Printing date 07.03.2024

ivoclar

Version number 10

Revision: 07.03.2024

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

· 1.1 Product identifier

· Trade name: ProBase Cold Polymer

• 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 Self-curing denture base material
- \cdot 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 *Fax:* +423 235 33 60

 Further information obtainable from: Regulatory Affairs sds@ivoclar.com
 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Skin Sens. 1 H317 May cause an allergic skin reaction.

· 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



· Signal word Warning

- · Hazard-determining components of labelling:
- dibenzoyl peroxide
- · Hazard statements

H317 May cause an allergic skin reaction.

· Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P262 Do not get in eyes, on skin, or on clothing.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

• 2.3 Other hazards Dust generation

Particular danger of slipping on leaked/spilled product.

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

· vPvB: Not applicable.

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Printing date 07.03.2024

Version number 10

Revision: 07.03.2024

Trade name: ProBase Cold Polymer

(Contd. of page 1)

1-<2.5%

SECTION 3: Composition/information on ingredients

· 3.2 Mixtures

• **Description:** > 95% polymethylmethacrylate

· Dangerous components:

CAS: 94-36-0 EINECS: 202-327-6 dibenzoyl peroxide Org. Perox. B, H241; Eye Irrit. 2, H319; Skin Sens. 1, H317

Reg.nr.: 01-2119511472-50-XXXX

• Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

• 4.1 Description of first aid measures

- · General information: No special measures required.
- After inhalation: Supply fresh air and to be sure call for a doctor.
- After skin contact:
- Rinse with water.

If skin irritation continues, consult a doctor.

- · After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing:
- Rinse out mouth and then drink plenty of water.
- 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: No special measures required.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away. Avoid formation of dust. Particular danger of slipping on leaked/spilled product.
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.
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.

(Contd. on page 3)

Printing date 07.03.2024

Version number 10

Revision: 07.03.2024

Trade name: ProBase Cold Polymer

(Contd. of page 2)

SECTION 7: Handling and storage

· 7.1 Precautions for safe handling

Only adequately trained personnel should handle this product. For use in dentistry only.

• 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 only in the original receptacle.

· Information about storage in one common storage facility: Not required.

• Further information about storage conditions: Protect from heat and direct sunlight.

• 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:

CAS: 94-36-0 dibenzoyl peroxide

WEL Long-term value: 5 mg/m^3

· Regulatory information WEL: EH40/2020

- Additional information: The lists valid during the making were used as basis.
- · 8.2 Exposure controls
- Appropriate engineering controls No further data; see section 7.
- · Individual protection measures, such as personal protective equipment
- General protective and hygienic measures:
- Usual hygienic measures for dental practice and dental laboratories.

Keep away from foodstuffs, beverages and feed.

Wash hands before breaks and at the end of work.

- Avoid contact with the skin.
- · Respiratory protection: Use respiratory protective device against the effects of dust.
- Hand protection



Protective gloves (EN 374)

After use of gloves apply skin-cleaning agents and skin cosmetics.

- Material of gloves
- Butyl rubber, BR

Chloroprene rubber, CR

- Natural rubber, NR
- Nitrile rubber, NBR

Fluorocarbon rubber (Viton)

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

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/face protection Safety glasses

(Contd. on page 4)

Printing date 07.03.2024

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Version number 10

Revision: 07.03.2024

(Contd. of page 3)

