

# Safety Data Sheet

acc. to OSHA HCS (29 CFR 1910.1200)

Printing date 05/21/2015

Reviewed on 05/21/2015

## 1 Identification

- **Product identifier**
- **Trade name:** TOBRADEX®
- **Article number:** No other identifiers
- **Recommended use and restriction on use**
- **Recommended use:** Pharmaceutical Product
- **Restrictions on use:** Contact manufacturer.
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**  
Alcon Laboratories, Inc.  
6201 S. Freeway  
Fort Worth, Texas 76134 USA  
Tel 1-817-551-4444  
E-mail: safety.datasheets@alcon.com
- **Emergency telephone number:**  
ChemTel Inc.  
(800)255-3924, +1 (813)248-0585

## 2 Hazard(s) identification

- **Classification of the substance or mixture**



GHS07

Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Additional information:**

There are no other hazards not otherwise classified that have been identified.

0 percent of the mixture consists of ingredient(s) of unknown toxicity.

- **Label elements**

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

tobramycin

- **Hazard statements**

H317 May cause an allergic skin reaction.

- **Precautionary statements**

P261 Avoid breathing mist/vapors/spray.

P280 Wear protective gloves.

P272 Contaminated work clothing must not be allowed out of the workplace.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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P302+P352 If on skin: Wash with plenty of water.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information:** Contains tobramycin. May produce an allergic reaction.

- **Hazard description:**

- **WHMIS-symbols:**

As of 11 February 2015, the current WHMIS system is being replaced by the GHS system. This is the classification under the older system.

Not hazardous under WHMIS.

- **Classification system:**

- **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 0

Reactivity = 0

- **Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

## 3 Composition/information on ingredients

- **Chemical characterization: Mixtures**

- **Description:** Mixture of the substances listed below with nonhazardous additions.

- **Dangerous components:**

|            |            |                       |      |
|------------|------------|-----------------------|------|
| 32986-56-4 | tobramycin | ⚠ Skin Sens. 1A, H317 | 0.3% |
|------------|------------|-----------------------|------|

- **Additional information:**

For the listed ingredients, the identity and exact percentages are being withheld as a trade secret.

## 4 First-aid measures

- **Description of first aid measures**

- **General information:** No special measures required.

- **After inhalation:**

Unlikely route of exposure.

Supply fresh air; consult doctor in case of complaints.

- **After skin contact:**

Wash with soap and water.

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

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- **After eye contact:**  
Product is indicated for ocular usage. In case of persistent or severe irritation after usage, discontinue use and seek medical advice.
- **After swallowing:**  
Unlikely route of exposure.  
Do not induce vomiting; immediately call for medical help.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed**  
This product may cause sensitization (allergic reactions) in some individuals.  
Allergic reactions
- **Danger** No further relevant information available.
- **Indication of any immediate medical attention and special treatment needed**  
Medical supervision for at least 48 hours.  
Treat skin and mucous membrane with antihistamine and corticoid preparations.  
Contains tobramycin. May produce an allergic reaction.

## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** The product is not flammable.
- **For safety reasons unsuitable extinguishing agents:** None.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.
- **Additional information** No further relevant information available.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Ensure adequate ventilation.  
For large spills, wear protective clothing.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Dispose contaminated material as waste according to item 13.  
Send for recovery or disposal in suitable receptacles.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

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## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling** No special measures required.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Avoid storage near extreme heat, ignition sources or open flame.  
No special requirements.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:** Storage Temperatures : 46 - 80 ° F / 8 - 26 °C.
- **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures for handling chemicals should be followed.  
Keep away from foodstuffs, beverages and feed.  
Wash hands before breaks and at the end of work.  
Do not inhale gases / fumes / aerosols.
- **Engineering controls:** No further relevant information available.
- **Breathing equipment:** Not required under normal conditions of use.
- **Protection of hands:**  
Gloves not required under normal conditions of use.  
Gloves should be worn by people previously sensitized to any component of the product. .
- **Eye protection:** Not required under normal conditions of use.
- **Body protection:**  
Not required under normal conditions of use.  
Protection may be required for spills.
- **Limitation and supervision of exposure into the environment**  
No further relevant information available.

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## 9 Physical and chemical properties

- Information on basic physical and chemical properties

- General Information

- Appearance:

Form: Liquid  
Color: Colorless

- Odor: Odorless

- Odor threshold: Not determined.

- pH-value: Not determined.

