SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier
Product name: Breeze Catalyst

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses
Main use category: Professional use
Use of the substance/mixture: Preparation intended for dental medical use

Uses advised against
No additional information available

1.3. Details of the supplier of the safety data sheet
Supplier:
SpofaDental a.s.
Markova 238
CZ-506 01 Jicin Czech Republic
T +420 493 583 204

Manufacturer:
PENTRON CLINICAL
1717 West Collins Avenue
Orange, CA 92867, USA
T +1-800-5377-123

Contact person: safety@kerrhawe.com - tel. 00-800-41-050-505 (08.00-17.00)

1.4. Emergency telephone number
Emergency number: CHEMTREC® Emergency Call Center. Emergency Telephone Number (for USA only) 001-800-424-9300 International and Maritime Telephone Number +1 (703) 527-3887

<table>
<thead>
<tr>
<th>Country</th>
<th>Organisation/Company</th>
<th>Address</th>
<th>Emergency number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gibraltar</td>
<td>GHA Call Centre Zone 2, Level3, St Bernard’s Hospital</td>
<td>Harbour Views Road</td>
<td>+350 200 79700,+350 200 72266</td>
</tr>
<tr>
<td>Ireland</td>
<td>National Poisons Information Centre</td>
<td>PO Box 1297 Beaumont Road 9 Dublin</td>
<td>+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)</td>
</tr>
<tr>
<td>Malta</td>
<td>Medicines &amp; Poisons Info Office</td>
<td>Mater Dei Hospital MSD Msida</td>
<td>+356 2545 6504</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>National Poisons Information Service (Newcastle Unit)</td>
<td>Claremont Place Newcastle-upon-Tyne, Newcastle</td>
<td>+44 191 2606182/+44 191 2606180 24H</td>
</tr>
</tbody>
</table>

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

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

- Skin Irrit. 2: H315
- Eye Irrit. 2: H319
- Skin Sens. 1: H317
- STOT SE 3: H335

Full text of hazard classes and H-statements: see section 16
2.2. Label elements

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

Hazard pictograms (CLP):

![Warning](ghs07)

Signal word (CLP): Warning

Hazardous ingredients:

- (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate; 2-hydroxyethyl methacrylate; 2-[(2-methyl-1-oxoallyl)oxy]ethyl 1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate; dibenzoyl peroxide, benzoyl peroxide

Hazard statements (CLP):

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

Precautionary statements (CLP):

- P261 - Avoid breathing mist, spray, vapours
- P264 - Wash hands thoroughly after handling
- P271 - Use only outdoors or in a well-ventilated area
- P272 - Contaminated work clothing should not be allowed out of the workplace
- P280 - Wear protective gloves, eye protection
- P302+P352 - IF ON SKIN: Wash with plenty of soap and water
- P333+P313 - IF skin irritation or rash occurs: Get medical advice/attention
- P304+P340 - IF INHALED: remove victim to fresh air and keep at rest in a position comfortable for breathing
- P312 - Call a POISON CENTER or doctor/physician if you feel unwell
- P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
- P337+P313 - If eye irritation persists: Get medical advice/attention
- P362+P364 - Take off contaminated clothing and wash it before reuse
- P403+P233 - Store in a well-ventilated place. Keep container tightly closed
- P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation

Extra phrases:

The product is seen as a medical device and therefore not subject to labelling (EU-regulation 1272/2008, article 1, paragraph 5d). A safety data sheet is not required for this product under Article 31 of REACH. This Product Safety Information Sheet has been created on a voluntary basis.

2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Not applicable

3.2. Mixtures

<table>
<thead>
<tr>
<th>Name</th>
<th>Product identifier</th>
<th>%</th>
<th>Classification according to Regulation (EC) No. 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate</td>
<td>(CAS-No.) 1565-94-2 (EC-No.) 216-367-7 (REACH-no) N/A</td>
<td>&lt; 50</td>
<td>Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335</td>
</tr>
<tr>
<td>2-hydroxyethyl methacrylate</td>
<td>(CAS-No.) 888-77-9 (EC-No.) 212-782-2 (REACH-no) 607-124-00-X (REACH-no) 01-211940169-29</td>
<td>&lt; 50</td>
<td>Skin Irrit. 2, H315 Eye Irrit. 2, H319 Skin Sens. 1, H317 STOT SE 3, H335</td>
</tr>
<tr>
<td>2-[(2-methyl-1-oxoallyl)oxy]ethyl 1,3-dihydro-1,3-dioxoisobenzofuran-5-carboxylate</td>
<td>(CAS-No.) 70293-55-9 (REACH-no) N/A</td>
<td>&lt; 50</td>
<td>Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335</td>
</tr>
<tr>
<td>dibenzoyl peroxide, benzoyl peroxide</td>
<td>(CAS-No.) 94-36-0 (EC-No.) 202-327-6 (REACH-no) 617-008-00-0 (REACH-no) 01-2119511472-50</td>
<td>&lt; 10</td>
<td>Org. Perox. B, H241 Eye Irrit. 2, H319 Skin Sens. 1, H317</td>
</tr>
</tbody>
</table>
Full text of H-statements: see section 16

