

Printing date 31.08.2016 Version number 5 Revision: 29.08.2016

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

· 1.1 Product identifier

Trade name: PANAVIA F 2.0; PASTE B (TC, White, Light, Opaque)

· Article number: 089-PB

· 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

· Manufacturer:

Kuraray Europe GmbH Philipp-Reis-Str. 4,

65795 Hattersheim am Main

Germany

Phone:+49 (0)69 305 35 840 Fax:+49 (0)69 305 35 640 E-mail: dental@kuraray.de

· Supplier:

J & S Davis

5 Whitworth Road, Stevenage,

Hertfordshir, SG1 4QS

Great Britain

Tel: +44- (0) 1438 747344 Fax: +44- (0)1438 758909 E-mail: jsdsales@js-davis.co.uk

· Further information obtainable from: Manufacturer or Supplier

1.4 Emergency telephone number:

National Poisons information Service (London Centre)

Guy's & St. Thomas' Hospital Trust

Medical Toxicology Unit

Avonley Road LONDON SE14 5ER

Emergency telephone: (local) 0870 600 6266 or +44 20 7771 5394

Administrative telephone: +44 20 7 771 53 10 Facsimile number: +44 20 7 771 53 09

SECTION 2: Hazards identification

- · 2.1 Classification of the substance or mixture
- · Classification according to Regulation (EC) No 1272/2008



Acute Tox. 4 H302 Harmful if swallowed.

- · 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:

sodium fluoride

· Hazard statements

H302 Harmful if swallowed.

· Precautionary statements

P264 Wash thoroughly after handling.

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P270 Do not eat, drink or smoke when using this product.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

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

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

regulations.

· Additional Information

EUH032 Contact with acids liberates very toxic gas.

- · Labelling of packages where the contents do not exceed 125 ml
- · Hazard-determining components of labelling: sodium fluoride
- · 2.3 Other hazards Not applicable
- · Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- · 3.1 Chemical characterisation: Substances None
- 3.2 Chemical characterisation: Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.
- Dangerous components:

CAS: 7681-49-4 sodium fluoride

<10%

EINECS: 231-667-8 Acute Tox. 3, H301; Skin Irrit. 2, H315; Eye Irrit. 2, H319

Other ingredients:

Hydrophobic aromatic dimethacrylate

Hydrophobic aliphatic dimethacrylate

Hydrophilic aliphatic dimethacrylate

Silanated barium glass filler

Catalysts

Accelerators

Pigments

Additional information: EUH032: Contact with acids liberates very toxic gas. (sodium fluoride)

SECTION 4: First aid measures

- 4.1 Description of first aid measures
- General information:

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

- · After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact: Rinse opened eye for several minutes under running water.
- **After swallowing:** Call for a doctor immediately.
- 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.

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

Mouth respiratory protective device.

Wear fully protective suit.

SECTION 6: Accidental release measures

· 6.1 Personal precautions, protective equipment and emergency procedures

Mount respiratory protective device.

- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up:

Dispose contaminated material as waste according to item 13.

· 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 Prevent formation of dust.
- · 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 refrigerator (2-8 °C).
- · Information about storage in one common storage facility:

Do not store together with acids.

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.

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

SECTION 8: Exposure controls/personal protection

- · Additional information about design of technical facilities: No further data; see item 7.
- · 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

- **Additional information:** The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Personal protective equipment:
- · General protective and hygienic measures:

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the skin.

Avoid contact with the eyes.

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Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:

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 protection: Safety glasses

SECTION	9: Physical	l and chem	nical pro	perties

	· 9.1 Information on	basic ph	ysical and	chemical	properties
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General Information

Appearance:

Form: Pasty
Colour: Coloured
Odour: Odourless
Odour threshold: Not determined

Important information on protection of health and environment, and on safety.

Not determined

· pH-value: Not determined

· Change in condition

Melting point/Melting range: 1012 °C (sodium fluoride) **Boiling point/Boiling range:** 1704 °C (sodium fluoride)

· Flash point: Not determined

· Flammability (solid, gaseous): Not determined

· Ignition temperature: Not determined

• Decomposition temperature: Not determined
• Self-igniting: Not determined

• **Danger of explosion:** Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined Upper: Not determined or Oxidising properties Not determined

· Vapour pressure: Not determined

Density: 2.0 g/cm³

Relative densityVapour densityNot determinedNot determined

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· Evaporation rate	Not determined	
· Solubility in / Miscibility with water:	Insoluble.	
· Partition coefficient (n-octanol/water):	Not determined	
· Viscosity: · Dynamic: · Kinematic:	Not determined Not determined Not determined	
Solvent separation test: Water: VOC (EC)	Not determined Not determined Not determined	
· Solids content: · 9.2 Other information	Not determined Not determined	

SECTION 10: Stability and reactivity

- 10.1 Reactivity No further relevant information available.
- 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 toxicological effects
- · Acute toxicity

Harmful if swallowed.

· LD/LC50	values	relevant	for	classification:
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7681-49-4 sodium fluoride

Oral LD50 44 mg/kg (mouse) 52 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 Based on available data, the classification criteria are not met.
- · CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)
- 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.

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.

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- 12.4 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.

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

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.

- · Uncleaned packaging:
- **Recommendation:** Disposal must be made according to official regulations.

SECTION 14: Transport informa	tion	
· 14.1 UN-Number · ADR, ADN, IMDG, IATA	Void	
, , ,	Void	
14.2 UN proper shipping name	77 1	
· 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 Transport in bulk according to Ann	nex II of	
Marpol and the IBC Code	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.
- · 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

H301 Toxic if swallowed.

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H315 Causes skin irritation.

H319 Causes serious eye irritation.

· Abbreviations and acronyms:

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

CLP: Classification, Labelling and Packaging PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EINECS: European Inventory of Existing Commercial Chemical Substances

WEL: Workplace Exposure Limit

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent STOT: Specific target organ toxicity

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International

Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

IBC: International Bulk Chemical

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

* Data compared to the previous version altered.

compared to the previous version altered.