

SAFETY DATA SHEET

1. Identification

Product identifier Uceris (budesonide) Rectal Foam
Other means of identification None.
Recommended use Anti-inflammatory agent.
Recommended restrictions None known.
Manufacturer/Importer/Supplier/Distributor information
Manufacturer: Salix Pharmaceuticals
8510 Colonnade Center Drive
Raleigh, NC 27615
Company Telephone: 1-919-862-1000
Company Fax: 1-919-862-1095
E-mail address: customerservice@salix.com
Emergency Telephone: 1-800-508-0024

2. Hazard(s) identification

Physical hazards Flammable aerosols Category 2
Health hazards Reproductive toxicity Category 2
OSHA defined hazards Not classified.

Label elements



Signal word Warning
Hazard statement Flammable aerosol. Suspected of damaging fertility or the unborn child.
Precautionary statement
Prevention Keep away from heat/sparks/open flames/hot surfaces. - No smoking. Do not spray on an open flame or other ignition source. Pressurized container: Do not pierce or burn, even after use. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wear protective gloves/protective clothing/eye protection/face protection.
Response If exposed or concerned: Get medical advice/attention.
Storage Store locked up. Protect from sunlight. Do not expose to temperatures exceeding 50°C/122°F.
Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.
Hazard(s) not otherwise classified (HNOC) None known.

3. Composition/information on ingredients

Mixtures

Chemical name	CAS number	%
Propylene glycol	57-55-6	40 - 50
Budesonide	51333-22-3	< 0.16

Constituents

Chemical name	CAS number	%
Isobutane	75-28-5	4 - 6
Butane	106-97-8	1 - 2
Propane	74-98-6	1 - 2

4. First-aid measures

Inhalation	If symptomatic, move to fresh air. Get medical attention if symptoms persist.
Skin contact	Wash with soap and water. Get medical attention if symptoms occur.
Eye contact	Any material that contacts the eye should be washed out immediately with water. If easy to do, remove contact lenses. Get medical attention if symptoms persist.
Ingestion	Seek medical advice.
Most important symptoms/effects, acute and delayed	Direct contact with eyes may cause temporary irritation. Suspected of damaging fertility or the unborn child.
Indication of immediate medical attention and special treatment needed	Treat symptomatically.

5. Fire-fighting measures

Suitable extinguishing media	Water. Water fog. Foam. Dry chemical. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	Aerosol cans may explode in a fire. Thermal decomposition or combustion may liberate toxic gases or fumes.
Special protective equipment and precautions for firefighters	Use water spray to keep fire-exposed containers cool.
Fire fighting equipment/instructions	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Extinguish all ignition sources. Avoid sparks, flames, heat and smoking. Wear protective clothing as described in Section 8 of this safety data sheet.
Methods and materials for containment and cleaning up	Absorb spill with vermiculite or other inert material, then place in a sealed container for chemical waste. Large Spills: Flush area with water. Prevent runoff from entering drains, sewers, or streams. Dike for later disposal.
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Keep away from heat, sparks and open flame. Do not breathe mist or vapor. Do not get on skin and clothing. Avoid contact with eyes. Use only with adequate ventilation. Wash thoroughly after handling. Observe good industrial hygiene practices. Pressurized container: Do not pierce or burn, even after use.
Conditions for safe storage, including any incompatibilities	Keep container closed. Keep cool. Aerosol cans: Must not be exposed to direct sunlight or temperatures above 50°C.

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Constituents	Type	Value
Propane (CAS 74-98-6)	PEL	1800 mg/m ³ 1000 ppm

US. ACGIH Threshold Limit Values

Constituents	Type	Value
Butane (CAS 106-97-8)	STEL	1000 ppm
Isobutane (CAS 75-28-5)	STEL	1000 ppm

US. NIOSH: Pocket Guide to Chemical Hazards

Constituents	Type	Value
Propane (CAS 74-98-6)	TWA	1800 mg/m ³

US. NIOSH: Pocket Guide to Chemical Hazards

Constituents	Type	Value
Butane (CAS 106-97-8)	TWA	1000 ppm
		1900 mg/m ³
		800 ppm
Isobutane (CAS 75-28-5)	TWA	1900 mg/m ³
		800 ppm

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
Propylene glycol (CAS 57-55-6)	TWA	10 mg/m ³	Aerosol.

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Ensure adequate ventilation, especially in confined areas.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields (or goggles).

Skin protection

Hand protection Chemical resistant gloves are recommended.

Other Wear chemical-resistant gloves, footwear, and protective clothing appropriate for the risk of exposure. Contact health and safety professional or manufacturer for specific information.

Respiratory protection If engineering controls do not maintain airborne concentrations below recommended exposure limits (where applicable) or to an acceptable level (in countries where exposure limits have not been established), an approved respirator must be worn. In the United States of America, if respirators are used, a program should be instituted to assure compliance with OSHA 29 CFR 1910.134. Respirator type: Air-purifying respirator with an appropriate, government approved (where applicable), air-purifying filter, cartridge or canister. Contact health and safety professional or manufacturer for specific information.

Thermal hazards Not applicable.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants.

9. Physical and chemical properties

Appearance White foam.

Physical state Liquid.

Form Foam.

Color White.

Odor Slight hydrocarbon.

Odor threshold Not available.

pH 3.5 - 4.5

Melting point/freezing point Not available.

Initial boiling point and boiling range Not available.

