

SECTION 1: PRODUCT AND COMPANY IDENTIFICATION**1.1 Product Identifier**

Product Name: MR Lock LC™ Maximum Retention Visible Light Cure Band Cement

Common Name: Orthodontic Band Cement

Material: Band Cement

Restrictions on Use: American Orthodontics' products are used for the treatment of malocclusions and craniofacial abnormalities as diagnosed by a trained dental professional or orthodontist. Federal law restricts this device to use by or on the order of a dentist or orthodontist.

EC No.: Information not available.

REACH Registration No.: Information not available.

CAS No. / IUPAC: Information not available.

1.2 Relevant Identified Uses/ Uses Advised Against

Relevant identified uses: Dental/Orthodontic use only

Uses advised against: Not for Consumer use. Please see "Restrictions on Use"

1.3 Details of the Supplier of the Safety Data Sheet**Company Name:**

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081
Phone: 920-457-5051
Fax: 920-457-1485

E-mail: info@americanortho.com

National Contact: Safety Department

1.4 Emergency Telephone Number**Emergency Response Number:**

920-457-5051

Only available during office hours: 8:00AM – 5:00PM (Central Time)

Language of Phone Service: English

SECTION 2: HAZARDS IDENTIFICATION**2.1 Classification of the substance or mixture****2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]**

Information not available.

2.1.2 Classification according to Directive 67/548/EEC

Information not available.

2.1.3 Additional information:

Information not available.

2.2 Label Elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictogram(s)

Information not available.

Signal Word(s): Not available.

Hazard Statements:

Information not available.

Precautionary Statements:

Information not available.

Supplemental Hazard information (EU):

Information not available.

2.3 Other Hazards

Information not available.

SECTION 3: COMPOSITION / INFORMATION ON INGREDIENTS

3.1 Substances

MR Lock LC™ Band Cement is a light-yellow paste. Ingredients / composition is proprietary.

SECTION 4: FIRST-AID MEASURES

4.1 Description of First-Aid Measures

General Notes

Avoid exposure to moisture and light. Wash with water if skin contact occurs.

Inhalation

No harm anticipated.

Skin Contact

Wash with copious amounts of water.

Eye Contact

Flush out with copious amounts of water. Seek medical attention if irritation persists.

Ingestion/Swallowing

No harm perceived, however, if large quantities are accidentally swallowed, seek medical attention. Advise of fluoride presence in material.

Self-Protection of First-Aider

Wash with water if skin contact occurs.

4.2 Important Symptoms and Effects

None known.

4.3 Medical Attention & Special Treatment Necessary

Not available.

SECTION 5: FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media:

Water contact acceptable.

Extinguishing Media which should not be used:

None.

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products:

None specific.

5.3 Advice for Firefighters

Firefighting Methods:

None.

Special protective equipment for fire-fighters:

None.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

For Non-Emergency Personnel

Protective Equipment

Not required under normal handling.

Emergency Procedure

Wash with water if skin contact occurs.

For Emergency Responders

Not required under normal handling.

6.2 Environmental Precautions

No precautionary measures required.

6.3 Methods & Material for Containment & Cleaning Up

For Containment

Not available.

For Cleaning Up

Small quantities: wipe up and dispose of as "household" trash. Do not dispose into sink.

Large quantities: dispose in accordance with all local, state and federal regulations.

Other Information

Not available.

6.4 Reference to other sections (as applicable)

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Protective Measures:

Measures to prevent fire:

Not applicable.

Measures to prevent aerosol and dust generation:

Not applicable.

Measure to protect the environment

Not applicable.

Advice on General Occupational Hygiene:

Avoid exposure to moisture and light.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures & Storage Conditions

Store at temperatures not exceeding 82°F (28°C).

Packaging Materials

Not available.
Requirements for Storage Rooms & Vessels
Not available.

Storage Class:
Not available.

SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

No data available.

8.2 Exposure Controls

8.2.1 Appropriate Engineering Controls

Substance/Mixture Related Measures to Prevent Exposure During Identified Uses:

Information not available.

Structural Measures to Prevent Exposure:

Information not available.

Organizational Measures to Prevent Exposure:

Information not available.

Technical Measures to Prevent Exposure

Information not available.

8.2.2 Personal Protective Equipment

8.2.2.1 Eye & Face Protection

Not required under normal handling.

8.2.2.2 Skin Protection

Hand Protection

Not required under normal handling.

Other Skin Protection

Not required under normal handling.

8.2.2.3 Respiratory Protection

Not applicable.

8.2.2.4 Thermal Hazards

Not applicable.

Reference Section 5 for specific personal protective equipment advice

8.2.3 Environmental Exposure Controls

Substance/Mixture Related Measures to Prevent Exposure

Information not available.

Instruction Measures to Prevent Exposure

Information not available.

Organizational Measure to Prevent Exposure

Information not available.

Technical Measures to Prevent Exposure

Information not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance:

Light yellow paste.

Odor:	Characteristic, slight.
Odor Threshold:	Not available.
pH:	Not applicable.
Melting Point/Freezing Point:	Not applicable.
Initial Boiling Point & Boiling Range:	Not applicable.
Flash Point:	Not applicable.
Evaporation Rate:	Not available.
Flammability (solid, gas):	Under extreme conditions.
Upper/Lower Flammability or Explosive Limits:	Not applicable.
Vapor Pressure:	Negligible at ambient temperatures.
Vapor Density:	Not applicable.
Relative Density:	Not available.
Solubility(ies):	Negligible (in water).
Partition Coefficient: n-octanol/water):	Not available.
Auto-Ignition Temperature:	Not applicable.
Decomposition Temperature:	Not available.
Viscosity:	Not available.
Explosive Property:	Not available.
Oxidizing:	No.

