

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

1.1. Product identifier

Product form : Mixture
Product name : SEP Part B

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/Importer/Representative/User/Distributor:

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

Australian Sponsor:

Emergo Australia, 201 Sussex St.
Darling Park, Tower II, Level 20
Sydney, NSW 2000 Australia
T +61 2 9006 1662

Switzerland Representative:

MedEnvoy Global BV
Leidschendam-Voorburg, Zug Branch Office
Gotthardstrasse 28, 6302 Zug, Switzerland
T +41 41 462 01 42

FDA Registration:

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012
/ Rules and Regulations
FDA Registration: 1420089

EC Representative:

Emergo Europe
Westervoortsedijk 60
6827 AT Arnhem
The Netherlands
T +31 70 345 8570

U.K. Person Responsible:

Emergo Consulting (UK) Limited
c/o Cr360 - UL International Compass House, Vision Park Histon
Cambridge CB24 9BZ
England, United Kingdom
T +44(0) 1223 772 671

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]

Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity - Single exposure, Category 3, H335
Respiratory tract irritation

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause respiratory irritation. Causes skin irritation. Causes serious eye irritation.

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2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Contains :

Bis[2-(Methacryloyloxy)ethyl] Phosphate

Hazard statements (CLP) :

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P261 - Avoid breathing fume, mist, vapours.

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection.

P302+P352 - IF ON SKIN: Wash with plenty of soap and water.

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, doctor if you feel unwell.

P321 - Specific treatment (see supplemental first aid instruction 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.

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

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.

2.3. Other hazards

Contains no PBT/vPvB substances $\geq 0.1\%$ assessed in accordance with REACH Annex XIII

Component	
Ethyl 4-Dimethylaminobenzoate (10287-53-3)	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

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

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]
Bis[2-(Methacryloyloxy)ethyl] Phosphate	CAS-No.: 32435-46-4	≥ 85	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Ethyl 4-Dimethylaminobenzoate	CAS-No.: 10287-53-3 EC-No.: 233-634-3	1 - 5	Acute Tox. 4 (Oral), H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H336
Camphorquinone	CAS-No.: 10373-78-1 EC-No.: 233-814-1	1 - 5	Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H336

Full text of H- and EUH-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.
First-aid measures after skin contact	: Wash skin with plenty of water. Take off immediately all contaminated clothing and wash it before reuse. If skin irritation 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.

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.
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.
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5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire	: Toxic fumes may be released.
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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.
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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. Avoid breathing fume, mist, vapours. Avoid contact with skin and eyes.
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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".
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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.
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 : Ensure good ventilation of the work station. Avoid breathing fume, mist, vapours. Wear personal protective equipment. Avoid contact with skin and eyes.
Hygiene measures : Wash contaminated clothing before reuse. 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

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Keep cool.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

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

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



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8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

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
Colour	: Yellow.
Appearance	: Clear liquid.
Odour	: Acrylic.
Odour threshold	: Not available
Melting point	: Not applicable
Freezing point	: Not available
Boiling point	: Not available
Flammability	: Not applicable
Lower explosion limit	: Not available
Upper explosion limit	: Not available
Flash point	: Not available
Auto-ignition temperature	: Not available
Decomposition temperature	: Not available
pH	: Not available
Viscosity, kinematic	: Not available
Solubility	: Not available
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not available
Particle characteristics	: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

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

None under recommended storage and handling conditions (see section 7).

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 hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
LD50 oral rat	> 2000 mg/kg (OECD 401: Acute Oral Toxicity, Rat, Male / female, Experimental value, Oral, 14 day(s))
LD50 dermal rat	> 2000 mg/kg (OECD 402: Acute Dermal Toxicity, 24 h, Rat, Male / female, Experimental value, Dermal, 15 day(s))

Skin corrosion/irritation : Causes skin irritation.
Serious eye damage/irritation : Causes serious eye irritation.
Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : May cause respiratory irritation.

Bis[2-(Methacryloyloxy)ethyl] Phosphate (32435-46-4)	
STOT-single exposure	May cause respiratory irritation.

Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
STOT-single exposure	May cause drowsiness or dizziness.

Camphorquinone (10373-78-1)	
STOT-single exposure	May cause respiratory irritation.

