

Safety Data Sheet According to HPR

Version 3

Reviewed on 05/09/2018

1 Identification

· Product identifier

· Trade name: CLEARFIL SE PROTECT ; PRIMER

· Article number: CA092-P

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

- No further relevant information available.
- · Application of the substance / the mixture Dental bonding material

· Details of the supplier of the safety data sheet

· Manufacturer:

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

- Contact information:

Kuraray America, Inc. 33 Maiden Lane, 6th Floor, New York, NY 10038 U.S.A. Tel: 800-879-1676 Fax: 888-700-5200 Website: www.kuraraydental.com • Emergency telephone number: For chemical emergency spill, leak, fire, exposure or accident Call CHEMTREC day and night Within USA and Canada: 1-800-424-9300 CCN706984 or +1 703-527-3887 (collect calls accepted)

2 Hazard(s) identification

· Classification of the substance or mixture GHS07 Skin Irritation - Category 2 H315 Causes skin irritation. Eye Irritation - Category 2A H319 Causes serious eye irritation.

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

· Label elements

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

- · Hazard pictograms GHS07
- · Signal word Warning

· Hazard-determining components of labeling:

2-hydroxyethyl methacrylate

Hazard statements

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P264 Wash thoroughly after handling. P272 Contaminated work clothing should not be allowed out of the workplace. P280 Wear protective gloves/protective clothing/eye protection/face protection. P302+P352 If on skin: Wash with plenty of 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 on this label). P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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25-45% w/w

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P337+P313	If eye irritation persists: Get medical advice/attention.
P501	Dispose of contents/container in accordance with local/regional/national/international regulations.

3 Composition/information on ingredients

· Chemical characterization: Mixtures

• Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

868-77-9 2-hydroxyethyl methacrylate

Skin Irritation - Category 2, H315; Eye Irritation - Category 2A, H319; Skin Sensitizer - Category 1, H317

• Other ingredients:

10-Methacryloyloxydecyl dihydrogen phosphate 12-Methacryloyloxydodecylpyridinium bromide Hydrophilic aliphatic dimethacrylate Water Initiators Accelerators Dyes

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; immediately call for medical help.

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, extinguishing 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.

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• Methods and material for containment and cleaning up: Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). • 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 protection against explosions and fires: No special measures required.

· Conditions for safe storage, including any incompatibilities

· Storage:

- Requirements to be met by storerooms and receptacles: Store in a refrigerator (2-8°C).
- Information about storage in one common storage facility: Not required.
- Further information about storage conditions:

Keep receptacle tightly sealed.

Store in cool, dry conditions in well sealed receptacles.

Protect from heat and direct sunlight.

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

8 Exposure controls/personal protection

• Additional information about design of technical systems: No further data; see item 7.

- · Control parameters
- · Components 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 that were valid during the creation 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.
- wash hands before breaks and at the end of
- Avoid contact with the eyes and skin. • **Breathing equipment:** Not required.
- Breathing equipment: Not requ
- · 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

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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 ch General Information Appearance: 	emical properties			
Form:	Liquid			
Color:	Blue			
· Odor:	Odorless			
· pH-value:	<2.5			
 Change in condition Melting point/Melting range: Boiling point/Boiling range: 	-12 °C (2-hydroxyethyl methacrylate) 205 °C (2-hydroxyethyl methacrylate)			
· Flash point:	97 °C (2-hydroxyethyl methacrylate)			
· Ignition temperature:	Not determined			
• Decomposition temperature:	Not determined			
• Danger of explosion:	Product does not present an explosion hazard.			
 Explosion limits: Lower: Upper: Oxidizing properties 	Not determined Not determined Not determined			
· Vapor pressure:	Not determined			
Density: Relative density Vapor density Evaporation rate	1.1 g/cm ³ Not determined Not determined Not determined			
 Solubility in / Miscibility with Water: 	Fully miscible.			
Partition coefficient (n-octanol/water	: Not determined			

Not determined

No further relevant information available.

10 Stability and reactivity

· Other information

· Viscosity:

• Reactivity No further relevant information available.

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· Chemical stability

• Thermal decomposition / conditions to be avoided:

No decomposition if used and stored 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

· Acute toxicity:

· LD/LC50 values that are relevant for classification:

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Oral LD50 4680 mg/kg (guinea pig)

3275 mg/kg (mouse)

5050 mg/kg (rat)

· Primary irritant effect:

• on the skin: Irritating effect

• on the eye: Irritating effect.

• Sensitization: Sensitization possible through skin contact.

· Additional toxicological information:

The product shows the following dangers according to internally approved calculation methods for preparations:

Irritant

· Carcinogenic categories

· IARC (International Agency for Research on Cancer)

None of the ingredients is listed.

· NTP (National Toxicology Program)

None of the ingredients is listed.

12 Ecological information

· Toxicity

- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behavior in environmental systems:
- · Bioaccumulative potential No further relevant information available.
- · Mobility in soil No further relevant information available.
- · Additional ecological information:
- · General notes:

Water hazard class 1 (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.

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13 Disposal considerations

· Waste treatment methods

· Recommendation:

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

· Uncleaned packagings:

• Recommendation: Disposal must be made according to official regulations.

14 Transport information

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· UN-Number			
· DOT, TDG, ADN, IMDG, IATA	Void		
· UN proper shipping name			
· DOT, ADN, IMDG, IATA	Void		
· TDG	Void		
· Transport hazard class(es)			
· DOT, TDG, ADN, IMDG, IATA			
Class	Void		
· Packing group			
DOT, TDG, IMDG, IATA	Void		
• Environmental hazards:			
· Marine pollutant:	No		
· Special precautions for user	Not applicable.		
· Transport in bulk according to Annex II of			
MARPOL73/78 and the IBC Code	Not applicable.		
· UN "Model Regulation":	Void		

15 Regulatory information

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·Sara	
Section 355 (extremely hazardous substances):	
None of the ingredient is listed.	
Section 313 (Specific toxic chemical listings):	
None of the ingredients is listed.	
SARA 311/312: See Section 2 for the information on physical and health hazards.	
TSCA (Toxic Substances Control Act):	
All ingredients are listed.	
Canadian substance listings:	
· Canadian Domestic Substances List (DSL)	
All ingredients are listed.	
Canadian Ingredient Disclosure list (limit 0.1%)	
None of the ingredients is listed.	
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· Canadian Ingredient Disclosure list (limit 1%)

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16 Other information

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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.

* * Data compared to the previous version altered.