



Safety Data Sheet

Section 1: Identification

Product identifier

- Product Name** • **Flunisolide Nasal Solution**
- Product Code** • AB34454; Core No. 344; NDC 24208-0344-25

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

- Recommended use** • Finished Pharmaceutical Product; Flunisolide nasal solution is indicated for the treatment of the nasal symptoms of seasonal or perennial rhinitis.
- Restrictions on use** • Refer to the product insert and/or prescribing information for restrictions on use and contraindications.

Details of the supplier of the safety data sheet

- Manufacturer** • Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609
United States
bausch.com
- Telephone (General)** • 1-800-553-5340

Emergency telephone number

- Manufacturer** • 1-800-535-5053 - 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** • Skin Mild Irritation 3
Eye Mild Irritation 2B

Label elements

UN GHS

WARNING

- Hazard statements** • Causes mild skin irritation
Causes eye irritation

Precautionary statements

- Prevention** • Wash thoroughly after handling.
Use personal protective equipment as required.
- Response** • IF ON SKIN: Wash with plenty of soap and water.

If skin irritation or rash occurs: Get medical advice/attention.
 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.

Storage/Disposal • Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container.
 Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

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	%	Classifications According to Regulation/Directive
Benzalkonium Chloride	CAS:63449-41-2 EINECS:264-151-6	0.01%	UN GHS: Skin Corr. 1B; Acute Tox. Oral 4; Acute Tox. Dermal 4; Aquatic Acute 1
Butylated Hydroxyanisole	CAS:25013-16-5 EINECS:246-563-8	< 0.1%	UN GHS: NDA
Citric Acid, Anhydrous	CAS:77-92-9 EINECS:201-069-1	< 0.1%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Edetate Disodium Dihydrate	CAS:139-33-3 EINECS:205-358-3	< 0.1%	UN GHS: NDA
Flunisolide	CAS:3385-03-3 EINECS:222-193-2	0.025%	UN GHS: NDA
Polyethylene Glycol 3350	CAS:25322-68-3	5% TO 10%	UN GHS: NDA
Propylene Glycol	CAS:57-55-6 EINECS:200-338-0	15% TO 25%	UN GHS: Skin Irrit. 3; Eye Irrit. 2B
Sodium Citrate, Anhydrous	CAS:68-04-2 EINECS:200-675-3	< 0.1%	UN GHS: Eye Irrit. 2A
Water	CAS:7732-18-5 EINECS:231-791-2	Balance	UN GHS: Classification criteria not met

Hydrochloric Acid (CAS:7647-01-0, EINECS:231-595-7) and/or Sodium Hydroxide (CAS# 1310-73-2, EINECS: 215-185-5) may be added to adjust the pH.

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

Section 4: First-Aid Measures

Description of first aid measures

- | | |
|-------------------|--|
| Inhalation | <ul style="list-style-type: none"> No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention. |
| Skin | <ul style="list-style-type: none"> Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention. |
| Eye | <ul style="list-style-type: none"> 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 | <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

- Watch for symptoms of hypercorticism, i.e., Cushing's syndrome, which could occur with excessive dose.

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

- | | |
|-------------------------------------|--|
| Suitable Extinguishing Media | <ul style="list-style-type: none"> SMALL FIRES: Dry chemical, CO₂, water spray or regular foam. LARGE FIRE: Water spray, fog or regular foam. |
|-------------------------------------|--|

- | | |
|---------------------------------------|---|
| Unsuitable Extinguishing Media | <ul style="list-style-type: none"> No data available |
|---------------------------------------|---|

Special hazards arising from the substance or mixture

- | | |
|---|---|
| Unusual Fire and Explosion Hazards | <ul style="list-style-type: none"> None known. |
|---|---|

- | | |
|--------------------------------------|---|
| Hazardous Combustion Products | <ul style="list-style-type: none"> None known. |
|--------------------------------------|---|

Advice for firefighters

- Structural firefighters' protective clothing will only provide limited protection. Wear positive pressure self-contained breathing apparatus (SCBA).

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. Evacuate immediate area. Ensure adequate ventilation. Refer to Section 8. |
|-----------------------------|--|

- | | |
|-----------------------------|---|
| Emergency Procedures | <ul style="list-style-type: none"> Keep unauthorized personnel away. Ventilate closed spaces before entering. Stop leak if you can do it without risk. |
|-----------------------------|---|

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

- 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. Dispose of in accordance with Section 13.