Trade name: ProBase Cold Polymer

SECTION 9: Physical and chemical prop	
9.1 Information on basic physical and chemical p	roperties
General Information	
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.
Melting point/freezing point:	150 °C
Boiling point or initial boiling point and boiling	
range	Undetermined.
Flammability	Not determined.
Lower and upper explosion limit	
Lower:	Not determined.
Upper:	Not determined.
Flash point:	250 °C
рН	Not applicable.
Viscosity:	
Kinematic viscosity	Not applicable.
Dynamic:	Not applicable.
Solubility	
water:	Nearly insoluble.
Partition coefficient n-octanol/water (log value)	Not determined.
Vapour pressure:	Not applicable.
Density and/or relative density	
Density at 20 °C:	$1.2 \ g/cm^3$
Relative density	Not determined.
Vapour density	Not applicable.
9.2 Other information Appearance: Form: Important information on protection of health and	Powder d
environment, and on safety.	Due due t is wet a life suiting
Ignition temperature:	Product is not selfigniting.
Explosive properties:	Product does not present an explosion hazard.
Change in condition Evaporation rate	Not applicable
•	Not applicable.
Information with regard to physical hazard classe	
Explosives	Void
Flammable gases	Void
Aerosols	Void
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
Self-heating substances and mixtures	Void
Substances and mixtures, which emit flammable	
gases in contact with water	Void
	Void
Oxidising liquids	
Oxidising liquids Oxidising solids Organic peroxides	Void Void

(Contd. on page 5) GB

Printing date 07.03.2024

Version number 10

Void

Revision: 07.03.2024

(Contd. of page 4)

Trade name: ProBase Cold Polymer

· Desensitised explosives

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

- 10.2 Chemical stability Stable under normal handling and storage conditions.
- *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: None under normal conditions of storage and use.

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.
- 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.
- · 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.
- Additional toxicological information: No further relevant information available.

• 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
- The product does not contain substances with endocrine disrupting properties.
- · 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.

(Contd. on page 6)

Printing date 07.03.2024

Version number 10

Revision: 07.03.2024

Trade name: ProBase Cold Polymer

(Contd. of page 5)

SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

· Uncleaned packaging:

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

SECTION 14: Transport informatio	n
· 14.1 UN number or ID number · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.2 UN proper shipping name · ADR/RID/ADN, ADN, IMDG, IATA	Void
· 14.3 Transport hazard class(es)	
· ADR/RID/ADN, ADN, IMDG, IATA · Class	Void
· 14.4 Packing group · ADR/RID/ADN, 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 t instruments	to IMO Not applicable.
• Transport/Additional information:	Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
· UN "Model Regulation":	Void

SECTION 15: Regulatory information

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

· National regulations:

· Other regulations, limitations and prohibitive regulations

The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).

• 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

H241 Heating may cause a fire or explosion.

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

• Abbreviations and acronyms:

IMO: International Maritime Organization

(Contd. on page 7)

Printing date 07.03.2024

Version number 10

Revision: 07.03.2024

Trade name: ProBase Cold Polymer

(Contd. of page 6) ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: 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 Org. Perox. B: Organic peroxides – Type B Eye Irrit. 2: Serious eye damage/eye irritation - Category 2 Skin Sens. 1: Skin sensitisation – Category 1 • * Data compared to the previous version altered.

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Safety data sheet according to 1907/2006/EC, Article 31

Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

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

· 1.1 Product identifier

· Trade name: ProBase Cold Monomer

• 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 Self-curing denture base material
- · 1.3 Details of the supplier of the safety data sheet

• Manufacturer/Supplier: Ivoclar Vivadent AG Bendererstrasse 2 9494 Schaan PRINCIPALITY OF LIECHTENSTEIN

Tel: +423 235 35 35 *Fax:* +423 235 33 60

 Further information obtainable from: Regulatory Affairs sds@ivoclar.com
 1.4 Emergency telephone number: +423 / 235 33 13 (Ivoclar Vivadent AG, 9494 Schaan, Liechtenstein)

SECTION 2: Hazards identification

· 2.1 Classification of the substance or mixture

· Classification according to Regulation (EC) No 1272/2008

Flam. Liq. 2 H225 Highly flammable liquid and vapour.

Skin Irrit. 2 H315 Causes skin irritation.

Skin Sens. 1 H317 May cause an allergic skin reaction.

STOT SE 3 H335 May cause respiratory irritation.

· 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



· Signal word Danger

· Hazard-determining components of labelling: methyl methacrylate 1,4-butanediol dimethacrylate · Hazard statements H225 Highly flammable liquid and vapour. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H335 May cause respiratory irritation. · Precautionary statements Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No P210 smoking. P261 Avoid breathing dust/fume/gas/mist/vapours/spray. P262 Do not get in eyes, on skin, or on clothing.

