

Safety Data Sheet (SDS)

Prepared in accordance with OSHA HazCom and GHS; compatible with EU REACH Annex II, as amended by (EU) 2020/878, WHMIS, and AU WHS requirements.

RODIN FlexiSplint Resin

Section 1. Product and Company Identification

Product Identifier: Photopolymer Resin

Trade Name: RODIN FlexiSplint

Synonyms: Dental Splint 3D Printing Resin

Recommended Use

Light-curable resin material intended for fabrication of 3D printed corrective oral appliances using validated CAD/CAM additive manufacturing systems.

Restrictions on Use

For professional dental/laboratory use only.

Not for direct intraoral placement in uncured state.

Manufacturer/Supplier

Pac-Dent, Inc.

670 Endeavor Circle

Brea, CA 92821

Phone: +1-909-839-0888

Email: info@pac-dent.com

Emergency telephone number

CHEMTREC (US): +1-800-424-9300

International: +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)



GHS08



GHS07



GHS09

Signal Word: Warning

Hazard Statements

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).

H412 Harmful to aquatic life with long lasting effects (uncured material only).

Precautionary Statements

Prevention

P261 Avoid breathing dust/fume/gas/mist/vapours/spray (uncured material only).

P264 Wash hands [and exposed skin] 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.

Response

P302 + P352 IF ON SKIN: Wash with plenty of soap and water.

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

P362 + P364 Take off contaminated clothing and wash it before reuse.

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.

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

Storage

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

Disposal

P501 Dispose of contents/container in accordance with local, regional, national, and international regulations.

Other Hazards

Uncured resin may cause irritation to skin, eyes, and respiratory tract.

Avoid direct contact with uncured material.

Does not meet criteria for PBT or vPvB based on available data.

Does not contain substances classified as endocrine disruptors above reportable thresholds based on available data.



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Section 3. Composition/Information on Ingredients

Chemical Name	CAS Number	EC Number	Concentration (% w/w)	Classification
Methacrylic Esters	Proprietary	Proprietary	25-55%	Skin Sens. 1 (H317), Eye Irrit. 2 (H319)
Photoinitiator system	Proprietary	Proprietary	<3%	Eye Irrit. 2 (H319), Aquatic Chronic 3 (H412)

*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

Description of First Aid Measures

General Advice

If medical advice is needed, have product container, label, or Safety Data Sheet available. Ensure medical personnel are aware of the material involved and take precautions to protect themselves.

After Inhalation

Remove person to fresh air and keep comfortable for breathing. If irritation, coughing, or other symptoms develop or persist, seek medical attention.

After Skin Contact

Immediately wash affected skin thoroughly with soap and water. Remove contaminated clothing and shoes. Wash contaminated clothing before reuse. If irritation, redness, or allergic skin reaction develops, seek medical advice/attention.

After Eye Contact

Immediately rinse cautiously with clean running water for at least 15 minutes, holding eyelids open. Remove contact lenses if present and easy to do. Continue rinsing. Seek medical attention if irritation persists.

After Swallowing

Rinse mouth thoroughly with water. Do not induce vomiting unless directed by medical personnel. Never give anything by mouth to an unconscious person. Seek medical attention if discomfort occurs or if significant quantity has been swallowed.

Most Important Symptoms and Effects, Both Acute and Delayed

Inhalation: May cause respiratory irritation, coughing, or discomfort from vapors or mist.

Skin Contact: May cause irritation, redness, or allergic skin sensitization after repeated exposure.

Eye Contact: Causes irritation, redness, tearing, and discomfort.

Ingestion: May cause gastrointestinal discomfort, nausea, or irritation.

Indication of Any Immediate Medical Attention and Special Treatment Needed

Treat symptomatically. No specific antidote is known. For sensitized individuals, manage allergic reactions according to clinical judgment.

Section 5. Fire-Fighting Measures

Extinguishing Media

Suitable Extinguishing Media

Use extinguishing media appropriate for the surrounding fire, including:

Alcohol-resistant foam

Carbon dioxide (CO₂)

Dry chemical powder

Water spray or fog (for cooling exposed containers)

Unsuitable Extinguishing Media

Do not use a direct water jet, as it may spread burning material.

Special Hazards Arising from the Substance or Mixture

The product is not classified as highly flammable; however, combustible organic components may burn under fire conditions. Exposure to heat may cause thermal decomposition of resin components, formation of irritating or hazardous fumes, pressure build-up in closed containers, and possible polymerization with release of heat. Hazardous combustion/decomposition products may include carbon monoxide (CO), carbon dioxide (CO₂), nitrogen oxides (NO_x), and acrid organic fumes.

Advice for Firefighters

Wear self-contained breathing apparatus (SCBA) and full protective firefighting gear.

Cool fire-exposed containers with water spray.

