

1 Identification


- **Product identifier**
- **Trade name:** ***ProBase Cold Monomer***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Denture base material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- **Ivoclar Vivadent Inc.**
1-6600 Dixie Road
Mississauga, Ontario
L5T 2Y2
Canada
Phone: +1 905 670 8499
Fax: +1 905 670 3102
- **Information department:** Quality Assurance / Regulatory Affairs
- **Emergency telephone number:**
24 Hour Emergency Assistance:
Emergency-Call USA - Infotrac: 1-800-535-5053
Emergency-Call Canada - Canutec: 1-613-996-6666

- **General SDS Assistance:**
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Flam. Liq. 2 H225 Highly flammable liquid and vapor.
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.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS02 GHS07
- **Signal word** Danger
- **Hazard-determining components of labeling:**
methyl methacrylate
1,4-butanediol dimethacrylate

Trade name: ProBase Cold Monomer

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· Hazard statements*Highly flammable liquid and vapor.**Causes skin irritation.**May cause an allergic skin reaction.**May cause respiratory irritation.***· Precautionary statements***Keep away from heat/sparks/open flames/hot surfaces. - No smoking.**Avoid breathing dust/fume/gas/mist/vapors/spray**Do not get in eyes, on skin, or on clothing.**Wear protective gloves/protective clothing/eye protection/face protection.**If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.**Dispose of contents/container in accordance with local/regional/national/international regulations.***· Classification system:****· NFPA ratings (scale 0 - 4)**

Health = 2

Fire = 3

Reactivity = 2

· HMIS-ratings (scale 0 - 4)

Health = 2

Fire = 3

Reactivity = 2

· Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**3 Composition/information on ingredients****· Chemical characterization: Mixtures****· Description:** Mixture of the substances listed below with nonhazardous additions.**· Dangerous components:**

80-62-6	methyl methacrylate	50-100%
2082-81-7	1,4-butanediol dimethacrylate	2.5-<10%

4 First-aid measures**· 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; immediately call for medical help.***· Information for doctor:****· Most important symptoms and effects, both acute and delayed** No further relevant information available.

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Trade name: **ProBase Cold Monomer**

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- **Indication of any immediate medical attention and special treatment needed**
No further relevant information available.

5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**
CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.
- **Additional information** Cool endangered receptacles with water spray.

6 Accidental release measures

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

7 Handling and storage

- **Handling:**
- **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 protection against explosions and fires:**
Keep ignition sources away - Do not smoke.
Protect against electrostatic charges.
- **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 oxidizing agents.
- **Further information about storage conditions:**
Keep receptacle tightly sealed.
Store receptacle in a well ventilated area.
Protect from heat and direct sunlight.
- **Specific end use(s)** No further relevant information available.

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Trade name: ProBase Cold Monomer

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8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

- **Components with limit values that require monitoring at the workplace:**

80-62-6 methyl methacrylate

PEL	Long-term value: 410 mg/m ³ , 100 ppm
REL	Long-term value: 410 mg/m ³ , 100 ppm
TLV	Short-term value: 410 mg/m ³ , 100 ppm Long-term value: 205 mg/m ³ , 50 ppm (SEN) NIC-DSEN

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
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 eyes and skin.
Do not inhale gases / fumes / aerosols.
- **Breathing equipment:**
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.
- **Recommended filter device for short term use:**
Filter A1
Filter A2
Filter A3
- **Protection of hands:**



Protective gloves

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

- **Material of gloves**
Butyl rubber, BR
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.
- **Not suitable are gloves made of the following materials:**
Commercial medical gloves do not provide protection against the sensitizing effect of methacrylates.
- **Eye protection:**



Tightly sealed goggles

US

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Trade name: **ProBase Cold Monomer**

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9 Physical and chemical properties· **Information on basic physical and chemical properties**· **General Information**· **Appearance:**

· Form:	Fluid
· Color:	Colorless
· Odor:	Pungent
· Odour threshold:	Not determined.

