

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product form : Mixture
Product name : Assure Plus

1.2. Relevant identified uses of the substance or mixture and uses advised against

1.2.1. Relevant identified uses

Use of the substance/mixture : For RX only

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Reliance Orthodontic Products, Inc. 1540 West Thorndale Ave.
Itasca, IL 60143 USA
630-773-4009, during normal business hours
www.RelianceOrthodontics.com

EC Representative:

Emergo Europe, Prinsessgracht 20
2514 AP The Hague, The Netherlands

Australian Sponsor: Emergo Australia, 201 Sussex St.

Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia

1.4. 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: Hazards identification

2.1. Classification of the substance or mixture

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

Flammable liquids, Category 2 H225
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Skin sensitisation, Category 1 H317
Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation H335

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. May cause respiratory irritation. Causes skin irritation. May cause an allergic skin reaction. Causes serious eye irritation.

2.2. Label elements

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

Hazard pictograms (CLP) :



Signal word (CLP) :

Danger

Hazardous ingredients :

Ethanol; 2-Hydroxyethyl Methacrylate; BisGMA

Hazard statements (CLP) :

H225 - Highly flammable liquid and vapour.
H315 - Causes skin irritation.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.

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Precautionary statements (CLP)	H335 - May cause respiratory irritation. : P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. P233 - Keep container tightly closed. P240 - Ground and bond container and receiving equipment. P241 - Use explosion-proof ventilating equipment. P261 - Avoid breathing vapours. P264 - Wash hands thoroughly after handling. P271 - Use only outdoors or in a well-ventilated area. P272 - Contaminated work clothing should not be allowed out of the workplace. P280 - Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 - IF ON SKIN: Wash with plenty of soap and water. P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. 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. P333+P313 - If skin irritation or rash 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. P370+P378 - In case of fire: Use dry 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 of contents and container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation, a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste, a hazardous or special waste collection point.
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2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
BisGMA	(CAS-No.) 1565-94-2	30 - 50	Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317
Ethanol	(CAS-No.) 64-17-5 (EC-No.) 200-578-6 (EC Index-No.) 603-002-00-5	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 (EC-No.) 212-782-2 (EC Index-No.) 607-124-00-X	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 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 or a doctor if you feel unwell.
First-aid measures after inhalation	: Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact	: Rinse skin with water/shower. 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 or a doctor if you feel unwell.

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4.2. Most important symptoms and effects, both 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. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

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 dust/fume/gas/mist/vapours/spray. 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".

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 : Dispose of materials or solid residues at an authorized site.

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 vapours may accumulate in the container. Use explosion-proof equipment. Wear personal protective equipment. Use only outdoors or in a well-ventilated area. Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with skin and eyes.
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.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Ethanol (64-17-5)		
Belgium	Limit value (mg/m ³)	1907 mg/m ³ (Ethanol; Belgium; Time-weighted average exposure limit 8 h)

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Ethanol (64-17-5)		
Belgium	Limit value (ppm)	1000 ppm (Ethanol; Belgium; Time-weighted average exposure limit 8 h)
France	VME (mg/m ³)	1900 mg/m ³ (Ethanol; France; Time-weighted average exposure limit 8 h)
France	VME (ppm)	1000 ppm (Ethanol; France; Time-weighted average exposure limit 8 h)
France	VLE (mg/m ³)	9500 mg/m ³ (Ethanol; France; Short time value)
France	VLE (ppm)	5000 ppm (Ethanol; France; Short time value)
Netherlands	Grenswaarde TGG 8H (mg/m ³)	260 mg/m ³
Netherlands	Grenswaarde TGG 8H (ppm)	136 ppm
Netherlands	Grenswaarde TGG 15MIN (mg/m ³)	1900 mg/m ³
Netherlands	Grenswaarde TGG 15MIN (ppm)	992 ppm
United Kingdom	WEL TWA (mg/m ³)	1920 mg/m ³
United Kingdom	WEL TWA (ppm)	1000 ppm
USA - ACGIH	ACGIH STEL (ppm)	1000 ppm