STOT-repeated exposure : Not classified

Ethyl 4-Dimethylaminobenzoate (10287-53-3)	
NOAEL (oral, rat, 90 days)	74 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 407 (Repeated Dose 28-Day Oral Toxicity Study in Rodents), Guideline: EU Method B.7 (Repeated Dose (28 Days) Toxicity (Oral))

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Aspiration hazard : Not classified

Ethyl 4-Dimethylaminobenzoate (10287-53-3)

Viscosity, kinematic : Not applicable

11.2. Information on other hazards

No additional information available

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.

Hazardous to the aquatic environment, short-term (acute) : Not classified

Hazardous to the aquatic environment, long-term (chronic) : Not classified

Bis[2-(Methacryloyloxy)ethyl] Phosphate (32435-46-4)

LC50 - Fish [1] : 156.693 mg/l Source: Ecological Structure Activity Relationships

Ethyl 4-Dimethylaminobenzoate (10287-53-3)

LC50 - Fish [1] : 1.9 mg/l (OECD 203: Fish, Acute Toxicity Test, 96 h, Oncorhynchus mykiss, Semi-static system, Fresh water, Experimental value)

EC50 - Crustacea [1] : 4.5 mg/l (OECD 202: Daphnia sp. Acute Immobilisation Test, 48 h, Daphnia magna, Static system, Fresh water, Experimental value, GLP)

EC50 72h - Algae [1] : 2.8 mg/l (OECD 201: Alga, Growth Inhibition Test, Pseudokirchneriella subcapitata, Semi-static system, Fresh water, Experimental value, GLP)

EC50 72h - Algae [2] : 0.96 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)

12.2. Persistence and degradability

Ethyl 4-Dimethylaminobenzoate (10287-53-3)

Persistence and degradability : Not readily biodegradable in water.

Camphorquinone (10373-78-1)

Persistence and degradability : Biodegradability in water: no data available.

ThOD : 2.41 g O₂/g substance

12.3. Bioaccumulative potential

Ethyl 4-Dimethylaminobenzoate (10287-53-3)

Partition coefficient n-octanol/water (Log Pow) : 3.2 (Experimental value, OECD 117: Partition Coefficient (n-octanol/water), HPLC method, 25 °C)

Bioaccumulative potential : Low potential for bioaccumulation (Log Kow < 4).

Camphorquinone (10373-78-1)

Bioaccumulative potential : No bioaccumulation data available.

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12.4. Mobility in soil

Ethyl 4-Dimethylaminobenzoate (10287-53-3)

Organic Carbon Normalized Adsorption Coefficient (Log Koc)	2.8 (log Koc, OECD 121: Estimation of the Adsorption Coefficient (Koc) on Soil and on Sewage Sludge using High Performance Liquid Chromatography (HPLC), Experimental value, GLP)
Ecology - soil	Low potential for adsorption in soil.

12.5. Results of PBT and vPvB assessment

Component

Ethyl 4-Dimethylaminobenzoate (10287-53-3)	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
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12.6. Endocrine disrupting properties

No additional information available

12.7. 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.

SECTION 14: Transport information

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

14.1. UN number or ID number

Not regulated for transport

14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable
Proper Shipping Name (IMDG) : Not applicable
Proper Shipping Name (IATA) : Not applicable
Proper Shipping Name (ADN) : Not applicable
Proper Shipping Name (RID) : Not applicable

14.3. Transport hazard class(es)

ADR
Transport hazard class(es) (ADR) : Not applicable

IMDG
Transport hazard class(es) (IMDG) : Not applicable

IATA
Transport hazard class(es) (IATA) : Not applicable

ADN
Transport hazard class(es) (ADN) : Not applicable

RID
Transport hazard class(es) (RID) : Not applicable

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14.4. Packing group

Packing group (ADR)	: Not applicable
Packing group (IMDG)	: Not applicable
Packing group (IATA)	: Not applicable
Packing group (ADN)	: Not applicable
Packing group (RID)	: Not applicable

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

No data available

Transport by sea

No data available

Air transport

No data available

Inland waterway transport

No data available

Rail transport

No data available

14.7. Maritime transport in bulk according to IMO instruments

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

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

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15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Revision date	Added	
	Display additional SDS EU addresses	Added	
	Issue date	Removed	
	Supersedes version of	Added	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures after inhalation	Modified	
4.1	First-aid measures after skin contact	Modified	
6.1	Emergency procedures	Modified	
7.1	Precautions for safe handling	Modified	
7.2	Storage conditions	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
H302	Harmful if swallowed.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity - Single exposure, Category 3, Respiratory tract irritation

Safety Data Sheet (SDS), EU

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.