SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: OXYMETAZOLINE HCL NASAL SPRAY 0.05%
Synonym: 304

Manufacturer Name: Perrigo Company
Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-476-3962 Code 333304 (International calls)

Email Address: SDSRequest@perrigo.com

Recommended use: Human drug – for relief of nasal congestion
Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not hazardous

Label Elements:

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Oxymetazoline hydrochloride	2315-02-8	0.05%
Water	7732-18-5	Proprietary
Polyethylene Glycol	25322-68-3	Proprietary
Povidone	9003-39-8	Proprietary
Monobasic Sodium Phosphate	7558-80-7	Proprietary
Dibasic Sodium Phosphate	7558-79-4	Proprietary
Propylene Glycol	57-55-6	Proprietary
Benzylkonium Chloride	68391-01-5	<0.1%
Edetate disodium	6381-92-6	Proprietary
Benzyl Alcohol	100-51-6	Proprietary

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

4. FIRST-AID MEASURES

Inhalation: Remove person to fresh air. If irritation occurs or symptoms develop, get medical attention.
Skin contact: Remove contaminated clothing. Wash skin with soap and water. If irritation or rash develops, get medical attention. Launder clothing before reuse.
Eye contact: Immediately flush eyes with water while lifting the upper and lower lids for 15 minutes. Get medical attention if irritation or other symptoms persist**.**
Ingestion: Rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention advice.

Most important symptoms/effects, acute and delayed: May cause mild eye irritation. Ingestion may cause lightheadedness, dizziness, irregular heartbeat.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not generally required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any extinguishing media appropriate for the fire situation.

Specific hazards arising from the chemical: Product is not flammable or combustible.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Contain and **c**ollect with an inert absorbent material. Place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of mists. Avoid eye contact. Avoid contact with skin and clothing. Wash thoroughly with soap and water after handling.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Oxymetazoline hydrochloride	5 ug/m3 TWA Perrigo OEL
Water	None Established
Polyethylene Glycol	None Established
Povidone	None Established
Monobasic Sodium Phosphate	None Established

Dibasic Sodium Phosphate	None Established
Propylene Glycol	10 mg/m3 TWA AIHA WEEL
Benzylkonium Chloride	None Established
Edetate disodium	None Established
Benzyl Alcohol	10 ppm TWA AIHA WEEL

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to minimize exposures levels.

Individual protection measures:
Respiratory protection: None needed under normal use conditions. If exposure levels are excessive and irritation is experienced, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.
Skin protection: Impervious gloves recommended if needed to avoid unintended contact.
Eye protection: Chemical safety goggles recommended if needed to avoid eye contact.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Clear, colorless solution.
Odor: Odorless

Odor threshold: Not applicable	**pH:** 6.1
Melting point/freezing point: No data available	**Boiling Point:** No data available
Flash point: No data available	**Evaporation rate:** Same as water
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: None	**UEL:** None
Vapor pressure: Same as water	**Vapor density:** Same as water
Relative density: Not determined	**Solubility(ies):** Soluble in water
Partition coefficient: n-octanol/water: Not available	**Auto-ignition temperature:** Not applicable
Decomposition temperature: No data available	**Viscosity:** Same as water

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.
Chemical stability: Stable.
Possibility of hazardous reactions: None known.
Conditions to avoid: None known.
Incompatible materials: None known.
Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract. Inhalation above the intended dose may cause increased congestion and nasal discharge, burning and stinging in the nose.
Ingestion: Ingestion may cause lightheadedness, dizziness, irregular heartbeat.
Skin contact: No adverse effects are expected. Minor irritation is possible.
Eye contact: Contact may cause irritation with redness and tearing.
Chronic Effects: None known.

Sensitization: Components are not skin sensitizers.
Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity. Oxymetazoline was not genotoxic in an Ames bacterial mutagenicity assay, an *in vitro* human lymphocyte chromosomal aberration assay and an *in vivo* mouse micronucleus assay.
Reproductive Toxicity: Rat fertility study with SC doses of 0.01-0.1 mg/kg/day of oxymetazoline resulted in impaired fertility in both females and males at doses ≥0.03 mg/kg/day as evidenced by reduced number of implantation sites, and reduced sperm motility/concentration. The SC NOAEL for female and male reproduction was established at 0.01 mg/kg/day. Oral studies in rats showed decreased number of corpora lutea (hormone-secreting structure in an ovary) and increased post-implantation deaths at 0.2 mg/kg/day, but no effects on fertility and mating parameters were observed. The oral NOAEL for female reproduction was established at 0.1 mg/kg/day. In a developmental study in rats, fetal toxicities such as decreased fetal weight/survival, structural abnormalities (external and skeletal malformations) and maternal toxicity were observed at 0.1 mg/kg/day SC. However, the abnormalities could not be completely ascribed to toxicity in the dams, indicating a potential developmental adverse effect of oxymetazoline in rats. The SC NOAEL for fetal effects was established at 0.03 mg/kg/day. In an oral study in rats, doses up to 0.2 mg/kg/day were not associated with fetal malformations but caused maternal toxicity and increased pup mortality and a dose ≥0.1 mg/kg/day resulted in delayed sexual maturation in the surviving pups. The oral NOAEL in rats for fetal development was established at 0.05 mg/kg/day. In rabbits, an oral dose of 1 mg/kg/day caused maternal toxicity and was associated with findings of delayed skeletal ossification in the developing fetus.
Carcinogenicity: None of the components are listed as carcinogens by IARC, NTP or OSHA. Oxymetazoline was not carcinogenic in transgenic mice given oral doses up to 2.5 mg/kg/day for 6 months.

Acute Toxicity Values: Acute Oral Toxicity Estimate (ATE) calculated: 2631 mg/kg; Acute Inhalation Toxicity Estimate (ATE) calculated: 400 mg/L
Oxymetazoline Hydrochloride: Oral rat LD50 1.3 mg/kg, Inhalation rat LC50 0.2 mg/L
Edetate disodium dihydrate: Oral rat LD50 2000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity values: No data is available
Persistence and degradability: No data is available
Bioaccumulative potential: No data is available
Mobility in soil: No data is available.
Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous
EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:
None

EPA TSCA Inventory: This product is a drug and not subject to TSCA**.**
CANADA:
Canadian CEPA: This product is a drug and not subject to CEPA regulations.

16. OTHER INFORMATION

NFPA Rating: Health = 1 Flammability = 0 Instability = 0
HMIS Rating: Health = 1 Flammability = 0 Physical Hazard = 0

SDS Revision History: Revised Section 9.
Date of preparation: April 26, 2023

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).