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.
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.

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

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

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.

Preparation Date: 14/May/2015
Revision Date: 14/May/2015
Section 4: First-Aid Measures

Description of first aid measures

Inhalation
- No inhalation exposure expected with this formulation under normal conditions of use. If signs/symptoms develop, get medical attention.

Skin
- Flush with fresh water if contact with skin or eyes. If skin irritation occurs: Get medical advice/attention.

Eye
- 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
- 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
- SMALL FIRES: Dry chemical, CO2, water spray or regular foam.
- LARGE FIRE: Water spray, fog or regular foam.

Unsuitable Extinguishing Media
- No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards
- None known.

Hazardous Combustion Products
- 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

Personal Precautions
- 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
- 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
**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

<table>
<thead>
<tr>
<th>Physical Form</th>
<th>Liquid</th>
<th>Color</th>
<th>Colorless</th>
</tr>
</thead>
<tbody>
<tr>
<td>Odor</td>
<td>No odor.</td>
<td>Odor Threshold</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

### General Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boiling Point</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting Point</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Specific Gravity/Relative Density</td>
<td>1.042</td>
</tr>
<tr>
<td>Water Solubility</td>
<td>Miscible</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>pH</td>
<td>5.1 to 5.4</td>
</tr>
</tbody>
</table>

### Volatility

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vapor Pressure</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Evaporation Rate</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### Flammability

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flash Point</td>
<td>Not relevant</td>
</tr>
<tr>
<td>LEL</td>
<td>Not relevant</td>
</tr>
<tr>
<td>UEL</td>
<td>Not relevant</td>
</tr>
</tbody>
</table>

### Environmental

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Octanol/Water Partition coefficient</td>
<td>No data available</td>
</tr>
</tbody>
</table>

### 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

<table>
<thead>
<tr>
<th>Components</th>
<th>Acute Toxicity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flunisolide (0.025%)</td>
<td>Ingestion/Oral-Rat LD50 • &gt;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</td>
</tr>
<tr>
<td>Benzalkonium Chloride (0.01%)</td>
<td>Ingestion/Oral-Mouse LD50 • 150 mg/kg; Behavioral: Somnolence (general depressed activity); Blood: Hemorrhage</td>
</tr>
<tr>
<td>Propylene Glycol (15% TO 25%)</td>
<td>Ingestion/Oral-Rat LD50 • 20 g/kg</td>
</tr>
</tbody>
</table>
Polyethylene Glycol 3350 (5% TO 10%) | Acute Toxicity: Ingestion/Oral - Rat LD50 • 28 g/kg
---|---
Citric Acid, Anhydrous (< 0.1%) | Acute Toxicity: Ingestion/Oral - Rat LD50 • 3 g/kg
Sodium Citrate, Anhydrous (< 0.1%) | 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%) | Acute Toxicity: Ingestion/Oral - Rat LD50 • 2 g/kg
Butylated Hydroxyanisole (< 0.1%) | Acute Toxicity: Ingestion/Oral - Rat LD50 • 2000 mg/kg

### GHS Properties

<table>
<thead>
<tr>
<th>GHS Properties</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Aspiration Hazard</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Germ Cell Mutagenicity</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Skin corrosion/Irritation</td>
<td>UN GHS • Skin Mild Irritation 3</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>STOT-RE</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>STOT-SE</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Toxicity for Reproduction</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Respiratory sensitization</td>
<td>UN GHS • Classification criteria not met</td>
</tr>
<tr>
<td>Serious eye damage/Irritation</td>
<td>UN GHS • Eye Irritation 2</td>
</tr>
</tbody>
</table>

### 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.

<table>
<thead>
<tr>
<th>Carcinogenic Effects</th>
<th>CAS</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butylated Hydroxyanisole</td>
<td>25013-16-5</td>
<td>Group 2B-Possible Carcinogen</td>
<td>Reasonably Anticipated to be Human Carcinogen</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class (es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>TDG</td>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>NDA</td>
<td>not regulated</td>
<td>NDA</td>
<td>NDA</td>
<td>NDA</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>63449-41-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Citric Acid, Anhydrous</td>
<td>77-92-9</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Butylated Hydroxyanisole</td>
<td>25013-16-5</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Polyethylene Glycol 3350</td>
<td>25322-68-3</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Flunisolide</td>
<td>3385-03-3</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sodium Citrate, Anhydrous</td>
<td>68-04-2</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### 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 %

Preparation Date: 14/May/2015  
Revision Date: 14/May/2015  
Format: GHS Language: English (US)  
UN GHS
### Europe

#### Other

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>UN No.</th>
<th>CLP No.</th>
<th>Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate, Anhydrous</td>
<td>68-04-2</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Benzalkonium Chloride</td>
<td>63449-41-2</td>
<td>Xn; R21/22 C; R34 N; R50</td>
<td></td>
</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Citric Acid, Anhydrous</td>
<td>77-92-9</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Butylated Hydroxyanisole</td>
<td>25013-16-5</td>
<td>Not Listed</td>
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</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
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</tr>
<tr>
<td>Polyethylene Glycol 3350</td>
<td>25322-68-3</td>
<td>Not Listed</td>
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<tr>
<td>Flunisolide</td>
<td>3385-03-3</td>
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</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>UN No.</th>
<th>CLP No.</th>
<th>Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate, Anhydrous</td>
<td>68-04-2</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Edetate Disodium Dihydrate</td>
<td>139-33-3</td>
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</tr>
<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Citric Acid, Anhydrous</td>
<td>77-92-9</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Butylated Hydroxyanisole</td>
<td>25013-16-5</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Water</td>
<td>7732-18-5</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Polyethylene Glycol 3350</td>
<td>25322-68-3</td>
<td>Not Listed</td>
<td></td>
</tr>
<tr>
<td>Flunisolide</td>
<td>3385-03-3</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Substance</th>
<th>UN No.</th>
<th>CLP No.</th>
<th>Labeling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium Citrate, Anhydrous</td>
<td>68-04-2</td>
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<td>Edetate Disodium Dihydrate</td>
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<tr>
<td>Benzalkonium Chloride</td>
<td>63449-41-2</td>
<td>S:(2)-36/37/39-45-61</td>
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<tr>
<td>Propylene Glycol</td>
<td>57-55-6</td>
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<tr>
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<td>Flunisolide</td>
<td>3385-03-3</td>
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</table>

### United States

#### Environment

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

<table>
<thead>
<tr>
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<th>UN No.</th>
<th>CLP No.</th>
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<tr>
<td>Flunisolide</td>
<td>3385-03-3</td>
<td>Not Listed</td>
<td></td>
</tr>
</tbody>
</table>
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
Section 16 - Other Information

Last Revision Date  14/May/2015
Preparation Date  14/May/2015
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