

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name:	BracePaste Prime Plus	
Common Name:	Bonding Agent	
Material:	Orthodontic Primer / Sealant	
EC No.:	Reference Section 3	
REACH Registration No.:	Reference Section 3	
CAS No. / IUPAC:	Reference Section 3	
Relevant Identified Uses / Uses Advised Against:	Relevant identified uses:	Dental / Orthodontic use only
	Uses advised against:	Not for consumer use.
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.	
Details of the Supplier of the Safety Data Sheet:	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
Emergency Telephone Number:	920-457-5051	Only available during office hours: 8:00AM – 5:00PM (Central Time) Language of Phone Service: English

2. HAZARDS IDENTIFICATION

Classification of the substance or mixture according to Regulation (EC) No. 1272/2008 [CLP]:				
Flam. Liq. 2	H255 Highly flammable liquid and vapor			
Skin Irrit. 2	H315 Causes skin irritation			
Eye Irrit. 2	H319 Causes serious eye irritation			
Skin Sens. 1	H317 May cause an allergic skin reaction			
Aquatic Chronic 3	H412 Harmful to aquatic life with long lasting effects			
Reference to Other Sections:				
See Section 7	For information on safe handling			
See Section 8	For information on personal protective equipment			
See Section 13	For disposal information			
Label Elements (Labeling according to Regulation (EC) No 1272/2008 [CLP]):				
Hazard Pictogram(s):	 GHS02	 GHS07	Signal Word(s): Danger	Hazard-determining components of labeling: 2-hydroxyethyl methacrylate di-urethane dimethacrylate
Hazard Statements:	H255	Highly flammable liquid and vapor		
	H315	Causes skin irritation		
	H319	Causes serious eye irritation		
	H317	May cause an allergic skin reaction		
	H412	Harmful to aquatic life with long lasting effects		
Precautionary Statements:	P210	Keep away from heat, hot surface, sparks, open flames and other ignition sources. No smoking.		
	P241	Use explosion-proof [electrical / ventilating / lighting] equipment.		
	P261	Avoid breathing dust / fume / gas / mist / vapors / spray.		
	P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].		
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.		
	P501	Dispose of contents / container in accordance with local / regional / national / international regulations.		

Label Elements (Labeling of packages where the contents do not exceed 125 ml):					
Hazard Pictogram(s):	 GHS02		 GHS07		Signal Word(s): Danger
			Hazard-determining components of labeling: 2-hydroxyethyl methacrylate di-urethane dimethacrylate		
Hazard Statements:	H317	May cause an allergic skin reaction			
	H412	Harmful to aquatic life with long lasting effects			
Precautionary Statements:	P261	Avoid breathing dust / fume / gas / mist / vapors / spray.			
	P501	Dispose of contents / container in accordance with local / regional / national / international regulations.			
Other Hazards:					
Results of PBT and vPvB assessment:		PBT:	Not applicable	vPcB:	Not applicable

3. COMPOSITION / INFORMATION OF INGREDIENTS

Mixtures (Description: Mixture of the substances listed below with nonhazardous additions.):				
Dangerous Components:		Wt. %	CAS No.	EINECS
Ethanol	Flam Liq. 2, H225	25 – 50	64-17-5	200-578-6
2-hydroxyethyl methacrylate	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317	10 – 25	868-77-9	212-782-2
10-MDP	Flam. Liq. 3, H226 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	10 – 25	85590-00-7	–
di-urethane dimethacrylate	Aquatic Chronic 2, H411 Skin Sens. 1B, H317	10 – 25	41137-60-4	–
dl-bornane-2, 3-dione	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335	< 2.5	10373-78-1	–
Additional Information: For the wording of the listed hazard phrases refer to section 16.				

4. FIRST-AID MEASURES

Description of First-Aid Measures:	
General information:	Immediately remove any clothing soiled by the product.
After inhalation:	Supply fresh air, consult doctor in case of complaints.
After skin contact:	Immediately wash with water and soap and rinse thoroughly.
After eye contact:	Rinse opened eye for several minutes under running water. Then consult a doctor.
After swallowing:	Seek medical treatment.
Most important symptoms and effects, both acute and delayed:	No further information available.
Indication of any immediate medical attention and special treatment necessary:	No further information available.