(Contd. on page 2)

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Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

Trade name: ProBase Cold Monomer

(Contd. of page 1)

P280	<i>Wear protective gloves/protective clothing/eye protection/face protection.</i>
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with
	water [or shower].
P501	Dispose of contents/container in accordance with local/regional/national/international
	regulations.
· 2.3 Other hazards	
· Results of PBT and	d 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:
-------------	-------------

Dungerous components.		
CAS: 80-62-6 EINECS: 201-297-1 Reg.nr.: 01-2119452498-28-XXXX	methyl methacrylate Flam. Liq. 2, H225; Skin Irrit. 2, H315; Skin Sens. 1, H317; STOT SE 3, H335	50-100%
CAS: 2082-81-7 EINECS: 218-218-1 Reg.nr.: 01-2119967415-30-XXXX	1,4-butanediol dimethacrylate Skin Sens. 1, H317	2.5-10%
CAS: 3077-12-1 EINECS: 221-359-1 Reg.nr.: 01-2120791684-40-xxxx	2,2'-[(4-methylphenyl)imino]bisethanol Eye Dam. 1, H318; Acute Tox. 4, H302; Skin Sens. 1, H317; Aquatic Chronic 3, H412	0.1-<1%
Additional informations Fourthowarding of the listed har and physica upfor to section 16		

• Additional information: For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

• 4.1 Description of first aid measures

· General information: Immediately remove any clothing soiled by the product.

• After inhalation:

Supply fresh air; consult doctor in case of complaints.

In case of unconsciousness place patient stably in side position for transportation.

- After skin contact:
- Immediately rinse with water.

If skin irritation continues, consult a doctor.

- After eye contact: Rinse opened eye for several minutes under running water. Then consult a doctor.
- After swallowing:

Rinse out mouth and then drink plenty of water.

Do not induce vomiting; call for medical help 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.

- · For safety reasons unsuitable extinguishing agents: Water with full jet
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

(Contd. on page 3)

GB

Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

Trade name: ProBase Cold Monomer

(Contd. of page 2)

- 5.3 Advice for firefighters
- *Protective equipment:* No special measures required.
- Additional information Cool endangered receptacles with water spray.

SECTION 6: Accidental release measures

- 6.1 Personal precautions, protective equipment and emergency procedures Wear protective equipment. Keep unprotected persons away.
- 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- **6.3** *Methods and material for containment and cleaning up:* Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust). 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

- Only adequately trained personnel should handle this product. Ensure good ventilation/exhaustion at the workplace. For use in dentistry only.
- *Information about fire and explosion protection: Keep ignition sources away - Do not smoke. Protect against electrostatic charges.*
- 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles:
- Store in a cool location.
- Store only in the original receptacle.

· Information about storage in one common storage facility: Store away from oxidising agents.

- Further information about storage conditions:
- Keep container tightly sealed.
- Store receptacle in a well ventilated area.
- Protect from heat and direct sunlight.
- 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:

CAS: 80-62-6 methyl methacrylate

- WEL Short-term value: 416 mg/m³, 100 ppm Long-term value: 208 mg/m³, 50 ppm
- · Regulatory information WEL: EH40/2020
- Additional information: The lists valid during the making were used as basis.

· 8.2 Exposure controls

· Appropriate engineering controls No further data; see section 7.

(Contd. on page 4)

