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**
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.

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.

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.

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.

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

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

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).

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

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

14.1. UN number
DOT (Domestic Surface Transportation) Not Applicable

14.2. UN proper shipping name
Not Applicable

14.3. Transport hazard class(es)
DOT Hazard Class: Not Applicable

14.4. Packing group
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.

End of Document