

SAFETY DATA SHEET

Opxtrex Eye Drop/Wash



HEALTH • HYGIENE • HOME

1. Product and company identification

Product name	: Opxtrex Eye Drop/Wash
Distributed by	: RB Health (Canada) Inc. 1680 Tech Avenue, Unit #2 Mississauga, Ontario L4W 5S9 CANADA Telephone: +1 905 283 7000
Emergency telephone number (Medical)	: 1-800-338-6167
Emergency telephone number (Transport)	: 1-800-424-9300 (U.S. & Canada) CHEMTREC Outside U.S. and Canada (North America), call Chemtrec:703-527-3887
Website:	: http://www.rbnainfo.com
Product use	: Eye protection Medicinal product

This SDS is designed for workplace employees, emergency personnel and for other conditions and situations where there is greater potential for large-scale or prolonged exposure, in accordance with the requirements of USDOL Occupational Safety and Health Administration.

This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations, and shown in Section 15 of this SDS.

SDS #	: D0176576 v4.0
Formulation #:	: EBCT9 v4.0

2. Hazards identification

Classification of the substance or mixture	: Not classified
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GHS label elements

Hazard pictograms	: Not applicable.
Signal word	: No signal word.
Hazard statements	: No known significant effects or critical hazards.

Precautionary statements

General	: Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.
Prevention	: Not applicable.
Response	: Not applicable.
Storage	: Not applicable.

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2. Hazards identification

- Disposal** : Not applicable.
- Supplemental label elements** : None known.
- Hazards not otherwise classified** : None known.

3. Composition/information on ingredients

Substance/mixture : The solution contains Hamamelis Water BPC 13.0% w/w in a solution containing the following excipients: Boric Acid, Borax, Benzalkonium Chloride and Purified Water

Ingredient name	%	CAS number
disodium tetraborate decahydrate	0.1 - 1	1303-96-4

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

4. First aid measures

Description of necessary first aid measures

- Eye contact** : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
- Inhalation** : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
- Skin contact** : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
- Ingestion** : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Most important symptoms/effects, acute and delayed

Potential acute health effects

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : No known significant effects or critical hazards.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No specific data.
- Inhalation** : No specific data.
- Skin contact** : No specific data.
- Ingestion** : No specific data.

Indication of immediate medical attention and special treatment needed, if necessary

- Notes to physician** : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
- Specific treatments** : No specific treatment.

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4. First aid measures

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training.

See toxicological information (Section 11)

5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous thermal decomposition products : No specific data.

Special protective actions for fire-fighters : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Small spill : Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill : Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations (see Section 13). Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

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7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8).

Conditions for safe storage, including any incompatibilities : Do not store above the following temperature: 30°C (86°F). Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Long term average storage temperature should not exceed 30°C. The following excursions are permitted:-

- 60°C – Not permitted
- 50°C – Not more than 4 weeks
- 40°C – Not more than 8 weeks

The excursions are not cumulative.

The product should not be stored below freezing point at any time.

8. Exposure controls/personal protection

Control

Occupational exposure limits

<u>Ingredient name</u>	<u>Exposure limits</u>
disodium tetraborate decahydrate	<p>OSHA PEL 1989 (United States, 3/1989). TWA: 10 mg/m³ 8 hours.</p> <p>NIOSH REL (United States, 10/2013). TWA: 5 mg/m³ 10 hours.</p> <p>ACGIH TLV (United States, 3/2015). TWA: 2 mg/m³ 8 hours. Form: Inhalable fraction STEL: 6 mg/m³ 15 minutes. Form: Inhalable fraction</p>

Appropriate engineering controls : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.

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8. Exposure controls/personal protection

Skin protection

- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

9. Physical and chemical properties

Appearance

- Physical state** : Liquid.
- Color** : Colorless.
- Odor** : Not available.
- Odor threshold** : Not available.
- pH** : 6 to 7.5 [Conc. (% w/w): 100%]
- Melting point** : Not available.
- Boiling point** : Not available.
- Flash point** : Not available.
- Evaporation rate** : Not available.
- Flammability (solid, gas)** : Not available.
- Lower and upper explosive (flammable) limits** : Not available.
- Vapor pressure** : Not available.
- Vapor density** : Not available.
- Relative density** : Not available.
- Solubility** : Not available.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Decomposition temperature** : Not available.
- Viscosity** : Not available.
- Flow time (ISO 2431)** : Not available.

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10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : Keep away from heat and direct sunlight.
- Incompatible materials** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
disodium tetraborate decahydrate	LD50 Oral	Rat	2660 mg/kg	-

Conclusion/Summary : Based on available data, the classification criteria are not met.

Irritation/Corrosion

Not available.

