

## 1. PRODUCT AND COMPANY IDENTIFICATION

### 1.1 Product Identifier

**Product Name:** American Orthodontics Porcelain Conditioner  
**Common Name:** Adhesives - Porcelain Conditioner  
**Material:** Isopropanol  
**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.:** 200-661-7  
**REACH Registration No.:** 01-2119457558-25-XXXX  
**CAS No. / IUPAC:** 67-63-0

### 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

### General Hazard Statement:

Hazards identification below pertains to Isopropanol. The mixture in the quantity provided is considered non-hazardous.

### 2.1 Classification of the substance or mixture

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

Flam. Liquid 2 H225: Highly flammable liquid and vapor.  
 Eye Irrit. 2 H319: Causes serious eye irritation.

**2.1.2 Classification according to Directive 67/548/EEC**

Flammability: F; R11 Highly flammable  
Acute Toxicity: R67 Vapours may cause drowsiness and dizziness.  
Irritation/Corrosion: Xi; R36 Irritating to eyes.

F - highly flammable  
Xi - irritant

**2.1.3 Additional information:**

R11 - Highly flammable  
R36 - Irritating to eyes  
R67 - Vapors may cause drowsiness and dizziness

**2.2 Label Elements**

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

**Hazard Pictogram(s)**



GHS02



GHS07

**Signal Word(s): Danger**

Hazard Statements:

H225: Highly flammable liquid and vapor.  
H319: Causes serious eye irritation.  
H336: May cause drowsiness or dizziness.

Precautionary Statements:

P102: Keep out of reach of children.  
P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.  
P233: Keep container tightly closed.  
P240: Ground/bond container and receiving equipment.  
P241: Use explosion-proof electrical/ventilating/lighting/.../ equipment.  
P242: Use only non-sparking tools.  
P243: Take precautionary measures against static discharge.  
P261: Avoid breathing dust/fume/gas/mist/vapours/spray.  
P264: Wash ... thoroughly after handling.  
P271: Use only outdoors or in a well-ventilated area.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P405: Store locked up.  
P501: Dispose of contents/container to ...  
P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.  
P370+P378: In case of fire: Use... to extinguish.  
P337+P313: If eye irritation persists: Get medical advice/attention.  
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.  
 P312: Call a POISON CENTER/doctor/.../if you feel unwell.  
 P403+P233: Store in a well-ventilated place. Keep container tightly closed.  
 P403+P235: Store in a well-ventilated place. Keep cool.

**Supplemental Hazard information (EU):**

**Safety Phrases:**

S2 - keep out of the reach of children  
 S7 - keep container tightly closed  
 S16 - keep away from sources of ignition - No smoking  
 S24/25 - avoid contact with skin and eyes  
 S26 - in case of contact with eyes, rinse immediately with plenty of water and seek medical advice

**3. COMPOSITION / INFORMATION ON INGREDIENTS**

<u>Ingredient(s)</u>	<u>CAS No.</u>	<u>EC No.</u>	<u>Wt. % Content (or Range)</u>
Isopropanol	67-63-0	200-661-7	unknown
Others	unknown	unknown	unknown

**4. FIRST-AID MEASURES**

**Route of exposure:** Inhalation and oral  
**General advice:** Take off contaminated clothing and shoes immediately.  
**Inhalation:** Move to fresh air.  
**Skin contact:** Wash off with plenty of water.  
**Eye contact:** Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.  
**Ingestion:** Drink plenty of water. Do NOT induce vomiting. Obtain medical attention.

**5. FIRE AND EXPLOSION HAZARDS**

**Suitable extinguishing media:** Water spray, Alcohol-resistant foam, Carbon dioxide (CO2), Dry powder  
**Extinguishing media not to be used for safety reasons:** High volume water  
**Further information:** Use water spray to cool unopened containers.

**6. ACCIDENTAL RELEASE MEASURES**

**Personal precautions:** Ensure adequate ventilation. Keep away from sources of ignition - No smoking.  
**Environmental precautions:** Do not flush into surface water or sanitary sewer system. Do not allow material to contaminate ground water system.  
**Methods for cleaning up:** Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).

## 7. HANDLING AND STORAGE

### HANDLING

Safe handling advice:

Ensure adequate ventilation.

Vapors are heavier than air and may spread along floors.

Avoid prolonged contact with skin. Wash hands with soap and water after handling.

Advice on protection against fire and explosion:

Keep away from sources of ignition - No smoking.

Keep away from flames and sparks, oxidizing agents, alkalis and isocyanides.

Vapors may form explosive mixtures with air.

Do not allow to enter drains (danger of explosion).

Take precautionary measures against static discharges.

### STORAGE

Requirements for storage areas and containers:

Keep container tightly closed.

Store between 5 and 25 °C in a dry, well ventilated place away from sources of heat, ignition and direct sunlight.

Storage classification (VCI system/Germany): 3; Flammable Liquids

Suitable Container Material: stainless steel

## 8. EXPOSURE CONTROLS / PERSONAL PROTECTION

### OCCUPATIONAL EXPOSURE LIMITS

Components Typ Control parameters Update Basis

2-propanol TWA 200 ppm 2009 ACGIH

2-propanol STEL 400 ppm 2009 ACGIH

Isopropyl alcohol REL 980 mg/m<sup>3</sup> 2005 NIOSH Pocket Guide to Chemical Hazard

REL 400 ppm 2005 NIOSH Pocket Guide to Chemical Hazard

Isopropyl alcohol STEL 1,225 mg/m<sup>3</sup> 2005 NIOSH Pocket Guide to Chemical Hazard

