This SDS packet was issued with item:
075890785

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

070447458 070447466 070447474 070447482 070447490 070447508 070451393 070451401 070451419 075890710
075890728 075890736 075890744 075890777 075890793 075890801 075890819 075890843 075890850 075890868
075890876
1.0 Commercial Product Name and Supplier

1.1 Commercial product name

ACTIVA BioACTIVE-BASE / LINER
ACTIVA BioACTIVE-RESTORATIVE

1.2 Application / Use

Dental material for use by dental professional only.

1.2.2 SIC

851 Human health activity

1.3 Manufacturer, Importer

Pulpdent Corporation
80 Oakland Street
P.O. Box 780
Watertown, MA 02472 USA
Telephone: 1 617 926-6666
Fax: 1 617 926-6262
Email: Pulpdent@pulpdent.com

1.4 Emergency Telephone Number

1-800-535-5053 (24 Hour / USA)

1.5 Authorized European Representative

International Business Solutions Ltd.
54 Mayfield Ridge
Hatch Warren, Basingstoke, RG22 4RS UK
Tel: 07989 407479 / Fax: 01256 350330
Email: s.williams5@btconnect.co.uk

2.0 Hazards Identification

2.1 Classification

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

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>Hazard Category</th>
<th>Hazard Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eye irritation</td>
<td>2</td>
<td>H319</td>
</tr>
<tr>
<td>STOT SE</td>
<td>3</td>
<td>H335</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>2</td>
<td>H315</td>
</tr>
<tr>
<td>Skin sensitization</td>
<td>1</td>
<td>H317</td>
</tr>
</tbody>
</table>

2.1.2 Classification according to Directive 67/548/EEC

(See SECTION 16 for full text of risk phrases)

Irritant; Xi; R 36/37/38 - 43

2.2 GHS Label Elements

Signal Word: WARNING

Restricted to use by dental professional only.

Hazard Statements

H319: Eye irritation. 2. May cause eye irritation.
H335: STOT SE. 3. May cause respiratory irritation.
H315: Skin irritation. 2. May cause skin irritation.
H317: Sensitization. 1. May cause an allergic skin reaction.

Precautionary Statements

P261: Avoid breathing vapor.
P280: Wear protective gloves and eye protection
P305+P351: If in eyes, rinse cautiously with water for several minutes.
P337+P313: If eye irritation persists, get medical advice/attention.
Pulpdent Corporation

Safety Data Sheet

Trade Name: ACTIVA BioACTIVE PRODUCTS

P302+P352: If on skin, wash with plenty of soap and water.
P333+P313: If irritation or rash occurs, get medical advice/attention.
P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

3.0 Composition

3.1 Chemical characterization of the preparation: Resin-modified glass ionomer dental material

3.2 Hazardous ingredients

<table>
<thead>
<tr>
<th>CAS Number</th>
<th>Name of the Ingredient</th>
<th>Concentration BASE/LINER</th>
<th>Concentration RESTORATIVE</th>
<th>Classification per 67/548/EEC</th>
<th>Classification per Regulation (EC) No.1278/2008 (CLP).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proprietary</td>
<td>Blend of diurethane and other methacrylates with modified polyacrylic acid</td>
<td>53.2%</td>
<td>44.6%</td>
<td>Irritant; Xi R 3637/38 - 43</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317</td>
</tr>
<tr>
<td>112945-52-5</td>
<td>Silica, amorphous</td>
<td>3.0%</td>
<td>6.7%</td>
<td>Irritant; Xi, R 36/37/38</td>
<td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td>
</tr>
<tr>
<td>7681-49-4</td>
<td>Sodium fluoride</td>
<td>0.90%</td>
<td>0.75%</td>
<td>Harmful (Xn); R22-36/38</td>
<td>Acute toxicity, 4, H302 Skin irritation, 2, H315 Eye irritation, 2, H319</td>
</tr>
</tbody>
</table>

4.0 First Aid Measures

4.1 General Information May be irritating to eyes, respiratory system and skin. Avoid contact with eyes and skin. Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.

4.2 Inhalation Move to fresh air. Administer oxygen/CPR as needed. Seek medical attention.

4.3 Skin Contact Take off contaminated clothing. Wash skin thoroughly with soap and water.

4.4 Eye Contact Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention.

4.5 Ingestion Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.

4.6 Precautions for first responders Ventilate the area. Wear eye and skin protection.

4.7 Information for physicians

Symptoms Irritation or redness in eyes, throat or on skin.

Hazards May be irritating to eyes, respiratory system, skin. May be sensitizing by skin contact.

Treatment As above under First Aid.

5.0 Fire Fighting Measures

5.1 Suitable extinguishing media Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool.

5.2 Extinguishing media to avoid Do not use direct water stream

5.3 Special exposure hazards in a fire Heat may cause polymerization with rapid release of energy.

5.4 Special protective equipment for fire-fighters A self-contained breathing apparatus should be worn by firefighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.

6.0 Accidental Release Measures

6.1 Personal precautions. Wear safety glasses, gloves and lab coat.
Environmental precautions
Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.