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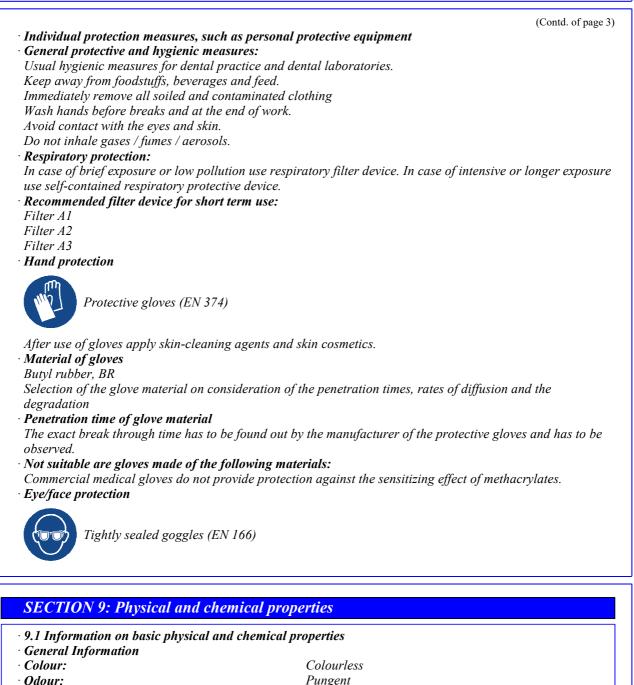
Safety data sheet according to 1907/2006/EC, Article 31

Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

Trade name: ProBase Cold Monomer



	00101110000	
· Odour:	Pungent	
· Odour threshold:	Not determined.	
• Melting point/freezing point:	-48 °C	
· Boiling point or initial boiling point and boil	ing	
range	101 °C	
· Lower and upper explosion limit		
·Lower:	2.1 Vol %	
· Upper:	12.5 Vol %	
· Flash point:	10 °C	
• Auto-ignition temperature:	430 °C	
· pH	Not determined.	
		(Contd. on page 5)

Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

Trade name: ProBase Cold Monomer

	(Contd. of page	
Viscosity:		
Kinematic viscosity	Not determined.	
Dynamic:	Not determined.	
Solubility		
water at 20 °C:	1.6 g/l	
Partition coefficient n-octanol/water (log value)	Not determined.	
Vapour pressure at 20 °C:	47 hPa	
Density and/or relative density		
Density at 20 °C:	0.943 g/cm^3	
Relative density	Not determined.	
Vapour density	Not determined.	
9.2 Other information	No further relevant information available.	
Appearance:		
Form:	Fluid	
Important information on protection of health an	nd	
environment, and on safety.		
Ignition temperature:	Product is not selfigniting.	
Explosive properties:	Product is not explosive. However, formation of	
	explosive air/vapour mixtures are possible.	
Change in condition		
Evaporation rate	Not determined.	
Information with regard to physical hazard classe	<i>es</i>	
Explosives	Void	
Flammable gases	Void	
Aerosols	Void	
Oxidising gases	Void	
Gases under pressure	Void	
Flammable liquids	Highly flammable liquid and vapour.	
Flammable solids	Void	
Self-reactive substances and mixtures	Void	
Pyrophoric liquids	Void	
Pyrophoric solids	Void	
Self-heating substances and mixtures	Void	
Substances and mixtures, which emit flammable		
gases in contact with water	Void	
Oxidising liquids	Void	
Oxidising solids	Void	
Organic peroxides	Void	
Corrosive to metals	Void	
Desensitised explosives	Void	

SECTION 10: Stability and reactivity

· 10.1 Reactivity No further relevant information available.

• 10.2 Chemical stability Stable under normal handling and storage conditions.

• Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

• 10.3 Possibility of hazardous reactions

Forms explosive gas mixture with air.

Reacts with strong oxidising agents.

Exothermic polymerisation.

• 10.4 Conditions to avoid No further relevant information available.

• 10.5 Incompatible materials: No further relevant information available.

(Contd. on page 6)

GB

Printing date 07.03.2024

Version number 12 (replaces version 11)

Revision: 07.03.2024

Trade name: ProBase Cold Monomer

(Contd. of page 5) • **10.6 Hazardous decomposition products:** None under normal conditions of storage and use.

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:
- Oral LD50 7872 mg/kg (rat)

CAS: 80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

Skin corrosion/irritation

Causes skin irritation.

- Serious eye damage/irritation Based on available data, the classification criteria are not met.
- · Respiratory or skin sensitisation
- May cause an allergic skin reaction.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- \cdot 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
- May cause respiratory irritation.
- 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.
- Additional toxicological information: No further relevant information available.
- · 11.2 Information on other hazards

· Endocrine disrupting properties

None of the ingredients is listed.

