Safety Data Sheet (SDS)

Prepared in accordance with OSHA Hazard Communication Standard, 29 CFR 1910.1200, Hazardous Products Regulations (HPR) and WHMIS 2015, Regulation (EC) No 1907/2006 (REACH) and Regulation (EC) No 1272/2008 (CLP), and GHS Rev. 4

RODIN BioArch RPD Resin

Section 1. Product and Company Identification

Product Identifier: Photopolymer Resin
Trade Name and/or synonyms: RODIN BioArch RPD
CAS#: N/A
Recommended use: 3D printed flexible partial denture bases.
Manufacturer/Supplier: Pac-Dent, Inc.
670 Endeavor Circle
Brea, CA 92821
Phone: 909-839-0888

Emergency telephone number: (U.S.) +1 800 424 9300
Emergency telephone number: (INT) +1 703 527 3887

Section 2. Hazard(s) Identification

GHS Hazard Classification of the Substance or Mixture:
Skin Sensitization – Category 1
Eye Irritation – Category 2
Acute Toxicity (Oral) – Category 5 (uncured material only)
Specific Target Organ Toxicity – Single Exposure (STOT SE) – Category 3 (respiratory irritation, uncured material only)
Hazardous to the Aquatic Environment – Chronic Category 3 (uncured material only)

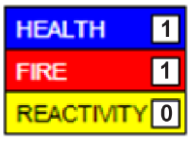
Signal Word: Warning
Hazard Statement(s):
H317 May cause an allergic skin reaction
H319 Causes serious eye irritation
H303 May be harmful if swallowed (uncured material only)
H335 May cause respiratory irritation (uncured material only)
H402 Hazardous to aquatic life (uncured material only)

Precautionary Statement(s):
P261 Avoid breathing dust or fume. (uncured material only)
P264 Wash thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P273 Avoid release to the environment.
P280 Wear protective gloves, protective clothing, eye protection and face protection.
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 attention.
P302+P352 IF ON SKIN: Wash with plenty of soap and water.
P333+P313 If skin irritation or rash occurs: Get medical attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents and container in accordance with local and national regulations.
Description of any hazards not otherwise classified: None
For a mixture, the percentage of total ingredient(s) of ingredient(s) with unknown acute toxicity: 2%

NFPA Ratings (0-4)

Health = 1
Fire = 1
Reactivity = 0

HMIS Ratings (0-4)



Health = 1
Fire = 1
Reactivity = 0
Personal Protection = B

Section 3. Composition/Information on Ingredients

Chemical Name, Common Name and Synonyms:	CAS # and other unique identifiers	% by Weight
Methacrylic Esters*	Proprietary*	25% – 55%
Photoinitiators*	Proprietary*	<3%

*Denotes that the specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret.

Section 4. First-Aid Measures

After inhalation: Remove the affected person to fresh air. Keep at rest in a position comfortable for breathing. Seek medical attention if symptoms such as irritation or respiratory discomfort persist.
After skin contact: Wash skin thoroughly with soap and water. Remove contaminated clothing and shoes and wash before reuse. Seek medical attention if irritation or sensitization develops.
After eye contact: Rinse cautiously with clean running water for several minutes, holding eyelids open. Continue rinsing for at least 15 minutes. Remove contact lenses if present and easy to do. Seek medical attention if irritation persists.
After swallowing: Rinse mouth with water. Do not induce vomiting. Seek medical attention if symptoms occur.
Notes to physician: Treat symptomatically after thorough decontamination.

Section 5. Fire-Fighting Measures

Suitable extinguishing agents: Use alcohol-resistant foam, carbon dioxide (CO_2), or dry chemical extinguishers.
Special hazards arising from the substance or mixture: Thermal decomposition of methacrylate-based resins may produce irritating or toxic fumes, including carbon oxides and nitrogen oxides. Heat exposure may cause exothermic polymerization.
Advice for firefighters: Firefighters should wear full protective clothing and self-contained breathing apparatus (SCBA). Use extinguishing media appropriate for the surrounding fire. Water spray may be used to cool exposed containers but may not be effective for extinguishing a fire involving this product.

Section 6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures: Avoid contact with skin and eyes. Wear appropriate personal protective equipment, including safety glasses with side shields, protective gloves, and laboratory coat, as described in Section 8. Ensure adequate ventilation.
Environmental precautions: Avoid releases to the environment. Prevent further leakage or spillage if safe to do so. Notify relevant authorities if required by local or national regulations.
Methods and material for containment and cleaning up: Exposure to sunlight or artificial light will cause the resin to polymerize. Allow the spilled material to cure, then collect the hardened material mechanically and place it into a suitable container for disposal.
Reference to other sections: Refer to Section 8 for information on personal protective equipment and Section 13 for disposal considerations.

