



21 August 2018

**Re: BVI Information on California Proposition 65**

Dear customer:

Beaver-Visitec International, Inc. (BVI) strives to provide high quality, safe products for all of our customers. We are dedicated to working with our customers to meet product safety requirements applicable to our medical devices, including California Proposition 65 standards. This letter is to inform our customers that products manufactured by Beaver-Visitec International (BVI) may contain chemicals which are listed on California's *Safe Drinking Water & Toxic Enforcement Act of 1986*.

According to California EPA's Office of Environmental Health Hazard Assessment (OEHHA): The California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65) requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list contains over 900 chemicals, including a wide range of naturally occurring and synthetic chemicals that are known to cause cancer or birth defects or other reproductive harm, additives or ingredients in pesticides, common household products, food, drugs, dyes, or solvents, chemicals used in manufacturing and construction, and by-products of chemical processes (e.g. motor vehicle exhaust). Businesses that are subject to Proposition 65 must provide a "clear and reasonable" warning before knowingly and intentionally exposing anyone to a listed chemical. This warning can be given by a variety of means, such as by labeling a product.

To further assist businesses, OEHHA develops numerical guidance levels, known as "safe harbor numbers" for determining whether a warning is necessary. However, a business may choose to provide a warning simply based on its knowledge, or assumption, about the presence of a listed chemical without attempting to evaluate the levels of exposure. At BVI we opted to evaluate the exposure and concluded if BVI's products exceed or not exceed the "no significant risk level". BVI has evaluated for the presence of chemicals weight (parts per million (PPM)) present in the chemicals, packaging and the finished product to determine if BVI is-at or lower-than the proposed safe harbor numbers.

Conclusion: Products marketed or sold by BVI may contain listed chemicals at levels that are below the Proposition 65 level of concern, or at a higher level as proposed by proposition 65 level of concern. However, since exposure per day is the most critical aspect of the proposition 65 requirements, and since our chemicals solidify and cure immediately after they are applied during the manufacturing process, we have determined that the warning label notification is not required based on the following reasons:

- Ophthalmic procedures conducted with our products typically last less than <15 minutes ( $\mu\text{g}/\text{day}$ ).
- Chemicals and adhesives are curing during the manufacturing process therefore does not present a health hazard to the user and/or patient as they do not emit any vapor, are not breathable, inhalable or consumed orally.
- BVI products are made of biocompatible materials.

If you have any additional questions, please contact BVI at the number listed below.

A handwritten signature in dark ink, appearing to read "Regina Shih", is written over a light-colored background.

Regina Shih

Vice President, Global of Quality Assurance and Regulatory Affairs

<https://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language>