

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

1.1. Product identifier

Product form : Mixture
Product name : SEP Part A

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]

Corrosive to metals, Category 1 H290
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

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) :



GHS05

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H290 - May be corrosive to metals.

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

Precautionary statements (CLP) :

P234 - Keep only in original packaging.

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.

P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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.

P390 - Absorb spillage to prevent material damage.

P406 - Store in a corrosive resistant container with a resistant inner liner.

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

Nitric Acid, ≥ 65 conc. < 70% (7697-37-2)	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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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 %

Component

Nitric Acid, ≥ 65 conc. < 70%(7697-37-2)	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 %
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SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Nitric Acid, ≥ 65 conc. < 70%	CAS-No.: 7697-37-2 EC-No.: 231-714-2 EC Index-No.: 007-030-00-3	1 - 5	Ox. Liq. 3, H272 Met. Corr. 1, H290 Acute Tox. 3 (Inhalation), H331 Skin Corr. 1, H314

Specific concentration limits:

Name	Product identifier	Specific concentration limits (%)
Nitric Acid, ≥ 65 conc. < 70%	CAS-No.: 7697-37-2 EC-No.: 231-714-2 EC Index-No.: 007-030-00-3	($5 \leq C < 20$) Skin Corr. 1B, H314 ($20 \leq C \leq 100$) Skin Corr. 1A, H314 ($65 \leq C \leq 100$) Ox. Liq. 3, H272

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 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 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 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".

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 : Ensure good ventilation of the work station. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. 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 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.

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8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



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	: Colourless.
Appearance	: Clear liquid.
Odour	: Odourless.
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

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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

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

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
LC50 Inhalation - Rat	> 2.65 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
LC50 Inhalation - Rat (Vapours)	1.7 mg/l Source: ECHA

Skin corrosion/irritation : Causes skin irritation.

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
pH	No data available in the literature

Serious eye damage/irritation : Causes serious eye irritation.

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
pH	No data available in the literature

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

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Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
NOAEL (oral, rat, 90 days)	1500 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)
NOAEC (inhalation, rat, gas, 90 days)	2.15 ppm Animal: rat, Guideline: OECD Guideline 413 (Subchronic Inhalation Toxicity: 90-Day Study), Guideline: OECD Guideline 412 (Subacute Inhalation Toxicity: 28-Day Study)

Aspiration hazard : Not classified

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
Viscosity, kinematic	No data available in the literature

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

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
LC50 - Fish [1]	1559 mg/l Test organisms (species): other:
LC50 - Fish [2]	1354 mg/l Test organisms (species): other:
LC50 - Other aquatic organisms [1]	39 mg/l Source: ECHA
EC50 - Crustacea [1]	180 mg/l (EC50; 48 h)
Threshold limit - Algae [1]	> 19 mg/l (EC0)

12.2. Persistence and degradability

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
Persistence and degradability	Biodegradability: not applicable.
Biochemical oxygen demand (BOD)	Not applicable
Chemical oxygen demand (COD)	Not applicable
ThOD	Not applicable

12.3. Bioaccumulative potential

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
BCF - Fish [1]	≤ 1 (BCF)
Partition coefficient n-octanol/water (Log Pow)	-0.21 Source: ICSC
Bioaccumulative potential	Does not contain bioaccumulative component(s).

12.4. Mobility in soil

Nitric Acid, >= 65 conc. < 70% (7697-37-2)	
Surface tension	No data available in the literature

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Nitric Acid, ≥ 65 conc. < 70% (7697-37-2)

Ecology - soil

No (test)data on mobility of the component(s) available.

12.5. Results of PBT and vPvB assessment

Component

Nitric Acid, ≥ 65 conc. < 70% (7697-37-2)

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. 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

UN-No. (ADR) : UN 2031
UN-No. (IMDG) : UN 2031
UN-No. (IATA) : UN 2031
UN-No. (ADN) : Not regulated
UN-No. (RID) : Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR) : NITRIC ACID
Proper Shipping Name (IMDG) : NITRIC ACID
Proper Shipping Name (IATA) : Nitric acid
Proper Shipping Name (ADN) : Not regulated
Proper Shipping Name (RID) : Not regulated
Transport document description (ADR) : UN 2031 NITRIC ACID, 8, II, (E)
Transport document description (IMDG) : UN 2031 NITRIC ACID, 8, II
Transport document description (IATA) : UN 2031 Nitric acid, 8, II

