

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Version	Revision Date:	SDS Number:	Date of last issue: 2019-09-24
2.2	2019-10-12	100000014650	Date of first issue: 2018-07-06

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Substance name : Blink® Tears Preservative Free Lubricating Eye Drops

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

Use of the Sub-stance/Mixture : Medical device

1.3 Details of the supplier of the safety data sheet

Company : Johnson & Johnson Vision Care
7500 Centurion Parkway
32256 Jacksonville, FL
US

Telephone : +19044431000

Telefax :

E-mail address : SDSJanssen@its.jnj.com
Responsible/issuing person

1.4 Emergency telephone number

CHEMTREC BE: +(32)-28083237
CHEMTREC International: +1 703-527-3887

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Supplemental Hazard Statements : Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Additional Labelling:

EUH210 Safety data sheet available on request.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

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None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature : Liquid

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification (REGULATION (EC) No 1272/2008)	Concentration (%)
boric acid	10043-35-3 233-139-2	Repr. 1B; H360FD	$\geq 0,3 - < 1$

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

- If inhaled : If breathed in, move person into fresh air.
If symptoms persist, call a physician.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and water.
If symptoms persist, call a physician.
- In case of eye contact : Rinse immediately with plenty of water, also under the eyelids,
for at least 5 minutes.
Remove contact lenses.
If eye irritation persists, consult a specialist.
- If swallowed : If swallowed, rinse mouth with water (only if the person is con-
scious).
Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

Hazardous combustion products : No information available.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.

Specific extinguishing methods : Remove undamaged containers from fire area if it is safe to do so.

Further information : In the event of fire, cool tanks with water spray.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : In the event of an accidental release the emergency response team must respond based on a risk assessment and use personal protective equipment as appropriate.
Do not breathe vapours or spray mist.
Evacuate personnel to safe areas.

6.2 Environmental precautions

Environmental precautions : Should not be released into the environment.
Prevent further leakage or spillage if safe to do so.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Large spills: Dam up. Soak up with inert absorbent material. Keep in properly labelled containers.
Small spills: Gently cover the spill with an absorbent towel or pad.
Large spills + Small spills: Keep in suitable, closed containers for disposal. Treat recovered material as described in the section "Disposal considerations".

6.4 Reference to other sections

For disposal information, see section 13

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Avoid inhalation, ingestion and contact with skin and eyes. To avoid thermal decomposition, do not overheat. For personal protection see section 8.

Advice on protection against fire and explosion : No data available

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of work-day.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : To maintain product quality, do not store in heat or direct sunlight. Store in original container. Keep away from heat and sources of ignition. Keep containers tightly closed in a dry, cool and well-ventilated place.

7.3 Specific end use(s)

Specific use(s) : No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
boric acid	10043-35-3	TLV 8 hr	2 mg/m ³	BE OEL
		TLV 15 min	6 mg/m ³	BE OEL
		TLV 8 hr	2 mg/m ³ (Borate)	BE OEL
		TLV 15 min	6 mg/m ³ (Borate)	BE OEL
		TWA	2 mg/m ³	J&J OEL/PBOEL HHC
disodium tetra-borate decahydrate	1303-96-4	TLV 8 hr	2 mg/m ³ (Borate)	BE OEL
		TLV 15 min	6 mg/m ³ (Borate)	BE OEL

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8.2 Exposure controls

Engineering measures

All personal protective equipment should be based on a risk assessment. Consult a Environment Health Safety expert if necessary.

Personal protective equipment

Eye protection	: No special precautions required.
Hand protection	
Remarks	: No special precautions required.
Skin and body protection	: No special precautions required.
Respiratory protection	: Engineering controls should always be the primary method of controlling exposures. In case of mist, spray or aerosol exposure wear suitable personal respiratory protection and protective suit. If respiratory protective equipment is needed for certain activities, the type as well as the corresponding protection factor will depend upon the risk assessment and air concentrations, hazards, physical and warning properties of substances present. No personal respiratory protective equipment normally required.
Protective measures	: The type of protective equipment must be selected based on the Environmental Health and Safety risk assessment. Consult a Environmental Health and Safety expert if necessary.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: liquid
Colour	: No data available
Odour	: odourless
Odour Threshold	: No data available
pH	: No data available
Melting point/freezing point	: No data available
Boiling point/boiling range	: No data available
Flash point	: No data available
Evaporation rate	: No data available
Upper explosion limit	: No data available

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Lower explosion limit	: No data available
Vapour pressure	: No data available
Relative vapour density	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies) Water solubility	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available

9.2 Other information

No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

None reasonably foreseeable.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : To avoid thermal decomposition, do not overheat.

10.5 Incompatible materials

Materials to avoid : None known.

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10.6 Hazardous decomposition products

None known.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

No data available

Skin corrosion/irritation

No data available

Respiratory or skin sensitisation

No data available

Germ cell mutagenicity

No data available

Carcinogenicity

No data available

Reproductive toxicity

Product:

Reproductive toxicity - Assessment : No toxicity to reproduction

Components:

boric acid:

Reproductive toxicity - Assessment : Sufficient evidence of reprotoxicity based on animals.

Teratogenicity - Assessment : Sufficient evidence of adverse effects on development based on animals.

STOT - single exposure

No data available

STOT - repeated exposure

No data available

Repeated dose toxicity

No data available

Aspiration toxicity

No data available

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SECTION 12: Ecological information

12.1 Toxicity

Components:

boric acid:

Toxicity to fish : NOEC (Danio rerio (zebra fish)): 5,6 mg/l
Exposure time: 34 d

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher..

12.6 Other adverse effects

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : In accordance with National, Federal, State and Local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

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14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable for product as supplied.

SECTION 15: Regulatory information

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

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : boric acid

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.
Not applicable

Other regulations : Restricted to professional users.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not applicable (mixture)

SECTION 16: Other information

Full text of H-Statements

H360FD : May damage fertility. May damage the unborn child.

Further information

Other information : This SDS received a major version update triggered by a periodical review of the totality of the content.

Date and Number Formats

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This document uses the following notation for printing dates and numbers:

Date: Dec 31th, 2012 as 2012-12-31

Numbers: 123456,78 as 123 456,78

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