

## INITIAL STATEMENT OF REASONS

### TITLE 22, CALIFORNIA CODE OF REGULATIONS

#### SECTION 12705(b). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

The Safe Drinking Water and Toxic Enforcement Act of 1986, codified at Health and Safety Code, section 25249.5 *et seq.* and commonly known as Proposition 65 (hereafter Proposition 65 or the Act), prohibits a person in the course of doing business from knowingly and intentionally exposing any individual to a chemical that has been listed as known to the State to cause cancer or reproductive toxicity, without first giving clear and reasonable warning to such individual (Health and Safety Code, section 25249.6). The Act also prohibits a business from knowingly discharging a listed chemical into water or onto or into land where such chemical passes or probably will pass into a source of drinking water (Health and Safety Code, section 25249.5).

For chemicals known to the State to cause cancer, an exemption from the warning requirement and the discharge prohibition is provided by the Act when a person in the course of doing business is able to demonstrate that an exposure for which he or she is responsible poses no significant risk, or that a discharge to drinking water which otherwise complies with applicable requirements would result in an exposure through drinking water at a level which poses no significant risk (Health and Safety Code, sections 25249.9 and 25249.10). A determination that a level of exposure poses no significant risk of cancer may be made by referencing Title 22, Cal. Code of Regs., sections 12701 to 12721.<sup>1</sup> Section 12701 describes alternative methods for making a determination that a given exposure poses no significant risk. One such method is through the application of a specific regulatory level established for the chemical in question, if one has been established in section 12705. The levels set in section 12705(b) supersede the levels established in section 12709 (Exposure to Trace Elements) and section 12711 (Levels Based on State or Federal Standards).

This proposed regulation sets forth a No Significant Risk Level (NSRL) for adoption into section 12705(b) that was developed by Office of Environmental Health Hazard Assessment (OEHHA) using scientific methods consistent with procedures outlined in section 12703. Details on the basis for the proposed NSRL are provided in the reference cited below, which is incorporated herein as if fully set forth. The reference is a risk assessment document prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

The proposed level described below for inclusion in section 12705 represents the level of exposure to the chemical which is calculated to result in no more than one excess case of cancer in an exposed population of 100,000, assuming exposure over a 70-year lifetime ( $10^{-5}$  lifetime risk of cancer), and is based on the OEHHA (2008) risk assessment document prepared by the Reproductive and Cancer Hazard Assessment Branch, in accordance with the principles in section 12703.

This proposed regulation would add the following NSRL into section 12705(b) for a chemical known to cause cancer according to methods outlined in section 12703:

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<sup>1</sup> All further references are to Title 22 of the California Code of Regulations, unless otherwise indicated.

Chemical	NSRL, in units micrograms per day	Reference
C.I. Direct Blue 218	50	OEHHA (2008)

**REASONABLE ALTERNATIVES TO THE REGULATION AND THE AGENCY'S REASONS FOR REJECTING THOSE ALTERNATIVES**

OEHHA is not aware of any alternatives to the proposed regulatory action.

**REASONABLE ALTERNATIVES TO THE PROPOSED REGULATORY ACTION THAT WOULD LESSEN ANY ADVERSE IMPACT ON SMALL BUSINESSES**

The proposed regulatory action will not adversely impact small business. The proposed regulation identifies levels below which businesses are exempt from Proposition 65 warning requirements and the discharge prohibition. It does not impose any requirement upon any business, including small business.

**EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT ADVERSE ECONOMIC IMPACT ON BUSINESS**

The regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The regulation identifies levels below which businesses are exempt from Proposition 65 warning requirements and the discharge prohibition. No costs or expenses are incurred by businesses to comply with the proposed regulation. There is no significant adverse economic impact on any business. In fact, the proposed regulatory action makes it easier for affected businesses to comply with Proposition 65 by helping them determine when the warning and discharge requirements may apply.

**DUPLICATION OR CONFLICTS WITH FEDERAL REGULATIONS CONTAINED IN THE CODE OF FEDERAL REGULATIONS**

Proposition 65 is a California law that has no federal counterpart. There are no federal regulations addressing the same issues and, thus, there is no duplication or conflict with federal regulations.

**REFERENCE**

Office of Environmental Health Hazard Assessment (OEHHA, 2008). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen C.I. Direct Blue 218. OEHHA, Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Oakland, March 2008.