

SECTION 1: Identification of the substance/mixture and of the company/undertaking
· 1.1 Product identifier

· **Trade name:** CLEARFIL MAJESTY ES Flow, CLEARFIL MAJESTY ES Flow Universal

· **Article number:** 177

· **Registration number** Not applicable

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

No further relevant information available.

· **Application of the substance / the mixture** Dental materials

· 1.3 Details of the supplier of the safety data sheet
· Supplier :

Kuraray Europe GmbH
 Philipp-Reis-Str. 4,
 65795 Hattersheim am Main
 Germany

Phone: +49 (0)69 305 35 835

E-mail: dental.eu@kuraray.com

· **Further information obtainable from:** Supplier

· 1.4 Emergency telephone number:

[Ireland] National Poisons Information Centre: 01 809 2566

3E Company; (Great Britain)+44 20 35147487 (United Kingdom)800 680 0425 (UK English)+44 8 08 189 0979 (Europe Non-Specific)+1 760 476 3962 *Kuraray Access Code: 334674

SECTION 2: Hazards identification
· 2.1 Classification of the substance or mixture
· Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

· Additional information

Medical devices as defined in Regulation (EU) 2017/745 and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

· 2.2 Label elements
· Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

· Hazard pictograms


GHS07

· Signal word Warning

· Hazard-determining components of labelling:

Triethyleneglycol dimethacrylate

· Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves.

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

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P321 Specific treatment (see on this label).

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

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- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients
· 3.2 Mixtures

- **Description:** Mixture of substances listed below with nonhazardous additions.

· Dangerous components:

CAS: 109-16-0	Triethyleneglycol dimethacrylate	 Skin Sens. 1B, H317	< 20%
EINECS: 203-652-6			

SECTION 4: First aid measures
· 4.1 Description of first aid measures

- **General information:** Immediately remove any clothing soiled by the product.

· After inhalation:

Supply fresh air and to be sure call for a doctor.

In case of unconsciousness place patient stably in side position for transportation.

- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

- **After eye contact:** Rinse opened eye for several minutes under running water.

- **After swallowing:** If symptoms persist consult doctor.

· 4.2 Most important symptoms and effects, both acute and delayed

No further relevant information available.

· 4.3 Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 5: Firefighting measures
· 5.1 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.

- **5.2 Special hazards arising from the substance or mixture** No further relevant information available.

· 5.3 Advice for firefighters

- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures
· 6.1 Personal precautions, protective equipment and emergency procedures See Section 8.

- **6.2 Environmental precautions:** No special measures required.

· 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to section 13.

Ensure adequate ventilation.

Contain spill, then place in a suitable container. Minimize dust generation. Do not flush to sewer or allow to enter waterways.

Vacuum or sweep material and place in a disposal container. Provide ventilation.

Use appropriate Personal Protective Equipment (PPE).

· 6.4 Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

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See Section 13 for disposal information.

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SECTION 7: Handling and storage
· 7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with skin and eyes. Do not swallow. Avoid generating dust. Do not breathe dust/fume/gas/mist/vapors/spray.

· Information about fire - and explosion protection: No special measures required.

· 7.2 Conditions for safe storage, including any incompatibilities
· Storage:

· Requirements to be met by storerooms and receptacles: Store in a cool location (2-25°C).

· Information about storage in one common storage facility: Not required.

· Further information about storage conditions:

Keep container tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

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

SECTION 8: Exposure controls/personal protection
· 8.1 Control parameters
· Ingredients with limit values that require monitoring at the workplace:

The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.

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

· 8.2 Exposure controls
· Appropriate engineering controls No further data; see section 7.

· Personal protective equipment:
· General protective and hygienic measures:

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

· Respiratory protection: Suitable respiratory protective device recommended.

· Hand protection


Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· 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.

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- Eye/face protection Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information	
· Physical state	Solid
· Colour:	Colored
· Odour:	Odourless
· Melting point/freezing point:	Not determined.
· Boiling point or initial boiling point and boiling range	Not determined.
· Flammability	Not determined.
· Lower and upper explosion limit	
· Lower:	Not applicable.
· Upper:	Not applicable.
· Flash point:	Not applicable
· Auto-ignition temperature:	Not applicable.
· Decomposition temperature:	Not applicable.
· pH	Not determined.
· Kinematic viscosity	Not applicable.
· Solubility	
· water:	Insoluble.
· Partition coefficient n-octanol/water (log value)	Not applicable.
· Vapour pressure:	Not applicable.
· Density at 20 °C:	1.8 g/cm ³
· Relative vapour density	Not applicable.
· Particle characteristics	Not determined.

