

Revision: 14.04.2020

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

· Product identifier

- · Trade name: Cavex Bite& White Whitening Barrier / Spacer
- UFI: NC60-709W-5005-NYVK
- *Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.*
- Application of the substance / the mixture Dental Products.
- \cdot Details of the supplier of the safety data sheet
- Manufacturer/Supplier: Cavex Holland B.V. Fustweg 5 2031 CJ Haarlem The Netherlands T +31 23 530 7700 E-Mail : dental@cavex.nl Website : www.cavex.nl
- Further information obtainable from: Product safety department
 Emergency telephone number: During normal opening times: +31 23 530 7700

2 Hazards identification

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



Skin Sens. 1 H317 May cause an allergic skin reaction. • Label elements

- · Labelling according to Regulation (EC) No 1272/2008
- The product is classified and labelled according to the CLP regulation.
- · Hazard pictograms



- · Signal word Warning
- · Hazard-determining components of labelling:
- (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]bismethacrylate
- Hazard statements
- H317 May cause an allergic skin reaction.

· Precautionary statements

- *P101 If medical advice is needed, have product container or label at hand.*
- P102 Keep out of reach of children.
- P103 Read label before use.
- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
- P280 Wear protective gloves.
- *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).
- *P501* Dispose of contents/container in accordance with local/regional/national/international regulations.

(Contd. on page 2)

GB

Printing date 14.04.2020

Revision: 14.04.2020

Trade name: Cavex Bite&White Whitening Barrier / Spacer

- Other hazards
- · Results of PBT and vPvB assessment
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

3 Composition/information on ingredients

• Chemical characterisation: Mixtures

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

· Dangerous componer	its:
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Dungerous compone	1113.	
	Silica, fused	50-70%
EINECS: 262-373-8	substance with a Community workplace exposure limit	
CAS: 1565-94-2	(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)]	<i>≥3-≤10%</i>
	bismethacrylate	
	📀 Eye Dam. 1, H318; 🚸 Skin Sens. 1, H317	
	1,12-Dodecanediol Dimethacrylate	2.5-7.5%
	𝚯 Skin Irrit. 2, H315; Eye Irrit. 2, H319	
· Additional informati	on: For the wording of the listed hazard phrases refer to section 16.	

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.

· 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 Firefighting measures

• Extinguishing media

- Suitable extinguishing agents: 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.

6 Accidental release measures

• Personal precautions, protective equipment and emergency procedures Not required.

- · Environmental precautions: No special measures required.
- Methods and material for containment and cleaning up:
- Dispose contaminated material as waste according to item 13. Ensure adequate ventilation.
- · Reference to other sections

See Section 7 for information on safe handling.

See Section 8 for information on personal protection equipment.

(Contd. on page 3)

(Contd. of page 1)

GB

Printing date 14.04.2020

Revision: 14.04.2020

(Contd. of page 2)

Trade name: Cavex Bite&White Whitening Barrier / Spacer

See Section 13 for disposal information.

7 Handling and storage

- · Handling:
- $\cdot \textit{Precautions for safe handling } \textit{Ensure good ventilation/exhaustion at the workplace}.$
- 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: No special requirements.
- Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: None.
- · Specific end use(s) No further relevant information available.

8 Exposure controls/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:

60676-86-0 Silica, fused

WEL Long-term value: 0.08 mg/m³ fused respirable dust

• 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.

- · 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:



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 through time has to be found out by the manufacturer of the protective gloves and has to be observed.

• Eye protection: Not required.

(Contd. on page 4)

Printing date 14.04.2020

Revision: 14.04.2020

Trade name: Cavex Bite&White Whitening Barrier / Spacer

(Contd. of page 3)

Physical and chemical properties		
Information on basic physical and chem	ical properties	
General Information		
Appearance:		
Form:	Pasty	
Colour:	Whitish	
Odour:	Odourless	
Odour threshold:	Not determined.	
pH-value:	Not applicable.	
Change in condition		
Melting point/freezing point:	Undetermined.	
Initial boiling point and boiling range:	Undetermined.	
Flash point:	>160 °C	
Flammability (solid, gas):	Not determined.	
Decomposition temperature:	Not determined.	
Auto-ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product does not present an explosion hazard.	
Explosion limits:		
Lower:	Not determined.	
Upper:	Not determined.	
Vapour pressure:	Not applicable.	
Density at 20 °C:	$1.8 g/cm^3$	
Relative density	Not determined.	
Vapour density	Not applicable.	
Evaporation rate	Not applicable.	
Solubility in / Miscibility with		
water:	Insoluble.	
Partition coefficient: n-octanol/water:	Not determined.	
Viscosity:		
Dynamic:	Not applicable.	
Kinematic:	Not applicable.	
Solvent content:		
Solids content:	28.0 %	
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: No dangerous decomposition products known.

(Contd. on page 5)

GB

Printing date 14.04.2020

Revision: 14.04.2020

Trade name: Cavex Bite&White Whitening Barrier / Spacer

(Contd. of page 4)

11 Toxicological information

- · Information on toxicological effects
- Acute toxicity Based on available data, the classification criteria are not met.
- 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
- May cause an allergic skin reaction.
- · 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.

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.
- · Mobility in soil No further relevant information available.
- Additional ecological information:
- · General notes: Not hazardous for water.
- Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · Other adverse effects No further relevant information available.

13 Disposal considerations

- · 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.

· UN-Number		
· ADR, ADN, IMDG, IATA	not regulated	
· UN proper shipping name		
· ADR, ÂDN, IMDĞ, IATA	not regulated	
· Transport hazard class(es)		
ADR, ADN, IMDG, IATA		
· Class	not regulated	
Packing group		
· ADR, IMDG, IATA	not regulated	

Printing date 14.04.2020

Revision: 14.04.2020

(Contd. of page 5)

Trade name: Cavex Bite&White Whitening Barrier / Spacer

· Environmental hazards:

and the IBC Code

· Special precautions for user

· Transport in bulk according to Annex II of Marpol

Not applicable.

Not applicable.

Not applicable.

not regulated

• UN "Model Regulation":

15 Regulatory information

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

· Directive 2012/18/EU

· Named dangerous substances - ANNEX I None of the ingredients is listed.

· Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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

H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H319 Causes serious eye irritation.

· Department issuing SDS: Product safety department

· Contact: .

Abbreviations and acronyms:
 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
 GHS: Globally Harmonised System of Classification and Labelling of Chemicals
 EINCCS: European Inventory of Existing Commercial Chemical Substances
 ELINCS: European List of Notified Chemical Substances
 CAS: Chemical Abstracts Service (division of the American Chemical Society)
 PBT: Persistent, Bioaccumulative and Toxic
 vPvB: very Persistent and very Bioaccumulative
 Skin Irrit. 2: Skin corrosion/irritation – Category 2
 Eye Dam. 1: Serious eye damage/eye irritation – Category 2
 Skin Sens. 1: Skin sensitisation – Category 1
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