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures
First-aid measures general : Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).
First-aid measures after inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.
First-aid measures after skin contact : Wash with plenty of soap and water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.
First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention.

4.2. Most important symptoms and effects, both acute and delayed
Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : May cause an allergic skin reaction. Causes skin irritation.
Symptoms/effects after eye contact : Causes serious eye irritation.

4.3. Indication of any immediate medical attention and special treatment needed
Treat symptomatically. In all cases of doubt, or when symptoms persist, seek medical attention.

SECTION 5: FIREFIGHTING MEASURES

5.1. Extinguishing media
Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture
Fire hazard : Non flammable.
Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters
Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper personal protective equipment, including respiratory protection.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures
General measures : Use personal protective equipment as required. Concerning personal protective equipment to use, see section 8. Do not breathe vapour. Avoid contact with skin and eyes.

For non-emergency personnel
Emergency procedures : Evacuate unnecessary personnel.

For emergency responders
Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area.

6.2. Environmental precautions
Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up
Methods for cleaning up : Soak up spills with inert solids, such as clay or diatomaceous earth as soon as possible. Collect spillage. Store away from other materials.

6.4. Reference to other sections
For further information refer to section 13. See Heading 8. Exposure controls and personal protection.
SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling
Precautions for safe handling: Use personal protective equipment as required. Avoid contact with skin and eyes. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour. Avoid breathing mist, spray, vapours. Use only outdoors or in a well-ventilated area.

Hygiene measures: Wash hands thoroughly after handling. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse.

7.2. Conditions for safe storage, including any incompatibilities
Storage conditions: Store in original container. Protect from sunlight. Store in a well-ventilated place. Store at room temperature. Keep container tightly closed.


Incompatible materials: Sources of ignition. Direct sunlight.

7.3. Specific end use(s)
No additional information available

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

<table>
<thead>
<tr>
<th>Substance</th>
<th>Local name</th>
<th>Ireland OEL (8 hours ref) (mg/m³)</th>
<th>Ireland WEL TWA (mg/m³)</th>
<th>United Kingdom OEL (8 hours ref) (mg/m³)</th>
<th>United Kingdom WEL TWA (mg/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-di-tert-butyl-p-cresol (128-37-0)</td>
<td>2,6-Diteriary-butyl-para-cresol</td>
<td>10 mg/m³</td>
<td>10 mg/m³</td>
<td>5 mg/m³</td>
<td>Dibenzoyl peroxide</td>
</tr>
<tr>
<td>Dibenzoyl peroxide, benzoyl peroxide (94-36-0)</td>
<td>Dibenzoyl peroxide</td>
<td>Sens.</td>
<td>5 mg/m³</td>
<td>Dibenzoyl peroxide</td>
<td>5 mg/m³</td>
</tr>
</tbody>
</table>

8.2. Exposure controls

Appropriate engineering controls: Ensure that there is a suitable ventilation system. Emergency eye wash fountains should be available in the immediate vicinity of any potential exposure.

Personal protective equipment: Personal protective equipment should be chosen according to the CEN standards and in discussion with the supplier of the protective equipment. Gloves. Protective goggles. Avoid all unnecessary exposure.

Hand protection: Wear protective gloves. Nitrile rubber gloves. Butyl rubber. Layer thickness: 0.2 - 0.4 mm. Breakthrough time: 8 (> 480 minutes). STANDARD EN 374.

Eye protection: Chemical goggles or safety glasses. STANDARD EN 166.

