

1. Identification

1.1. Product identifier

Product Identity Stimate Nasal Spray
Alternate Names Stimate Nasal Spray

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

Intended use See Technical Data Sheet.
Application Method See Technical Data Sheet.

1.3. Details of the supplier of the safety data sheet

Company Name CSL Behring L.L.C.
1020 First Avenue
PO Box 61501
King of Prussia, PA

Emergency

24 hour Emergency Telephone No. Emergency Response: (800) 424-9300
Emergency Product Information: (800) 504-5434
Customer Service: CSL Behring L.L.C. (610) 878-4000

2. Hazard(s) identification

2.1. Classification of the substance or mixture

No applicable GHS categories.

2.2. Label elements

Using the Toxicity Data listed in section 11 and 12 the product is labeled as follows.

No applicable GHS categories.

[Prevention]:

No GHS prevention statements

[Response]:

No GHS response statements

[Storage]:

No GHS storage statements

[Disposal]:

No GHS disposal statements

3. Composition/information on ingredients

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Composition/Information on Ingredients

Desmopressin acetate (1.5 mg/ml) (16789-98-3), Active Ingredient
Chlorobutanol (5.0 mg/ml) (57-15-8), Preservative

Sodium Chloride (9 mg/ml) (7647-14-5), Osmotic Balance Adjustment
 Hydrochloric acid (7647-01-0), pH Adjustment
 Water for injection (7732-18-5), Volume Adjustment

4. First aid measures

4.1. Description of first aid measures

General	In all cases of doubt, or when symptoms persist, seek medical attention. Never give anything by mouth to an unconscious person.
Inhalation	Remove to fresh air, keep patient warm and at rest. If breathing is irregular or stopped, give artificial respiration. If unconscious place in the recovery position and obtain immediate medical attention. Give nothing by mouth.
Eyes	Irrigate copiously with clean water for at least 15 minutes, holding the eyelids apart and seek medical attention.
Skin	Remove contaminated clothing. Wash skin thoroughly with soap and water or use a recognized skin cleanser.
Ingestion	Rinse from mouth and seek medical guidance. Induce vomiting only as directed by medical personnel. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed

Overview	<p>Potential Health Effects: This product contains, as an active ingredient, desmopressin acetate. It is a synthetic analogue of the natural human hormone arginine vasopressin. This is a biologically active pharmaceutical product with specific therapeutic effects. It is licensed by the FDA for certain medical indications and is only to be administered as prescribed by a licensed physician.</p> <p>Emergency Overview: This product is a sterile prescription pharmaceutical. It is to be administered only at the order of a licensed physician. This product is safe when used for its intended purpose and administered as directed by a physician. In addition, no adverse health effects are anticipated as a result of incidental contact or exposure to this product by those handling it or administering it in a therapeutic setting. More detailed information is available in the product package insert. Please report adverse events in patients using this product to the manufacturer at the telephone number listed above.</p> <p>Eye Contact: May cause eye irritation due to the pH level. Skin Contact: May cause skin irritation in sensitive individuals due to the pH level. Skin Absorption: This product is designed to be absorbed from the nasal mucosa. It is not expected to be absorbed appreciable through the intact skin. Ingestion: Not intended for oral use. Expected to be relatively non-toxic if ingested. See section 2 for further details.</p>
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5. Fire-fighting measures

5.1. Extinguishing media

Recommended extinguishing media; alcohol resistant foam, CO₂, powder, water spray.
 Do not use: water jet.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition: Packaging material fire may produce carbon monoxide and other gaseous asphyxiants, plus airborne particulate matter.

5.3. Advice for fire-fighters

This product is neither flammable nor explosive. The only fire hazard would involve packaging material.

Firefighting personnel should respond with appropriate protective clothing, firefighting gear and breathing equipment, as trained. All other personnel should exit the area and proceed to a gathering point in an area unaffected by fire and smoke.

ERG Guide No. ----

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Put on appropriate personal protective equipment (see section 8).

6.2. Environmental precautions

Do not allow spills to enter drains or waterways.

Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

6.3. Methods and material for containment and cleaning up

Large Spill: Absorb spills with material suitable for aqueous solutions and dispose in solid waste container, or mop spilled material with detergent/water or bleach/water solution and dispose in sanitary sewer. Ventilate area, if desired.

Small Spill: Clean area of spill with wetted toweling and dispose in solid waste container, or follow procedure for large spills.

7. Handling and storage

7.1. Precautions for safe handling

Wear suitable protective clothing (may include gloves, gowns, plastic aprons, masks, caps, safety eye glasses, face shields or respirators) and prevent physical damage to package to avoid breakage and spilling.

See section 2 for further details. - [Prevention]:

7.2. Conditions for safe storage, including any incompatibilities

Handle containers carefully to prevent damage and spillage.

Incompatible materials: No data available.

Store in accordance with the conditions specified in the product package insert.

See section 2 for further details. - [Storage]:

7.3. Specific end use(s)

No data available.

8. Exposure controls and personal protection

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

8.2. Exposure controls

Respiratory Not Required

Eyes None required to provide protection against the product. Eye protection may be required by procedure of administration.

Skin	None required for protection against the product. Medical-grade examination or surgical gloves may be required by procedure of administration.
Engineering Controls	Not Applicable
Other Work Practices	Use good personal hygiene practices. Wash hands before eating, drinking, smoking or using toilet. Promptly remove soiled clothing and wash thoroughly before reuse.

