

SAFETY DATA SHEETS

This SDS packet was issued with item:

071460450

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

071221043 071221076 071221126 071221134 071221142 071221167 071221175 071222314 071222322 071222330
071222348 071222355 071222363 071222397 071222405 071222421 071222439 071222462 071222470
071222488 071222496 071222579 071222587 071222595 071222801

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

071456987 071456995 071457001 071457019 071460435 071460443 071460468 071460476 071460484

Safety Data Sheet
according to HPR, Schedule 1

Printing date 12/12/2019

Version number 1

Reviewed on 12/12/2019

1 Identification


- **Product identifier**
- **Trade name:** ***Tetric Prime***
- **Application of the substance / the mixture** *Light-curing resin-based dental restorative 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 Irritation - Category 2 H315 Causes skin irritation.
Eye Irritation - Category 2A H319 Causes serious eye irritation.
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:**
*urethane dimethacrylate
Bis-GMA*
 - **Hazard statements**
*Causes skin irritation.
Causes serious eye irritation.*

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May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves / eye protection / face protection.

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

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

· **Additional information:**

Medical devices are exempt from the labeling provisions of GHS according to the Hazard Communication Standard (HCS).

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**



3 Composition/Information on ingredients

· **Chemical characterization: Mixtures**

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

· **Dangerous components:**

| | | |
|-----------------|-------------------------|-------------|
| CAS: 72869-86-4 | urethane dimethacrylate | 7-13% w/w * |
| CAS: 13760-80-0 | ytterbium trifluoride | 5-10% w/w * |
| CAS: 36425-15-7 | Bis-GMA | 1-5% w/w * |

* Actual concentration ranges are withheld as a trade secret.

4 First aid measures

· **Description of first aid measures**

· **After inhalation:**

Supply fresh air and to be sure call for a doctor.

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

· **After skin contact:**

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.

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

6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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 exposure to the light.
Protect from heat and direct sunlight.
Keep receptacle tightly sealed.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **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.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
Keep away from foodstuffs, beverages and feed.

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- **Breathing equipment:** Not required.
- **Protection of hands:**



Protective gloves

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

- **Material of gloves**
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:** Safety glasses

9 Physical and chemical properties

| | |
|--|---|
| · Information on basic physical and chemical properties | |
| · General Information | |
| · Appearance: | Pasty |
| · Form: | According to product specification |
| · Color: | Characteristic |
| · Odor: | Not determined. |
| · Odor threshold: | Not determined. |
| · pH-value: | Not determined. |
| · Change in condition | |
| · Melting point/Melting range: | Undetermined. |
| · Boiling point/Boiling range: | Undetermined. |
| · Flash point: | Not applicable. |
| · 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 determined. |
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapor density | Not determined. |
| · Evaporation rate | Not determined. |
| · Solubility in / Miscibility with Water: | Nearly insoluble. |
| · Partition coefficient (n-octanol/water): | Not determined. |
| · Viscosity: | |
| · Dynamic: | Not determined. |
| · Kinematic: | Not determined. |

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· **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.
Photoreactive (Danger of polymerization).
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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**
- **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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Trade name: **Tetric Prime**

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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, ADR, ADN, IMDG, IATA | Void |
| · UN proper shipping name | Void |
| · DOT/TDG | Void |
| · ADR, ADN, IMDG, IATA | Void |
| · Transport hazard class(es) | |
| · DOT, ADR, ADN, IMDG, IATA | |
| · Class | Void |
| · Packing group | |
| · DOT/TDG, 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": | 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): |
|--|

| |
|------------------------------------|
| None of the ingredients is listed. |
|------------------------------------|

| |
|---|
| · TSCA (Toxic Substances Control Act): |
|---|

| | |
|----------------|---------|
| CAS: 1565-94-2 | Bis-GMA |
|----------------|---------|

| | |
|-----------------|-------------------------|
| CAS: 72869-86-4 | urethane dimethacrylate |
|-----------------|-------------------------|

| | |
|-----------------|-----------------------|
| CAS: 13760-80-0 | ytterbium trifluoride |
|-----------------|-----------------------|

- **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:**

urethane dimethacrylate

Bis-GMA

· **Hazard statements**

Causes skin irritation.

Causes serious eye irritation.

May cause an allergic skin reaction.

· **Precautionary statements**

Wear protective gloves / eye protection / face protection.

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

If eye irritation persists: Get medical advice/attention.

Wash contaminated clothing before reuse.

· **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 the latest revision of the safety data sheet** 12/12/2019 / -

· **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

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

Printing date 12.12.2019

Version number 1


Revision: 12.12.2019

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

- **1.1 Product identifier**
- **Trade name: *Tetric Prime***
- **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** Light-curing resin-based dental restorative 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@ivoclarvivadent.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 Irrit. 2 H315 Causes skin irritation.
Eye Irrit. 2 H319 Causes serious eye irritation.
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 CLP regulation.
- **Hazard pictograms**
- 
GHS07
- **Signal word** Warning
- **Hazard-determining components of labelling:**
urethane dimethacrylate
Bis-GMA
- **Hazard statements**
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H317 May cause an allergic skin reaction.
- **Precautionary statements**
P280 Wear protective gloves / eye protection / face protection.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P337+P313 If eye irritation persists: Get medical advice/attention.
P363 Wash contaminated clothing before reuse.

