

Safety Data Sheet

acc. to OSHA HCS (29 CFR 1910.1200)

Printing date: 11/11/2016

Revision: 11/11/2016

1 Identification

- **Product identifier**
- **Trade name:** DMGD001 Nano ORB Preserved Ocular Emulsion
- **Recommended use and restriction on use**
- **Recommended use:** Pharmaceutical Product
- **Restrictions on use:** Contact manufacturer/supplier
- **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.
+1 (813) 676-1670

2 Hazard(s) identification

- **Classification of the substance or mixture**
The product is not classified as hazardous according to the Globally Harmonized System (GHS).
- **Additional information:**
There are no other hazards not otherwise classified that have been identified.
0 % of the mixture consists of component(s) of unknown toxicity.

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- **Label elements**
 - **GHS label elements** Not regulated.
 - **Hazard pictograms:** Not regulated.
 - **Signal word:** Not regulated.
 - **Hazard statements:** Not regulated.
 - **NFPA ratings (scale 0 - 4)**



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



3 Composition/information on ingredients

- **Chemical characterization:** Mixtures
- **Components:** None in reportable quantities.
- **Additional information:**
For the listed ingredient(s), the identity and/or exact percentage(s) are being withheld as a trade secret.

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For the wording of the listed Hazard Statements refer to section 16.

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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.

- **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.

- **Most important symptoms and effects, both acute and delayed:**

This product may cause sensitization (allergic reactions) in some individuals.

Allergic reactions

- **Danger:** No 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.

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 relevant information available.

- **Advice for firefighters**

- **Protective equipment:**

Wear self-contained respiratory protective device.

Wear fully protective suit.

- **Additional information:** No 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).

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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.

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 : 59 - 77 °F / 15 - 25 °C.

· **Specific end use(s)** No relevant information available.

8 Exposure controls/personal protection

· **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.

· **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 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.

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· Limitation and supervision of exposure into the environment

No relevant information available.

9 Physical and chemical properties

· Information on basic physical and chemical properties
· Appearance:
Form:

Liquid

Color:

White

· Odor:

Odorless

· Odor threshold:

Not determined.

· pH-value:

7

· Melting point/Melting range:

Not determined.

· Boiling point/Boiling range:

Not determined.

· Flash point:

Not applicable.

· Flammability (solid, gaseous):

Not applicable.

· Auto-ignition temperature:

Not determined.

· Decomposition temperature:

Not determined.

· Danger of explosion:

Product does not present an explosion hazard.

· Explosion limits
Lower:

Not determined.

Upper:

Not determined.

· Vapor pressure:

Not determined.

· Density:

Not determined.

· Relative density:

Not determined.

· Vapor density:

Not determined.

· Evaporation rate:

Not determined.

· Solubility in / Miscibility with
Water:

Soluble.

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

· Viscosity
Dynamic:

Not determined.

Kinematic:

Not determined.

· Other information

No relevant information available.

10 Stability and reactivity

· Reactivity: No relevant information available.

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- **Chemical stability:**
- **Thermal decomposition / conditions to be avoided:**
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No relevant information available.
- **Incompatible materials** No 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 relevant information available.

- **Carcinogenic categories**

- **NTP (National Toxicology Program):**

None of the ingredients are listed.

- **OSHA-Ca (Occupational Safety & Health Administration):**

None of the ingredients are listed.

- **Probable route(s) 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 relevant information available.
- **Persistence and degradability** No relevant information available.
- **Bioaccumulative potential:** No relevant information available.
- **Mobility in soil:** No relevant information available.
- **Additional ecological information**
- **General notes:** Generally not hazardous for water
- **Other adverse effects** No 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, IMDG, IATA Not regulated.

- **UN proper shipping name**

- DOT, ADR, IMDG, IATA Not regulated.

- **Transport hazard class(es)**

- DOT, ADR, 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.

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 are listed.

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

None of the ingredients are listed.

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· TSCA (Toxic Substances Control Act)

All ingredients are listed.

· Proposition 65 (California)
· Chemicals known to cause cancer:

None of the ingredients are listed.

· 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 are listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients are listed.

· Carcinogenic categories
· EPA (Environmental Protection Agency):

None of the ingredients are listed.

· IARC (International Agency for Research on Cancer):

None of the ingredients are listed.

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

None of the ingredients are listed.

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 11/11/2016 / -
· Abbreviations and acronyms:

ADR: 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

CAS: Chemical Abstracts Service (division of the American Chemical Society)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

· Sources

SDS Prepared by:

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