SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: Tobramycin and Dexamethasone Ophthalmic Suspension 0.3%/0.1%
Synonym: 8M5

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 – antibiotic and steroid combination for topical ophthalmic use
Restrictions on use: Prescription use only.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Skin Sensitization Category 1 Reproductive Toxicity Category 1B

Label Elements:
Danger!



Hazard statement(s)

May cause an allergic skin reaction.
May damage fertility or the unborn child.

Precautionary statement(s)
Obtain special instructions before use.
Do not handle until all safety precautions have been read and understood.
Avoid breathing mists.

Precautionary statement(s)

Contaminated clothing must not be allowed out of the workplace.
Wear protective clothing and gloves.
IF on skin: wash with plenty of soap and water. If skin irritation or rash occurs: Get medical attention. Wash contaminated clothing before reuse.
IF exposed or concerned: Get medical attention.
Store locked up.
Dispose in accordance with local and national regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Tobramycin	32986-56-4	0.3%
Dexamethasone	50-02-2	0.1%
Water	7732-18-5	Proprietary

Hydroxyethyl Cellulose	9004-62-0	Proprietary
Benzalkonium Chloride	8001-54-5	Proprietary
Edetate Disodium Dihydrate	6381-92-6	Proprietary
Tyloxapol	25301-02-4	<0.1%
Sodium Chloride	7647-14-5	Proprietary
Sodium Sulfate Anhydrous	7757-82-6	Proprietary
Sodium hydroxide	1310-73-2	pH Adjustment
Sulfuric Acid	7664-93-9	pH Adjustment

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: This product is intended for use on the skin or eyes. For unintended contact, wash skin with soap and water. If irritation or rash develops, get medical attention. Remove contaminated clothing and wash it before reuse.
Eye contact: This product is intended for use in the eyes. For unintended contact, immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists**.**
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.

Most important symptoms/effects, acute and delayed: May cause mild eye and skin irritation. Swallowing may cause gastrointestinal upset and toxic effects. Contains ingredients that may cause adverse effects on reproduction and the unborn child.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is recommended for ingestion.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use any media that is suitable for the surrounding fire..

Specific hazards arising from the chemical: This 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 unintended contact with eyes, 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:

Tobramycin	PERRIGO OEB2 (100-1000 ug/m3) TWA
Dexamethasone	PERRIGO OEB4 (1-10 ug/m3) TWA
Water	None Established
Hydroxyethyl Cellulose	None Established
Benzalkonium Chloride	None Established
Edetate Disodium Dihydrate	None Established
Tyloxapol	None Established
Sodium Chloride	None Established
Sodium Sulfate Anhydrous	None Established
Sodium hydroxide	2 mg/m3 TWA OSHA PEL 2 mg/m3 Ceiling ACGIH TLV
Sulfuric Acid	1 mg/m3 TWA OSHA PEL 0.2 mg/m3 (thoracic) TWA ACGIH TLV

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.
Skin protection: None required for normal use. Impervious gloves recommended for bulk handling.
Eye protection: None required for normal use. Chemical safety goggles recommended for bulk handling.
Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): White to off-white suspension
Odor: No odor

Odor threshold: Not determined	**pH:** Not determined
Melting point/freezing point: Not determined	**Boiling Point:** Not determined
Flash point: None	**Evaporation rate:** Same as water
Flammability (solid, gas): Not applicable	**VOC:** Not determined
Flammable limits: LEL: Not applicable	**UEL:** Not applicable
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 available
Decomposition temperature: Not available	**Viscosity:** Not determined

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: Avoid oxidizing agents.
Hazardous decomposition products: Thermal decomposition may yield carbon and nitrogen oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:
Inhalation: Inhalation of mists may cause minor irritation of the mucous membranes and upper respiratory tract.
Ingestion: Swallowing may cause gastrointestinal upset and toxic effects.
Skin contact: No adverse effects are expected. Minor irritation is possible.
Eye contact: This product is intended for use in the eye. Contact may cause slight irritation.
Chronic Effects: Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria.
Sensitization: May cause skin sensitization. Tobramycin is a skin sensitizer.

Germ Cell Mutagenicity: Components are not classified as germ cell mutagens.
Reproductive Toxicity: Dexamethasone has been shown to be teratogenic in mice and rabbits following topical ophthalmic application in multiples of the therapeutic dose. In the mouse, corticosteroids produce fetal resorptions and a specific abnormality, cleft palate. In the rabbit, corticosteroids have produces fetal resorptions and multiple abnormalities involving the head, ears, limbs and palate. Tobramycin may cause adverse reproductive effects. Aminoglycosides can cause fetal harm when administered to a pregnant woman. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin during pregnancy.
Carcinogenicity: Long-term animal studies have not been performed to evaluate the carcinogenic potential of topical corticosteroids or tobramycin. None of the components are listed as carcinogens by IARC, NTP or OSHA.

Acute Toxicity Values: Tobramycin: Oral rat LD50 >7500 mg/kg
Dexamethasone: LD50 oral rat >3000 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): Refer to Section 2 for the OSHA Hazard Classification
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: New SDS
Date of preparation: December 4, 2019

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).