INITIAL STATEMENT OF REASONS

TITLE 27, CALIFORNIA CODE OF REGULATIONS SECTION 25705(b).

SECTION 25705(b). SPECIFIC REGULATORY LEVELS POSING NO SIGNIFICANT RISK

PURPOSE OF PROPOSED REGULATION

This proposed regulation sets forth the no significant risk level (NSRL) for a chemical listed under Proposition 65[1] that will be adopted into Title 27, California Code of Regulations, section 25705(b)[2]. This NSRL was derived using scientific methods outlined in Section 25703.

Details on the basis for this proposed level are provided in the document cited below, which is available on the Office of Environmental Health Hazard Assessment (OEHHA) website at www.oehha.ca.gov and is included in the rulemaking record. The cited document is a risk assessment prepared by OEHHA describing and summarizing the derivation of the regulatory level listed below.

The proposed regulation would adopt into Section 25705(b) the following regulatory level for one chemical known to cause cancer:

Chemical	NSRL, in units micrograms per day (**μg/day)**	Reference
Chlorothalonil	27	OEHHA (2011)

Levels established for carcinogens in Section 25705(b) supersede any existing levels for these carcinogens in Section 25705 (c) and Section 25705 (d). A specific regulatory level currently exists for chlorothalonil in Section 25705(d). In order to minimize potential confusion, this proposed rulemaking action seeks to add the new level for chlorothalonil in Section 25705(b), while simultaneously deleting the level for chlorothalonil from Section 25705(d).

BACKGROUND

Proposition 65 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[3]. The Act also prohibits a business from knowingly

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, Codified at Health and Safety Code section 25249.5 et seq., commonly referred to as Proposition 65.
[2] All further references are to sections of Title 27 of the California Code of Regulations.
[3] Health and Safety Code, section 25249.6

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[4].

The Act provides an exemption from the warning requirement if a person in the course of doing business is able to demonstrate that an exposure for which the person is responsible poses no significant risk of cancer[5]. The Act also provides an exemption from the prohibition against discharging a listed chemical into sources of drinking water if the amount discharged does not constitute a "significant amount", as defined, and the discharge is in conformity with all other laws and regulatory requirements[6]. Section 25701 describes alternative methods for making a determination that a given exposure poses no significant risk. One such method is the application of a specific regulatory level for the chemical in question established in section 25705(b). The levels set in section 25705(b) supersede the levels established in section 25709 (Exposure to Trace Elements) and section 25711 (Levels Based on State or Federal Standards).

Regulations previously adopted by OEHHA provide guidance for determining whether an exposure to, or a discharge of, a chemical known to cause cancer meets the statutory exemption[7]. These regulations provide three ways by which a person in the course of doing business may make such a determination:

1. By conducting a risk assessment in accordance with the principles described in Section 25703 to derive a NSRL, which is defined as 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); or
2. By application of the specific regulatory level adopted for the chemical in Section 25705; or
3. In the absence of such a level, by using a risk assessment conducted by a state or federal agency, provided that such assessment substantially complies with Section 25703(a).

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

OEHHA is not aware of any reasonable 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

[4] Health and Safety Code, section 25249.5
[5] Health and Safety Code, sections 25249.10 and 25249.11
[6] Health and Safety Code, sections 25249.9 and 25249.11
[7] Title 27, California Code of Regulations, sections 25701-25721

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, 2011). No Significant Risk Level (NSRL) for the Proposition 65 Carcinogen Chlorothalonil. OEHHA, Reproductive and Cancer Hazard Assessment Branch, California Environmental Protection Agency, Oakland, March 2011.