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- **Additional information:**

Medical devices as defined in Directive 93/42/EEC and which are invasive or used in direct physical contact with the human body, are exempted from the provisions of Regulation (EC) No 1272/2008 (CLP/GHS) usually if they are in the finished state and intended for the final user.

- **2.3 Other hazards**

- **Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterisation: Mixtures**

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

- **Dangerous components:**

| | | |
|---|--|----------|
| CAS: 72869-86-4 EINECS: 276-957-5 Reg.nr.: 01-2120751202-68-XXXX | urethane dimethacrylate Eye Irrit. 2, H319; Skin Sens. 1, H317; Aquatic Chronic 3, H412 | 10-<25% |
| CAS: 13760-80-0 EINECS: 237-354-2 Reg.nr.: 17-2119404130-64-XXXX | ytterbium trifluoride Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335 | 2.5-<10% |
| CAS: 41637-38-1 EC number: 609-946-4 Reg.nr.: 01-2119980659-17-XXXX | Bis-EMA Aquatic Chronic 4, H413 | 2.5-10% |
| CAS: 36425-15-7 NLP: 500-089-0 | Bis-GMA Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317 | 2.5-<10% |

- **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**

- **After inhalation:**

Supply fresh air and to be sure call for a doctor.

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

- **After skin contact:**

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.

- **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.

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- 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: Not required.
 - 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.

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 exposure to the light.
 - Protect from heat and direct sunlight.
 - Keep container tightly sealed.
- 7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- 8.1 Control parameters
- Ingredients with limit values that require monitoring at the workplace:
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- Additional information: The lists valid during the making were used as basis.
- 8.2 Exposure controls
- Personal protective equipment:
 - General protective and hygienic measures:
 - Usual hygienic measures for dental practice and dental laboratories.
 - Wash hands before breaks and at the end of work.
 - Avoid contact with the eyes and skin.
 - Keep away from foodstuffs, beverages and feed.
 - Respiratory protection: Not required.
 - Protection of hands:



Protective gloves (EN 374)

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

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- **Material of gloves**
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:** Safety glasses

SECTION 9: Physical and chemical properties

· 9.1 Information on basic physical and chemical properties

· General Information

· Appearance:

- | | |
|---------------------------|------------------------------------|
| · Form: | Pasty |
| · Colour: | According to product specification |
| · Odour: | Characteristic |
| · Odour threshold: | Not determined. |

- | | |
|--------------------|-----------------|
| · pH-value: | Not determined. |
|--------------------|-----------------|

· Change in condition

- | | |
|---|---------------|
| · Melting point/freezing point: | Undetermined. |
| · Initial boiling point and boiling range: | Undetermined. |

- | | |
|-----------------------|-----------------|
| · Flash point: | Not applicable. |
|-----------------------|-----------------|

- | | |
|-------------------------------------|------------------------------|
| · Auto-ignition temperature: | Product is not selfigniting. |
|-------------------------------------|------------------------------|

- | | |
|--------------------------------|---|
| · Explosive properties: | Product does not present an explosion hazard. |
|--------------------------------|---|

· Explosion limits:

- | | |
|-----------------|-----------------|
| · Lower: | Not determined. |
| · Upper: | Not determined. |

- | | |
|---------------------------|-----------------|
| · Vapour pressure: | Not determined. |
|---------------------------|-----------------|

- | | |
|---------------------------|-----------------|
| · Density: | Not determined. |
| · Relative density | Not determined. |
| · Vapour density | Not determined. |
| · Evaporation rate | Not determined. |

- | | |
|--|-------------------|
| · Solubility in / Miscibility with water: | Nearly insoluble. |
|--|-------------------|

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

· Viscosity:

- | | |
|---------------------|-----------------|
| · Dynamic: | Not determined. |
| · Kinematic: | Not determined. |

- | | |
|--------------------------------|--|
| · 9.2 Other information | No further relevant information available. |
|--------------------------------|--|

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
Stable under normal handling and storage conditions.

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- Photoreactive (Danger of polymerization).
- **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**
Protect from exposure to the light.
Keep away from heat and direct sunlight.
- **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 toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Skin corrosion/irritation**
Causes skin irritation.
- **Serious eye damage/irritation**
Causes serious eye irritation.
- **Respiratory or skin sensitisation**
May cause an allergic skin reaction.
- **Additional toxicological information:** No further relevant information available.
- **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.

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.
- **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.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Other adverse effects** No further relevant information available.

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.

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

SECTION 14: Transport information

| | |
|--|--|
| · 14.1 UN-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 Transport in bulk according to Annex II of Marpol 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 |

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**
The product is a medical device according to the Directive 93/42/EEC.
- **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**
- H315 Causes skin irritation.
- H317 May cause an allergic skin reaction.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H412 Harmful to aquatic life with long lasting effects.
- H413 May cause long lasting harmful effects to aquatic life.

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

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Abbreviations and acronyms:

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

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

Skin Irrit. 2: Skin corrosion/irritation – Category 2

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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

Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4

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