DENTSPLY International
DENTSPLY PROSTHETICS

Safety Data Sheet

Safety Data Sheet (in compliance with Regulation (EC) 1907/2006, Regulation (EC) 1272/2008 and Regulation (EC) 453/2010)

Date Issued: 23 September 1997
Document Number: 159
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Revision Number: 5

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier:

Trade Name (as labeled):	**Biolon® C&B Resin Powder**
Part/Item Number:	**681004, 681007-681008, 681010-681013, 681015-681016, 681018-681020, 681023, 681033, 681036-681037, 681039-681042, 681044-681045, 681093-681095, 681097, 681099, 681101, 681103-681104, 681113-681115, 681117, 681119, 681121, 681123-681124**

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against:

Recommended Use:	**Resin used in crown & bridge dental appliances.**
Restrictions on Use:	**For Professional Use Only**

1.3 Details of the Supplier of the Safety Data Sheet:

Manufacturer/Supplier Name:	**DENTSPLY Prosthetics**
Manufacturer/Supplier Address:	**570 West College Ave.** **York, PA 17401**
Manufacturer/Supplier Telephone Number:	**717-845-7511 (Product Information)**
Email address:	**Prosthetics_MSDS@Dentsply.com**

1.4 Emergency Telephone Number:

Emergency Contact Telephone Number:	**800-424-9300 Chemtrec**

2. HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture:

GHS Classification:

Health	Environmental	Physical
Not Hazardous	Not Hazardous	Not Hazardous

EU Classification: Not classified as dangerous

OSHA Specific Hazards: Combustible Dust

2.2 Label Elements:

Signal Word: Warning

Hazard Phrases	Precautionary Phrases
May form combustible dust concentrations in air.	Keep away from all ignition sources including heat, sparks, and flame.

2.3 Other Hazards: None known.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.2 Mixture:

Hazardous Components	C.A.S. #	EINECS #	Classification	WT %
Methyl Methacrylate Copolymers	Proprietary	Proprietary	Not applicable	90-100
Non-hazardous Ingredients	Proprietary	Proprietary	Not applicable	<10

The exact concentration is being withheld as a trade secret.

Refer to Section 16 for the full text of the GHS and EU Classifications.

4. FIRST AID MEASURES

4.1 Description of First Aid Measures:	
Eye	Flush victim's eyes with large quantities of water. Get medical attention if irritation develops.
Skin	Wash skin with soap and water. Remove contaminated clothing and shoes. Get medical attention if irritation or symptoms of exposure occur. Launder clothing before re-use.
Inhalation	Remove victim to fresh air. If breathing is difficult have qualified personnel administer oxygen. Get medical attention if symptoms persist.
Ingestion	Do not induce vomiting. Never give anything by mouth to an unconscious or convulsing person. Get medical attention if you feel unwell.
4.2 Most Important Symptoms and Effects, Both Acute and Delayed:	
Dust may cause mechanical eye and respiratory irritation. Individuals with sensitivity to methacrylates may develop an allergic reaction when exposed to this product.	
4.3 Indication of Any Immediate Medical Attention and Special Treatment Needed:	
Immediate medical attention should not be required.	
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.	

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing Media:	Water fog, carbon dioxide dry chemical. Do not use a water stream. Water stream can disperse dust in air producing a fire hazard and possible explosion hazard if exposed to ignition source.
5.2 Special Hazards Arising from the Substance or Mixture:	
Dust generated in processing of this material may present a potential fire and explosion hazard if suspended in air at high concentrations. Settled dust presents a fire hazard. Re-suspension of the dust into the air by vibration, traffic, material handling, etc. in high concentrations in the presence of an ignition source could result in a dust explosion. Minimize the generation and accumulation of dust. Thermal decomposition may release carbon oxides, ethyl methacrylate and methyl	

methacrylate.	
5.3 Advice for Fire-Fighters:	
Fire Fighting Procedures:	Cool fire exposed containers and structures with water. Do not use solid water jet as that may create a dust cloud that can present an explosion hazard.
Precautions for Fire Fighters:	Firefighters should wear full emergency equipment and approved positive pressure self-contained breathing apparatus. Do not enter fire area without proper protection.

Recommended Protective Equipment for Fire Fighters:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**THERMAL**
			

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures:			
Eliminate all sources of ignition. Avoid contact with skin, eyes or clothing. Avoid breathing dust. Wear appropriate protective clothing as described in Section 8. Powders that become wet may cause surfaces to be extremely slippery and present a slip hazard.			
Recommended Personal Protective Equipment for Containment and Clean-up:			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**
			

6.2 Environmental Precautions:
Do not allow spills to enter sewers or waterways. Report releases as required by local, state, and national authorities.
6.3 Methods and Material for Containment and Cleaning up:
Scoop or shovel up using methods that minimize the generation of airborne dust. Non-sparking tools should be used. Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentrations. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Place dry material into an appropriate container for disposal. Flush spill area with water to remove residue.
6.4 Reference to Other Sections:
Refer to Section 8 for Personal Protective Equipment and Section 13 for Disposal information.