· 9.2 Other information

· Information with regard to physical hazard classes

· Explosives	Product does not present an explosion hazard.
· Flammable gases	Void
· Aerosols	Void
· Oxidising gases	Void
· Gases under pressure	Void
· Flammable liquids	Void
· Flammable solids	Void
· Self-reactive substances and mixtures	Void
· Pyrophoric liquids	Void
· Pyrophoric solids	Void
· Self-heating substances and mixtures	Void
· Substances and mixtures, which emit flammable gases in contact with water	Void
· Oxidising liquids	Void
· Oxidising solids	Void
· Organic peroxides	Void
· Corrosive to metals	Void
· Desensitised explosives	Void

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.

- 10.2 Chemical stability No hazardous reaction when handled and stored according to provisions.

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- **10.3 Possibility of hazardous reactions** No dangerous reactions known.
- **10.4 Conditions to avoid** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** Carbon monoxide and carbon dioxide

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

- **Acute toxicity** Based on available data, the classification criteria are not met.

- **LD/LC50 values relevant for classification:**

109-16-0 Triethyleneglycol dimethacrylate

Oral	LD50	2,000 mg/kg (mouse)
		10,800 mg/kg (rat)

- **Primary irritant effect:**

- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.

- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

- **Respiratory or skin sensitisation**

May cause an allergic skin reaction.

- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.

- **Carcinogenicity** Based on available data, the classification criteria are not met.

- **Reproductive toxicity** Based on available data, the classification criteria are not met.

- **STOT-single exposure** Based on available data, the classification criteria are not met.

- **STOT-repeated exposure** Based on available data, the classification criteria are not met.

- **Aspiration hazard** Based on available data, the classification criteria are not met.

- **11.2 Information on other hazards**

- **Endocrine disrupting properties**

None of the ingredients is listed.

SECTION 12: Ecological information

- **12.1 Toxicity**

- **Aquatic toxicity:** No further relevant information available.

- **12.2 Persistence and degradability** No further relevant information available.

- **12.3 Bioaccumulative potential** No further relevant information available.

- **12.4 Mobility in soil** No further relevant information available.

- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Endocrine disrupting properties** For information on endocrine disrupting properties see section 11.

- **12.7 Other adverse effects**

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

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· Uncleaned packaging:**· Recommendation:**

Dispose of packaging according to regulations on the disposal of packagings.

Waste Framework Directive (Directive 2008/98/EC on waste)

[No. 177] O-ring used at the top of the plunger in the syringe contains 0.1% or more of SVHC.

Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

SCIP number [Low and Super Low Type]: 0562e53a-3f62-429f-b45d-d8eb10a87366

SCIP number [High Type]: c7edd175-240e-448c-b5da-ed61029da991

The SCIP number shall be communicated down to waste operators of the product.

For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>**SECTION 14: Transport information****· 14.1 UN number or ID number**

· ADR, ADN, IMDG, IATA Void

· 14.2 UN proper shipping name

· ADR, ADN, IMDG, IATA Void

· 14.3 Transport hazard class(es)· ADR, ADN, IMDG, IATA
· Class Void**· 14.4 Packing group**

· ADR, ADN, IMDG, IATA Void

· 14.5 Environmental hazards:

Not applicable.

· 14.6 Special precautions for user

Not applicable.

· 14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

· UN "Model Regulation":

Void

SECTION 15: Regulatory information**· 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

· Directive 94/33/EC: Care should be taken when people under 18 handle this product.

· Directive 94/85/EEC: No further relevant information available.

· Named dangerous substances - ANNEX I None of the ingredient is listed.

· Regulation (EU) No 649/2012

None of the ingredients is listed.

· Regulation (EC) No 273/2004 on drug precursors

None of the ingredients is listed.

· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

None of the ingredients is listed.

· Regulation (EC) No 1005/2009 on substances that deplete the ozone layer – ANNEX I (Ozone-depleting potential)

None of the ingredients is listed.

· Waste Framework Directive (Directive 2008/98/EC on waste)

[No. 177] O-ring used at the top of the plunger in the syringe contains 0.1% or more of SVHC.

Octamethylcyclotetrasiloxane (D4) (CAS 556-67-2)

SCIP number [Low and Super Low Type]: 0562e53a-3f62-429f-b45d-d8eb10a87366

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Trade name: CLEARFIL MAJESTY ES Flow, CLEARFIL MAJESTY ES Flow Universal

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SCIP number [High Type]: c7edd175-240e-448c-b5da-ed61029da991

The SCIP number shall be communicated down to waste operators of the product.

For more information about the directive, visit ECHA website: <https://echa.europa.eu/understanding-wfd>

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

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

This Safety Data Sheets is in compliance with Regulation (EC) No 1907/2006, Article 31 as amended by Regulation (EU) 2020/878.

- **Relevant phrases**

H317 May cause an allergic skin reaction.

- **Classification according to Regulation (EC) No 1272/2008**

The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.

- **Abbreviations and acronyms:**

ELINCS: European List of Notified Chemical Substances

Skin Sens. 1: Skin sensitisation – Category 1

Skin Sens. 1B: Skin sensitisation – Category 1B