· **pH-value:** Not determined.· **Change in condition**

· Melting point/Melting range:	-48 °C (-54 °F)
· Boiling point/Boiling range:	101 °C (214 °F)

· **Flash point:** 10 °C (50 °F)· **Ignition temperature:** 430 °C (806 °F)· **Auto igniting:** Product is not selfigniting.· **Danger of explosion:** Product is not explosive. However, formation of explosive air/vapor mixtures are possible.· **Explosion limits:**

· Lower:	2.1 Vol %
· Upper:	12.5 Vol %

· **Vapor pressure at 20 °C (68 °F):** 47 hPa (35 mm Hg)· **Density at 20 °C (68 °F):** 0.943 g/cm³ (7.869 lbs/gal)· **Relative density** Not determined.· **Vapour density** Not determined.· **Evaporation rate** Not determined.· **Solubility in / Miscibility with**· **Water at 20 °C (68 °F):** 1.6 g/l· **Partition coefficient (n-octanol/water):** Not determined.· **Viscosity:**· **Dynamic:** Not determined.· **Kinematic:** Not determined.· **Other information** No further relevant information available.**10 Stability and reactivity**· **Reactivity** No further relevant information available.· **Chemical stability** Stable under normal handling and storage conditions.· **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.· **Possibility of hazardous reactions**· **Forms explosive gas mixture with air.**· **Reacts with strong oxidizing agents.**· **Exothermic polymerization.**· **Conditions to avoid** No further relevant information available.· **Incompatible materials:** No further relevant information available.· **Hazardous decomposition products:** None under normal conditions of storage and use.

US

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Trade name: **ProBase Cold Monomer**

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11 Toxicological information· **Information on toxicological effects**· **Acute toxicity:**· **LD/LC50 values that are relevant for classification:**

80-62-6 methyl methacrylate

Oral LD50 7872 mg/kg (rat)

· **Primary irritant effect:**· **on the skin:** Irritant to skin and mucous membranes.· **on the eye:** No irritating effect.· **Sensitization:** Sensitization possible through skin contact.· **Additional toxicological information:** No further relevant information available.· **Carcinogenic categories**· **IARC (International Agency for Research on Cancer)**

80-62-6 methyl methacrylate

3

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information· **Toxicity**· **Aquatic toxicity:** No further relevant information available.· **Persistence and degradability** No further relevant information available.· **Behavior in environmental systems:**· **Bioaccumulative potential** No further relevant information available.· **Mobility in soil** No further relevant information available.· **Additional ecological information:**· **General notes:**

Water hazard class 1 (Self-assessment): slightly hazardous for water

Do not allow product to reach ground water, water course or sewage system.

· **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 of together with household garbage. Do not allow product to reach sewage system.

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

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




US

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Trade name: **ProBase Cold Monomer**

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14 Transport information

· UN-Number · DOT, ADR, IMDG, IATA	UN1247
· UN proper shipping name · DOT · ADR · IMDG, IATA	Methyl methacrylate monomer, stabilized 1247 Methyl methacrylate monomer, stabilized METHYL METHACRYLATE MONOMER, STABILIZED
· Transport hazard class(es) · DOT	
	
· Class · Label	3 Flammable liquids 3
· ADR	
	
· Class · Label	3 (F1) Flammable liquids 3
· IMDG, IATA	
	
· Class · Label	3 Flammable liquids 3
· Packing group · DOT, ADR, IMDG, IATA	II
· Environmental hazards: · Marine pollutant:	No
· Special precautions for user · Danger code (Kemler): · EMS Number:	Warning: Flammable liquids 339 F-E,S-D
· Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.
· Transport/Additional information:	
· ADR · Excepted quantities (EQ)	Code: E2 Maximum net quantity per inner packaging: 30 ml Maximum net quantity per outer packaging: 500 ml
· IMDG · Limited quantities (LQ)	1L

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Trade name: **ProBase Cold Monomer**

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- | | |
|-----------------------------------|---|
| · Excepted quantities (EQ) | Code: E2
Maximum net quantity per inner packaging: 30 ml
Maximum net quantity per outer packaging: 500 ml |
| · UN "Model Regulation": | UN1247, Methyl methacrylate monomer, stabilized, 3, II |

15 Regulatory information

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

- Sara

- **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

- **Section 313 (Specific toxic chemical listings):**

80-62-6 methyl methacrylate

- **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

- **Proposition 65**

- **Chemicals known to cause cancer:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

- **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

- **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

- **Carcinogenic categories**

- **EPA (Environmental Protection Agency)**

80-62-6 methyl methacrylate

NL

- **TLV (Threshold Limit Value established by ACGIH)**

80-62-6 methyl methacrylate

A4

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **GHS label elements**

The product is classified and labeled according to the Globally Harmonized System (GHS).

