

Safety Data Sheet

according to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations

Date of Revision: 11/28/2018 Version: 4

SECTION 1: Identification

Identification

: Mixture Product form Product name : Assure Plus

Recommended use and restrictions on use

Use of the substance/mixture : For RX only

Supplier 1.3.

Manufacturer

Reliance Orthodontic Products Inc. 1540 West Thorndale Ave. Itasca, IL 60143 USA

630-773-4009, during normal business hours

www.RelianceOrthodontics.com

Emergency telephone number

Emergency number : CHEMTREC - 24-Hour Hazmat Emergency Communications Center

Domestic: 1-800-424-9300 Outside the U.S.: 1-703-527-3887, collect calls accepted

SECTION 2: Hazard(s) identification

Classification of the substance or mixture

GHS-US classification

Flammable liquids H225 Highly flammable liquid and vapor

Category 2 H315

Skin corrosion/irritation Causes skin irritation Category 2

Serious eye damage/eye

H319 Causes serious eye irritation

irritation Category 2

Skin sensitization, Category H317 May cause an allergic skin reaction

Specific target organ

toxicity (single exposure)

Category 3

Full text of H statements: see section 16

GHS Label elements, including precautionary statements

H335

GHS-US labeling

Hazard pictograms (GHS-US)





May cause respiratory irritation

Hazard statements (GHS-US) : H225 - Highly flammable liquid and vapor

H315 - Causes skin irritation

H317 - May cause an allergic skin reaction H319 - Causes serious eye irritation H335 - May cause respiratory irritation

Precautionary statements (GHS-US) P210 - Keep away from heat/sparks/open flames/hot surfaces. - No smoking

P233 - Keep container tightly closed

P240 - Ground/Bond container and receiving equipment P241 - Use explosion-proof ventilating equipment

P242 - Use only non-sparking tools

P243 - Take precautionary measures against static discharge

P261 - Avoid breathing vapors

P264 - Wash hands thoroughly after handling P271 - Use only outdoors or in a well-ventilated area

P272 - Contaminated work clothing must not be allowed out of the workplace

P280 - Wear face protection, eye protection, protective gloves

P302+P352 - If on skin: Wash with plenty of water

P303+P361+P353 - If on skin (or hair): Take off immediately all contaminated clothing. Rinse

skin with water/shower

P304+P340 - If inhaled: Remove person to fresh air and keep comfortable for breathing

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P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing

P312 - Call a POISON CENTER, a doctor if you feel unwell
P321 - Specific treatment (see First aid measures on this label)
P332+P313 - If skin irritation occurs: Get medical advice/attention
P337+P313 - If eye irritation persists: Get medical advice/attention
P362+P364 - Take off contaminated clothing and wash it before reuse

P363 - Wash contaminated clothing before reuse P370+P378 - In case of fire: Use sand to extinguish

P403+P233 - Store in a well-ventilated place. Keep container tightly closed

P403+P235 - Store in a well-ventilated place. Keep cool

P405 - Store locked up

P501 - Dispose in a safe manner in accordance with local/national regulations

2.3. Other hazards which do not result in classification

No additional information available

2.4. Unknown acute toxicity (GHS US)

Not applicable

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	GHS-US classification
BisGMA	(CAS-No.) 1565-94-2	30 - 50	Skin Irrit. 2, H315 Eye Irrit. 2B, H320 Skin Sens. 1, H317
Ethanol	(CAS-No.) 64-17-5	30 - 50	Flam. Liq. 2, H225 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335
2-Hydroxyethyl Methacrylate	(CAS-No.) 868-77-9	10 - 30	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
10-Methacryloyloxydecyl Dihydrogen Phosphate	(CAS-No.) 85590-00-7	5 - 10	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of hazard classes and H-statements : see section 16

SECTION 4: First-aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center/doctor/physician if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison

center/doctor/physician if you feel unwell.

First-aid measures after skin contact : Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. If skin

irritation or rash occurs: Get medical advice/attention.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to

do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

First-aid measures after ingestion : Call a poison center/doctor/physician if you feel unwell.

4.2. Most important symptoms and effects (acute and delayed)

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Symptoms/effects after eye contact : Eye irritation.

4.3. Immediate medical attention and special treatment, if necessary

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Suitable (and unsuitable) extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Specific hazards arising from the chemical

Fire hazard : Highly flammable liquid and vapor.

Reactivity : Highly flammable liquid and vapor.

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5.3. Special protective equipment and precautions for fire-fighters

Protection during firefighting

: Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures

: Ventilate spillage area. No open flames, no sparks, and no smoking. Avoid breathing mist,

vapors. Avoid contact with skin and eyes.

