

Safety Data Sheet

according to 1907/2006/EC, Article 31

1. Identification of the substance/preparation and of the company/undertaking

Product name: PURE Single Bond (5 ml - REF 721290)
Application of the substance/the preparation: For dental use only
Manufacturer/Supplier: R&H Nederland B.V.
Bedrijfsweg 4
NL-5061 JZ Oosterwijk
Information in case of emergency: +31 (0)13 - 522 91 20

2. Hazards identification

Classification of the substance or mixture

Classification according to Directive 67/548/EEC or 1999/45/EC

Indications of danger: Xi - Irritant
R phrases: Irritating to eyes, respiratory system and skin.
May cause sensitisation by skin contact.
Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Hazard categories:
Skin corrosion/irritation: Skin Irrit. 2
Serious eye damage/eye irritation: Eye Irrit. 2
Respiratory/skin sensitization: Skin Sens. 1
Specific target organ toxicity - single exposure: STOT SE 3

Hazard Statements:
Causes skin irritation.
May cause an allergic skin reaction.
Causes serious eye irritation.
May cause respiratory irritation.

Label elements

Hazardous components which must be listed on the label

2-hydroxyethyl methacrylate

Signal word: Warning

Pictograms: GHS07



Hazard statements

H315 May cause an allergic skin reaction.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.

Precautionary statements

P280 Wear protective gloves/protective clothing/eye protection/face protection.
P302+P352 IF ON SKIN: Wash with plenty of water.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313 If eye irritation persists: Get medical advice/attention.

Additional advice on labelling

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.

3. Composition/information on ingredients

Mixtures

Hazardous components

EG-No.	Chemical name	Quantity
CAS-No.	Classification according to Directive 67/548/EEC	
Index-No.	Classification according to Regulation (EC) No. 1272/2008 [CLP]	
REACH-No.		

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212-782-2	2-hydroxyethyl methacrylate	35 - < 40 %
868-77-9	Xi - Irritant R36/38-43	
607-124-00-X	Eye Irrit. 2, Skin Irrit. 2, Skin Sens. 1; H319 H315 H317	
217-388-4	GDMA	20 - < 25 %
1830-78-0	Xi - Irritant R36/37/38	
	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315 H319 H335	
276-957-5	Urethane dimethacrylate	20 - < 25 %
72869-86-4	R52-53	
	Aquatic Chronic 3; H412	

Full text of R-, H- and EUH-phrases: see section 16.

4. First aid measures

Description of first aid measures

After contact with skin

After contact with skin, wash immediately with: Water and soap.

After contact with eyes

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

After ingestion

Seek medical attention if problems persist.

5. Firefighting measures

Extinguishing media

Suitable extinguishing media

Water. Foam. Extinguishing powder. Carbon dioxide (CO₂). Sand.

Additional information

Co-ordinate fire-fighting measures to the fire surroundings.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Avoid contact with skin and eyes

Environmental precautions

Do not allow to enter into surface water or drains.

Methods and material for containment and cleaning up

Wipe up with absorbent material (eg. cloth, fleece). Clear contaminated areas thoroughly

7. Handling and storage

Precautions for safe handling

Advice on safe handling

Avoid contact with skin and eyes.

Restricted to professional users. Keep out of the reach of children.

Observe instructions for use.

Further information on handling

After use replace the closing cap immediately.

Conditions for safe storage, including any incompatibilities

Further information on storage conditions

Substances sensitive to light.

Recommended storage temperature: 4 - 8 °C

8. Exposure controls/personal protection

Control parameters

Exposure controls

Protective and hygiene measures: When using do not eat, drink or smoke.

Eye/face protection: Framed glasses.

Hand protection: Single-use gloves.

Skin protection: Lab apron.

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9. Physical and chemical properties

Information on basic physical and chemical properties

Physical state: viscous, liquid
Colour: colourless

Changes in the physical state

Density at 23 °C: 1,13 g/cm³
Water solubility (at 23 °C): insoluble

Solubility in other solvents

Ethanol. (partially soluble)

10. Stability and reactivity

Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

Conditions to avoid

Light.
UV-radiation/sunlight.

11. Toxicological information

Acute toxicity

Based on available data, the classification criteria are not met.

CAS-No.	Chemical name	Exposure routes	Method	Dose	Species	Source
868-77-9	2-hydroxyethyl methacrylate	oral	LD50	5050 mg/kg	Rat	
1830-78-0	GDMA	oral	LD50	>2000 mg/kg	Rat	OECD 423
72869-86-4	Urethane dimethacrylate	oral	LD50	>2000 mg/kg	Rat	OECD 401

Irritation and corrosivity

Causes skin irritation.
Causes serious eye irritation.

Sensitising effects

May cause an allergic skin reaction. (2-hydroxyethyl methacrylate)

STOT-single exposure

May cause respiratory irritation

12. Ecological information

Toxicity

CAS-No.	Chemical name	Aquatic toxicity	Method	Dose	[h] [d]	Species	Source
868-77-9	2-hydroxyethyl methacrylate	Acute fish toxicity	LC50	227 mg/l	96 h	Pimephales promelas	
1830-78-0	GDMA	Acute fish toxicity	LC50	43.2 mg/l	96 h	Poecilia reticulata (Guppy)	
72869-86-4	Urethane dimethacrylate	Acute fish toxicity	LC50	10.1 mg/l	96 h	Brachydanio rerio (zebra-fish)	OECD 203

Persistence and degradability

CAS-No.	Chemical name	Method	Value	d	Source
72869-86-4	Urethane dimethacrylate	OECD 301 F	22%	28	
	Product is not easily biodegradable				

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Bioaccumulative potential

Partition coefficient n-octanol/water

CAS-No.	Chemical name	Log Pow
868-77-9	2-hydroxyethyl methacrylate	0,47
72869-86-4	Urethane dimethacrylate	3.39

Further information

According to the criteria of the EC-classification and labelling "dangerous for the environment" (93/21/EEC) the material/product is not to be classified as dangerous to the environment.

13. Disposal considerations

Waste treatment methods

Advice on disposal

Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

14. Transport information

Land transport (ADR/RID)

UN-Number: –

Inland waterways transport (ADN)

UN-Number: –

Marine transport (IMDG)

UN-Number: –

Air transport (ICAO)

UN-Number: –

Other applicable information

Not a hazardous material with respect to these transportation regulations.

15. Regulatory information

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

National regulatory information

Additional information

16. Other information

Relevant R-phrases (Number and full text)

- 36/37/38 Irritating to eyes, respiratory system and skin.
- 36/38 Irritating to eyes and skin.
- 43 May cause sensitisation by skin contact
- 52 Harmful to aquatic organisms.
- 53 May cause long-term adverse effects in the aquatic environment.

Relevant H- and EUH-phrases (Number and full text)

- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.

Further Information

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal.

(The data for the hazardous ingredients were taken respectively from the last version of the sub-contractor's safety data sheet.)