7. HANDLING AND STORAGE

7.1 Precautions for Safe Handing:

Avoid contact with the eyes, skin and clothing. Avoid breathing dust. Wear protective clothing and equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Minimize the generation and accumulation of dust. Keep dust away from open flames, hot surfaces and sources of ignition. Follow good housekeeping practices to keep surfaces, including areas overhead such as piping, drop ceilings, ductwork, etc. free from settled dust. Dry powders can build static electricity charges when subjected to friction of transfer and in mixing operations. Provide adequate precautions, such as electrical grounding and bonding.

Do not reuse containers. Empty containers retain product residues and can be hazardous. Follow all SDS precautions when handling empty containers.

7.2 Conditions for Safe Storage, Including Any Incompatibilities: Store in a cool, dry, well-ventilated area away from heat, and sources of ignition. Keep container tightly closed when not in use. Keep away from oxidizing agents and other incompatible materials.

7.3 Specific End Use (s): For professional use only.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control Parameters:

Occupational Exposure Limits:

Methyl Methacrylate Copolymers	United States	5 mg/m^3 (respirable), 15 mg/m3 (total dust) TWA OSHA PEL (As PNOC)
	Germany	4 mg/m^3 TWA DFG MAK (Inhalable) (As Dust, general threshold limit value)
	United Kingdom	10 mg/m^3 TWA UK OEL (Inhalable) 4 mg/m^3 TWA UK OEL (Respirable)
	European Union	None Established
Non-hazardous Ingredients	United States	None Established
	Germany	None Established
	United Kingdom	None Established
	European Union	None Established

Biological Exposure Limits: None Established

8.2 Exposure Controls:

Appropriate Engineering Controls: Use adequate general or local exhaust ventilation to maintain exposures below the occupational exposure limits. Provide local exhaust ventilation where product is processed in a manner that generates dust. It is recommended that all dust control equipment such as local exhaust ventilation and material transport systems involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen deficient environment. Ensure that dust handling systems (such as exhaust ducts, dust collectors, vessels and processing equipment) are designed in a manner to prevent the escape of dust into the work area (i.e. there is no leakage from the equipment). Use

only appropriately classified electrical equipment.

Individual Protection Measures (PPE):

Specific Eye/face Protection: None needed under normal use. Wear safety glasses if needed to avoid eye contact.
Specific Skin Protection: None needed under normal use. Wear impervious gloves such as rubber if needed to avoid skin contact. Recommended glove: Rubber. Consult glove supplier for thickness and breakthrough times.
Specific Respiratory Protection: None should be needed for normal use. If the exposure limits are exceeded, an approved respirator with dust/mist cartridges or supplied air respirator appropriate for the form and concentration of the contaminants should be used. Selection and use of respiratory equipment must be in accordance with applicable regulations and good industrial hygiene practice.
Specific Thermal Hazards: None required

Recommended Personal Protective Equipment			
EYES/FACE	**HANDS**	**RESPIRATORY**	**SKIN**

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties:

Appearance:	Colored free-flowing powder.	**Explosive limits:**	**LEL:** Not applicable **UEL:** Not applicable
Odor:	Characteristic odor.	**Vapor pressure (mmHg):**	Not applicable
Odor threshold:	Not determined	**Vapor density:**	Not applicable
pH:	Not applicable	**Relative density:**	Not available
Melting/freezing point:	Not available	**Solubility(ies):**	Insoluble
Initial boiling point and boiling range:	Not applicable	**Partition coefficient: n-octanol/water:**	Not applicable
Flash point:	>280°C, 536°F	**Auto-ignition temperature:**	Not available
Evaporation rate:	Not applicable	**Decomposition temperature:**	Not available
Flammability (solid, gas):	Polymer dust is combustible	**Viscosity:**	Not applicable
Explosive Properties:	High concentrations of dust in the presence of an ignition source could result in a dust explosion.	**Oxidizing Properties:**	None

9.2 Other Information: None available

10. STABILITY AND REACTIVITY

10.1 Reactivity: None known.

10.2 Chemical Stability: Stable.

10.3 Possibility of Hazardous Reactions: None known.

10.4 Conditions to Avoid: Excessive heat (temperatures greater than 572°F (300°C). Keep away heat, sparks or ignition sources.