Section 7 - Handling and Storage**Precautions for safe handling****Handling**

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use only in accordance with product literature.

Conditions for safe storage, including any incompatibilities**Storage**

- Keep tightly closed. Store at room temperature 15-30°C (59-86°F), to maintain product integrity. Use before expiration date marked on carton and/or container.

Incompatible Materials or Ignition Sources

- None specified.

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**

- 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**

- 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 HEPA 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 protective eyewear (goggles, face shield, or safety glasses) when handling bulk product before closed in final packaging. In the event of a spill, appropriate eye protection should be worn.

Hands

- Wear appropriate 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

- Wash thoroughly after handling.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties**Information on Physical and Chemical Properties**

Material Description			
Physical Form	Liquid	Color	Colorless
Odor	No odor.	Odor Threshold	Not relevant
General Properties			
Boiling Point	No data available	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	5.1 to 5.4
Specific Gravity/Relative Density	= 1.042	Water Solubility	Miscible
Viscosity	No data available		
Volatility			
Vapor Pressure	Not relevant	Vapor Density	Not relevant
Evaporation Rate	No data available		
Flammability			
Flash Point	Not relevant	UEL	Not relevant
LEL	Not relevant	Autoignition	Not relevant
Environmental			
Octanol/Water Partition coefficient	No data available		

Section 10: Stability and Reactivity

Reactivity

- No dangerous reaction known under conditions of normal use.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Avoid exposure to extreme heat or cold.

Incompatible materials

- No data available

Hazardous decomposition products

- No data available

Section 11 - Toxicological Information

Information on toxicological effects

Components		
Flunisolide (0.025%)	3385-03-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • >500 µg/kg; Behavioral: Somnolence (general depressed activity); Blood: Aplastic anemia; Nutritional and Gross Metabolic: Gross Metabolite Changes: Weight loss or decreased weight gain; Multi-dose Toxicity: Inhalation-Human TCLo • 46.7 µg/kg 4 Week(s)-Intermittent; Peripheral Nerve and Sensation: Sensory change involving trigeminal nerve; Lungs, Thorax, or Respiration: Other changes
Benzalkonium Chloride (0.01%)	63449-41-2	Acute Toxicity: Ingestion/Oral-Mouse LD50 • 150 mg/kg; Behavioral: Somnolence (general depressed activity); Blood: Hemorrhage
Propylene Glycol (15% TO 25%)	57-55-6	Acute Toxicity: Ingestion/Oral-Rat LD50 • 20 g/kg

Polyethylene Glycol 3350 (5% TO 10%)	25322-68-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 28 g/kg
Citric Acid, Anhydrous (< 0.1%)	77-92-9	Acute Toxicity: Ingestion/Oral-Rat LD50 • 3 g/kg
Sodium Citrate, Anhydrous (< 0.1%)	68-04-2	Acute Toxicity: Intraperitoneal-Rat LD50 • 1548 mg/kg; Behavioral: Convulsions or effect on seizure threshold ; Lungs, Thorax, or Respiration: Cyanosis ; Gastrointestinal: Changes in structure or function of salivary glands
Edetate Disodium Dihydrate (< 0.1%)	139-33-3	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2 g/kg
Butylated Hydroxyanisole (< 0.1%)	25013-16-5	Acute Toxicity: Ingestion/Oral-Rat LD50 • 2000 mg/kg

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 • Eye Irritation 2

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - May cause mild irritation.
- Chronic (Delayed)**
 - No data available.

Skin

- Acute (Immediate)**
 - May cause mild irritation.
- Chronic (Delayed)**
 - No data available.

Eye

- Acute (Immediate)**
 - May cause irritation.
- Chronic (Delayed)**
 - No data available

Ingestion

- Acute (Immediate)**
 - Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.
- Chronic (Delayed)**
 - No data available.