Flash point -113.8 °F (-81.0 °C) (propane/isobutane/butane mixture)

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%) Not available.

Vapor pressure 2 - 3 bar at 68°F (20°C)

Vapor density Not available.

Relative density Not available.

Solubility(ies)	
Solubility (water)	Not available.
Partition coefficient (n-octanol/water)	No data available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Stable under the prescribed storage conditions.
Possibility of hazardous reactions	Hazardous polymerization will not occur.
Conditions to avoid	Pressurized container: Must not be exposed for temperatures above 50°C.
Incompatible materials	Strong oxidizing agents. Acids.
Hazardous decomposition products	Thermal decomposition or combustion may liberate toxic gases or fumes.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Prolonged skin contact may cause temporary irritation.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	No harmful effects expected in amounts likely to be ingested by accident.

Symptoms related to the physical, chemical and toxicological characteristics	Direct contact with eyes may cause temporary irritation.
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Information on toxicological effects

Acute toxicity	No adverse effects are expected.
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Components	Species	Test Results
Propylene glycol (CAS 57-55-6)		
Acute		
<i>Oral</i>		
LD50	Rat	30 g/kg
Constituents	Species	Test Results
Propane (CAS 74-98-6)		
Acute		
<i>Inhalation</i>		
LC50	Rat	1355 mg/l
Isobutane (CAS 75-28-5)		
Acute		
<i>Inhalation</i>		
LC50	Mouse	1237 mg/l, 2 Hours
Skin corrosion/irritation	Prolonged skin contact may cause temporary irritation.	
Serious eye damage/eye irritation	Direct contact with eyes may cause temporary irritation.	
Respiratory or skin sensitization		
Respiratory sensitization	Not assigned.	
Skin sensitization	Not assigned.	
Germ cell mutagenicity	Not assigned.	
Carcinogenicity	Not assigned.	
OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)		
Not listed.		

Reproductive toxicity	Suspected of damaging fertility or the unborn child.
Specific target organ toxicity - single exposure	Not assigned.
Specific target organ toxicity - repeated exposure	Not assigned.
Aspiration hazard	Not applicable.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.	
Persistence and degradability	No data available.	
Bioaccumulative potential	Not available.	
Partition coefficient n-octanol / water (log Kow)		
Propylene glycol (CAS 57-55-6)		-0.92
Propane (CAS 74-98-6)		2.36
Butane (CAS 106-97-8)		2.89
Isobutane (CAS 75-28-5)		2.8, at 20 °C
Bioconcentration factor (BCF)		
Isobutane (CAS 75-28-5)		30.8, L/kg wet weight
Mobility in soil	Not available.	
Other adverse effects	Not available.	

13. Disposal considerations

Disposal instructions	Do not discharge into drains, water courses or onto the ground.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The Waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Recover and recycle, if practical.
Contaminated packaging	Since emptied containers retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

UN number	UN1950
UN proper shipping name	Aerosols, flammable
Transport hazard class(es)	
Class	2.1
Subsidiary risk	-
Label(s)	2.1
Packing group	Not applicable.
Environmental hazards	
Marine pollutant	Yes
Special precautions for user	Not available.
Special provisions	N82
Packaging exceptions	306
Packaging non bulk	None
Packaging bulk	None

IATA

UN number	UN1950
UN proper shipping name	Aerosols, flammable
Transport hazard class(es)	
Class	2.1
Subsidiary risk	-
Packing group	Not applicable.
Environmental hazards	No.
ERG Code	10L
Special precautions for user	Not available.

IMDG

UN number UN1950
UN proper shipping name AEROSOLS, flammable
Transport hazard class(es)
Class 2
Subsidiary risk -
Packing group Not applicable.
Environmental hazards
Marine pollutant Yes
EmS Not available.
Special precautions for user Not available.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations This product is hazardous according to OSHA 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

CERCLA Hazardous Substance List (40 CFR 302.4)

Butane (CAS 106-97-8)	LISTED
Isobutane (CAS 75-28-5)	LISTED
Propane (CAS 74-98-6)	LISTED

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - Yes
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Butane (CAS 106-97-8)
Isobutane (CAS 75-28-5)
Propane (CAS 74-98-6)

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations**US. Massachusetts RTK - Substance List**

Butane (CAS 106-97-8)
Isobutane (CAS 75-28-5)
Propane (CAS 74-98-6)

US. New Jersey Worker and Community Right-to-Know Act

Butane (CAS 106-97-8)
Isobutane (CAS 75-28-5)
Propane (CAS 74-98-6)
Propylene glycol (CAS 57-55-6)

US. Pennsylvania Worker and Community Right-to-Know Law

Butane (CAS 106-97-8)
Isobutane (CAS 75-28-5)
Propane (CAS 74-98-6)
Propylene glycol (CAS 57-55-6)

US. Rhode Island RTK

Butane (CAS 106-97-8)
Isobutane (CAS 75-28-5)
Propane (CAS 74-98-6)

US. California Proposition 65

Not Listed.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates this product complies with the inventory requirements administered by the governing country(s).

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	15-January-2015
Revision date	-
Version #	01
Further information	The classification for health and environmental hazards is derived by a combination of calculation methods and test data, if available.
HMIS® ratings	Health: 1* Flammability: 3 Physical hazard: 0
Disclaimer	To the best of our knowledge, the information contained herein is accurate. However, neither the above named supplier nor any of its subsidiaries assumes any liability whatsoever for completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.