See section 2 for further details. - [Prevention]:

9. Physical and chemical properties

Appearance	Clear Liquid
Odor	Unspecified
Odor threshold	Not Measured
pH	4
Melting point / freezing point	Not Measured
Initial boiling point and boiling range	Not Measured
Flash Point	Not Measured
Evaporation rate (Ether = 1)	Not Measured
Flammability (solid, gas)	Not Applicable
Upper/lower flammability or explosive limits	Lower Explosive Limit: Not Measured Upper Explosive Limit: Not Measured
Vapor pressure (Pa)	Not Measured
Vapor Density	Not Measured
Specific Gravity	Not Measured
Solubility in Water	Complete
Partition coefficient n-octanol/water (Log Kow)	Not Measured
Auto-ignition temperature	Not Measured
Decomposition temperature	Not Measured
Viscosity (cSt)	Not Measured

9.2. Other information

No other relevant information.

10. Stability and reactivity

10.1. Reactivity

Hazardous Polymerization will not occur.

10.2. Chemical stability

Stable under normal circumstances.

10.3. Possibility of hazardous reactions

No data available.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

No data available.

10.6. Hazardous decomposition products

Packaging material fire may produce carbon monoxide and other gaseous asphyxiants, plus airborne particulate matter.

11. Toxicological information

Acute toxicity

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

Note: When no route specific LD50 data is available for an acute toxin, the converted acute toxicity point estimate was used in the calculation of the product's ATE (Acute Toxicity Estimate).

Classification	Category	Hazard Description
Acute toxicity (oral)	---	Not Applicable
Acute toxicity (dermal)	---	Not Applicable
Acute toxicity (inhalation)	---	Not Applicable
Skin corrosion/irritation	---	Not Applicable
Serious eye damage/irritation	---	Not Applicable
Respiratory sensitization	---	Not Applicable
Skin sensitization	---	Not Applicable
Germ cell mutagenicity	---	Not Applicable
Carcinogenicity	---	Not Applicable
Reproductive toxicity	---	Not Applicable
STOT-single exposure	---	Not Applicable
STOT-repeated exposure	---	Not Applicable
Aspiration hazard	---	Not Applicable

12. Ecological information

12.1. Toxicity

No additional information provided for this product. See Section 3 for chemical specific data.

Aquatic Ecotoxicity

There are no ingredients in this product which are classified as hazardous, and/or no hazardous ingredients above the GHS cut off percentage.

12.2. Persistence and degradability

There is no data available on the preparation itself.

12.3. Bioaccumulative potential

Not Measured

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

This product contains no PBT/vPvB chemicals.

12.6. Other adverse effects

No data available.

13. Disposal considerations
13.1. Waste treatment methods

Observe all federal, state and local regulations when disposing of this substance.

14. Transport information

	DOT (Domestic Surface Transportation)	IMO / IMDG (Ocean Transportation)	ICAO/IATA
14.1. UN number	Not Applicable	Not Regulated	Not Regulated
14.2. UN proper shipping name	Not Regulated	Not Regulated	Not Regulated
14.3. Transport hazard class(es)	DOT Hazard Class: Not Applicable	IMDG: Not Applicable Sub Class: Not Applicable	Air Class: Not Applicable
14.4. Packing group	Not Applicable	Not Applicable	Not Applicable
14.5. Environmental hazards			
IMDG	Marine Pollutant: No		
14.6. Special precautions for user			
	No further information		

15. Regulatory information

Regulatory Overview	The regulatory data in Section 15 is not intended to be all-inclusive, only selected regulations are represented.
Toxic Substance Control Act (TSCA)	All components of this material are either listed or exempt from listing on the TSCA Inventory.
WHMIS Classification	Not Regulated
US EPA Tier II Hazards	Fire: No Sudden Release of Pressure: No Reactive: No Immediate (Acute): No Delayed (Chronic): No
EPCRA 311/312 Chemicals and RQs:	
To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.	
EPCRA 302 Extremely Hazardous:	
Hydrochloric acid	

EPCRA 313 Toxic Chemicals:

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Carcinogens (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Developmental Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Female Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Proposition 65 - Male Repro Toxins (>0.0%):

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

New Jersey RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

Pennsylvania RTK Substances (>1%) :

To the best of our knowledge, there are no chemicals at levels which require reporting under this statute.

16. Other information

The information and recommendations contained herein are based upon data believed to be correct. However, no guarantee or warranty of any kind, expressed or implied, is made with respect to the information contained herein. We accept no responsibility and disclaim all liability for any harmful effects which may be caused by exposure to our products. Customers/users of this product must comply with all applicable health and safety laws, regulations, and orders.

The full text of the phrases appearing in section 3 is:

Not Applicable

This is the first version in the GHS SDS format. Listings of changes from previous versions in other formats are not applicable.

The information contained herein is based upon data considered true and accurate. CSL Behring makes no warranties, express or implied, as to the adequacy of the information contained herein. This information is offered solely for the user's consideration, investigation, and verification. Report to the manufacturer any allegations of health effects resulting from handling or accidental contact with this material.

Revision History:

10/22/2015 4.2 Potential Health Effects. Editorial correction.

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