

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2



Revision: 08.01.2020

Hazardous according to criteria of Australian Safety and Compensation Council.

1 Identification

- **Product identifier**
- **Trade name: GC Reline Soft/Extra Soft Primer R**
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Auxillary for dental technology
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
GC Australasia Dental Pty Ltd
1753 Botany Road
Banksmeadow, NSW 2019
Tel: +61 2 9301 8200
- **Further information obtainable from:** Regulatory affairs
- **Emergency telephone number:** 24 hours Emergency: 13 11 26.

2 Hazard(s) Identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapour.
Eye Irrit. 2A H319 Causes serious eye irritation.
STOT SE 3 H336 May cause drowsiness or dizziness.
- **Label elements**
- **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).
- **Exemptions**
The product, regulated as an invasive medical device by the Regulation (EC) 2017/745, is exempted from labelling requirements for substances and mixtures (according to the provision of the Art 1.5).
- **Hazard pictograms**

GHS02 GHS07
- **Signal word** Danger
- **Hazard statements**
Highly flammable liquid and vapour.
Causes serious eye irritation.
May cause drowsiness or dizziness.
- **Precautionary statements**
Keep away from heat/sparks/open flames/hot surfaces. No smoking.
Wear protective gloves / eye protection / face protection.
IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

(Contd. on page 2)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 1)

- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.*
- Store locked up.*
- Dispose of contents/container in accordance with local/regional/national/international regulations.*
- **Other hazards**
 - **Results of PBT and vPvB assessment**
 - **PBT:** Not applicable.
 - **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- **Chemical characterisation: Mixtures**
- **Description:**

Only substances required to be mentioned according to Annex II of regulation 1907/2006 are listed. Information on the other substances that may be present can be obtained upon request.

- **Dangerous components:**

141-78-6	ethyl acetate	Flam. Liq. 2, H225; Eye Irrit. 2A, H319; STOT SE 3, H336	90-<100%
----------	---------------	--	----------

- **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.
If symptoms persist consult doctor.
- **After inhalation:**
Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.
Take affected persons into fresh air and keep quiet.
- **After skin contact:** *If skin irritation continues, consult a doctor.*
- **After eye contact:**
Protect unharmed eye.
Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
Rinse out mouth and then drink plenty of water.
If symptoms persist consult doctor.
- **Information for doctor:**
- **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*
- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire Fighting Measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** *Water with full jet*

(Contd. on page 3)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 2)

- **Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** Wear self-contained respiratory protective device.
- **Additional information**
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures**
Remove persons from danger area.
Keep away from ignition sources.
Avoid contact with the eyes and skin.
Wear protective clothing.
- **Environmental precautions:**
Do not allow product to reach sewage system or any water course.
Do not allow to penetrate the ground/soil.
- **Methods and material for containment and cleaning up:**
Ensure adequate ventilation.
Absorb liquid components with liquid-binding material.
Dispose of the material collected according to regulations.
- **Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

7 Handling and Storage

- **Handling:**
- **Precautions for safe handling**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid contact with the eyes and skin.
- **Information about fire - and explosion protection:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
Do not spray onto a naked flame or any incandescent material.
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool location.
Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Further information about storage conditions:**
Keep container tightly sealed.
Store in cool, dry conditions in well sealed receptacles.
Protect from heat and direct sunlight.
Store in a cool place.

(Contd. on page 4)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 3)

· **Specific end use(s)** No further relevant information available.

8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.

· **Control parameters**

· **Ingredients with limit values that require monitoring at the workplace:**

141-78-6 ethyl acetate

WES Short-term value: 1440 mg/m³, 400 ppm

Long-term value: 720 mg/m³, 200 ppm

· **Additional information:** The lists valid during the making were used as basis.

· **Exposure controls**

· **Personal protective equipment:**

· **General protective and hygienic measures:**

The usual precautionary measures are to be adhered to when handling chemicals.

Avoid contact with the eyes and skin.

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

· **Respiratory protection:** Suitable respiratory protective device recommended.

· **Protection of hands:**



Protective gloves

· **Material of gloves**

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· **Penetration time of glove material**

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

· **Eye protection:**



Tightly sealed goggles

9 Physical and Chemical Properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

Form: Fluid

Colour: Colourless

· **Odour:** Ester-like

· **Odour threshold:** Not determined.

(Contd. on page 5)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 4)

· pH-value:	Not determined.
· Change in condition	
Melting point/freezing point:	-83 °C (-181.4 °F)
Initial boiling point and boiling range:	77 °C (170.6 °F)
· Flash point:	-1 °C (-33.8 °F)
· Flammability (solid, gas):	Not applicable.
· Ignition temperature:	Undetermined.
· Decomposition temperature:	Not determined.
· Auto-ignition temperature:	Product is not selfigniting.
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	2.1 Vol %
Upper:	11.5 Vol %
· Vapour pressure:	Not determined.
· Density at 20 °C (68 °F):	0.9 g/cm ³ (7.5105 lbs/gal)
· Relative density	Not determined.
· Vapour density	Not determined.
· Evaporation rate	Not determined.
· Solubility in / Miscibility with water:	Fully miscible.
· Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	
Dynamic:	Not determined.
Kinematic:	Not determined.
· Solvent content:	
Organic solvents:	90.0 %
VOC (EC)	810.0 g/l
· Other information	No further relevant information available.

