BIOGENERAL

Regulatory Compliance Statement

We would like to inform you that we do not produce the resin used for your design and/or specification. The resin is selected solely by you, the Customer, based on your design and/or specification requirements. We encourage you to review the resin Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) to determine the suitability for your application.

Biogeneral, Inc. obtains the resin from upstream suppliers, and does not conduct additional testing. We **do not intentionally add chemical substances listed below** to any of our manufacturing processes.

Conflict Minerals
Biogeneral, Inc. does not intentionally add any conflict minerals during the manufacturing of our products. Any conflict mineral would be naturally occurring trace amounts.

CPSIA
Biogeneral, Inc. does not intentionally add heavy metals or phthalates to our manufacturing process. Since we do not expect these substances to be present, routine analysis is not performed on our purchased resin to analyze for them.

Latex-Free
Biogeneral, Inc. does not intentionally add any latex or natural rubber latex additives to its products.

Prop 65
Biogeneral, Inc. does not intentionally add substances of concern, as outlined in California Proposition 65, to its products. While Biogeneral, Inc. does not routinely test for the presence of substances of concern, we do seek information regarding resin compositions from our suppliers and can provide the Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) for your review.

REACH (25 June 2025)
Biogeneral, Inc. does not intentionally add chemicals on the REACH SVHC Candidate List to our product or use them in our manufacturing process.

European Union Directive 2011/65/EU (RoHS 2) and 2015/863/EU (RoHS 3)
Reportable substances have not been intentionally added to our products by Biogeneral, Inc. Biogeneral, Inc. does not specifically analyze the product for these substances. While we do not test the resin we purchase, we do exercise good product stewardship and seek information regarding resin composition from our suppliers and can provide the Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) for your review.

Regulation (EU) 2017/745 of the European Parliament and of the Council (05 April 2017)
Biogeneral, Inc. does not intentionally add substances of concern, as outlined in EU 2014/745, to its products. While Biogeneral, Inc. does not routinely test for the presence of substances of concern, we do seek information regarding resin compositions from our suppliers and can provide the Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) for your review.

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Dodd-Frank Wall Street Reform Act, Section 1502
Substances on the Toxic in Packaging Clearinghouse list of heavy metals have not been intentionally added to our products by Biogeneral, Inc. While we do not test the resin we purchase, we do exercise good product stewardship and seek information regarding resin composition from our suppliers and can provide the Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) for your review.

TSE/BSE
Biogeneral, Inc. does not manufacture, formulate, or process its product with any Animal-Derived Ingredients.

EU MDR Compliance
Biogeneral does not manufacture medical devices and are not required to meet the EU MDR requirements. Customers can reference the provided the Safety Data Sheet (SDS) or reference the CAS Registry Number® (CAS RN®) for the resin selected in their specification to determine suitability for use in their application.

We believe this information to be correct, but it is subject to revision as substance regulation and threshold levels evolve. We trust this information proves satisfactory. Please understand that we cannot complete any customer forms for legal reasons. Biogeneral, Inc. is solely responsible for extruding resin to our Customer's design and/or specification. As the resin Biogeneral uses is solely selected by the Customer for their design and/or specification, it is the Customer's responsibility to ascertain the suitability for their application through additional analysis or testing.

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