STEL 500 ppm 2005 NIOSH Pocket Guide to Chemical Hazard

Isopropyl alcohol PEL 980 mg/m<sup>3</sup> 02 2006 OSHA table Z-1

PEL 400 ppm 02 2006 OSHA table Z-1

Isopropyl alcohol TWA 980 ppm 1989 OSHA table Z-1-A

TWA 400 mg/m<sup>3</sup> 1989 OSHA table Z-1-A

Isopropyl alcohol STEL 1,225 mg/m<sup>3</sup> 1989 OSHA table Z-1-A

STEL 500 ppm 1989 OSHA table Z-1-A

Isopropyl alcohol TWA PEL 980 mg/m<sup>3</sup> 09 2006 US-California OELs

TWA PEL 400 ppm 09 2006 US-California OELs

Isopropyl alcohol STEL 1,225 mg/m<sup>3</sup> 09 2006 US-California OELs

STEL 500 ppm 09 2006 US-California OELs

Isopropyl alcohol ST ESL 7850 09 2008 US-Texas Effects Screening Levels

Isopropyl alcohol AN ESL 785 09 2008 US-Texas Effects Screening Levels

Isopropyl alcohol TWA 980 mg/m<sup>3</sup> 06 2008 US-Tennessee OELs

TWA 400 ppm 06 2008 US-Tennessee OELs

Isopropyl alcohol STEL 1,225 mg/m<sup>3</sup> 06 2008 US-Tennessee OELs

STEL 500 ppm 06 2008 US-Tennessee OELs

Propan-2-ol AGW 500 mg/m<sup>3</sup> 06 2008 Germany TRGS 900

AGW 200 ppm 06 2008 Germany TRGS 900  
Isopropyl alcohol MAK 500 mg/m<sup>3</sup> 2008 Germany DFG MAK  
MAK 200 mg/m<sup>3</sup> 2008 Germany DFG MAK

**EUROPEAN OCCUPATIONAL EXPOSURE LIMITS**

Contains no substances with occupational exposure limit values.

**PERSONAL PROTECTIVE EQUIPMENT**

**Respiratory protection:** No personal respiratory protective equipment normally required. In inadequately ventilated areas, where workplace limits are exceeded, where unpleasant odors exist or where aerosols are in use, or smoke and mist occur, use self-contained breathing apparatus or breathing apparatus with a type A filter or appropriate combined filter (e.g. where aerosols are in use, or smoke and mist occur, A-P2 or ABEK-P2), in compliance with EN 141.

**Hand protection:** The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other., Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time., Be aware that in daily use the durability of a chemical resistant protective glove can be notably shorter than the break through time measured according to EN 374, due to the numerous outside influences (e.g. temperature).

Gloves suitable for permanent contact: Material: Nitrile rubber/nitrile latex  
Break through time:  $\geq$  480 min  
Material thickness: 0.35 mm  
Material: butyl-rubber  
Break through time:  $\geq$  480 min  
Material thickness: 0.5 mm

Gloves suitable for splash protection: Material: Polychloroprene  
Break through time:  $\geq$  240 min  
Material thickness: 0.5 mm

Unsuitable glove: Material: Natural rubber/natural latex, Polyvinylchloride

**Eye protection:** Tightly fitting safety goggles

**Hygiene measures:** Take off all contaminated clothing immediately.

**Protective measures:** Avoid contact with the skin and the eyes. Do not breathe vapors or spray mist.

**9. PHYSICAL AND CHEMICAL PROPERTIES****9.1 Basic Physical & Chemical Properties**

Appearance:	Clear liquid
Odor:	Characteristic for alcohol
pH:	N/A
Melting Point/Freezing Point:	N/A
Initial Boiling Point & Boiling Range:	82.3°C
Flash Point:	53°F (Method: open cup)
Flammability (solid, gas):	Flammable
Explosive Limits in Air:	Lower 2%, Upper 12%
Vapor Pressure:	96mm Hg @ 100°C
Vapor Density:	> 1
Solubility(ies):	Soluble in Water
Auto-Ignition Temperature:	662°F
Oxidizing:	N/A

**9.2 Other Information**

Specific Gravity (H <sub>2</sub> O=1):	~0.8
Reactivity in Water:	Not reactive

**10. STABILITY AND REACTIVITY**

**Chemical Stability:** Generally stable

**Conditions of Instability:** Avoid exposure to heat, open flames, and sparks.

**Possibility of Hazardous Reactions:** Vapors may form explosive mixture with air

**Conditions to Avoid:** Avoid heat, open flames, and sparks.

**Incompatible Materials:** Isocyanides, strong oxidizing agents, alkali metals

**Hazardous/Thermal Decomposition Products:** No decomposition if used as directed

**11. TOXICOLOGICAL INFORMATION**

**Potential Acute Health Effects:** Eye irritation upon contact. Skin irritation upon prolonged exposure.

**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

**Carcinogenic or Potential Carcinogenic Effects:** No ingredients listed as a carcinogen

**12. ECOLOGICAL INFORMATION**

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

**13. DISPOSAL CONSIDERATIONS**

**Product:** Following pre-treatment and observing the regulations for hazardous wastes, it must be taken to a permitted hazardous wastes landfill or hazardous wastes incinerator.

**Contaminated packaging:** Can be used after re-conditioning.

**Waste code of the European Union: EWC:** A waste code in accordance with the European Waste Catalogue (EWC) may not be assigned to this product since it admits of a classification only when the consumer uses it for some purpose.

**14. TRANSPORTATION INFORMATION**

- 14.1 UN Number**  
UN-1219
- 14.2 UN Proper Shipping Name**  
Isopropanol
- 14.3 Transport Hazard Class(es)**  
Class 3, Flammable Liquid
- 14.4 Packing Group**  
II
- 14.5 Environmental Hazards**  
N/A
- 14.6 Special Precautions for User**  
See current Dangerous Goods Regulations

**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:** 06/09/2015

**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.**