Fight fire from a safe distance or protected location.

Prevent contaminated firefighting runoff from entering drains, waterways, or soil.



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Section 6. Accidental Release Measures

Personal Precautions, Protective Equipment and Emergency Procedures

Avoid contact with skin, eyes, and clothing. Ensure adequate ventilation. Wear appropriate personal protective equipment, including safety glasses or chemical splash goggles, protective gloves (e.g., nitrile), and protective clothing/laboratory coat as needed. Avoid breathing vapors, mist, or aerosols generated during cleanup. For non-emergency personnel, isolate the area and avoid unnecessary exposure.

Environmental Precautions

Avoid release to the environment. Prevent material from entering drains, sewers, surface water, or soil. Contain spill if safe to do so. Notify relevant authorities if required by applicable local, regional, or national regulations.

Methods and Material for Containment and Cleaning Up

Small Spills:

Absorb with inert material such as sand, vermiculite, or absorbent pads.

Transfer collected material into a suitable waste container.

Uncured Resin Residue:

Exposure to sunlight or artificial light may initiate polymerization.

Resin may be cured under controlled light exposure prior to disposal where appropriate.

Large Spills:

Dike or contain spill area.

Collect mechanically using non-sparking tools where appropriate.

Place waste into labeled disposal containers.

After cleanup, wash contaminated surfaces with suitable cleaning agents while preventing environmental release.

Reference to Other Sections

Section 8 for exposure controls and personal protective equipment

Section 13 for disposal considerations

Section 7 for safe handling and storage information

Section 7. Handling and Storage

Precautions for Safe Handling

Use only in accordance with professional instructions and validated processing procedures. Avoid contact with skin, eyes, and clothing. Avoid breathing vapors, mist, or aerosols that may be generated during handling, printing, cleaning, or finishing operations. Wear appropriate personal protective equipment as described in Section 8. Use only in well-ventilated areas. Wash hands thoroughly after handling and before eating, drinking, or smoking. Keep containers tightly closed when not in use. Avoid contamination of the product with foreign materials. Do not reuse empty containers. Residual uncured resin may remain hazardous. Protect material from unintended exposure to sunlight, UV light, or other curing light sources.

Conditions for Safe Storage, Including Any Incompatibilities

Store in the original tightly closed container in a cool, dry, and well-ventilated place.

Recommended storage temperature: 4°C to 25°C (40°F to 75°F)

Protect from direct sunlight, UV/curing light sources, excessive heat, moisture, and sources of ignition. Do not freeze. Keep away from strong oxidizing agents, strong reducing agents, peroxides, amines, and polymerization initiators. Store upright to prevent leakage.

Specific End Use(s)

Light-curable dental resin intended for fabrication of 3D printed corrective oral appliances using validated CAD/CAM additive manufacturing systems. For professional dental laboratory or clinical use only.

Section 8. Exposure Controls / Personal Protection

Control Parameters

No specific occupational exposure limits have been established for this mixture as a whole. Where applicable, occupational exposure limits for individual components should be observed in accordance with local regulations. Use adequate ventilation during handling, printing, cleaning, finishing, or other operations that may generate vapors, aerosols, or dust. Local exhaust ventilation is recommended where airborne exposure may occur.

Exposure Controls

Appropriate Engineering Controls

Use in a well-ventilated area.

Provide local exhaust ventilation where vapors, mist, or airborne particulates may be generated.

Use enclosed or automated processing systems where practical.

Maintain eyewash stations and hand-washing facilities in work areas.

Individual Protection Measures (Personal Protective Equipment)

Eye / Face Protection

Wear safety glasses with side shields or chemical splash goggles where splashing or contact is possible. Face protection may be used for high-exposure operations.

Skin Protection

Hand Protection

Wear chemical-resistant protective gloves (e.g., nitrile gloves). Replace gloves if contaminated or damaged.

Body Protection

Wear suitable protective clothing, laboratory coat, or apron to prevent repeated or prolonged skin contact.

Respiratory Protection

Respiratory protection is not normally required under normal conditions of use with adequate ventilation. If ventilation is insufficient, or if vapors, aerosols, dust, or mist are generated, use approved respiratory protection in accordance with applicable regulations.



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RODIN FlexiSplint Resin**General Hygiene Measures**

Wash hands thoroughly after handling and before breaks, eating, drinking, or smoking.

Remove contaminated clothing and wash before reuse.

Avoid contact with skin, eyes, and clothing.

Do not eat, drink, or smoke while handling the product.

Environmental Exposure Controls

Avoid release to drains, soil, and waterways. Handle waste and residues in accordance with Section 13.

