

safety data sheet

to product

ProBase Cold Monomer 550 ml

1. Identification of the substance / preparation and company

Emergency number:

Tox Info Suisse, Freiestrasse 16, 8032 Zürich; Tox-Info Suisse: 145 (24h-operation); info@toxinfo.ch;
In case of emergency: Tel. 145; (abroad: +41 44 251 51 51); information: +41 44 251 66 66

Company name:



abc dental ag

Gaswerkstrasse 6, 8952 Schlieren
Tel. 044 755 51 00, Fax 044 755 51 01



Condor Dental Research CO Sàrl

Ch. des Ciberles 2, CP 300, 1896 Vouvry
Tel. 024 482 61 61, Fax 024 482 61 69



Curaden AG Dentaldepot

Riedstrasse 12, 8953 Dietikon
Tel. 041 319 45 00, Fax 041 319 45 90



dema dent AG

Furtbachstrasse 16, 8107 Buchs
Tel. 044 838 65 65, Fax 044 838 65 66



Flexdental Services SA

Route de la Corniche 1, 1066 Epalinges
Tel. 0848 336 825, Fax 021 907 67 02



Jordi Röntgentechnik AG

Dammstrasse 70, 4142 Münchenstein
Tel. 061 417 93 93, Fax 061 417 93 94



Kaladent AG

Schachenstrasse 2, 9016 St. Gallen
Tel. 071 282 80 80, Fax 071 282 80 81



Lometral AG

Binzenholzstrasse 20, 5704 Egliswil
Tel. 062 775 05 05, Fax 062 775 33 07



Novadent AG

Sägereistrasse 17, 8152 Glattbrugg
Tel. 044 880 20 20, Fax 044 811 04 40



Smart Dentist AG

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Tel. 044 726 20 20, Fax 044 726 20 25

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/26/2018

Version number 11.1

Reviewed on 04/26/2018

1 Identification

- **Product identifier**
- **Trade name:** ***ProBase Cold Monomer***
- **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 identification

- **Classification of the substance or mixture**

<i>Flammable Liquids - Category 2</i>	<i>H225 Highly flammable liquid and vapour.</i>
<i>Skin Irritation - Category 2</i>	<i>H315 Causes skin irritation.</i>
<i>Skin Sensitizer - Category 1</i>	<i>H317 May cause an allergic skin reaction.</i>
<i>Specific Target Organ Toxicity - Single Exposure - Category 3</i>	<i>H335 May cause respiratory irritation.</i>

- **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

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· **Hazard statements**

Highly flammable liquid and vapour.

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· **Precautionary statements**

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Ground and bond container and receiving equipment.

Use explosion-proof [electrical/ventilating/lighting] equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

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

Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Call a POISON CENTER/doctor if you feel unwell.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep container tightly closed.

Store in a well-ventilated place. Keep cool.

Store locked up.

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 Health = 2

FIRE 3 Fire = 3

REACTIVITY 2 Reactivity = 2

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

CAS: 80-62-6	methyl methacrylate	60-100% w/w
CAS: 2082-81-7	1,4-butanediol dimethacrylate	3-5% w/w

4 First aid measures

· **Description of first aid measures**

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

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

5 Firefighting 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.

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- **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.

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:**

CAS: 80-62-6 methyl methacrylate

EL Short-term value: 100 ppm

Long-term value: 50 ppm

S

EV Short-term value: 100 ppm

Long-term value: 50 ppm

- **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 and dental laboratories.

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

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· **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

9 Physical and chemical properties

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

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

· **pH-value:** Not determined.

· **Change in condition**

· Melting point/Melting range:	-48 °C
· Boiling point/Boiling range:	101 °C

· **Flash point:** 10 °C

· **Ignition temperature:** 430 °C

· **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:** 47 hPa

· Density at 20 °C:	0.943 g/cm ³
· Relative density	Not determined.
· Vapor density	Not determined.
· Evaporation rate	Not determined.

· **Solubility in / Miscibility with**

· **Water at 20 °C:** 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.

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Trade name: **ProBase Cold Monomer**

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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.

11 Toxicological information

- **Information on toxicological effects**
 - **Acute toxicity:**
- | | | |
|---|------|------------------|
| · LD/LC50 values that are relevant for classification: | | |
| CAS: 80-62-6 methyl methacrylate | | |
| Oral | LD50 | 7872 mg/kg (rat) |
- **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)**

CAS: 80-62-6 methyl methacrylate

3

- **NTP (National Toxicology Program)**

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.