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Clear liquid.
Colour	: Pale yellow
Odour	: Ethanol odor
Odour threshold	: No data available
pH	: 2.5 - 3.5
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: Not applicable
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: Not applicable
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: 0.9 - 1.1
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available

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Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

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

10.6. Hazardous decomposition products

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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: 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)
LC50 inhalation rat (mg/l)	117 - 125 mg/l air (Equivalent or similar to OECD 403, 4 h, Rat, Male/female, Experimental value)

10-Methacryloyloxydecyl Dihydrogen Phosphate (85590-00-7)	
LD50 oral rat	> > mg/kg

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

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 sensitisation	: May cause an allergic skin reaction.
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Acute aquatic toxicity	: Not classified
Chronic aquatic toxicity	: Not classified

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Ethanol (64-17-5)	
LC50 fish 1	14200 mg/l (US EPA, 96 h, Pimephales promelas, Flow-through system, Fresh water, Experimental value)
EC50 72h algae (1)	275 mg/l (Equivalent or similar to OECD 201, Chlorella vulgaris, Static 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)
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	Biodegradable in the soil. Readily biodegradable in water.
Biochemical oxygen demand (BOD)	0.8 - 0.967 g O ₂ /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 (Other, 72 h, Cyprinus carpio, Static system, Fresh water, Read-across)
Log Pow	-0.31 (Experimental value)
Bioaccumulative potential	Not bioaccumulative.

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)
Ecology - soil	Highly mobile in soil.

12.5. Results of PBT and vPvB assessment

Component	
Ethanol (64-17-5)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.
Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

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14.1. UN number

UN-No. (ADR)	: 1170
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (ADN)	: Not regulated
UN-No. (RID)	: Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated
Transport document description (ADR)	: UN 1170 ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION), 3, III, (D/E)

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: 3
Danger labels (ADR)	: 3



IMDG

Transport hazard class(es) (IMDG)	: Not regulated
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IATA

Transport hazard class(es) (IATA)	: Not regulated
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ADN

Transport hazard class(es) (ADN)	: Not regulated
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RID

Transport hazard class(es) (RID)	: Not regulated
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14.4. Packing group

Packing group (ADR)	: III
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not regulated
Packing group (RID)	: Not regulated

14.5. Environmental hazards

Dangerous for the environment	: No
Marine pollutant	: No
Other information	: No supplementary information available

14.6. Special precautions for user

- Overland transport

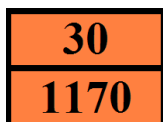
Classification code (ADR)	: F1
Special provisions (ADR)	: 144, 601
Limited quantities (ADR)	: 5I
Excepted quantities (ADR)	: E1
Packing instructions (ADR)	: P001, IBC03, LP01, R001
Mixed packing provisions (ADR)	: MP19
Portable tank and bulk container instructions (ADR)	: T2

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Portable tank and bulk container special provisions (ADR) : TP1
Tank code (ADR) : LGBF
Vehicle for tank carriage : FL
Transport category (ADR) : 3
Special provisions for carriage - Packages (ADR) : V12
Special provisions for carriage - Operation (ADR) : S2
Hazard identification number (Kemler No.) : 30
Orange plates :



Tunnel restriction code (ADR) : D/E
EAC code : •2YE

- Transport by sea

Not regulated

- Air transport

Not regulated

- Inland waterway transport

Not regulated

- Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions
Contains no substance on the REACH candidate list
Contains no REACH Annex XIV substances

15.1.2. National regulations

Germany

Reference to AwSV : Water hazard class (WGK) 3, severe hazard to waters (Classification according to AwSV, Annex 1)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : Ethanol is listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : Ethanol is listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : Ethanol is listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : Ethanol is listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

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Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Flam. Liq. 2	Flammable liquids, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
Skin Sens. 1	Skin sensitisation, Category 1
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H225	Highly flammable liquid and vapour.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II)

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