



Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • OCEAN Saline Nasal Spray

Product Code • 301875260019; 301875260033

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

Recommended use • Relieves dryness of nasal membranes.

Restrictions on use • Use in accordance with product literature.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC

Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac

Manufacturer • +1 352-323-3500 - International - Infotrac

Consumer product: 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 • Classification criteria not met

Label elements

UN GHS

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:8001-54-5	< 0.1%	UN GHS: Skin Corr. 1C; Eye Dam. 1; Acute Tox. Oral 3
Benzyl alcohol	CAS:100-51-6 EINECS:202-859-9	< 1%	UN GHS: Acute Tox. Oral 4; Acute Tox. Inhal. 4
Sodium chloride	CAS:7647-14-5 EINECS:231-598-3	0.65%	UN GHS: Skin Irrit. 2; Eye Irrit. 2A; Acute Tox. Oral 5
Sodium Phosphate	CAS:7558-80-7 EINECS:231-449-2	< 1%	UN GHS: NDA
Water	CAS:7732-18-5 EINECS:231-791-2	> 95%	UN GHS: Classification Criteria Not Met

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

Section 4: First-Aid Measures

Description of first aid measures

Inhalation

- No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of mists, remove to fresh air and get medical attention.

Skin

- No specific treatment is necessary since this material is not likely to be hazardous by contact with the skin or mucous membranes.

Eye

- No specific treatment is necessary since this material is not irritating to the eye.

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

- No data available

Indication of any immediate medical attention and special treatment needed

Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media • Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media • No data available

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards • None known - product is not flammable or combustible.

Hazardous Combustion Products • No data available

Advice for firefighters

- As in any fire, wear self-contained breathing apparatus and full protective gear to prevent contact with skin and eyes.

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. Refer to Section 8.

Emergency Procedures

- No emergency procedures are expected to be necessary when used in accordance with product literature.

Environmental precautions

- No data available

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.

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.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed and store in upright position. Store at room temperature.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- Refer to the occupational exposure limits / guidelines for the individual product components.

Exposure Limits/Guidelines		
	Result	Other Agency Information
Benzyl alcohol (100-51-6)	TWAs	10 ppm TWA

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

- No respiratory protection required during normal handling.

Eye/Face

- No eye protection is required during normal handling.

Hands

- Gloves are not required under normal handling conditions.

Skin/Body

- No special personal protection required under conditions of intended use. In the event of a bulk spill, wear appropriate protective clothing.

Environmental Exposure Controls

- No data available

Section 9 - Physical and Chemical Properties

Information on Physical and Chemical Properties

Material Description			
Physical Form	Liquid	Color	Clear Colorless .
Odor	Not relevant	Odor Threshold	Not relevant
General Properties			
Boiling Point	100 C(212 F) approximately	Melting Point	Not relevant
Decomposition Temperature	No data available	pH	6.5 to 7.7
Specific Gravity/Relative Density	= 1 Water=1 approximately	Water Solubility	Not relevant
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 reactions known.

Chemical stability

- Stable under normal temperatures and pressures.

Possibility of hazardous reactions

- No data available

Conditions to avoid

- Extreme heat or cold. Do not freeze.

Incompatible materials

- None.

Hazardous decomposition products

- None expected.

Section 11 - Toxicological Information

Information on toxicological effects

- Other Material Information**
- Toxicological information refers to raw materials only. Concentrations and toxicological effects are substantially reduced in the product.

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 • Classification criteria not met
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 • Classification criteria not met

Potential Health Effects

Inhalation

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Skin

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Eye

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Ingestion

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Other

- Acute (Immediate)**
 - Under normal conditions of use, no health effects are expected.
- Chronic (Delayed)**
 - Under normal conditions of use, no health effects are expected.

Carcinogenic Effects		
	CAS	NTP
Benzyl alcohol	100-51-6	Evidence of Carcinogenicity

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
Benzalkonium chloride	8001-54-5	Yes	No	No
Benzyl alcohol	100-51-6	Yes	Yes	Yes
Sodium Phosphate	7558-80-7	Yes	Yes	Yes
Sodium chloride	7647-14-5	Yes	Yes	Yes
Water	7732-18-5	Yes	Yes	Yes

Canada

Labor

Canada - WHMIS - Classifications of Substances

• Benzyl alcohol	100-51-6	B3, D2B
• Sodium chloride	7647-14-5	Uncontrolled product according to WHMIS classification criteria
• Benzalkonium chloride	8001-54-5	D1B, E
• Water	7732-18-5	Uncontrolled product according to WHMIS classification criteria

• Sodium Phosphate	7558-80-7	Uncontrolled product according to WHMIS classification criteria
Canada - WHMIS - Ingredient Disclosure List		
• Benzyl alcohol	100-51-6	1 %
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

Europe

Other

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

• Benzyl alcohol	100-51-6	Xn; R20/22
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

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

• Benzyl alcohol	100-51-6	Xn R:20/22 S:(2)-26
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

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

• Benzyl alcohol	100-51-6	S:(2)-26
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

United States

Environment

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

• Benzyl alcohol	100-51-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

U.S. - RCRA (Resource Conservation & Recovery Act) - List for Hazardous Constituents

• Benzyl alcohol	100-51-6	
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

U.S. - RCRA (Resource Conservation & Recovery Act) - TSD Facilities Ground Water Monitoring

• Benzyl alcohol	100-51-6	
• Sodium chloride	7647-14-5	Not Listed

• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

United States - California

Environment

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

• Benzyl alcohol	100-51-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

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

• Benzyl alcohol	100-51-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

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

• Benzyl alcohol	100-51-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

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

• Benzyl alcohol	100-51-6	Not Listed
• Sodium chloride	7647-14-5	Not Listed
• Benzalkonium chloride	8001-54-5	Not Listed
• Water	7732-18-5	Not Listed
• Sodium Phosphate	7558-80-7	Not Listed

Section 16 - Other Information

Last Revision Date

- 20/May/2015

Preparation Date

- 19/May/2015

Disclaimer/Statement of Liability

- To the best of our knowledge, the information contained herein is accurate. However, neither Valeant Pharmaceuticals International, 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 Valeant Pharmaceuticals International, Inc. or any of its subsidiaries be liable for any special, incidental or consequential damages.