SECTION 12: Ecological information

- 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
- The product does not contain substances with endocrine disrupting properties.
- 12.7 Other adverse effects 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 product to reach ground water, water course or sewage system.

SECTION 13: Disposal considerations

- · 13.1 Waste treatment methods
- · Recommendation

Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.

(Contd. on page 7)

^{· 12.1} Toxicity

[•] Aquatic toxicity: No further relevant information available.

Printing date 07.03.2024

*

Version number 12 (replaces version 11)

Revision: 07.03.2024

(Contd. of page 6)

Trade name: ProBase Cold Monomer

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

14.1 UN number or ID number	
ADR/RID/ADN, IMDG, IATA	UN1247
14.2 UN proper shipping name	
ADR/RID/ADN	1247 METHYL METHACRYLATE MONOMER,
	STABILIZED
IMDG, IATA	METHYL METHACRYLATE MONOMER, STABILIZE
14.3 Transport hazard class(es)	
ADR/RID/ADN	
Class	3 (F1) Flammable liquids.
Label	3
IMDG, IATA	· · · · · · · · · · · · · · · · · · ·
Class Label	3 Flammable liquids. 3
14.4 Packing group	
ADR/RID/ADN, IMDG, IATA	II
14.5 Environmental hazards:	No
Marine pollutant:	
14.6 Special precautions for user	Warning: Flammable liquids.
Hazard identification number (Kemler code):	339
EMS Number:	F-E,S-D
Stowage Category	B SW2 Class of living an artes
Stowage Code	SW2 Clear of living quarters.
14.7 Maritime transport in bulk according to IM	
instruments	Not applicable.
Transport/Additional information:	
ADR/RID/ADN	
Limited quantities (LQ)	1L
Excepted quantities $(\widetilde{E}Q)$	Code: E2
	Maximum net quantity per inner packaging: 30 ml
	Maximum net quantity per outer packaging: 500 ml
Transport category	2
Tunnel restriction code	D/E

Printing date 07.03.2024

Revision: 07.03.2024

Trade name: ProBase Cold Monomer

(Contd. of page 7)

· IMDG · Limited quantities (LQ) · Excepted quantities (EQ)	1L Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· UN "Model Regulation":	UN 1247 METHYL METHACRYLATE MONOMER, STABILIZED, 3, II

SECTION 15: Regulatory information

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

- · Directive 2012/18/EU
- \cdot Qualifying quantity (tonnes) for the application of lower-tier requirements 5000 t
- Qualifying quantity (tonnes) for the application of upper-tier requirements 50000 t
- · National regulations:
- Other regulations, limitations and prohibitive regulations
- The product is a medical device according to Regulation 2017/745 on Medical Devices (MDR).
- 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

H225 Highly flammable liquid and vapour. H302 Harmful if swallowed. H315 Causes skin irritation. H317 May cause an allergic skin reaction. H318 Causes serious eye damage. H335 May cause respiratory irritation. H412 Harmful to aquatic life with long lasting effects. · Abbreviations and acronyms: IMO: International Maritime Organization ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road) RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail) IMDG: International Maritime Code for Dangerous Goods IATA: International Air Transport Association GHS: Globally Harmonised System of Classification and Labelling of Chemicals EINECS: European Inventory of Existing Commercial Chemical Substances ELINCS: European List of Notified Chemical Substances CAS: Chemical Abstracts Service (division of the American Chemical Society) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Flam. Liq. 2: Flammable liquids – Category 2 Acute Tox. 4: Acute toxicity - Category 4 Skin Irrit. 2: Skin corrosion/irritation - Category 2 Eye Dam. 1: Serious eye damage/eye irritation - Category 1 Skin Sens. 1: Skin sensitisation – Category 1 STOT SE 3: Specific target organ toxicity (single exposure) - Category 3 Aquatic Chronic 3: Hazardous to the aquatic environment - long-term aquatic hazard - Category 3 • * Data compared to the previous version altered.