- Change in condition

Melting point/Melting range: Undetermined.

Boiling point/Boiling range:  $100 \pm 1.0$  °C ( $212 \pm 34$  °F)

- Flash point: Not applicable.

- Flammability (solid, gaseous): Not applicable.

- Auto-ignition temperature: Not determined.

- Decomposition temperature: Not determined.

- Auto igniting: Product is not self-igniting.

- Danger of explosion: Product does not present an explosion hazard.

- Explosion limits:

Lower: Not determined.

Upper: Not determined.

- Vapor pressure at 20 °C (68 °F): 23 hPa (17 mm Hg)

- Density at 20 °C (68 °F):  $1.00 \pm 0.03$  g/cm<sup>3</sup> ( $8.345 \pm 0.25$  lbs/gal)

- Relative density: Not determined.

- Vapour density: Not determined.

- Evaporation rate: Not determined.

- Solubility in / Miscibility with

Water: Not miscible or difficult to mix.

- Partition coefficient (n-octanol/water): Not determined.

- Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

- Other information: No further relevant information available.

## 10 Stability and reactivity

- Reactivity

- Chemical stability

- Thermal decomposition / conditions to be avoided:

No decomposition if used and stored according to specifications.

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- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Possible in traces.

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **LD/LC50 values that are relevant for classification:** None.
- **Primary irritant effect:**
- **on the skin:** No irritant effect.
- **on the eye:** Slight irritant effect on eyes.
- **Sensitization:** Sensitizing effect by skin contact is possible with prolonged exposure.
- **Subacute to chronic toxicity:** No further relevant information available.
- **Additional toxicological information:** Toxic and/or corrosive effects may be delayed up to 24 hours.
- **Carcinogenic categories**

### · NTP (National Toxicology Program)

None of the ingredients is listed.

### · OSHA-Ca (Occupational Safety & Health Administration)

None of the ingredients is listed.

### · Probable Routes of Exposure

Eye contact.

Skin contact.

- **Acute effects (acute toxicity, irritation and corrosivity):** From product as supplied: None.
- **Repeated Dose Toxicity:** Repeated exposures may result in skin and/or respiratory sensitivity.

## 12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water
- **Other adverse effects** No further relevant information available.

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## 13 Disposal considerations

- **Waste treatment methods**

- **Recommendation:**

Must not be disposed of together with household garbage. Do not allow product to reach sewage system. The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.

- **Uncleaned packagings:**

- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- **UN-Number**

- DOT, ADR, ADN, IMDG, IATA Not Regulated

- **UN proper shipping name**

- DOT, ADR, ADN, IMDG, IATA Not Regulated

- **Transport hazard class(es)**

- DOT, ADR, ADN, IMDG, IATA

- **Class** Not Regulated

- **Packing group**

- DOT, ADR, IMDG, IATA Not Regulated

- **Environmental hazards:**

- **Marine pollutant:** No

- **Special precautions for user** Not applicable.

- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

- **UN "Model Regulation":** -

## 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

- **United States (USA)**

- **SARA**

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

None of the ingredients are listed.

- **TSCA (Toxic Substances Control Act):**

7732-18-5 | water

- **Proposition 65 (California)**

- **Chemicals known to cause cancer:**

None of the ingredients are listed.

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· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients are listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **TLV (Threshold Limit Value established by ACGIH)**

None of the ingredients is listed.

· **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

· **State Right to Know Listings**

None of the ingredients is listed.

· **Canadian substance listings:**

· **Canadian Domestic Substances List (DSL)**

All ingredients are listed.

· **Canadian Ingredient Disclosure list (limit 0.1%)**

None of the ingredients is listed.

· **Canadian Ingredient Disclosure list (limit 1%)**

None of the ingredients is listed.

· **Other regulations, limitations and prohibitive regulations**

This product has been classified in accordance with hazard criteria of the Controlled Products Regulations and the SDS contains all the information required by the Controlled Products Regulations.

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

## 16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Date of preparation / last revision** 05/21/2015 / -

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
NFPA: National Fire Protection Association (USA)  
HMIS: Hazardous Materials Identification System (USA)  
WHMIS: Workplace Hazardous Materials Information System (Canada)  
LC50: Lethal concentration, 50 percent  
LD50: Lethal dose, 50 percent  
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1  
Skin Sens. 1A: Sensitisation - Skin, Hazard Category 1A

**Sources**

SDS Prepared by:

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