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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.

14 Transport information

- | | |
|---|--|
| · UN-Number | |
| · DOT, TDG, IMDG, IATA | UN1247 |
| · UN proper shipping name | |
| · DOT | Methyl methacrylate monomer, stabilized |
| · TDG | 1247 Methyl methacrylate monomer, stabilized |
| · IMDG, IATA | METHYL METHACRYLATE MONOMER, STABILIZED |
| · Transport hazard class(es) | |
| · DOT | |
|  | |
| · Class | 3 Flammable liquids |
| · Label | 3 |
| · TDG (Transport dangerous goods): | |
|  | |
| · Class | 3 (F1) Flammable liquids |
| · Label | 3 |
| · IMDG, IATA | |
|  | |
| · Class | 3 Flammable liquids |
| · Label | 3 |
| · Packing group | |
| · DOT, TDG, IMDG, IATA | II |
| · Environmental hazards: | |
| · Marine pollutant: | No |
| · Special precautions for user | Warning: Flammable liquids |
| · Danger code (Kemler): | 339 |
| · EMS Number: | F-E,S-D |

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- | | |
|--|---|
| · Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code | Not applicable. |
| · Transport/Additional information: | |
| · TDG | |
| · 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 |
| · 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):

CAS: 80-62-6 methyl methacrylate

· TSCA (Toxic Substances Control Act):

All ingredients are 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 vapour.

Causes skin irritation.

May cause an allergic skin reaction.

May cause respiratory irritation.

· Precautionary statements

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Ground and bond container and receiving equipment.

Use explosion-proof [electrical/ventilating/lighting] equipment.

Use non-sparking tools.

Take actions to prevent static discharges.

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

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Trade name: ProBase Cold Monomer

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Wash thoroughly after handling.

Use only outdoors or in a well-ventilated area.

Contaminated work clothing should not be allowed out of the workplace.

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

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Call a POISON CENTER/doctor if you feel unwell.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

In case of fire: Use for extinction: CO₂, powder or water spray.

Store in a well-ventilated place. Keep container tightly closed.

Store in a well-ventilated place. Keep cool.

Store locked up.

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** 04/26/2018 / 11

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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

Safety Data Sheet
according to HPR, Schedule 1

Printing date 04/26/2018

Version number 9.1

Reviewed on 04/26/2018

1 Identification


- **Product identifier**
- **Trade name:** ***ProBase Cold Polymer***
- **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 identification

- **Classification of the substance or mixture**
Skin Sensitizer - Category 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/vapours/spray.
Contaminated work clothing should not be allowed out of the workplace.
Wear protective gloves.
IF ON SKIN: Wash with plenty of water.

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Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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.

3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** > 95% Polymethylmethacrylate

· **Dangerous components:**

CAS: 94-36-0 dibenzoyl peroxide

≤1% w/w

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 Firefighting 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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- **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:**

CAS: 94-36-0 dibenzoyl peroxide

EL Long-term value: 5 mg/m³

EV Long-term value: 5 mg/m³

- **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 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.
- **Breathing equipment:** Use respiratory protective device against the effects of dust.

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· **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

· **Odor threshold:** Not determined.

· **pH-value:** Not applicable.

· **Change in condition**

Melting point/Melting range: 150 °C

Boiling point/Boiling range: Undetermined.

· **Flash point:** 250 °C

· **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:** 1.2 g/cm³

· **Relative density** Not determined.

· **Vapor 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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- **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:**
- **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)

CAS: 94-36-0 dibenzoyl peroxide

· NTP (National Toxicology Program)
--

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

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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 | Void |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | Void |
| · DOT, TDG, ADN, IMDG, IATA | Void |
| · Class | Void |
| · Packing group | Void |
| · DOT, TDG, IMDG, IATA | Void |
| · Environmental hazards: | No |
| · 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": | Void |

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):**

CAS: 94-36-0 dibenzoyl peroxide

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

All ingredients are listed.

- **GHS label elements**

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

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· **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/vapours/spray.

Contaminated work clothing should not be allowed out of the workplace.

Wear protective gloves.

IF ON SKIN: Wash with plenty of water.

Specific treatment (see on this label).

If skin irritation or rash occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

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** 04/26/2018 / 9

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

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)

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

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