Conclusion/Summary

- Skin** : Based on available data, the classification criteria are not met.
- Eyes** : Based on available data, the classification criteria are not met.
- Respiratory** : Based on available data, the classification criteria are not met.

Sensitization

Not available.

Conclusion/Summary

- Skin** : Based on available data, the classification criteria are not met.
- Respiratory** : Based on available data, the classification criteria are not met.

Mutagenicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Carcinogenicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Reproductive toxicity

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11. Toxicological information

Product/ingredient name	Maternal toxicity	Fertility	Development toxin	Species	Dose	Exposure
disodium tetraborate decahydrate	-	-	-	Rat	Oral: 9.6 mg/kg bw/day expressed as quantity of B	-

Conclusion/Summary : Based on available data, the classification criteria are not met.

Teratogenicity

Not available.

Conclusion/Summary : Based on available data, the classification criteria are not met.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.

Inhalation : No known significant effects or critical hazards.

Skin contact : No known significant effects or critical hazards.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.

Inhalation : No specific data.

Skin contact : No specific data.

Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.

Potential delayed effects : Not available.

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11. Toxicological information

Potential chronic health effects

Not available.

- Conclusion/Summary** : Based on available data, the classification criteria are not met.
- General** : No known significant effects or critical hazards.
- Carcinogenicity** : No known significant effects or critical hazards.
- Mutagenicity** : No known significant effects or critical hazards.
- Teratogenicity** : No known significant effects or critical hazards.
- Developmental effects** : No known significant effects or critical hazards.
- Fertility effects** : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Not available.

12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
disodium tetraborate decahydrate	Acute EC50 1645 mg/l Fresh water	Crustaceans - Cypris subglobosa	48 hours

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

- Soil/water partition coefficient (K_{oc})** : Not available.

- Other adverse effects** : No known significant effects or critical hazards.

13. Disposal considerations

- Disposal methods** : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid

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13. Disposal considerations

dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

14. Transport information

Regulatory information	UN number	Proper shipping name	Classes	PG*	Label	Additional information
DOT Classification	Not Regulation	Not applicable.	Not available.	-		-
TDG Classification	Not Regulation	Not applicable.	Not available.	-		-
Mexico Classification	Not Regulation	Not applicable.	Not available.	-		-
IMDG Class	Not Regulation	Not applicable.	Not available.	-		-
IATA-DGR Class	Not Regulation	Not applicable.	Not available.	-		-

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

PG* : Packing group

15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

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15. Regulatory information

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
disodium tetraborate decahydrate	< 0.1	No.	No.	No.	No.	Yes.

State regulations

- Massachusetts** : None of the components are listed.
- New York** : None of the components are listed.
- New Jersey** : The following components are listed: BORATE COMPOUNDS, Inorganic
- Pennsylvania** : None of the components are listed.

Canada

- WHMIS (Canada)** : Class D-2A: Material causing other toxic effects (Very toxic).
- Canadian lists**
- Canadian NPRI** : None of the components are listed.
- CEPA Toxic substances** : None of the components are listed.
- Canada inventory** : All components are listed or exempted.

Label elements

- Precautionary measures** : Read label before use.
KEEP OUT OF REACH OF CHILDREN AND PETS.
Keep cool and protect from sunlight.
Do not ingest.

16. Other information

Hazardous Material Information System (U.S.A.) :

Health	*	0
Flammability		0
Physical hazards		0
Personal protection		A

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16. Other information

Caution: HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. Although HMIS® ratings are not required on MSDSs under 29 CFR 1910.1200, the preparer may choose to provide them. HMIS® ratings are to be used with a fully implemented HMIS® program. HMIS® is a registered mark of the National Paint & Coatings Association (NPCA). HMIS® materials may be purchased exclusively from J. J. Keller (800) 327-6868.

The customer is responsible for determining the PPE code for this material.

National Fire Protection Association (U.S.A.) :



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Copyright ©2001, National Fire Protection Association, Quincy, MA 02269. This warning system is intended to be interpreted and applied only by properly trained individuals to identify fire, health and reactivity hazards of chemicals. The user is referred to certain limited number of chemicals with recommended classifications in NFPA 49 and NFPA 325, which would be used as a guideline only. Whether the chemicals are classified by NFPA or not, anyone using the 704 systems to classify chemicals does so at their own risk.

Key to abbreviations :

- ATE = Acute Toxicity Estimate
- BCF = Bioconcentration Factor
- GHS = Globally Harmonized System of Classification and Labelling of Chemicals
- IATA = International Air Transport Association
- IBC = Intermediate Bulk Container
- IMDG = International Maritime Dangerous Goods
- LogPow = logarithm of the octanol/water partition coefficient
- MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
- UN = United Nations

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Revision comments : Changed supplier address on section 1

Indicates information that has changed from previously issued version.

Notice to reader

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16. Other information

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, 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.