

PROPOSITION 65 STATEMENT AND FREQUENTLY ASKED QUESTIONS

California's Safe Drinking Water and Toxic Enforcement Act of 1986 (commonly referred to as "Proposition 65") is a right-to-know statute that requires everyone in the state's chain of commerce to ensure that California consumers receive warnings prior to being exposed to certain chemicals contained in consumer products. Proposition 65 specifically requires that "No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving a clear and reasonable warning." Over the last 30 years, manufacturers, distributors, and retailers of consumer products sold in California provided some variation of the Proposition 65 "safe harbor" warnings, i.e., warning language automatically deemed to meet the clear and reasonable standard set by the state. For example, you may have previously seen the following safe harbor warnings on DeRoyal products as well as products sold by other medical device companies:

- **WARNING:** This product contains a chemical known to the state of California to cause cancer.
- **WARNING:** This product contains a chemical known to the state of California to cause birth defects or other reproductive harm.

However, effective August 31, 2018, the state of California has adopted new Proposition 65 regulations that change the content and format requirements of safe harbor warnings. These new safe harbor warnings require warning symbols, a reference to the Proposition 65 website, and content based on the types of listed chemicals, the number of listed chemicals, and the method of transmission. The new regulations further specify different safe harbor warnings for products that contain only carcinogens, only reproductive toxicants, both listed carcinogens and listed reproductive toxicants, or a listed chemical that is both a carcinogen and reproductive toxicant. Finally, the regulations allow the safe harbor warning to be provided in either long or short format. An example of the new long and short warning format is as follows:

Long Form:



WARNING: This product can expose you to chemicals including [name of one or more chemicals], which is [are] known to the state of California to cause cancer and birth defects or other reproductive harm. For more information go to www.P65Warnings.ca.gov.

Short Form:



WARNING: Cancer and Reproductive Harm - www.P65Warnings.ca.gov.

FREQUENTLY ASKED QUESTIONS

What is the purpose of this Proposition 65 Statement?

The purpose of this statement is to inform customers that DeRoyal will change applicable product labels and product marketing information to implement the revised Proposition 65 safe harbor warning requirements starting August 31, 2018.

Does this warning mean that DeRoyal products are unsafe?

No. A Proposition 65 warning enforces the California consumer's right to know that he or she is being exposed to carcinogens or reproductive toxins that exceed certain minimum threshold levels. This is not the same as a state or federal regulatory decision that a product is "safe" or "unsafe." Further, as a medical device manufacturer, DeRoyal complies with U.S. Food and Drug Administration regulations governing the marketing and sale of medical devices.

When are warnings included on DeRoyal product labeling or marketing information?

A warning is included if there is no minimum threshold level for a listed chemical or if it cannot be demonstrated that exposure to a listed chemical falls below the minimum threshold levels specified in Proposition 65 and its accompanying regulations.

Why are warnings included on DeRoyal products sold outside of California?

DeRoyal sells products globally through direct purchases and distribution networks and markets products globally through printed materials and online content. As such, it may not be known at the time of initial purchase from DeRoyal whether a product will ultimately be sold or used in California or whether a person accessing marketing content is located in California. Therefore, in order to ensure compliance, DeRoyal has decided to apply Proposition 65 warnings on all products and product information that require such warning in California even if California is not the final shipping destination for the product or if a consumer accessing marketing content is not located in California.

Where can I get more information?

For more information, please visit the Proposition 65 website at the following:

https://oehha.ca.gov/media/downloads/proposition-65/general-info/p65plain_1.pdf.

