

Material Safety Data Sheet Cover-Sheet – This page provides additional New Zealand specific information for this product and must be read in conjunction with the Safety Data Sheet (SDS) attached

| Product Name: | CLEARFIL MAJESTY ES Flow, CLEARFIL MAJESTY ES Flow Universal |
|------------------------|--|
| Manufacturer: | Kuraray Noritake Dental Inc. |
| SDS Expiry: | 29 September 2029 |
| Supplier Details: | Henry Schein New Zealand 243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745 Ph. 0800 808 855 www.henryschein.co.nz |
| Emergency Contacts: | Poisons/Hazardous Chemical Info Centre – 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police |
| HSNO Class/Category: | 6 |
| HSNO Group Standard: | Dental Products Subsidiary Hazard Group Standard 2020 HSR002558 |
| Statements/Pictograms: | As per attached Safety Data Sheet (SDS) |
| Date Prepared: | This coversheet was prepared – March 2025 |

This SDS coversheet has been produced by Henry Schein NZ and has been prepared in accordance with NZ EPA advice on making overseas SDS compliant to HSNO Act. The above information is based on the present state of our knowledge of the product at the time of publication. It is given in good faith, no warranty is implied with respect to the quality or the specifications of the product. Users must satisfy that the product is entirely suitable for their purpose. The SDS and this coversheet may be revised from time to time, please ensure you have a current copy.





Safety Data Sheet according to WHS Regulations

Version number 5 (replaces version 4)

Revision date: 27.09.2024

SECTION 1: Identification

· Product identifier

[·] Trade name: CLEARFIL MAJESTY ES Flow, CLEARFIL MAJESTY ES Flow Universal

- · Article number: AZ177
- · Registration number Not applicable
- \cdot 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

· Details of the supplier of the safety data sheet

· Manufacturer:

Supplier : [Australia] HENRY SCHEIN HALAS
Building 3, Level 6, 189 O'Riordan Street, Mascot, NSW 2020
Australia
Freephone: 1300 65 88 22
www.henryschein.com.au
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243-249 Bush Road, Rosedale, Auckland 0632
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Further information obtainable from: Supplier
Emergency telephone number: [Australia] Poisons Information Centre; 131 126

[New Zealand] National Poisons Centre; 0800 764 766

3E Company; (Australia)+61 280363166 (Australia English)+61 1 800 686 951 (New Zealand)+64 800 451719 *Kuraray Access Code: 334674

SECTION 2: Hazard(s) Identification

· Classification of the substance or mixture

Skin sensitisation - Category 1 H317 May cause an allergic skin reaction.

· Label elements

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



· Signal word Warning

· Hazard-determining components of labelling:

Triethyleneglycol dimethacrylate (<20 %)

- · 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).

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< 20%



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- (Contd. of page 1) P501 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.

SECTION 3: Composition and Information on Ingredients

- · Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.
- · Dangerous components:

109-16-0 Triethyleneglycol dimethacrylate

Skin sensitisation – Category 1B, H317

SECTION 4: First Aid Measures

· 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.
- · Most important symptoms and effects, both acute and delayed No further relevant information available.

 \cdot Indication of any immediate medical attention and special treatment needed

No further relevant information available.

SECTION 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.
- Special hazards arising from the substance or mixture No further relevant information available.
- · Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental Release Measures

· Personal precautions, protective equipment and emergency procedures See Section 8.

- · Environmental precautions: No special measures required.
- · 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).
- · 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.

SECTION 7: Handling and Storage

· 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.

· 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.

Protect from heat and direct sunlight.

- Store in cool, dry conditions in well sealed receptacles.
- · Storage class: 13
- · Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls and personal protection

[•] Ingredients with limit values that require monitoring at the workplace:

7631-86-9 Silicon dioxide

WES (Australia) Long-term value: 2 mg/m³

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

- · 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 trough 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

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| Information on basic physical and chemical pr | operties |
|--|----------------------|
| 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. |
| Viscosity: | |
| Kinematic viscosity | Not applicable. |
| Dynamic: | Not applicable. |
| Solubility | |
| water: | Insoluble. |
| Partition coefficient n-octanol/water (log value | e) Not applicable. |
| Vapour pressure: | Not applicable. |
| Density and/or relative density | |
| Density at 20 °C: | 1.8 g/cm^3 |
| Relative vapour density | Not applicable. |
| Particle characteristics | Not determined. |

· Explosive p · Explosives Product does not present an explosion hazard. Product does not present an explosion hazard.

SECTION 10: Stability and Reactivity

· Reactivity No further relevant information available.

- · Chemical stability No hazardous reaction when handled and stored according to provisions.
- · 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: Carbon monoxide and carbon dioxide

SECTION 11: Toxicological Information

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

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

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· LD/LC50 values relevant for classification:

109-16-0 Triethyleneglycol dimethacrylate

Oral LD50 2,000 mg/kg (mouse)

10,800 mg/kg (rat)

• 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.
- \cdot 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.

 \cdot Aspiration hazard Based on available data, the classification criteria are not met.

SECTION 12: Ecological Information

· Toxicity

- · Aquatic toxicity: No further relevant information available.
- Persistence and degradability No further relevant information available.
- · Bioaccumulative potential No further relevant information available.
- Mobility in soil No further relevant information available.
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- Endocrine disrupting properties For information on endocrine disrupting properties see section 11.
- · 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

· Recommendation

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

· Recommendation: Dispose of packaging according to regulations on the disposal of packagings.

SECTION 14: Transport information

| · UN number or ID number | | |
|------------------------------|------|--------------------|
| · ADG, IMDG, IATA | Void | |
| · UN proper shipping name | | |
| · ADG, IMDG, IATA | Void | |
| · Transport hazard class(es) | | |
| · ADG, ADN, IMDG, IATA | | |
| Class | Void | |
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[·] Uncleaned packaging:



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|--|-----------------------------|--------------------|
| · Packing group · ADG, IMDG, IATA | Void | |
| · Environmental hazards: | Not applicable. | |
| · Special precautions for user | Not applicable. | |
| Maritime transport in bulk according instruments | g to IMO Not applicable. | |
| · UN "Model Regulation": | Void | |

SECTION 15: Regulatory information

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

· Australian Inventory of Industrial Chemicals

All ingredients are listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

· New Zealand Inventory of Chemicals

All ingredients are listed.

· HSNO Approval numbers

None of the ingredients is listed.

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.

Relevant phrases

- H317 May cause an allergic skin reaction.
- · Abbreviations and acronyms:
- ELINCS: European List of Notified Chemical Substances
- Skin sensitisation Category 1: Skin sensitisation Category 1

Skin sensitisation – Category 1B: Skin sensitisation – Category 1B * Data compared to the previous version altered.