Carcinogenic Effects

- In rats, administration of flunisolide at an oral dose of 2.5 mcg/kg/day (less than the maximum recommended daily intranasal dose in adults and children on a mg/m² basis) for 24 months resulted in an increased incidence of mammary gland adenoma and islet cell adenoma of the pancreas in females. There were no significant increases in the incidence of any tumor type in rats at an oral dose of 1.0 mcg/kg (less than the maximum recommended daily intranasal dose in adults and children on a mg/m² basis). Flunisolide showed no mutagenic activity in in vitro test systems including the

Ames Assay and the Rec-Assay, and no clastogenic activity in either the in vitro chromosomal aberration assay in Chinese hamster lung fibroblast cells or the in vivo mouse bone marrow chromosomal aberration assay.

Carcinogenic Effects			
	CAS	IARC	NTP
Butylated Hydroxyanisole	25013-16-5	Group 2B-Possible Carcinogen	Reasonably Anticipated to be Human Carcinogen

Reproductive Effects

- Pregnancy Category C. As with other corticosteroids, flunisolide has been shown to be teratogenic and fetotoxic in rabbits and rats at oral doses of 40 and 200 mcg/kg/day respectively (approximately 2 and 4 times, respectively, the maximum recommended daily intranasal dose in adults on a mg/m² basis). There are no adequate and well controlled studies in pregnant women.

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	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

- 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	EU EINECS	TSCA
Propylene Glycol	57-55-6	Yes	Yes	Yes
Edetate Disodium Dihydrate	139-33-3	Yes	Yes	Yes
Benzalkonium Chloride	63449-41-2	Yes	Yes	Yes
Citric Acid, Anhydrous	77-92-9	Yes	Yes	Yes
Butylated Hydroxyanisole	25013-16-5	Yes	Yes	Yes
Polyethylene Glycol 3350	25322-68-3	Yes	No	Yes
Flunisolide	3385-03-3	No	Yes	No
Sodium Citrate, Anhydrous	68-04-2	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Sodium Citrate, Anhydrous	68-04-2	Uncontrolled product according to WHMIS classification criteria
• Edetate Disodium Dihydrate	139-33-3	Uncontrolled product according to WHMIS classification criteria (including 3.5%)
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Uncontrolled product according to WHMIS classification criteria
• Citric Acid, Anhydrous	77-92-9	E (including 40%)
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

Canada - WHMIS - Ingredient Disclosure List

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	1 %
• Citric Acid, Anhydrous	77-92-9	1 %
• Butylated Hydroxyanisole	25013-16-5	1 %

• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

Europe

Other

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Classification

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Xn; R21/22 C; R34 N; R50
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Labelling

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	C N R:21/22-34-50 S:(2)-36/37/39-45-61
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

EU - CLP (1272/2008) - Annex VI - Table 3.2 - Safety Phrases

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	S:(2)-36/37/39-45-61
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

United States

Environment

U.S. - CERCLA/SARA - Hazardous Substances and their Reportable Quantities

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

United States - California

Environment

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

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	carcinogen, initial date 1/1/90
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

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

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	developmental toxicity, initial date 5/15/98

U.S. - California - Proposition 65 - No Significant Risk Levels (NSRL)

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	4000 µg/day NSRL
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

U.S. - California - Proposition 65 - Reproductive Toxicity - Female

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed
• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	female reproductive toxicity, initial date 5/15/98

U.S. - California - Proposition 65 - Reproductive Toxicity - Male

• Sodium Citrate, Anhydrous	68-04-2	Not Listed
• Edetate Disodium Dihydrate	139-33-3	Not Listed
• Benzalkonium Chloride	63449-41-2	Not Listed
• Propylene Glycol	57-55-6	Not Listed
• Citric Acid, Anhydrous	77-92-9	Not Listed

• Butylated Hydroxyanisole	25013-16-5	Not Listed
• Water	7732-18-5	Not Listed
• Polyethylene Glycol 3350	25322-68-3	Not Listed
• Flunisolide	3385-03-3	Not Listed

Section 16 - Other Information

Last Revision Date	<ul style="list-style-type: none">• 14/May/2015
Preparation Date	<ul style="list-style-type: none">• 14/May/2015
Disclaimer/Statement of Liability	<ul style="list-style-type: none">• To the best of our knowledge, the information contained herein is accurate. However, neither Bausch & Lomb, Inc. nor any of its subsidiaries assumes any liability whatsoever for the accuracy or 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. NO WARRANTY, EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS OR OTHERWISE IS MADE. In no event shall Bausch & Lomb, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.