Section 7. Handling and Storage

Precautions for safe handling: Avoid contact with eyes, skin, and clothing. Avoid breathing vapors or mists, particularly when the material is heated or aerosolized. Wear appropriate protective equipment as described in Section 8. Use with adequate ventilation. Wash thoroughly with soap and water after handling. Keep containers tightly closed when not in use. Do not reuse containers. Empty containers may retain product residues and should be handled with the same precautions as full containers.
Conditions for safe storage, including and incompatibilities: Store in a tightly closed container in a cool (−2 to 32 °C / 29 to 90 °F), well-ventilated area away from incompatible materials. Protect from heat and UV or intense light exposure. Do not store near sources of excessive heat. Avoid conditions that may lead to inhibitor depletion. Do not allow the material to freeze
Specific end use(s): For professional use only.

Section 8. Exposure Controls / Personal Protection

Control parameters: No occupational exposure limits have been established for the components of this mixture.
Exposure controls: Use in a well-ventilated area. Enclosed processing is recommended where feasible to minimize exposure.
Personal protective equipment:
Eye / face protection: Use safety goggles with side shields or chemical splash goggles when there is a risk of splashing or eye contact.
Skin protection: Wear protective gloves when handling uncured material. Depending on conditions of use, protective clothing such as a lab coat or apron may be used to prevent skin contact.
Hand protection: Protective gloves are recommended.
Material of gloves / breakthrough time: Not determined.
Respiratory protection: Respiratory protection is not normally required. If the material is handled at elevated temperatures or under mist-forming conditions, use approved respiratory protection in accordance with applicable regulations and good industrial hygiene practice.
General hygiene measures: Wash hands thoroughly after handling and before eating, drinking, or smoking. Avoid contact with skin and eyes. See Section 7 for handling and storage precautions.

Section 9. Physical and Chemical Properties

Information on basic physical and chemical properties
General Information
Appearance
Form: Liquid
Color: Pigmented (varies by product variant)
Odor: Fruity, ester-like odor.
Odor Threshold: Not available
pH value at 20°C (68°F): Not applicable (non-aqueous)
Melting point/Melting range: Not available
Boiling point/Boiling range: Not available
Flash point: 93 °C (>200 °F) (PMCC)
Evaporation rate: Not available
Flammability (solid, gaseous): Not available
Auto-Ignition Temperature: Not available
Decomposition temperature: Not available

Explosion limits
Lower: Not available
Upper: Not available
Vapor Pressure: Not available
Density: Not available
Relative density: Not available
Solubility: Nearly insoluble in water
Vapor Density: Not available
Evaporation rate: Not available
Partition coefficient (n-octanol/water): Not available
Viscosity: 220–250 cP at 25 °C (77 °F) (Brookfield)
Solvent content: Not available
Organic solvents: Not available
Water: Not available
Solids content: Not available
Other information: 1.10–1.125 at 25 °C (77 °F)

Section 10. Stability and Reactivity

Reactivity: No hazardous reactions are expected under normal conditions of use and storage.
Chemical stability: Stable under recommended storage and handling conditions.
Possibility of hazardous reactions: Uncontrolled polymerization may occur if inhibitors are depleted or if exposed to excessive heat or UV light, generating heat and pressure.
Conditions to avoid: Heat, UV or intense light exposure, contamination, and conditions that may lead to inhibitor depletion.
Incompatible materials: Strong oxidizing agents, strong reducing agents, peroxides, and amines.
Hazardous decomposition products: Thermal decomposition may produce irritating or toxic fumes, including carbon oxides and nitrogen oxides.

Section 11. Toxicological Information

Acute toxicity: Based on available data, the mixture is not classified for acute systemic toxicity. The uncured material may be harmful if swallowed.
Skin corrosion/irritation: May cause skin irritation and an allergic skin reaction. See Section 2.
Serious eye damage/eye irritation: May cause eye irritation. See Section 2.
Respiratory or skin sensitization: May cause an allergic skin reaction. See Section 2.
Specific target organ toxicity – single exposure (STOT SE): May cause respiratory irritation (uncured material only).
LD_{50} / LC_{50} values relevant for classification: No data available.
Additional toxicological information: No additional data available.
IARC (International Agency for Research on Cancer): None of the components are listed.
NTP (National Toxicology Program): None of the components are listed.
CMR Assessment (CLP): Based on available data and in accordance with Regulation (EC) No 1272/2008 (CLP), this mixture is not classified as carcinogenic, mutagenic, or toxic for reproduction (CMR).