10.5 Incompatible materials: Avoid oxidizing agents.

10.6 Hazardous Decomposition Products: Thermal decomposition may release carbon oxides, styrene and methyl methacrylate.

11. TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects:

Potential Health Effects:
Eyes: Dust may cause irritation with redness and tearing.
Skin: No adverse effects are normally expected. Individuals with sensitivity to methacrylates may develop an allergic reaction.
Ingestion: Swallowing large amounts may cause nausea, vomiting and diarrhea.
Inhalation: Inhalation of dust may cause irritation of the nose, throat and upper respiratory tract.

Chronic Health Effects: Prolonged or repeated overexposure may cause skin irritation or sensitization in some individuals.

Irritation: No data available. May cause mechanical eye and respiratory tract irritation.

Corrosivity: This product is not classified as corrosive.

Sensitisation: Individuals with sensitivity to methacrylates may develop an allergic reaction.

Carcinogenicity: None of the components of this product are listed as carcinogens by OSHA, IARC, NTP, ACGIH or the EU Directive.

Mutagenicity: No data available.

Medical Conditions Aggravated by Exposure:
Individuals with pre-existing skin and respiratory disorders may be at increased risk from exposure.

Acute Toxicity Data:
No toxicity data available

Reproductive Toxicity Data: No data available

Specific Target Organ Toxicity (STOT):
Single Exposure: No data available.

Repeated Exposure: No data available.

12. ECOLOGICAL INFORMATION

12.1 Toxicity: No ecotoxicity data available.
12.2 Persistence and Degradability: No data is currently available
12.3 Bio-accumulative Potential: No data is currently available
12.4 Mobility in Soil: No data is currently available
12.5 Results of PBT and vPvB Assessment: Not required
12.6 Other Adverse Effects: None known

13. DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods:

Regulations: Dispose in accordance with all national and local regulations.
Properties (Physical/Chemical) Affecting Disposal: Follow all SDS precautions when handling empty containers.
Waste Treatment Recommendations: Treat in accordance with national and local regulations.

14. TRANSPORT INFORMATION

	14.1 UN Number	14.2 UN Proper Shipping Name	14.3 Hazard Class(s)	14.4 Packing Group	14.5 Environmental Hazards
DOT	None	Not Regulated	None	None	None
ADR/RID	None	Not Regulated	None	None	None
IMDG	None	Not Regulated	None	None	None
IATA/ICAO	None	Not Regulated	None	None	None

14.6 Special Precautions for User: Not applicable.

14.7 Transport in Bulk According to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture:

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA): This product is not subject to CERCLA reporting requirements. Many states have more stringent release reporting requirements. Report spills required under federal, state and local regulations.

Toxic Substances Control Act (TSCA): This product is a medical device and not subject to chemical notification requirements.

Clean Water Act (CWA): This material is not regulated under the Clean Water Act.

Clean Air Act (CAA): This material is not regulated under the Clean Air Act.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:

Immediate Hazard:	No	**Pressure Hazard:**	No
Delayed Hazard:	No	**Reactivity Hazard:**	No
Fire Hazard:	Yes		

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372):

Components	C.A.S. #	WT %
None		

State Regulations

California: This product contains the following substances known to the state of California to cause cancer and/or reproductive toxicity:

Components	C.A.S. #	WT %
None		

International Regulations

Canadian Workplace Hazardous Materials Information System (WHMIS): Medical devices are not subject to WHMIS.

Canadian Environmental Protection Act: This product is a medical device and not subject to chemical notification requirements.

This SDS has been prepared according to the criteria of the Controlled Products Regulation (CPR) and the SDS contains all of the information required by the CPR.

European Inventory of Existing Chemicals (EINECS): This product is a medical device and not subject to chemical notification requirements.

EU REACH: This product is a medical device and not subject to chemical notification requirements.

Australian Inventory of Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

China Inventory of Existing Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Japanese Existing and New Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Philippine Inventory of Chemicals and Chemical Substances: This product is a medical device and not subject to chemical notification requirements.

Korean Existing Chemicals List: This product is a medical device and not subject to chemical notification requirements.

15.2 Chemical Safety Assessment: None required.

16. OTHER INFORMATION

HMIS Hazard Rating:
Health – 1 Flammability – 2 Physical Hazard– 0

Full text of Classification abbreviations used in Section 2 and 3:
None

Supersedes: 15 August 2014
Revision Summary: Removed errant phrase.
Date Revised: 26 June 2015

Data Sources: US NLM ChemID Plus and HSDB, Substance SDS for components, IUCLID Dataset EU Chemical Bureau, ESIS, Country websites for occupational exposure limits.