Section 9. Physical and Chemical Properties

Property	Value
Appearance	Pigmented liquid resin
Color	Various shades / intentionally pigmented
Odor	Mild fruity / ester-like odor
Odor Threshold	Not determined
Physical State	Liquid
pH	Not applicable (non-aqueous mixture)
Melting Point / Freezing Point	Not determined
Initial Boiling Point / Boiling Range	Not determined
Flash Point	93°C (>200°F) (PMCC)
Evaporation Rate	Not determined
Flammability	Not classified as flammable
Upper / Lower Explosive Limits	Not determined
Vapor Pressure	Not determined
Vapor Density	Not determined
Relative Density	Not determined
Density	Not determined
Solubility in Water	Practically insoluble / nearly insoluble
Partition Coefficient (n-octanol/water)	Not determined
Auto-Ignition Temperature	Not determined
Decomposition Temperature	Not determined
Viscosity	220-250 cP at 25°C (77°F) (Brookfield)
Explosive Properties	Not determined
Oxidizing Properties	Not determined
Other Information	
Specific Gravity	1.10-1.125 at 25°C (77°F)
VOC Content	Not determined
Polymerization Behavior	Polymerizes upon exposure to curing light

Section 10. Stability and Reactivity**Reactivity**

The product is stable under recommended conditions of storage and use. Uncured resin may undergo polymerization when exposed to heat, UV light, visible curing light, or contamination with reactive substances.

Chemical Stability

Stable when stored in the original sealed container under recommended storage conditions. Product contains polymerizable components that may gradually react if improperly stored or exposed to light, heat, or contamination.

Possibility of Hazardous Reactions

Hazardous polymerization may occur under certain conditions. Conditions that may initiate uncontrolled polymerization include:

Exposure to sunlight, UV light, or curing light sources

Elevated temperatures

Contamination with peroxides, amines, reducing agents, or other reactive materials

Inhibitor depletion over time

Bulk heating in closed containers

Runaway polymerization may generate heat and pressure and may rupture sealed containers.

Conditions to Avoid



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Heat
Direct sunlight
UV / curing light exposure
Sources of ignition
Contamination
Extended storage outside recommended temperature range
Incompatible Materials
Keep away from:
Strong oxidizing agents
Strong reducing agents
Organic peroxides
Amines
Polymerization initiators
Strong acids or bases where reactive incompatibility may occur
Hazardous Decomposition Products
Thermal decomposition or combustion may generate:
Carbon monoxide (CO)
Carbon dioxide (CO₂)
Nitrogen oxides (NO_x)
Irritating organic fumes
Acrid smoke

Section 11. Toxicological Information

Information on Hazard Classes as Defined in Applicable GHS Regulations

Acute Toxicity

Based on available data, the mixture is not classified for acute toxicity. Uncured material may be harmful if swallowed in significant quantities and may cause irritation of the mouth, throat, or gastrointestinal tract.

Skin Corrosion / Irritation

Not classified as corrosive. Prolonged or repeated skin contact may cause irritation, redness, or dryness.

Serious Eye Damage / Eye Irritation

Classified as Eye Irritation Category 2. Direct contact with uncured material may cause redness, tearing, pain, and discomfort.

Respiratory Sensitization

Not classified based on available data.

Skin Sensitization

Classified as Skin Sensitization Category 1. Repeated or prolonged exposure may cause allergic skin reaction in susceptible individuals.

Germ Cell Mutagenicity

Not classified based on available data.

Carcinogenicity

Not classified based on available data. The components of this product are not intentionally added at reportable concentrations as carcinogens listed by:

IARC (International Agency for Research on Cancer)

NTP (National Toxicology Program)

OSHA

Reproductive Toxicity

Not classified based on available data.

Specific Target Organ Toxicity - Single Exposure

May cause respiratory irritation if vapors, mist, or aerosols are generated during handling or processing.

Specific Target Organ Toxicity - Repeated Exposure

Not classified based on available data.

Aspiration Hazard

Not classified.

Information on Other Hazards

Likely Routes of Exposure

Skin contact

Eye contact

Inhalation of vapors, mist, or dust generated during processing

Accidental ingestion

Symptoms Related to Physical, Chemical and Toxicological Characteristics

Eye irritation

Skin redness or rash

Allergic skin reaction

Respiratory discomfort if airborne exposure occurs

Gastrointestinal discomfort if swallowed

Delayed and Immediate Effects

Repeated skin exposure may result in delayed sensitization.



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Section 12: Ecological Information

Toxicity

Harmful to aquatic life with long lasting effects. Uncured resin components may present toxicity to aquatic organisms. Avoid release to the environment.

Persistence and Degradability

No specific data are available for the mixture. Uncured polymerizable resin components are not expected to degrade rapidly under normal environmental conditions. Cured material is expected to be relatively inert.

Bioaccumulative Potential

No specific data are available for the mixture. Certain organic components may have some potential for bioaccumulation depending on environmental conditions.

