

ORA SOOTHE

PROFESSIONAL RINSE AND HYGIENE RINSE

SAFETY DATA SHEET

Revision Date: 03/24/2021

Revision Number: OS-SDS RV3

1. PRODUCT AND COMPANY IDENTIFICATION

1.1. PRODUCT IDENTIFIERS

Product name: OraSoothe Oral Coating Rinse (Oral Hydrogel Wound Dressing)
Product code(s):
Synonyms: Oral Hydrogel Wound Dressing
CAS#: N/A
RTECS: Not available
TSCA: TSCA 8(b) inventory: No products were found.
CI#: Not available

1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Identified uses: This product manages the pain in all types of oral wounds, mouth sores, injuries and ulcers of the oral mucosa. It adheres to oral tissue and forms a protective barrier between the wound and further irritation and contamination. It provides the moist wound environment required for optimal wound healing. Examples of oral lesions include canker sores (aphthous ulcers), tooth extraction sites, oral mucositis, oral stomatitis, traumatic ulcers such as is caused by braces and dentures, and irritation and pain following deep tooth scaling. This product is appropriate for all patient populations.

1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: McMerlin Dental Products, LP dba MCMP
1610 W. Polo Rd.
Grand Prairie, TX 75052
USA
Telephone: +1.800.755.0044
Fax: +1.888.690.8744

2. HAZARDS IDENTIFICATION

2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

This substance or mixture is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200).

2.2. GHS LABEL ELEMENTS, INCLUDING PRECAUTIONARY STATEMENTS

This substance or mixture is not considered hazardous by the Globally Harmonized System (GHS).

2.3. HAZARDS NOT OTHERWISE CLASSIFIED (HNOC)

None.

2.4. OTHER HAZARDS

Not available.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. SUBSTANCES

Synonyms: Oral Hydrogel Wound Dressing
Formula: Proprietary formulation.
Molecular weight: Not available.
CAS-No.: Not available.
EC-No.: Not available.
No components need to be disclosed according to the applicable regulations.

4. FIRST AID MEASURES

4.1. DESCRIPTION OF FIRST AID MEASURES

Skin contact

Wash with soap and water. Get medical attention if irritation develops.

Eye contact

Check for and remove any contact lenses. In case of contact, immediately flush eyes with plenty of water for at least 5 minutes. Get medical attention if irritation occurs.

Inhalation

Not available.

Ingestion

Non-toxic. Safe when swallowed.

4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

The most important known symptoms and effects are described in the labeling (see section 2.2) and/or in section 11.

4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No data available.

5. FIREFIGHTING MEASURES

5.1. EXTINGUISHING MEDIA

Suitable extinguishing media

Use dry chemical powder. Use water spray, fog or foam. Do not use water jet.

5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

No data available.

5.3. ADVICE FOR FIREFIGHTERS

Wear self-contained breathing apparatus for firefighting, if necessary.

5.4. FURTHER INFORMATION

No data available.

6. ACCIDENTAL RELEASE MEASURES

6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

Appropriate attire to prevent contamination. For personal protection see section 8.

6.2. ENVIRONMENTAL PRECAUTIONS

No special environmental precautions required.

6.3. METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by mopping contaminated surface.

6.4. REFERENCE TO OTHER SECTIONS

For disposal see section 13.

7. HANDLING AND STORAGE

7.1. PRECAUTIONS FOR SAFE HANDLING

Keep away from excessive heat.

7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

Keep container tightly closed. Keep container in a cool, dry area.

7.3. SPECIFIC END USE(S)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. CONTROL PARAMETERS

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

8.2. EXPOSURE CONTROLS

Appropriate engineering controls

General hygiene practice.

Personal protective equipment

Eye/face protection

Appropriate attire to prevent contamination, e.g. face mask or face mask with shield.

Skin protection

Appropriate attire to prevent contamination, e.g. nitrile rubber gloves.

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the CE approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario.

Body Protection

Body protection is not required.

Respiratory protection

Respiratory protection is not required.

Control of environmental exposure

No special environmental precautions required.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

- | | | |
|----|--|--|
| a) | Appearance: | Form: Slightly viscous clear to opaque gel |
| | | Color: White to amber |
| b) | Odor: | Mint, cinnamon, and clove |
| c) | Odor Threshold: | No data available |
| d) | pH: | 7.0 - 7.6 |
| e) | Melting point/freezing point | No data available |
| f) | Initial boiling point and boiling range: | No data available. |
| g) | Flash point: | No data available. |
| h) | Evaporation rate: | No data available. |

i)	Flammability (solid, gas):	No data available.
j)	Upper/lower flammability or explosive limits:	No data available.
k)	Vapor pressure:	No data available.
l)	Vapor density:	No data available.
m)	Relative density:	No data available.
n)	Water solubility:	No data available.
o)	Partition coefficient: n-octanol/water:	No data available.
p)	Auto-ignition temperature:	No data available.
q)	Decomposition temperature:	No data available.
r)	Viscosity:	No data available.
s)	Explosive properties:	No data available.
t)	Oxidizing properties:	No data available.

9.2. OTHER SAFETY INFORMATION

No data available

10. STABILITY AND REACTIVITY

10.1. REACTIVITY

No data available.

10.2. CHEMICAL STABILITY

The product is stable.

10.3. POSSIBILITY OF HAZARDOUS REACTIONS

No data available.

10.4. CONDITIONS TO AVOID

Avoid excessive heat, cold, and moisture.

10.5. INCOMPATIBLE MATERIALS

No data available.

10.6. HAZARDOUS DECOMPOSITION PRODUCTS

No data available.

11. TOXICOLOGICAL INFORMATION

11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

Acute toxicity

LD50: No data available.

LC50: No data available.

Inhalation: No data available

Skin corrosion/irritation

No data available.

Serious eye damage/eye irritation

No data available.

Respiratory or skin sensitization

No data available.

Germ cell mutagenicity

No data available.

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

ACGIH: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
NTP: No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.
OSHA: No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

Reproductive toxicity

No data available.

Specific target organ toxicity - single exposure

No data available.

Specific target organ toxicity - repeated exposure

No data available.

Aspiration hazard

No data available.

Additional Information

RTECS: Not available

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

12. ECOLOGICAL INFORMATION

12.1. TOXICITY

Ecotoxicity: No data available.
BOD5 and COD: No data available.

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

PBT/vPvB assessment not available as chemical safety assessment not required/not conducted.

12.6. OTHER ADVERSE EFFECTS

No data available.

13. DISPOSAL CONSIDERATIONS

13.1. WASTE TREATMENT METHODS

Product

Waste must be disposed of in accordance with federal, state and local environmental control regulations.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods.

IMDG

Not dangerous goods.

IATA
Not dangerous goods.

15. REGULATORY INFORMATION

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 313.

SARA 311/312 Hazards

No SARA Hazards

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components

No components are subject to the Pennsylvania Right to Know Act.

New Jersey Right To Know Components

No components are subject to the New Jersey Right to Know Act.

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

HMIS Rating

Health hazard:	0
Chronic Health Hazard:	0
Flammability:	0
Physical Hazard:	0

NFPA Rating

Health hazard:	0
Fire Hazard:	0
Reactivity Hazard:	0

Further information

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Preparation Information
MCMP, LP
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+1.800.755.0044
+1.888.690.8744

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