Skin and body protection: Wear suitable protective clothing

Respiratory protection: Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. Extra personal protection: A/P2 filter respirator for organic vapour and harmful dust. Standard EN 141. EN 140. EN 405

Other information: Do not eat, drink or smoke during use.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Physical state: Liquid
Appearance: Paste.
Colour: White.
Odour: Fruity. Ester.
Odour threshold: Not determined
pH: Not determined
Relative evaporation rate (butylacetate=1) : Not determined
Melting point : Not determined
Freezing point : Not determined
Boiling point : Not determined
Flash point : Not determined
Auto-ignition temperature : Not determined
Decomposition temperature : Not determined
Flammability (solid, gas) : Non flammable
Vapour pressure : Not determined
Relative vapour density at 20 °C : Not determined
Relative density : 1.5 - 1.8 g/cm³
Solubility : In water, material is partially soluble.
Log Pow : Not determined
Viscosity, kinematic : Not determined
Viscosity, dynamic : Not determined
Explosive properties : Not explosive.
Oxidising properties : Non flammable.
Explosive limits : Not determined

9.2. Other information
No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity
No additional information available

10.2. Chemical stability
Not established.

10.3. Possibility of hazardous reactions
Not established.

10.4. Conditions to avoid
Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials
oxidizing materials. reducing materials.

10.6. Hazardous decomposition products
No decomposition if stored and used normally.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects
Acute toxicity : Not classified

<table>
<thead>
<tr>
<th>Compound</th>
<th>LD50 oral rat</th>
<th>LC50 inhalation rat (Vapours - mg/l/4h)</th>
<th>LC50 dermal rabbit</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-di-tert-butyl-p-cresol (128-37-0)</td>
<td>890 mg/kg</td>
<td></td>
<td></td>
</tr>
<tr>
<td>dibenzoyl peroxide, benzoyl peroxide (94-36-0)</td>
<td>7710 mg/kg</td>
<td>7 mg/l/4h</td>
<td></td>
</tr>
<tr>
<td>2-hydroxyethyl methacrylate (868-77-9)</td>
<td>5050 mg/kg</td>
<td></td>
<td>&gt; 3000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation : Causes skin irritation.
    pH: Not determined
Serious eye damage/irritation : Causes serious eye irritation.
    pH: Not determined
Respiratory or skin sensitisation : May cause an allergic skin reaction.
Germ cell mutagenicity : Not classified
    Based on available data, the classification criteria are not met
Carcinogenicity : Not classified
    Based on available data, the classification criteria are not met
Reproductive toxicity: Not classified
Based on available data, the classification criteria are not met

STOT-single exposure: May cause respiratory irritation.

STOT-repeated exposure: Not classified
Based on available data, the classification criteria are not met

Aspiration hazard: Not classified
Based on available data, the classification criteria are not met

Potential adverse human health effects and symptoms: Based on available data, the classification criteria are not met.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

<table>
<thead>
<tr>
<th>Compound</th>
<th>LC50 fish 1</th>
<th>EC50 algae</th>
<th>IC50 algae</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-di-tert-butyl-p-cresol (128-37-0)</td>
<td>&gt; 0.57 mg/l</td>
<td>0.42 mg/l (48 hours - Daphnia magna)</td>
<td>0.31 mg/l</td>
</tr>
<tr>
<td>dibenzoyl peroxide, benzoyl peroxide (94-36-0)</td>
<td>0.24 mg/l (96h - Oryzias latipes)</td>
<td>0.07 mg/l 48h (Daphnia magna)</td>
<td></td>
</tr>
<tr>
<td>2-hydroxyethyl methacrylate (868-77-9)</td>
<td>227 mg/l (96 hours - Pimephales promelas)</td>
<td>&gt; 280 mg/l Daphnia magna, 48 hours</td>
<td>836 mg/l 72 hours - Pseudokirchneriella subcapitata</td>
</tr>
</tbody>
</table>

12.2. Persistence and degradability

Breeze Catalyst
Persistence and degradability: Not established.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Biodegradation</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-di-tert-butyl-p-cresol (128-37-0)</td>
<td>10% (OECD 301D method)</td>
</tr>
<tr>
<td>dibenzoyl peroxide, benzoyl peroxide (94-36-0)</td>
<td>84% MITI-test</td>
</tr>
<tr>
<td>2-hydroxyethyl methacrylate (868-77-9)</td>
<td>84% (OECD 301D method)</td>
</tr>
</tbody>
</table>

12.3. Bioaccumulative potential

Breeze Catalyst
Log Pow: Not determined
Bioaccumulative potential: Not established.