6.1.2. For emergency responders

Protective equipment

: Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

Dispose of materials or solid residues at an authorized site.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up

: Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public

waters

Other information

6.4. Reference to other sections
For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling

: Avoid shock and friction. Keep away from naked flames/heat. Take precautions against electrostatic charges. Use spark-/explosionproof appliances and lighting system. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Ground/bond container and receiving equipment. Use only non-sparking tools. Take precautionary measures against static discharge. Flammable vapors may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing mist, vapors. Avoid contact with skin and

Hygiene measures

: Wash contaminated clothing before reuse. Contaminated work clothing should not be allowed out of the workplace. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures

: Ground/bond container and receiving equipment.

Storage conditions

: Store in a well-ventilated place. Keep cool. Keep container tightly closed. Store locked up.

SECTION 8: Exposure controls/personal protection

3.1. Control parameters

Ethanol (64-17-5)		
ACGIH	ACGIH STEL (ppm)	1000 ppm (Ethanol; USA; Short time value; TLV - Adopted Value)
10-Methacryloyloxyded	cyl Dihydrogen Phosphate (85590-00-7)	
Not applicable		
2-Hydroxyethyl Methacrylate (868-77-9)		
Not applicable		
BisGMA (1565-94-2)		
Not applicable		

8.2. Appropriate engineering controls

Appropriate engineering controls : Ensure good ventilation of the work station.

Environmental exposure controls : Avoid release to the environment.

8.3. Individual protection measures/Personal protective equipment

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Hand protection:

Protective gloves

Eye protection:

Protective goggles

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Appearance : Clear liquid.
Color : Pale yellow
Odor : Ethanol odor
Odor threshold : No data available
pH : 2.5 - 3.5

Melting point : Not applicable
Freezing point : No data available
Boiling point : No data available

Flash point : > °C

Relative evaporation rate (butyl acetate=1) : No data available Flammability (solid, gas) : Not applicable.

Vapor pressure : No data available Relative vapor density at 20 °C : No data available

Relative density : 0.9 - 1.1

No data available Solubility Log Pow No data available Auto-ignition temperature No data available Decomposition temperature No data available Viscosity, kinematic No data available No data available Viscosity, dynamic **Explosion limits** No data available No data available Explosive properties Oxidizing properties No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapor.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

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Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Information on toxicological effects 11.1.

Acute toxicity : Not classified

Ethanol (64-17-5)		
LD50 oral rat	10740 mg/kg (Rat; Experimental value,Rat; Experimental value)	
LD50 dermal rabbit	> 16000 mg/kg (Rabbit; Literature study)	
ATE US (oral)	10740 mg/kg body weight	
10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)		
LD50 oral rat	> > mg/kg	
2-Hydroxyethyl Methacrylate (868-77-9)		

2-Hydroxyethyl Methacrylate (868-77-9)		
LD50 oral rat	5564 mg/kg body weight (Rat; Experimental value)	
LD50 dermal rabbit	> 5000 mg/kg body weight (Rabbit; Experimental value)	
ATE US (oral)	5564 mg/kg body weight	

Skin corrosion/irritation : Causes skin irritation.

pH: 2.5 - 3.5

Serious eye damage/irritation : Causes serious eye irritation.

pH: 2.5 - 3.5

Respiratory or skin sensitization : May cause an allergic skin reaction.

Germ cell mutagenicity : Not classified Carcinogenicity : Not classified

Ethanol (64-17-5)	
IARC group 1 - Carcinogenic to humans	
10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)	
IARC group 4 - Probably not carcinogenic to humans	

: Not classified Reproductive toxicity

Specific target organ toxicity – single exposure : May cause respiratory irritation.

Specific target organ toxicity - repeated

exposure

: Not classified

Aspiration hazard : Not classified

Symptoms/effects after inhalation : May cause respiratory irritation.

Symptoms/effects after skin contact : Irritation. May cause an allergic skin reaction.

Eye irritation. Symptoms/effects after eye contact

SECTION 12: Ecological information

12	.1.		Γ	XC	ic	ity	1

Ecology - general : The product is not considered harmful to aquatic organisms or to cause long-term adverse

effects in the environment.

Ethanol (64-17-5)		
LC50 fish 1	14200 mg/l (LC50; US EPA; 96 h; Pimephales promelas; Flow-through system; Fresh water; Experimental value)	
10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)		
EC50 Daphnia 1	> mg/l	
NOEC chronic fish	48h 10 mg/l	
2-Hydroxyethyl Methacrylate (868-77-9)		
LC50 fish 1	227 mg/l (LC50; 96 h)	
EC50 Daphnia 1	171 mg/l (NOEC; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)	

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2-Hydroxyethyl Methacrylate (868-77-9)	
EC50 Daphnia 2	380 mg/l (EC50; OECD 202: Daphnia sp. Acute Immobilisation Test; 48 h; Daphnia magna; Static system; Fresh water; Experimental value)
Threshold limit algae 1	836 mg/l (ErC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value)
Threshold limit algae 2	345 mg/l (EbC50; OECD 201: Alga, Growth Inhibition Test; 72 h; Pseudokirchneriella subcapitata; Static system; Fresh water; Experimental value)

12.2. Persistence and degradability

Ethanol (64-17-5)		
Persistence and degradability	Readily biodegradable in water. Biodegradable in the soil. Highly mobile in soil.	
Biochemical oxygen demand (BOD)	0.8 - 0.967 g O₂/g substance	
Chemical oxygen demand (COD)	1.7 g O ₂ /g substance	
ThOD	2.1 g O ₂ /g substance	
BOD (% of ThOD)	0.43	

2-Hydroxyethyl Methacrylate (868-77-9)	
Persistence and degradability	Readily biodegradable in water. Biodegradability in soil: no data available. Adsorbs into the soil.

