



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 ST OPAQUER

Manufacturer: Kuraray

SDS Expiry: 21 June 2027

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

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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 – July 2023

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.





Printing date 21.06.2022 Version number 3 Revision date: 21.06.2022

1 Identification

· Product identifier

· Trade name: CLEARFIL ST OPAQUER

· Article number: AZ013

· Registration number Not applicable

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

No further relevant information available.

- · Application of the substance / the mixture Dental filling material
- · Details of the supplier of the safety data sheet
- · Manufacturer:

Kuraray Noritake Dental Inc. 1621, Sakazu, Kurashiki, Okayama, 710-0801, Japan

· Supplier:

< Australia >

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AUSTRALIAN POISONS INFORMATION CENTRE

24 hours service: phone 13 11 26 Police/Firebrigade/Ambulance: 000

< New Zealand >

Poisons/Hazardous Chemical Info Centre 0800POISON/0800764766 (24 Hours) Phone 111 for Fire, Ambulance or Police

2 Hazard(s) Identification

· Classification of the substance or mixture

This product is classified as non-hazardous according to WHS/NOHSC(AU) and HSNO(NZ), and is non-dangerous according to ADG Code(AU) and NZS5433(NZ).

Skin Irrit. 2 H315 Causes skin irritation.

Eye Irritation 2A H319 Causes serious eye irritation.

Carc. 2 H351 Suspected of causing cancer. Route of exposure: Inhalation.

· Additional information :

Medical devices as defined in Directive 93/42/EEC 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.

- · Label elements
- · GHS label elements

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

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Safety Data Sheet according to WHS Regulations

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· Hazard pictograms





· Signal word Warning

$\cdot \ Hazard\text{-}determining \ components \ of \ labelling:$

bisphenol A diglycidylmethacrylate triethylene glycol dimethacrylate titanium dioxide

· Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H351 Suspected of causing cancer. Route of exposure: Inhalation.

· Precautionary statements

P264 Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing

protection.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P308+P313 IF exposed or concerned: Get medical advice/attention.

P321 Specific treatment (see on this label).

P362+P364 Take off contaminated clothing and wash it before reuse. P332+P313 If skin irritation occurs: Get medical advice/attention. P337+P313 If eye irritation persists: Get medical advice/attention.

P405 Store locked up.

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

regulations.

- · Other hazards
- · **PBT:** Not applicable. · **vPvB:** Not applicable.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

· Dangerous components:		
		10-25%
EINECS: 216-367-7	♦ Skin Irrit. 2, H315; Eye Irritation 2A, H319	
		2.5-10%
EINECS: 203-652-6	Skin Irrit. 2, H315; Eye Irritation 2A, H319; STOT SE 3, H335	

Other ingredients:

Silanated silica filler

Colloidal silica

Silanated colloidal silica

dl-Camphorquinone

Catalysts Accelerators

Pigments

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4 First Aid Measures

- · Description of first aid measures
- · 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. If symptoms persist, consult a doctor.

· After swallowing:

Do not induce vomiting; call for medical help immediately.

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.

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

Wear self-contained respiratory protective device.

Wear fully protective suit.

6 Accidental Release Measures

- · Personal precautions, protective equipment and emergency procedures See Section 8.
- Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · Methods and material for containment and cleaning up:

Pick up mechanically. Ensure adequate ventilation.

· 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.

- · 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.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

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· 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:

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.
- · Exposure controls
- · 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.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not required.
- · Protection of hands:



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.

· Eye protection:



Tightly sealed goggles

9 Physical and Chemical Properties

- · Information on basic physical and chemical properties
- · General Information
- · Appearance:

Form: Pasty

Colour: According to product specification

· Odourless

· pH-value: Not determined

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· Change in condition	
Melting point/freezing point:	Not determined
Initial boiling point and boiling range:	Not determined
· Flash point:	Not determined
· Ignition temperature:	Not determined
· Decomposition temperature:	Not determined
· Explosive properties:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined
Upper:	Not determined
· Oxidising properties	Not determined
· Vapour pressure:	Not determined
· Density:	1.1 g/cm ³
· Relative density	Not determined
Vapour density	Not determined
Evaporation rate	Not determined
· Solubility in / Miscibility with	
water:	Insoluble.
Partition coefficient: n-octanol/water:	Not determined.
· Viscosity:	Not determined
· 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: Carbon monoxide and carbon dioxide

11 Toxicological Information

- · Information on toxicological effects
- · Primary irritant effect:
- · Skin corrosion/irritation Irritant to skin and mucous membranes.
- · Serious eye damage/irritation Irritating effect
- · Respiratory or skin sensitisation Sensitisation possible through skin contact.

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.

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- · Mobility in soil No further relevant information available.
- · 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.

- · Results of PBT and vPvB assessment
- · **PBT:** Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

·Recommendation

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

4 Transport information		
· UN-Number	****	
· ADG, ADN, IMDG, IATA	Void	
· UN proper shipping name		
· ADG, ADN, IMDG, IATA	Void	
· Transport hazard class(es)		
· ADG, ADN, IMDG, IATA		
· Class	Void	
· Packing group		
· ADG, IMDG, IATA	Void	
· Environmental hazards:		
· Marine pollutant:	No	
· Special precautions for user	Not applicable.	
· Transport in bulk according to Ann	nex II of	
Marpol and the IBC Code	Not applicable.	
· UN "Model Regulation":	Void	

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.

- · Chemical safety assessment
- · Named dangerous substances ANNEX I None of the ingredient is listed.
- · Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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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.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances
Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A
Carc. 2: Carcinogenicity – Category 2
STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

 \cdot * Data compared to the previous version altered.

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