Section 12: Ecological Information

Aquatic Toxicity: Based on mixture classification, the uncured resin is classified as hazardous to aquatic life (Chronic Category 3). Specific component-level aquatic toxicity data are not available.
Persistence and degradability: No data is currently available.
Bioaccumulative potential: No data is currently available.
Mobility in Soil: No data is currently available.
Behavior in environmental systems: No data is currently available.
Additional ecological information: Avoid release of uncured material to the environment. Cured material is considered inert.
General Notes: Release into the environment should be avoided. Refer to section 13 for disposal information.
Results of PBT and vPvB assessment - For the EU: This mixture has not been assessed for PBT or vPvB properties in accordance with Annex XIII of Regulation (EC) No 1907/2006 (REACH)
Other adverse effects: None known.

Section 13. Disposal Considerations

Waste Treatment Methods
Recommendation: Cure material before disposal. Dispose in accordance with applicable local, regional, national, and international regulations. Consult relevant waste authorities to ensure proper classification and disposal of waste.
In the United States, disposal may be subject to the Resource Conservation and Recovery Act (RCRA). Guidance for the classification of hazardous waste is provided in 40 CFR Part 261.
Uncleaned packaging

Recommendation: Rinse with alcohol. Collect rinse material and dispose of in accordance with applicable local, regional, national, and international regulations.
Recommended cleansing agent: alcohol

Section 14. Transport Information

Transport Information
UN Number: Not regulated.
UN Proper Shipping Name: Not regulated.
Transport Hazard Class(es): Not regulated.
Packing Group: Not applicable.
Environmental Hazards: Not applicable.
Special Precautions for User: None.
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.
Transport Regulations by Mode
U.S. Department of Transportation (DOT): Not hazardous according to U.S. DOT regulations.
International Maritime Dangerous Goods Code (IMDG): Not regulated as dangerous goods.
International Air Transport Association (IATA): Not regulated as dangerous goods.
ADR (European Agreement concerning the International Carriage of Dangerous Goods by Road): Not regulated.
Additional Transport Information
Danger code (Kemler): N/A
EMS Number: N/A
Australian HazChem Code: N/A

Section 15. Regulatory Information

Safety, health and environmental regulations / legislation specific for the substance or mixture.
U.S. Regulations
OSHA (Occupational Safety & Health Administration): None of the components are listed.
SARA (Superfund Amendments and Reauthorization Act):
Acute Health Hazard: Yes
Chronic Health Hazard: Yes
Fire Hazard: No
Pressure Hazard: No
Reactivity Hazard: No
SARA Section 355 (Extremely hazardous substances**):** None.
SARA Section 313 (Toxic Release Inventory): None.
TSCA (Toxic Substances Control Act): None of the components are listed.
California Proposition 65:
Chemicals known to the state of California to cause cancer and/or reproductive toxicity: None.
Chemicals known to cause developmental toxicity**:** None known.
EPA (Environmental Protection Agency) None of the components are listed.
NIOSH-OSHA (National Institute for Occupational Safety and Health): None of the components are listed.
TLV (Threshold Limit Value established by ACGIH): None of the components are listed.
EU Regulations
REACH Regulation (EC) No 1907/2006: This mixture does not contain substances subject to authorization (Annex XIV) or restriction (Annex XVII) at concentrations requiring declaration.
CLP Regulation (EC) No 1272/2008: This mixture is classified and labeled according to CLP, aligned with GHS Rev. 4.
CMR Status (CLP): Based on available data, the mixture is not classified as carcinogenic, mutagenic, or toxic for reproduction (CMR) under Regulation (EC) No 1272/2008.
SVHC (Substances of Very High Concern): This product does not contain SVHCs above 0.1% (w/w) according to the current ECHA Candidate List.
Chemical Safety Assessment: A Chemical Safety Assessment has not been carried out. Under REACH, a CSA is not required for mixtures supplied for professional use as medical device materials.
Canada
WHMIS 2015 / Hazardous Products Regulations (HPR): This product is classified as hazardous in accordance with the Hazardous Products Regulations and WHMIS 2015, aligned with GHS Rev. 4.
Domestic Substances List (DSL): All components are listed on or exempt from the Canadian Domestic Substances List.
Occupational Exposure Limits: No occupational exposure limits have been established for the components of this mixture.
GHS Label elements: This product is classified and labeled according to the Globally Harmonized System (GHS)
Hazard pictograms:

Signal Word: Warning

Hazard-determining components of labeling: See Section 2.
Hazard statements: See Section 2.
Precautionary statements: See Section 2.

Section 16. Other Information

Abbreviations and Acronyms: None.
Other information not contained elsewhere: None.