5. FIREFIGHTING MEASURES

Extinguishing Media	Suitable extinguishing media:	CO ₂ , powder or water spray. Fight larger fires with water spray / alcohol resistant foam.
	For safety reasons unsuitable extinguishing agents:	Water with full jet.
	Special hazards arising from substance / mixture:	No further relevant information available.
Advice for Firefighters:	Protective equipment:	No special measures required.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures:	Wear protective equipment. Keep unprotected persons away.
	Keep away from ignition sources.
Environmental precautions:	Do not allow to enter sewers / surfaces or ground water.

Methods and material for containment and cleaning up:	Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
	Dispose contaminated material as waste according to section 13.
	Ensure adequate ventilation
Reference to Other Sections:	
See Section 7	For information on safe handling
See Section 8	For information on personal protective equipment
See Section 13	For disposal information

7. HANDLING AND STORAGE

Precautions for safe-handling:	Ensure good ventilation / exhaustion at the workplace.
	Prevent formation of aerosols.
Information about fire and explosive protection:	Keep ignition sources away. Do not smoke.
	Protect against electrostatic charges.
Conditions for safe storage, including any incompatibilities:	
Storage (<i>Requirements to be met by storerooms and receptacles</i>):	Store between 3°C and 25°C.
	Close container immediately after use.
	Protect product from light incidence.
Information about storage in one common storage facility:	Not required.
Further information about storage conditions:	Keep receptable tightly sealed.
Specific end use(s):	No further relevant information available.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters (Ingredients with limit values that require monitoring at the workplace):			
Ethanol (64-17-5)	OEL (Ireland)	Short-term value: 1000 ppm	—
	WEL (Great Britain)	Long-term value: 1920 mg/m3, 1000 ppm	—
	PEL (USA)	Long-term value, 1900 mg/m3, 1000 ppm	—
	REL (USA)	Long-term value, 1900 mg/m3, 1000 ppm	—
	TLV (USA)	Short-term value: 1880 mg/m3, 1000 ppm	A3
Additional Information: The lists valid during the making were used as basis.			
Exposure Controls:			
Appropriate engineering controls:		No further data, see Section 7	
Individual Protection Measures, such as personal protective equipment:			
General protective and hygienic measures:		Keep away from foodstuffs, beverages, and feed.	
		Immediately remove all soiled and contaminated clothing.	
		Wash hands before breaks and at the end of work.	
		Avoid contact with the eyes and skin.	
Respiratory protection:		Not necessary if room is well-ventilated.	
Hand protection:	Protective gloves	Material of gloves:	Penetration time of glove material:
		Butyl rubber, BR	0.3 mm: Penetration time 60 min
		Nitril rubber, NBR	0.11 mm: Penetration time 10 min
Eye / face protection:		Tightly sealed goggles.	

9. PHYSICAL AND CHEMICAL PROPERTIES

Basic Physical and Chemical Properties:	
Physical State:	Liquid
Color:	Yellowish
Odor:	Alcohol-like
Odor Threshold:	Not determined
Melting Point / Freezing Point:	Undetermined
Boiling point or initial boiling point and boiling point range:	Ethanol (64-17-5): 78°C
Flammability:	Not applicable