- **Hazard pictograms**



GHS02 GHS07

- **Signal word** Danger

- **Hazard-determining components of labeling:**

methyl methacrylate

1,4-butanediol dimethacrylate

- **Hazard statements**

Highly flammable liquid and vapor.

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Trade name: ProBase Cold Monomer

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Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· **Precautionary statements**

Keep away from heat/sparks/open flames/hot surfaces. - No smoking.

Avoid breathing dust/fume/gas/mist/vapors/spray

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

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

If on skin (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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

· **National regulations:**

· **Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· **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.

· **Date of preparation / last revision** 05/21/2015 / 10

· **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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

Flam. Liq. 2: Flammable liquids, Hazard Category 2

Skin Irrit. 2: Skin corrosion/irritation, Hazard Category 2

Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

STOT SE 3: Specific target organ toxicity - Single exposure, Hazard Category 3

· *** Data compared to the previous version altered.**

1 Identification


- **Product identifier**
- **Trade name:** ***ProBase Cold Polymer***
- **Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.
- **Application of the substance / the mixture** Denture base material
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
Ivoclar Vivadent Inc.
175 Pineview Drive, Amherst, N.Y. 14228
USA
Tel. +1 800 533 6825
Fax +1 716 691 2285

- **Ivoclar Vivadent Inc.**
1-6600 Dixie Road
Mississauga, Ontario
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- **Information department:** Quality Assurance / Regulatory Affairs
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24 Hour Emergency Assistance:
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Emergency-Call Canada - Canutec: 1-613-996-6666

- **General SDS Assistance:**
US: 1-800-533-6825
Canada: 1-800-263-8182

2 Hazard(s) identification

- **Classification of the substance or mixture**
Skin Sens. 1 H317 May cause an allergic skin reaction.

- **Label elements**
- **GHS label elements**
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms**

GHS07
- **Signal word** Warning
- **Hazard-determining components of labeling:**
dibenzoyl peroxide
- **Hazard statements**
May cause an allergic skin reaction.
- **Precautionary statements**
Avoid breathing dust/fume/gas/mist/vapors/spray
Do not get in eyes, on skin, or on clothing.

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US

Trade name: ProBase Cold Polymer

(Contd. of page 1)

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

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

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



Health = 0

Fire = 1

Reactivity = 0

· **HMIS-ratings (scale 0 - 4)**



Health = 0

Fire = 1

Reactivity = 0

· **Other hazards**

Dust generation

Particular danger of slipping on leaked/spilled product.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** > 95% Polymethylmethacrylate

· **Dangerous components:**

94-36-0	dibenzoyl peroxide	1-<2.5%
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4 First-aid measures

· **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. If symptoms persist, consult a doctor.

· **After swallowing:**

Rinse out mouth and then drink plenty of water.

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 Fire-fighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:**

CO₂, extinguishing powder or water spray. Fight larger fires with water spray or alcohol resistant foam.

· **Special hazards arising from the substance or mixture** No further relevant information available.

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Trade name: ProBase Cold Polymer

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- **Advice for firefighters**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Particular danger of slipping on leaked/spilled product.
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:** Pick up mechanically.
- **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.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
Only adequately trained personnel should handle this product.
For use in dentistry only.
- **Information about protection against explosions and fires:** No special measures required.
- **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.
- **Specific end use(s)** No further relevant information available.

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.
- **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

94-36-0 dibenzoyl peroxide

PEL	Long-term value: 5 mg/m ³
REL	Long-term value: 5 mg/m ³
TLV	Long-term value: 5 mg/m ³

- **Additional information:** The lists that were valid during the creation were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
Usual hygienic measures for dental practice.
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
Avoid contact with the skin.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.