Mobility in Soil

No specific data are available. Liquid uncured material may adsorb to soil or sediment surfaces and may exhibit limited mobility in water due to low water solubility.

Results of PBT and vPvB Assessment

Based on available information, this mixture does not contain components meeting criteria for PBT (Persistent, Bioaccumulative and Toxic) or vPvB (very Persistent and very Bioaccumulative) at reportable concentrations.

Endocrine Disrupting Properties

No components are known to be present at reportable concentrations that are identified as endocrine disruptors based on available data.

Other Adverse Effects

No additional adverse environmental effects are known. Prevent uncontrolled release of uncured product to drains, waterways, and soil. Refer to Section 13 for disposal considerations.

Section 13. Disposal Considerations

Waste Treatment Methods**Product Disposal**

Where practical, cure uncured resin prior to disposal to reduce hazard. Dispose of contents in accordance with applicable local, regional, national, and international regulations. Do not discharge uncured material into drains, surface water, or soil. Waste classification should be determined by the waste holder based on composition, contamination, and applicable regulations.

Contaminated Packaging

Containers and packaging may retain hazardous residues of uncured resin. Do not reuse empty containers. Dispose of contaminated packaging in accordance with applicable regulations. Where appropriate, containers may be drained and allowed to cure before disposal.

Cleaning Materials

Cleaning agents (e.g., alcohol used for rinsing) and contaminated absorbents should be collected and disposed of in accordance with applicable regulations. Do not discharge cleaning solutions into drains or the environment.

Additional Disposal Information

Follow all applicable regulatory requirements for hazardous waste handling and disposal in the region of use.

Section 14. Transport Information

UN Number or ID Number

Not applicable

UN Proper Shipping Name

Not applicable

Transport Hazard Class(es)

Not applicable

Packing Group

Not applicable

Environmental Hazards

Not classified as environmentally hazardous for transport.

Special Precautions for User

No special precautions required under normal conditions of transport. Transport in tightly closed containers. Avoid exposure to excessive heat, direct sunlight, and conditions that may initiate polymerization.

Maritime Transport in Bulk According to IMO Instruments

Not applicable

Additional Transport Information

This product is not regulated as dangerous goods under:

US DOT (Department of Transportation)

IATA (International Air Transport Association)

IMDG (International Maritime Dangerous Goods Code)

ADR/RID (European road/rail transport)



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Section 15. Regulatory Information

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

This Safety Data Sheet is prepared to support hazard communication under applicable requirements, including:

OSHA Hazard Communication Standard (29 CFR 1910.1200)

Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Regulation (EC) No 1907/2006 (REACH), as amended

Commission Regulation (EU) 2020/878 (SDS requirements)

Canada WHMIS / Hazardous Products Regulations

Australia Work Health and Safety (WHS) requirements

REACH Status

Applicable REACH obligations, including substance restrictions, authorization, and SVHC communication requirements, should be evaluated based on current supplier and substance information.

PBT and vPvB Assessment

Based on available information, this mixture does not contain substances meeting the criteria for PBT or vPvB at reportable concentrations.

Endocrine Disrupting Properties

No components are known to be present at reportable concentrations that are identified as endocrine disruptors based on available information.

Other Regulatory Information

This product is intended for professional dental use and should be handled in accordance with applicable occupational safety regulations.

Chemical Safety Assessment

A Chemical Safety Assessment has not been carried out for this mixture.

Section 16. Other Information

Abbreviations and Acronyms

GHS - Globally Harmonized System of Classification and Labelling of Chemicals

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

PBT - Persistent, Bioaccumulative and Toxic

vPvB - Very Persistent and Very Bioaccumulative

STOT - Specific Target Organ Toxicity

SCBA - Self-Contained Breathing Apparatus

Key Literature References and Sources for Data

Supplier Safety Data Sheets for raw materials

European Chemicals Agency (ECHA) database

OSHA Hazard Communication Standard (29 CFR 1910.1200)

Regulation (EC) No 1907/2006 (REACH)

Commission Regulation (EU) 2020/878

Classification Procedure

The classification of this mixture is based on:

Available data on individual components

Application of GHS classification criteria

Bridging principles and expert judgment

Relevant Hazard Statements (Full Text)

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

Training Advice

Users should be trained in:

Safe handling of light-curable resin materials

Use of appropriate personal protective equipment

Prevention of skin contact and inhalation exposure

Proper waste handling and disposal practices

Use only as directed for professional dental or laboratory applications.

Disclaimer

The information provided in this Safety Data Sheet is based on current knowledge and is intended to describe the product for the purposes of health, safety, and environmental requirements only. It should not be construed as guaranteeing any specific property of the product. The user is responsible for ensuring compliance with all applicable laws and regulations