

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product Identifier

Product Name: Eagle FluorSure™ Sealant, Eagle FluorSure™ Light Curable Fluoride Releasing Sealant

Common Name: Adhesives - Dental Sealant w/Fluoride

Material: Sodium Fluoride

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.: 231-667-8

REACH Registration No.: 01-2119539420-47-XXXX

CAS No. / IUPAC: 7681-49-4

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

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture – relative only to Fluoride

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]

Acute Toxicity: T; R25 Toxic if swallowed.

Irritation/Corrosion: Xi; R36/R38 Irritating to eyes and skin

2.1.2 Classification according to Directive 67/548/EEC

T - Toxic

2.1.3 Additional information:

R25-Toxic if swallowed

R36/38 – Irritating to eyes and skin

R32 – Contact with acids liberates very toxic gas

S ½ - Keep locked up and out of reach of children

S22 – do not breathe dust
 S36 – wear suitable protective clothing
 S45 – in case of accident or if you feel unwell, seek medical advice immediately (show the label where possible)

2.2 Label Elements

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

Hazard Pictogram(s)

GHS06



Signal Word(s) - DANGER

Hazard Statements:

- H301: Toxic if swallowed
- H315: Causes skin irritation
- H319: Causes serious eye irritation

Precautionary Statements:

- P270: Do not eat, drink or smoke when using this product
- P280: Wear protective gloves/protective clothing/eye protection/face protection
- P301+P310: IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician
- P302+P352: IF ON SKIN: Wash with plenty of soap and water.
- P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Supplemental Hazard information (EU):

- EUH032: Contact with acids liberates very toxic gas

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Fluoride	7681-49-4	231-667-8	proprietary
Others	unknown	unknown	unknown

4. FIRST-AID MEASURES

Eye Contact: In case of eye contact, immediately rinse with clean water for 15 minutes. Seek medical advice immediately.

Skin Contact: Wash skin thoroughly with mild soap and water. Remove contaminated clothing and shoes. Wash clothing before re-using.

Inhalation: Remove person to fresh air and keep warm and at rest. If breathing is difficult, give oxygen. Seek medical advice immediately.

Ingestion: Do not induce vomiting. Give nothing to drink. Seek medical advice immediately.

5. FIRE AND EXPLOSION HAZARDS

5.1 Extinguishing Media

Suitable Extinguishing Media: CO2, Powder, Water, Sand

Extinguishing Media which should not be used: None

5.2 Special Exposure Hazards from Substance/Mixture

Hazardous Combustion Products: None in quantities as packaged. Not Combustible.

Specific Hazards: In case of fire may liberate toxic gases

5.3 Advice for Firefighters

Firefighting Methods: Use water stream to cool containers. Keep public away from danger area.

Special protective equipment for fire-fighters: Wear self-contained breathing apparatus. Wear impervious protective suits, gloves and boots.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment & Emergency Procedures

Personal Precautions: Avoid dust production; Avoid all contact with this substance;

Protective Equipment: Wear safety glasses; Use rubber gloves; Wear impervious safety shoes; Wear respiratory protection equipment

Emergency Procedures: Keep public away from danger area

6.2 Environmental Precautions

Do not allow to enter into surface water or drains soil/subsoil

6.3 Methods & Material for Containment & Cleaning Up

After Spillage and/or leakage: Sweep or shovel spills into appropriate container for disposal.

Other Information: Waste are considered toxic. Dispose this substance and its packaging following local/regional and national regulations. Flush with water empty package to avoid release of residues. Dispose the substance in an appropriate container.

7. HANDLING AND STORAGE

7.1 Precautions for Safe-Handling

Do not breathe dust.

Avoid all contact with this substance.

Use suitable respiratory equipment.

Wash hands plentifully and other exposed areas with water after handling.

Remove contaminated clothing and shoes.

Wash clothing before re-using.

Provide adequate ventilation to minimize dust concentrations.

7.2 Conditions for Safe Storage, Including Any Incompatibilities

Keep away from acids.
 Store in dry, well-ventilated area.
 Keep packaging closed when not in use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Health Factors & Target Organs:

Skeletal Fluorosis: Osteosclerosis or increased bone density due to excessive absorption and retention of fluorides.

Eyes: Irritation of the eyes

Respiratory: Irritation of the respiratory system

8.1 Control Parameters

Component	OSHA PELs (Permissible Exposure Limits)	ACGIH TLVs (Threshold Limit Values)
Fluoride (Inorganic)	2.5 mg/m ³ TWA	2.5 mg/m ³ TLV

8.2 Exposure Controls

Skin Protection: Use rubber or neoprene gloves and protective long-sleeved clothing. In emergency, use particle impermeable clothing, category 3 type 5

Eye Protection: Wear safety glasses with side protection

Respiratory Protection: Use respiratory protection mask with filter type P3 according to EN 143:2000 or FFP3 according to EN 149: 2001 or THP3 according to EN 146: 1992 or TMP3 according to EN 12942: 1999

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Basic Physical & Chemical Properties

Appearance: Tooth-Shade paste
 Odor: Negligible
 Solubility(water): Virtually Insoluble

9.2 Other Information

Reactivity in Water: Not reactive
 Specific Gravity: ~2.2

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under storage conditions (room temperature)

Conditions of Instability: Not Applicable

Possibility of Hazardous Reactions: Contact with acids

Conditions to Avoid: Avoid exposure to light and temperatures above 75°F (24°C).

Incompatible Materials: Avoid contact with acids due to possible release of HF

Hazardous Decomposition Products: Not applicable

Hazardous Polymerization: None in quantities as packaged

11. TOXICOLOGICAL INFORMATION

Potential Acute Health Effects: Possibility of skin irritation or sensitization if not washed promptly

Potential Chronic Health Effects: Possibility of skin sensitization or irritation upon prolonged or repeated exposure.

Signs and Symptoms of Exposure: Skin/Eye irritation

Medical Conditions Generally Aggravated by Exposure: None Known

Carcinogen or Potential Carcinogenic Effects: No ingredient listed as a carcinogen

Other Potential Health Effects: None Known

12. ECOLOGICAL INFORMATION

No ecological damage or impact anticipated upon exposure to the environment in quantities as packaged.

13. DISPOSAL CONSIDERATIONS

Waste is considered toxic. Dispose this substance and its packaging following local/regional and national regulations. Flush with water empty package to avoid release of residues. Dispose the substance in an appropriate container.

14. TRANSPORTATION INFORMATION

14.1 UN Number
1690

14.2 UN Proper Shipping Name
Sodium Fluoride

14.3 Transport Hazard Class(es)
Class 6.1

14.4 Packing Group
III

14.5 Environmental Hazards
T: Toxic
Transport Hazard symbol: 6
Marine Pollutant: No

15. REGULATORY INFORMATION

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

EU Regulations

None

Other EU Regulations:

None

National Regulations (USA):

None

15.2 Chemical Safety Assessment:

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

16. ADDITIONAL INFORMATION

16.1 Indication of changes/revision to SDS:

1. New format
2. Inclusion of EC Requirements
3. *Revision Date:* 06/08/2015

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.**