Method for clean up
Contain spilled material. Absorb or wipe up spill with suitable material (e.g. paper towels). Collect for disposal in a covered container. Wash area of spill with alcohol or soap and water.

Handling and Storage
For use only by dental professionals. Practice good hygiene. Avoid direct/strong light sources, extremes of temperature (>27°C/80°F, <5°C/40°F), contamination, cross contamination of two-part materials. Recap immediately after use.

Keep container tightly closed. Store in original container at cool room temperature (<25°C). Avoid direct/strong light, sources of ignition, extremes of temperature. Shelf life for properly stored, unopened product is two years from date of manufacture.

Dental base/liner, cement or restorative

Exposure limit values
PEL: Not established. TLV: Not established.

No special equipment required under normal conditions of use.
None required. Good general ventilation is sufficient to control any airborne vapors.
No special requirements other than the usual surgical gloves.
No special requirements other than the usual safety glasses worn by dental staff.
No special requirements. Good personal hygiene, safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.
Emergency eye wash fountain should be available. Wash hands after use.

Cure material before disposing.

Part A Part B
Yellowish Off-white
Tooth-colored Off-white

Faint, characteristic

Not determined
Not determined
Not determined
Not applicable
Not applicable
Not determined
< 1 mm Hg

Base / Liner 1.460 g/mL 1.380 g/mL
Safety Data Sheet

Trade Name: Activa BioACTIVE PRODUCTS

9.2.9 Solubility in water  
Restorative 1.580 g/mL 1.620 g/mL

9.2.10 Partition coefficient  
Not determined

9.2.11 Viscosity  
Not determined

9.2.12 Vapor density  
Not determined

9.2.13 Evaporation rate  
Not determined

10.0 Stability and reactivity

10.1 Conditions to avoid  
Temperature > 38°C, intense light, cross-contamination.

10.2 Materials to avoid  
Reducing and oxidizing agents, peroxides, amines.

10.3 Hazardous decomposition products  
Under fire conditions, amounts greater than that supplied in this product may polymerize with heat build-up, release of oxides of carbon and nitrogen.

10.4 Further information  
Stable material if stored and used as directed. Polymerization will occur when light-cured material is exposed to direct light.

11.0 Toxicological information

11.1 Acute toxicity  
Finished products in paste form present a minimal health hazard under normal conditions of use and in the quantities necessary for dental procedures.

Sodium fluoride: Oral rat LD₅₀: 180 mg/kg
Silica, amorphous: Oral rat LD₅₀: 3160 mg/kg

11.2 Irritation and corrosiveness  
May be irritating to eyes, respiratory tract, mucous membranes or skin on contact or with prolonged exposure.

11.3 Sensitization  
May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.

11.4 Sub-acute, sub-chronic and prolonged toxicity  
Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) may cause eye and respiratory irritation.

11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity  
None known

11.6 Empirical data  
Biocompatibility has been tested and found to be acceptable.

11.7 Clinical experience  
ACTIVA BioACTIVE PRODUCTS are new products that have been evaluated by dentist consultants. There have been no reports of adverse events.

12.0 Ecological Information

12.1 Ecotoxicity  
Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.

13.0 Disposal Considerations

13.1 Regulations  
Follow all local and national government regulations in disposing material or contaminated packaging.

14.0 Transport Information

14.1 Restrictions  
None. Not regulated.
### 15.0 Regulatory Information

<table>
<thead>
<tr>
<th>15.1 EU</th>
<th>Class IIA medical devices under MDD 93/42/EEC.</th>
</tr>
</thead>
<tbody>
<tr>
<td>15.2 US FDA</td>
<td>Class II medical devices.</td>
</tr>
<tr>
<td>15.3 Health Canada</td>
<td>Class III medical devices</td>
</tr>
</tbody>
</table>

### 16.0 Other information

<table>
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<tr>
<th>16.1 List of relevant R phrases</th>
</tr>
</thead>
<tbody>
<tr>
<td>R36/37/38: Irritating to eyes, respiratory system and skin.</td>
</tr>
<tr>
<td>R43: Sensitizing by skin contact.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16.2 Hazard Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>H319: Eye irritation. Hazard category 2.</td>
</tr>
<tr>
<td>H335: Specific Target Organ Toxicity - Single exposure; hazard category 3. Respiratory tract irritation.</td>
</tr>
<tr>
<td>H315: Skin irritation. Hazard category 2.</td>
</tr>
<tr>
<td>H317: Skin Sensitization. Hazard category 1.</td>
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<th>16.4 Restrictions on use</th>
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<tbody>
<tr>
<td>ACTIVA BioACTIVE PRODUCTS are to be sold to and used by dental professionals only.</td>
</tr>
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</table>

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<tr>
<th>16.5 Further information</th>
</tr>
</thead>
<tbody>
<tr>
<td>The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.</td>
</tr>
</tbody>
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<th>16.6 Sources of key data</th>
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<tbody>
<tr>
<td>National Institute for Occupational Safety (NIOSH)</td>
</tr>
<tr>
<td>US Occupational Safety and Health Administration (OSHA)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>16.7 Information which has been added, deleted or revised.</th>
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</thead>
<tbody>
<tr>
<td>This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically, Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.</td>
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