not Listed |

Canada - WHMIS - Ingredient Disclosure List

- | | | |
|---------------------------------|------------|------------|
| • Hyaluronic acid (sodium salt) | 9067-32-7 | Not Listed |
| • Dextranomer | 56087-11-7 | Not Listed |

United States - California

Environment

U.S. - California - Proposition 65 - Carcinogens List

- | | | |
|---------------------------------|------------|------------|
| • Hyaluronic acid (sodium salt) | 9067-32-7 | Not Listed |
| • Dextranomer | 56087-11-7 | Not Listed |

U.S. - California - Proposition 65 - Developmental Toxicity

• Hyaluronic acid (sodium salt)	9067-32-7	Not Listed
• Dextranomer	56087-11-7	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Female		
• Hyaluronic acid (sodium salt)	9067-32-7	Not Listed
• Dextranomer	56087-11-7	Not Listed
U.S. - California - Proposition 65 - Reproductive Toxicity - Male		
• Hyaluronic acid (sodium salt)	9067-32-7	Not Listed
• Dextranomer	56087-11-7	Not Listed

Section 16 - Other Information

Revision Date	<ul style="list-style-type: none">• 22/February/2016
Last Revision Date	<ul style="list-style-type: none">• 22/February/2016
Preparation Date	<ul style="list-style-type: none">• 22/February/2016
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