



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: PANAVIA SA Cement Universal

Manufacturer: Kuraray Noritake Dental Inc.

SDS Expiry: 19 April 2028

Supplier Details: Henry Schein New Zealand

243-249 Bush Road, Rosedale, Auckland, 0632 PO Box 101 140, North Shore, Auckland 0745

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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 – November 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 19.04.2023 Version number 2 Revision date: 19.04.2023

SECTION 1: Identification of the substance/mixture and of the company/undertaking

· 1.1 Product identifier

· Trade name: PANAVIA SA Cement Universal

· Article number: 231

· 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 Resin-based dental adhesive cement

· 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:

(UK) 0 800 680 0425 (GB) +44 20 35147487 (AU) +61 2 80363166

* 3E Company

* 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 Irrit. 2 H315 Causes skin irritation.

Eye Irrit. 2 H319 Causes serious eye irritation.

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 (GB 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 GB CLP regulation.

· Hazard pictograms



GHS07

- · Signal word Warning
- $\cdot \ Hazard\text{-}determining \ components \ of \ labelling:$

2-hydroxyethyl methacrylate potassium persulfate

· 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.

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P280 Wear protective gloves / 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.

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).

P337+P313 If eye irritation persists: Get medical advice/attention.

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

regulations.

· Labelling of packages where the contents do not exceed 125 ml

- · Precautionary statements EUH032 Contact with acids liberates very toxic gas.
- · 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: 1565-94-2	bisphenol A diglycidylmethacrylate	1-10%
EINECS: 216-367-7	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319	
CAS: 109-16-0	Triethyleneglycol dimethacrylate	1-10%
EINECS: 203-652-6	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 1344-28-1	aluminium oxide	1-5%
EINECS: 215-691-6	substance with a Community workplace exposure limit	
CAS: 868-77-9	2-hydroxyethyl methacrylate	1-3%
EINECS: 212-782-2	♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	
CAS: 7681-49-4	sodium fluoride	<1%
EINECS: 231-667-8	♦ Acute Tox. 3, H301; ♦ Skin Irrit. 2, H315; Eye Irrit. 2, H319, EUH032	
CAS: 13463-67-7	titanium dioxide	<1%
EINECS: 236-675-5	& Carc. 2, H351	
CAS: 7727-21-1	potassium persulfate	<1%
EINECS: 231-781-8	Ox. Sol. 3, H272; & Resp. Sens. 1, H334; O Acute Tox. 4, H302; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317; STOT SE 3, H335	

· Other ingredients:

Silanated barium glass filler

Hydrophobic aromatic dimethacrylate

Silanated amorphous silica

Silane coupling agent

10-Methacryloyloxydecyl dihydrogen phosphate

Catalysts

Accelerators

Pigments

dl-Camphorquinone

· Additional information:

Silicon oxide; Nanoform, Silanated amorphous silica, particle size 1 - 100 nm

Aluminium oxide; Nanoform, particle size 1 - 100 nm

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SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- · General information:

Avoid contact with eyes.

Avoid contact with skin.

· 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.

If skin irritation continues, consult a doctor.

After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

- · 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.

- 5.2 Special hazards arising from the substance or mixture No further relevant information available.
- · 5.3 Advice for firefighters
- · Protective equipment: Wear fully protective suit.

SECTION 6: Accidental release measures

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

Pick up mechanically. Ensure adequate ventilation.

· 6.4 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.

SECTION 7: Handling and storage

- · 7.1 Precautions for safe handling No special precautions are necessary if used correctly.
- · 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:

Store away from oxidising agents.

Store away from reducing agents.

· 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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· 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:

7681-49-4 sodium fluoride

WEL Long-term value: 2.5 mg/m³ as F

1344-28-1 aluminium oxide

WEL Long-term value: 10* 4** mg/m³ *inhalable dust **respirable dust

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- · Appropriate engineering controls No further data; see item 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.

Avoid contact with the eyes and skin.

- · Respiratory protection: Not required.
- · Hand protection



Protective gloves

Neoprene 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/face protection



Tightly sealed goggles

SECTION 9: Physical and chemical properties

- · 9.1 Information on basic physical and chemical properties
- · General Information
- · Physical state Solid

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· Colour:	Coloured
Odour:	Odourless
Odour threshold:	Not determined
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 determined
Upper:	Not determined
Flash point:	Not determined
Auto-ignition temperature:	Not determined
Decomposition temperature:	Not determined
pH	Not determined
Viscosity:	Not determined
Kinematic viscosity	Not determined
Dynamic:	Not determined
Solubility	Trov determined
water:	Insoluble.
Partition coefficient n-octanol/water (log value)	Not determined
Vapour pressure:	Not determined
Density and/or relative density	Trov determined
Density:	$1.8-1.9 \text{g/cm}^3$
Relative density	Not determined
Relative vapour density	Not determined
Particle characteristics	See item 3.
	244 14411 21
9.2 Other information	
Appearance:	D (
Form:	Pasty
Important information on protection of health an	ld
environment, and on safety.	
Explosive properties:	Product does not present an explosion hazard.
Change in condition	
Softening point/range	NT - 1 - 1
Oxidising properties	Not determined
Evaporation rate	Not determined
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

Void

Void

Void

Void

Void Void

Void

SECTION 10: Stability and reactivity

· Self-heating substances and mixtures

gases in contact with water

· Oxidising liquids

· Organic peroxides

· Corrosive to metals

· Desensitised explosives

· Oxidising solids

· Substances and mixtures, which emit flammable

· 10.1 Reactivity No further relevant information available.

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- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- · 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:

868-77-9 2-hydroxyethyl methacrylate

Oral LD50 4,680 mg/kg (guinea pig) 3,275 mg/kg (mouse) 5,050 mg/kg (rat)

- · Skin corrosion/irritation Causes skin irriation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · 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: Disposal must be made according to official regulations.

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, IMDG, IATA	Void	
· 14.5 Environmental hazards: · Marine pollutant:	No	
· 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 No further relevant information available.
- · Directive 94/33/EC: Care should be taken when people under 18 handle this product.
- · Directive 94/85/EEC: No further relevant information available.
- · Chemical safety assessment
- · Named dangerous substances ANNEX I None of the ingredient is listed.
- · Regulation (EU) No 649/2012
- · 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.

· 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.

· Relevant phrases

- H272 May intensify fire; oxidiser.
- H301 Toxic if swallowed.
- H302 Harmful if swallowed.
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.

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H319 Causes serious eye irritation.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

EUH032 Contact with acids liberates very toxic gas.

· Abbreviations and acronyms:

ELINCS: European List of Notified Chemical Substances

Ox. Sol. 3: Oxidizing solids – Category 3 Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 4: Acute toxicity – Category 4

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Resp. Sens. 1: Respiratory sensitisation – Category 1

Skin Sens. 1: Skin sensitisation – Category 1

Carc. 2: Carcinogenicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

* * Data compared to the previous version altered.

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