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Trade name: ProBase Cold Polymer

(Contd. of page 3)

· Protection of hands:

Protective gloves

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 protection: Safety glasses**9 Physical and chemical properties****· Information on basic physical and chemical properties****· General Information****· Appearance:****Form:**

Powder

Color:

According to product specification

· Odor:

Characteristic

· Odour threshold:

Not determined.

· pH-value:

Not applicable.

· Change in condition**Melting point/Melting range:**

150 °C (302 °F)

Boiling point/Boiling range:

Undetermined.

· Flash point:

250 °C (482 °F)

· Flammability (solid, gaseous):

Not determined.

· Auto igniting:

Product is not selfigniting.

· Danger of explosion:

Product does not present an explosion hazard.

· Explosion limits:**Lower:**

Not determined.

Upper:

Not determined.

· Vapor pressure:

Not applicable.

· Density at 20 °C (68 °F):1.2 g/cm³ (10.014 lbs/gal)**· Relative density**

Not determined.

· Vapour density

Not applicable.

· Evaporation rate

Not applicable.

· Solubility in / Miscibility with**Water:**

Nearly insoluble.

· Partition coefficient (n-octanol/water): Not determined.

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US

Trade name: ProBase Cold Polymer

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- **Viscosity:**
 - **Dynamic:** Not applicable.
 - **Kinematic:** Not applicable.
- **Other information** No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability** Stable under normal handling and storage conditions.
- **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:** None under normal conditions of storage and use.

11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**
- **Primary irritant effect:**
 - **on the skin:** No irritant effect.
 - **on the eye:** No irritating effect.
- **Sensitization:** Sensitization possible through skin contact.
- **Additional toxicological information:** No further relevant information available.
- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

94-36-0	dibenzoyl peroxide
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- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**

Water hazard class 1 (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.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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US

Trade name: ProBase Cold Polymer

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· **Other adverse effects** No further relevant information available.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Take to an approved landfill or a waste incineration plant, under conditions approved by the local authority.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

14 Transport information

- **UN-Number**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **UN proper shipping name**
- **DOT, ADR, ADN, IMDG, IATA** Void
- **Transport hazard class(es)**
- **DOT, ADR, ADN, IMDG, IATA**
- **Class** Void
- **Packing group**
- **DOT, ADR, IMDG, IATA** Void
- **Environmental hazards:**
- **Marine pollutant:** No
- **Special precautions for user** Not applicable.
- **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.
- **Transport/Additional information:** Product is not classified as a dangerous good for transport (ADR, IMDG, IATA).
- **UN "Model Regulation":** -

15 Regulatory information

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

· **Section 355 (extremely hazardous substances):**

None of the ingredients is listed.

· **Section 313 (Specific toxic chemical listings):**

94-36-0 | dibenzoyl peroxide

· **TSCA (Toxic Substances Control Act):**

All ingredients are listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

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Trade name: ProBase Cold Polymer

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· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories**· EPA (Environmental Protection Agency)**

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

94-36-0 | dibenzoyl peroxide

A4

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· GHS label elements

The product is classified and labeled according to the Globally Harmonized System (GHS).

· Hazard pictograms

GHS07

· Signal word Warning**· Hazard-determining components of labeling:**

dibenzoyl peroxide

· Hazard statements

May cause an allergic skin reaction.

· Precautionary statements

Avoid breathing dust/fume/gas/mist/vapors/spray

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

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

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

· National regulations:**· Other regulations, limitations and prohibitive regulations**

The product is a medical device according to the Directive 93/42/EEC.

This product is classified as a medical device under US and Canadian regulations and has been reviewed by the US Food and Drug Administration and Health Canada.

· 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.

· Date of preparation / last revision 05/21/2015 / 8**· 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

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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Trade name: *ProBase Cold Polymer*

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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)
NFPA: National Fire Protection Association (USA)
HMIS: Hazardous Materials Identification System (USA)
Skin Sens. 1: Sensitisation - Skin, Hazard Category 1

· *** Data compared to the previous version altered.**

US