12.3. Bioaccumulative potential

Ethanol (64-17-5)		
BCF fish 1	1 (BCF; Other; 72 h; Cyprinus carpio; Static system; Fresh water; Read-across)	
Log Pow	-0.31 (Experimental value)	
Bioaccumulative potential	Low potential for bioaccumulation (Log Kow < 4).	

2-Hydroxyethyl Methacrylate (868-77-9)	
BCF fish 1	1.3 - 1.5 (BCF)
Log Pow	-0.55 - 0.49 (0.42; Experimental value; OECD 107: Partition Coefficient (n-octanol/water): Shake Flask Method; 25 °C)
Bioaccumulative potential	Low potential for bioaccumulation (BCF < 500).

12.4. Mobility in soil

Ethanol (64-17-5)	
Surface tension	0.022 N/m (20 °C)
Log Koc	Koc,PCKOCWIN v1.66; 1; Read-across

12.5. Other adverse effects

Effect on the global warming : No known effects from this product.

GWPmix comment : No known effects from this product.

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Additional information : Flammable vapors may accumulate in the container.

SECTION 14: Transport information

Department of Transportation (DOT)

In accordance with DOT

Transport document description : UN1170 Ethanol solutions, 3, III

UN-No.(DOT) : UN1170

Proper Shipping Name (DOT) : Ethanol solutions

Class (DOT) : 3 - Class 3 - Flammable and combustible liquid 49 CFR 173.120

Packing group (DOT) : III - Minor Danger

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Hazard labels (DOT) : 3 - Flammable liquid



DOT Packaging Non Bulk (49 CFR 173.xxx) : 203 DOT Packaging Bulk (49 CFR 173.xxx) : 242

DOT Special Provisions (49 CFR 172.102)

: 24 - Alcoholic beverages containing more than 70 percent alcohol by volume must be transported as materials in Packing Group II. Alcoholic beverages containing more than 24 percent but not more than 70 percent alcohol by volume must be transported as materials in

Packing Group III.

B1 - If the material has a flash point at or above 38 C (100 F) and below 93 C (200 F), then the bulk packaging requirements of 173.241 of this subchapter are applicable. If the material has a flash point of less than 38 C (100 F), then the bulk packaging requirements of 173.242 of this

subchapter are applicable.

IB3 - Authorized IBCs: Metal (31A, 31B and 31N); Rigid plastics (31H1 and 31H2); Composite (31HZ1 and 31HA2, 31HB2, 31HN2, 31HD2 and 31HH2). Additional Requirement: Only liquids with a vapor pressure less than or equal to 110 kPa at 50 C (1.1 bar at 122 F), or 130 kPa at 55 C (1.3 bar at 131 F) are authorized, except for UN2672 (also see Special Provision IP8 in Table

2 for UN2672).

T2 - 1.5 178.274(d)(2) Normal..... 178.275(d)(3)

TP1 - The maximum degree of filling must not exceed the degree of filling determined by the following: Degree of filling = 97 / 1 + a (tr - tf) Where: tr is the maximum mean bulk temperature during transport, and tf is the temperature in degrees celsius of the liquid during filling.

DOT Packaging Exceptions (49 CFR 173.xxx) : 4b;19 DOT Quantity Limitations Passenger aircraft/rail : 60 L

(49 CFR 173.27)

DOT Quantity Limitations Cargo aircraft only (49 : 220 L

CFR 175.75)

DOT Vessel Stowage Location : A - The material may be stowed "on deck" or "under deck" on a cargo vessel and on a

passenger vessel.

Emergency Response Guide (ERG) Number : 12

Other information : No supplementary information available.

TDG

Transport by sea

Not regulated

Air transport

Not regulated

SECTION 15: Regulatory information

15.1. US Federal regulations

2-Hydroxyethyl Methacrylate (868-77-9)

Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. International regulations

CANADA

No additional information available

EU-Regulations

No additional information available

National regulations

No additional information available

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15.3. US State regulations

No additional information available

SECTION 16: Other information

Revision date

Full text of H-phrases:

H225	Highly flammable liquid and vapor
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H320	Causes eye irritation
H335	May cause respiratory irritation

SDS US (GHS HazCom 2012)

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product

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