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR) : 8
Danger labels (ADR) : 8



IMDG

Transport hazard class(es) (IMDG) : 8
Danger labels (IMDG) : 8

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IATA

Transport hazard class(es) (IATA) : 8

Danger labels (IATA) : 8



ADN

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

RID

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

14.4. Packing group

Packing group (ADR) : II

Packing group (IMDG) : II

Packing group (IATA) : II

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) : C1

Limited quantities (ADR) : 1I

Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02

Special packing provisions (ADR) : PP81, B15

Mixed packing provisions (ADR) : MP15

Portable tank and bulk container instructions (ADR) : T8

Portable tank and bulk container special provisions (ADR) : TP2

Tank code (ADR) : L4BN

Tank special provisions (ADR) : TU42

Vehicle for tank carriage : AT

Transport category (ADR) : 2

Hazard identification number (Kemler No.) : 80

Orange plates :

Tunnel restriction code (ADR) : E

Transport by sea

Limited quantities (IMDG) : 1 L

Excepted quantities (IMDG) : E2

Packing instructions (IMDG) : P001

Special packing provisions (IMDG) : PP81

IBC packing instructions (IMDG) : IBC02

IBC special provisions (IMDG) : B15, B20

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Tank instructions (IMDG)	: T8
Tank special provisions (IMDG)	: TP2
EmS-No. (Fire)	: F-A
EmS-No. (Spillage)	: S-B
Stowage category (IMDG)	: D
Segregation (IMDG)	: SGG1A, SG36, SG49
Properties and observations (IMDG)	: Colourless liquid.Oxidant; may cause fire in contact with organic materials such as wood, cotton or straw, evolving highly toxic gases (brown fumes). Highly corrosive to most metals. Causes severe burns to skin, eyes and mucous membranes.

Air transport

PCA Excepted quantities (IATA)	: E2
PCA Limited quantities (IATA)	: Y840
PCA limited quantity max net quantity (IATA)	: 0.5L
PCA packing instructions (IATA)	: 851
PCA max net quantity (IATA)	: 1L
CAO packing instructions (IATA)	: 855
CAO max net quantity (IATA)	: 30L
ERG code (IATA)	: 8L

Inland waterway transport

Not regulated

Rail transport

Not regulated

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 substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

ANNEX I RESTRICTED EXPLOSIVES PRECURSORS

List of substances which shall not be made available to, or introduced, possessed or used by, members of the general public, whether on their own or in mixtures or substances that include those substances, unless the concentration is equal to or lower than the limit values set out in column 2, and for which suspicious transactions and significant disappearances and thefts are to be reported to the relevant national contact point within 24 hours.

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Name	CAS-No.	Limit value	Upper limit value for licensing under Article 5(3)	Combined Nomenclature (CN) code for a separate chemically defined compound meeting the requirements of Note 1 to Chapter 28 or 29 of the CN, respectively	Combined Nomenclature code for mixture without constituents which would determine classification under another CN code
Nitric acid	7697-37-2	3 % w/w	10% w/w	ex 2808 00 00	ex 3824 99 96

Please see https://home-affairs.ec.europa.eu/policies/internal-security/counter-terrorism-and-radicalisation/protection/legislation-chemicals-used-home-made-explosives_en

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)

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
	Hazard pictograms (CLP)	Modified	
	Precautionary statements (CLP)	Modified	
	Hazard statements (CLP)	Modified	
	Issue date	Removed	
	Revision date	Added	
	Supersedes version of	Added	
	Signal word (CLP)	Modified	
	Display additional SDS EU addresses	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
14	Transport information	Modified	

Full text of H- and EUH-statements:	
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
H272	May intensify fire; oxidiser.
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H331	Toxic if inhaled.
Met. Corr. 1	Corrosive to metals, Category 1
Ox. Liq. 3	Oxidising Liquids, Category 3
Skin Corr. 1	Skin corrosion/irritation, Category 1

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Full text of H- and EUH-statements:	
Skin Corr. 1A	Skin corrosion/irritation, Category 1, Sub-Category 1A
Skin Corr. 1B	Skin corrosion/irritation, Category 1, Sub-Category 1B

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.