9.2 Other Information

Specific Gravity (H20=1): ca 2

SECTION 10: STABILITY AND REACTIVITY**10.1 Reactivity**

Information not available.

10.2 Chemical Stability

Stable except when exposed to light or extreme temperatures.

10.3 Conditions of Instability

Exposure to light.

10.4 Possibility of Hazardous Reactions

Information not available.

10.5 Conditions to Avoid

Exposure to light.

10.6 Incompatible Materials

None known.

10.7 Hazardous Decomposition Products

None known.

10.8 Hazardous Polymerization

May occur when large quantities are involved and only upon exposure to intense light.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Information

Acute Toxicity
None known.

Chronic Health Effects
None known.

Skin Corrosion
Not available.

Serious Eye Damage/Irritation
Not available.

Respiratory/Skin Sensitization
Not available.

Germ Cell Mutagenicity
Not available.

Carcinogenicity
No ingredients listed as a carcinogen.

Reproductive Toxicity
Not available.

Summary of Evaluation of the CMR properties
Not available.

STOT-Single Exposure
Not available.

STOT-Repeated Exposure
Not available.

Aspiration Hazard
Not available.

Signs & Symptoms of Exposure
None known.

Medical Conditions Generally Aggravated by Exposure
None known.

Other Potential Health Effects
None known.

11.1.1 Acute Toxicity

Method: Not available.
Species: Not available.
Routes of Exposure: Not available.
Effective Dose: Not available.
Exposure Limit: Not available.
Results: Not available.

SECTION 12: ECOLOGICAL INFORMATION

No ecological damage or impact anticipated when handled as indicated.

12.1 Toxicity

Acute (Short-Term) Toxicity: Not available.
Fish: N/A
Crustacea: N/A
Algae/Aquatic Plants: N/A
Other Organisms: N/A
Chronic (Long-Term) Toxicity: Not available.

Fish: N/A
Crustacea: N/A
Algae/Aquatic Plants: N/A
Other Organisms: N/A

12.2 Persistence and Degradability

Abiotic Degradation: Not available.
Physical- and photo-chemical elimination: Not available.
Biodegradation: Not available.

12.3 Bioaccumulative Potential

Partition coefficient n-octanol/water (log Kow): Not available.
Bio concentration Factor (BCF): Not available.

12.4 Mobility in Soil

Known or predicted distribution to environmental compartments: Not available.
Surface tension: Not available.
Adsorption/Desorption: Not available.

12.5 Results of PBT and vPvB Assessment

Not available.

12.6 Other Adverse Effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS**13.1 Waste Treatment Methods****13.1.1 Product/Packaging disposal:**

Large quantities: dispose of in accordance with all federal, state, and local regulations. Do not dispose into sink.

Small quantities: dispose into trash.

Waste Codes/Waste Designations according to LoW: Not available.

13.1.2 Waste Treatment – relevant information:

Not available.

13.1.3 Sewage Disposal –relevant information:

Do not dispose into sink.

13.1.4 Other Disposal recommendations:

Not available.

SECTION 14: TRANSPORTATION INFORMATION**14.1 UN Number**

Not applicable.

14.2 UN Proper Shipping Name

Not applicable.

14.3 Transport Hazard Class(es)

Not available.

14.4 Packing Group

Not available.

14.5 Environmental Hazards

Not available.

14.6 Special Precautions for User

Not available.

14.7 Transport in Bulk According to Annex II of MARPOL73/78 and the IBC Code

Not available.

SECTION 15: REGULATORY INFORMATION

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

EC Medical Device Directive: Class IIa product
Authorizations and/or restrictions on use: Not available.
Authorization: N/A
Restrictions on use: N/A

Other EU Regulations:

Information according to 1999/13/EEC about limitation of emissions of volatile organic compounds (VOC-Guideline): Not available.

National Regulations (USA):

U.S. FDA Dental Device: Class II Product

15.2 Chemical Safety Assessment:

No chemical safety assessment has been carried out for this substance/mixture by the supplier.

SECTION 16: ADDITIONAL INFORMATION**16.1 Indication of changes/revision to SDS:**

1. New format
2. Inclusion of EC Requirements
3. **Revision Date:** 11/09/2018

16.2 Abbreviations and acronyms:

None.

16.3 Key literature references and sources for data

1. Guidance on the Compilation of Safety Data Sheets; European Chemical Agency (ECHA); Version 2.1, February 2014
2. Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16 December 2008 on classification, labelling, and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006

16.4 Classification and procedure used to derive classification for mixtures according to Regulation (EC) 1272/2008[CLP]:

None.

Some of the information presented and conclusions drawn herein are from sources other than direct test data on the product itself. The information in the SDS was obtained from sources that we believe are reliable and is believed to be valid and accurate. American Orthodontics, however, makes no warranty, express or implied, regarding its correctness of the information provided. The conditions or method of handling, storage, use and disposal of the product are beyond our control and may be beyond our knowledge. For this and other reasons, we do not assume responsibility and expressly disclaim liability for loss, damage, or expense arising out of or in any way connected with the handling, storage, use or disposal of the product. If the product is used as a component in another product or used in a way other than recommended by the Company, this SDS information may not be applicable. **Reasonable safety precautions must always be observed.**