<table>
<thead>
<tr>
<th>Compound</th>
<th>Bioconcentration factor (BCF REACH)</th>
<th>Log Pow</th>
<th>Bioaccumulative potential</th>
</tr>
</thead>
<tbody>
<tr>
<td>2,6-di-tert-butyl-p-cresol (128-37-0)</td>
<td>330-1800</td>
<td>3.79</td>
<td>Potentially bioaccumulable.</td>
</tr>
<tr>
<td>dibenzoyl peroxide, benzoyl peroxide (94-36-0)</td>
<td>5.62</td>
<td>3.71</td>
<td></td>
</tr>
<tr>
<td>2-hydroxyethyl methacrylate (868-77-9)</td>
<td>1.3 - 1.5</td>
<td>0.47</td>
<td></td>
</tr>
<tr>
<td>(1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate (1565-94-2)</td>
<td>2.46</td>
<td>4.94</td>
<td></td>
</tr>
</tbody>
</table>

12.4. Mobility in soil

Breeze Catalyst
Ecology - soil: insoluble in water.
12.5. Results of PBT and vPvB assessment

**Breeze Catalyst**

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Additional information: Avoid release to the environment

**SECTION 13: DISPOSAL CONSIDERATIONS**

13.1. Waste treatment methods

Regional legislation (waste): Dispose as hazardous waste.

Waste treatment methods: Do not discharge into drains.

Product/Packaging disposal recommendations: Dispose in a safe manner in accordance with local/national regulations. Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

Ecology - waste materials: Avoid release to the environment.

European List of Waste (LoW) code: 18 01 06* - chemicals consisting of or containing dangerous substances

**SECTION 14: TRANSPORT INFORMATION**

In accordance with ADR / RID / IMDG / IATA / ADN

14.1. UN number

Not regulated for transport

14.2. UN proper shipping name

14.3. Transport hazard class(es)

14.4. Packing group

14.5. Environmental hazards

No supplementary information available

14.6. Special precautions for user

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

**SECTION 15: REGULATORY INFORMATION**

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

**EU-Regulations**

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008

<table>
<thead>
<tr>
<th>Class/Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10</td>
<td>Breeze Catalyst - 2,6-di-tert-butyl-p-cresol - (1-methylethylidene)bis[4,1-phenyleneoxy(2-hydroxy-3,1-propanediyl)] bismethacrylate - 2-hydroxyethyl methacrylate</td>
</tr>
<tr>
<td>3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1</td>
<td>2,6-di-tert-butyl-p-cresol</td>
</tr>
</tbody>
</table>

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

**National regulations**

### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: OTHER INFORMATION

Indication of changes:
Composition/information on ingredients. Hazards identification.

<table>
<thead>
<tr>
<th></th>
<th>Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Removed</td>
<td></td>
</tr>
<tr>
<td>2.1</td>
<td>Modified</td>
<td></td>
</tr>
<tr>
<td>2.2</td>
<td>Modified</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Modified</td>
<td></td>
</tr>
<tr>
<td>3.2</td>
<td>Removed</td>
<td></td>
</tr>
</tbody>
</table>


Other information:
- None.

Date of issue: 29/09/2011
Revision date: 30/08/2017
Supersedes: 20/05/2014
Date of total revision: 30/08/2017
Version: 4.0
Signature: A. Åsebø Murel

Full text of H- and EUH-statements:

<table>
<thead>
<tr>
<th>Acute Tox. 4 (Oral)</th>
<th>Acute toxicity (oral), Category 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aquatic Acute 1</td>
<td>Hazardous to the aquatic environment — Acute Hazard, Category 1</td>
</tr>
<tr>
<td>Aquatic Chronic 1</td>
<td>Hazardous to the aquatic environment — Chronic Hazard, Category 1</td>
</tr>
<tr>
<td>Eye Irrit. 2</td>
<td>Serious eye damage/eye irritation, Category 2</td>
</tr>
<tr>
<td>Org. Perox. B</td>
<td>Organic Peroxides, Type B</td>
</tr>
<tr>
<td>Skin Irrit. 2</td>
<td>Skin corrosion/irritation, Category 2</td>
</tr>
<tr>
<td>Skin Sens. 1</td>
<td>Skin sensitisation, Category 1</td>
</tr>
<tr>
<td>STOT SE 3</td>
<td>Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation</td>
</tr>
<tr>
<td>H241</td>
<td>Heating may cause a fire or explosion</td>
</tr>
<tr>
<td>H302</td>
<td>Harmful if swallowed</td>
</tr>
<tr>
<td>H315</td>
<td>Causes skin irritation</td>
</tr>
<tr>
<td>H317</td>
<td>May cause an allergic skin reaction</td>
</tr>
<tr>
<td>H319</td>
<td>Causes serious eye irritation</td>
</tr>
<tr>
<td>H335</td>
<td>May cause respiratory irritation</td>
</tr>
<tr>
<td>H400</td>
<td>Very toxic to aquatic life</td>
</tr>
<tr>
<td>H410</td>
<td>Very toxic to aquatic life with long lasting effects</td>
</tr>
</tbody>
</table>

The information in this safety data sheet is based on information from the manufacturer/supplier, present European and national legislation, and presupposes that the product is used within the specified area of application.