Lower and Upper Explosive Limit:	Lower: Upper:	3.5 Vol % 15 Vol %	Ethanol (64-17-5) Ethanol (64-17-5)
Flash Point:	13°C	Ethanol (64-17-5)	
Decomposition Temperature:	Not determined		
pH at 20°C:	2.5		
Viscosity:	Kinematic Viscosity: Dynamic:		Not determined Not determined
Solubility (Water):	Partly miscible		
Partition coefficient n-octanol / water (log value):			Not determined
Vapor Pressure at 20°C:	59 hPa	Ethanol (64-17-5)	
Vapor Pressure at 50°C:	280 hPa	Ethanol (64-17-5)	
Density and / or Relative Density:	Density:	Not determined	
	Relative Density:	Not determined	
	Vapor Density:	Not determined	
Other Information:			
Appearance / Form:	Liquid		
Important information on protection and health and environment, and on safety:			
Ignition Temperature:	Product is not self-igniting.		
Explosive Properties:	Product is not explosive. However, formation of explosive air / vapor mixtures are possible.		
Change in Condition:	Evaporation Rate:	Not determined	
Information regarding physical hazard classes:			
Explosives:	Void		
Flammable Gasses:	Void		
Aerosols:	Void		
Oxidizing Gases:	Void		
Gases Under Pressure:	Void		
Flammable Liquids:	Highly flammable liquid and vapor.		
Flammable solids:	Void		
Self-reactive substances and mixtures:	Void		
Pyrophoric liquids:	Void		
Pyrophoric solids:	Void		
Self-heating substances and mixtures:	Void		
Substances and mixtures, which emit flammable gases in contact with water:			Void
Oxidizing liquids:	Void		
Oxidizing solids:	Void		
Organic peroxides:	Void		
Corrosive to metals:	Void		
Desensitized explosives:	Void		

10. STABILITY AND REACTIVITY

Reactivity:	No further relevant information available.	
Chemical Stability:	Thermal decomposition / conditions to be avoided:	No decomposition if used according to specifications.
Possibility of Hazardous Reactions:	No dangerous reaction known.	
Conditions to Avoid:	No further relevant information available.	
Incompatible Materials:	No further relevant information available.	
Hazardous Decomposition Products:	No dangerous decomposition products known.	
	Carbon monoxide and carbon dioxide.	

11. TOXICOLOGICAL INFORMATION

Information on Hazard Classes as Defined in Regulation (EC) No 1272/2008					
Acute Toxicity:	Based on available data, the classification criteria are not met.				
	LD/LC50 values relevant for classification:	Ethanol	LD-50 Oral	10470 mg/kg rat	OECD 401
			LD-50 Inhalativ	117 mg/l rat	OECD 402
Primary Irritant Effect:		Skin Corrosion / Irritation:		Causes skin irritation.	
		Serious eye damage / irritation:		Causes series eye irritation.	
Respiratory or Skin Sensitization:		May cause an allergic skin reaction.			
Germ Cell Mutagenicity:		Based on available data, the classification criteria are not met.			
Carcinogenicity:		Based on available data, the classification criteria are not met.			
Reproductive Toxicity:		Based on available data, the classification criteria are not met.			
STOT-Single Exposure:		Based on available data, the classification criteria are not met.			
STOT-Repeated Exposure:		Based on available data, the classification criteria are not met.			
Aspiration Hazard:		Based on available data, the classification criteria are not met.			
Information on Other Hazards					
Endocrine Disrupting Properties:		None of the ingredients are listed.			

12. ECOLOGICAL INFORMATION

Toxicity:	Aquatic Toxicity:	No further relevant information available.			
Persistence and Degradability:		No further relevant information available.			
Bioaccumulative Potential:		No further relevant information available.			
Mobility in Soil:		No further relevant information available.			
Results of PBT and vPvB Assessment:		PBT:	Not applicable	vPvB:	Not applicable
Endocrine Disrupting Properties:		The product does not contain substances with endocrine disrupting properties.			
Other Adverse Effects (General Notes / Additional Ecological Information):		Water hazard class 1 (German Regulation) (Self-Assessment): Slightly Hazardous for water			
		Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.			