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 reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

-AU-

(Contd. on page 6)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 5)

11 Toxicological Information

- Information on toxicological effects
- Acute toxicity

· LD/LC50 values relevant for classification:

141-78-6 ethyl acetate

Oral	LD50	4,935 mg/kg (rabbit)
Inhalative	LC50/4 h	1,600 mg/l (rat (f+m))

- Primary irritant effect:
- Serious eye damage/irritation Irritating effect.
- Additional toxicological information:
The product shows the following dangers according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version:
Irritant
- Repeated dose toxicity No further relevant information available.
- CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)
No further relevant information available.

12 Ecological Information

- Toxicity
- Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- Behaviour in environmental systems:
- Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- Additional ecological information:
- General notes:
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- Results of PBT and vPvB assessment
- PBT: Not applicable.
- vPvB: Not applicable.
- Other adverse effects No further relevant information available.

13 Disposal considerations

- Waste treatment methods
- Recommendation
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packaging:
- Recommendation: Disposal must be made according to official regulations.
- Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

- UN-Number
 - ADG, IMDG, IATA
- UNI173

(Contd. on page 7)

AU

Safety Data Sheet

according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 6)

· **UN proper shipping name**
 · **ADG**
 · **IMDG, IATA**

1173 ETHYL ACETATE mixture
 ETHYL ACETATE mixture

· **Transport hazard class(es)**
 · **ADG**



· **Class**
 · **Label**

3 (F1) Flammable liquids.
 3

· **IMDG, IATA**



· **Class**
 · **Label**

3 Flammable liquids.
 3

· **Packing group**
 · **ADG, IMDG, IATA**

II

· **Environmental hazards:**
 · **Marine pollutant:**

No

· **Special precautions for user**
 · **Hazard identification number (Kemler code):**
 · **EMS Number:**
 · **Stowage Category**

Warning: Flammable liquids.
 33
 F-E,S-D
 B

· **Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

· **Transport/Additional information:**

· **ADG**
 · **Limited quantities (LQ)**
 · **Excepted quantities (EQ)**

1L
 Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

· **Transport category**
 · **Tunnel restriction code**

2
 D/E

· **IMDG**
 · **Limited quantities (LQ)**
 · **Excepted quantities (EQ)**

1L
 Code: E2
 Maximum net quantity per inner packaging: 30 ml
 Maximum net quantity per outer packaging: 500 ml

· **UN "Model Regulation":**

UN 1173 ETHYL ACETATE MIXTURE, 3, II

-AU-

(Contd. on page 8)

Safety Data Sheet according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 7)

15 Regulatory information

· **Safety, health and environmental regulations/legislation specific for the substance or mixture**

· **Australian Inventory of Chemical Substances**

141-78-6 ethyl acetate

· **Standard for the Uniform Scheduling of Medicines and Poisons**

None of the ingredients is listed.

· **GHS label elements** The product is classified and labelled according to the Globally Harmonised System (GHS).

· **Hazard pictograms**



GHS02 GHS07

· **Signal word** Danger

· **Hazard statements**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

· **Precautionary statements**

P201 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P202 Wear protective gloves / eye protection / face protection.

P231 IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P232 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

P233 Continue rinsing.

P234 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Directive 2012/18/EU**

· **Named dangerous substances - 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

· **Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

16 Other information

· **Relevant phrases**

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

H336 May cause drowsiness or dizziness.

· **Department issuing SDS:** Regulatory affairs

· **Contact:** msds@gc.dental

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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)

(Contd. on page 9)

Safety Data Sheet
according to WHS Regulations

Printing date 08.01.2020

Version number 2

Revision: 08.01.2020

Trade name: GC Reline Soft/Extra Soft Primer R

(Contd. of page 8)

*VOC: Volatile Organic Compounds (USA, EU)**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**Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A**STOT SE 3: Specific target organ toxicity (single exposure) – Category 3***· Sources**

- ECHA (<http://echa.europa.eu/>)

- EnviChem (www.echemportal.org)

· * Data compared to the previous version altered.*This version replaces all previous versions.***Disclaimer:**

The information contained herein is believed to be true and accurate. However, all statements, recommendations or suggestions are made without any guarantee, representation or warranty, express or implied, on our part. Therefore, no warranty is made or to be implied that the information set out in this document is accurate or complete, and we accordingly exclude all liability in connection with the use of this information or the products referred to herein. All such risks are assumed by the purchaser/user. The information contained herein is also subject to change without notice. For the avoidance of doubt, however, nothing in this document excludes or limits our liability for death or personal injury caused by our negligence or for fraudulent misrepresentation.

AU