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:	
Recommendation:	Must not be disposed together with household garbage. Do not allow product to reach sewage system.
	Must be specially treated adhering to official regulations.
Uncleaned packaging:	
Recommendation:	Disposal must be made according to official regulations.
Recommended Cleansing Agents:	Water, if necessary together with cleansing agents
	Alcohol

14. TRANSPORT INFORMATION

UN Number or ID Number:	ADR, IMDG, IATA:		UN1170		
UN Proper Shipping Name:	ADR:	1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)			
	IMDG:	ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)			
	IATA:	ETHANOL			
Transport Hazard Class(es):	ADR:		Class: 3 (F1) Flammable Liquids		Label: 3
	IMDG, IATA:		Class: 3 Flammable Liquids		Label: 3
Packing Group:	ADR, IMDG, IATA:		II		

Environmental Hazards:		Not applicable		
Special Precautions for User:		Warning:	Flammable Liquids	
		Hazard Identification Number (Kemler Code): 33		
		EMS Numbers:	F-E, S-D	
		Stowage Category:	A	
Maritime Transport in Bulk According to IMO Instruments			Not applicable	
Transport / Additional Information:	ADR:	Limited Quantities (LQ):	1L	
		Excepted Quantities (EQ):	Code E2	
			Maximum net quantity per inner packaging: 30 ml	
			Maximum net quantity per outer packaging: 500 ml	
		Transport Category:	2	
	IMDG:	Tunnel Restriction Code:	D/E	
		Limited Quantities (LQ):	1L	
		Excepted Quantities (EQ):	Code E2	
			Maximum net quantity per inner packaging: 30 ml	
			Maximum net quantity per outer packaging: 500 ml	
UN “Model Regulation”:		UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, II		

15. REGULATORY INFORMATION

Safety, health, and environmental regulations / legislation specific for the substance or mixture:			
Directive 2012/18/EU:	Named dangerous substance – ANNEX I:		None of the ingredients is listed.
	Seveso Category:		P5c FLAMMABLE LIQUIDS
	Qualifying quantity (tonnes) for the application of lower-tier requirements:		5,000 t
	Qualifying quantity (tonnes) for the application of upper-tier requirements:		50,000 t
Regulation (EC) No 1907/2006 ANNEX XVII:		Condition of Restriction: 3	
Directive 2011-65-EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment:		Annex II: None of the ingredients is listed.	
Regulation (EU) 2019/1148:	ANNEX I – Restricted Explosives Precursors (Upper limit value for the purpose of licensing under Article 5(3)):		None of the ingredients is listed.
	ANNEX II – Reportable Explosives Precursors:		None of the ingredients is listed.
	Regulation (EC) No 273/2004 on drug precursors:		None of the ingredients is listed.
	Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors:		None of the ingredients is listed.
National Regulations:	Technical Instructions (air):	Class: NK	Share in %: 25-50
	Water Hazard Class:	Water hazard class I (self-assessment): slightly hazardous for water.	
	Chemical Safety Assessment:	A chemical safety assessment has not been carried out.	

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. This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

Hazard Statements:

H225	Highly flammable liquid and vapor
H226	Flammable liquid and vapor
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H411	Toxic to aquatic life with long lasting effects

Abbreviations and Acronyms:

ADR:	European Agreement Concerning the International Carriage of Dangerous Goods by Road
IMDG:	International Maritime Code for Dangerous Goods
IATA:	International Air Transport Association
GHS:	Globally Harmonized System of Classification and Labelling of Chemical
EINECS:	European Inventory of Existing Commercial Chemical Substances
ELINCS:	European List of Notified Chemical Substances
CAS:	Chemical Abstracts Service (Division of the American Chemical Society)
LC50:	Lethal Concentration, 50 percent
LD50:	Lethal Dose, 50 percent
PBT:	Persistent, Bioaccumulative, and Toxic
vPvB:	Very Persistent and very Bioaccumulative
Flam. Liq. 2:	Flammable liquids – Category 2
Flam. Liq. 3:	Flammable liquids – Category 3
Skin Irrit. 2:	Skin corrosion / irritation – Category 2
Eye Irrit. 2:	Serious eye damage / eye irritation – Category 2
Skin Sens. 1:	Skin sensitization – Category 1
Skin Sens. 1B:	Skin sensitization – Category 1B
STOT SE 3:	Specific target organ toxicity (single exposure) – Category 3
Aquatic Chronic 2:	Hazardous to the aquatic environment – long-term aquatic hazard – Category 2
Aquatic Chronic 3:	Hazardous to the aquatic environment – long-term aquatic hazard – Category 3

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.**