

## California Lists 4-Methylimidazole as a Proposition 65 Carcinogen

On January 7, 2011, OEHHA added to the Proposition 65 list of carcinogens 4-Methylimidazole, which is used in the manufacture of pharmaceuticals, photographic chemicals, dyes and pigments, cleaning and agricultural chemicals, rubber, and in certain food products including caramel coloring, soy sauce, Worcestershire sauce, wine, and ammoniated molasses. Proposition 65, California's "Safe Drinking Water and Toxic Enforcement Act of 1986," requires the state, through the Office of Environmental Health Hazard Assessment (OEHHA), to keep a list of chemicals known to cause cancer or reproductive harm or birth defects. The list now identifies more than 800 chemicals and includes many common chemicals found in pesticides, household and industrial cleaning products, household goods, drugs, foods, and things such as tobacco smoke and wood dust.

If a product contains a chemical on the Proposition 65 list, all businesses with ten or more employees are required to provide a "clear and reasonable warning" before exposing Californians to that product. The warning requirement, which applies to manufacturers and retailers alike, becomes effective one year after the chemical is placed on the Proposition 65 list. This means that unless the listing of 4-Methylimidazole by OEHHA can be successfully challenged in the courts or a business can establish an exemption to the warning requirement, all products containing 4-Methylimidazole will be required to carry Proposition 65 compliant warning no later than January 7, 2012.<sup>1</sup>

### For More Information:

To learn more about [Orrick's Proposition 65 practice](#), please visit our website.

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<sup>1</sup> The list of the 800-plus Proposition 65 chemicals can be found on the OEHHA website at: [http://www.oehha.ca.gov/prop65/prop65\\_list/Newlist.html](http://www.oehha.ca.gov/prop65/prop65_list/Newlist.html).

The Proposition 65 listing for 4-Methylimidazole can be found on the OEHHA website at: [http://www.oehha.org/prop65/prop65\\_list/010711list.html](http://www.oehha.org/prop65/prop65_list/010711list.html).

Information on how Proposition 65 is enforced can be found on the State of California Attorney General's website at: <http://ag.ca.gov/prop65/index.php>.

Background information on Proposition 65 can be found on the OEHHA website at: <http://www.oehha.ca.gov/prop65.html>.

The regulations for Proposition 65 warnings can be found on the OEHHA website at: [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/RegsArt6.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/RegsArt6.pdf).

## Proposition 65 Compliance

In order for a warning to be Proposition 65 compliant, the following considerations must be satisfied:

- The Warning Must Be “Clear.” The text of the warning must communicate that the chemical is known to cause cancer, or reproductive harm. The regulation provides the following safe-harbor “clear” warning language for a carcinogen:
  - WARNING: This product contains a chemical known to the state of California to cause cancer, or birth defects or other reproductive harm.
- The Warning Must Be “Reasonable.” The warning must be conspicuous enough that a consumer would probably see it before the exposure. If it appears on a label with other warnings, it must be no smaller than the other warnings. The other language should not contradict the warning language. Further, any language included in the warning, elsewhere on the warning label and/or elsewhere on the product that somehow softens the warning will likely be determined to fall outside the safe harbor.

## Proposition 65 Exemptions

A business has “safe harbor” from Proposition 65 warning requirements if exposure to a chemical occurs at or below the no significant risk level NSRL.<sup>2</sup> The NSRL is defined as the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime. In other words, a person exposed to the chemical at the “no significant risk level” for 70 years would not have more than a “one in 100,000” chance of developing cancer as a result of that exposure. OEHHA has proposed an NSRL for 4-Methylimidazole of 16 micrograms per day.<sup>3</sup> Although OEHHA has proposed the NSRL, it is unlikely that OEHHA will adopt an NSRL for 4-Methylimidazole within the next year.

As a practical matter, even if an NSRL is established for 4-Methylimidazole, it may be difficult for a business to establish that the 4-Methylimidazole in its product falls within the NSRL. Proposition 65 compliance is based on how much of a substance the average person is exposed to, not on how much is in the product. For exposures to consumer products, lifetime exposure must be calculated using the average rate of intake or exposure for average users of the consumer product, and not on a per capita basis for the general population. The average rate of intake or exposure must be based on data for use on a general category or categories of consumer products, such as the United States Department of Agriculture Home Economic Research Report, Foods Commonly Eaten by Individuals: Amount Per Day and Per Eating Occasion.

## Proposition 65 Remedies and Enforcement

The primary remedies available under Proposition 65 are injunctions and civil and criminal penalties of up to \$2500 per violation per day. Proposition 65 is enforced through litigation brought either by “public enforcers” (including the California Attorney General and certain district attorneys) or by “citizen enforcers” (organizations or private Californian citizens). Most Proposition 65 actions are filed by citizen enforcers.

Since 1986, few Proposition 65 cases have been fully litigated through trial. Of note, it was an Orrick, Herrington & Sutcliffe attorney who recorded the first trial win in a Proposition 65 case against the California Attorney General. The vast majority of the cases have been settled out of court or resolved through consent judgments. Citizen enforcers collect millions of dollars in settlements from manufacturers and retailers every year. Not surprisingly, the number of Proposition 65 cases filed each year continues to increase. In 2010, there were more than 700 notices of violation served; this year there have already been more than 100 notices served. The majority of the notices have been directed to businesses manufacturing or selling household goods, accessories, personal care products and foods and nutritional supplements.

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<sup>2</sup> The determination of an NSRL by OEHHA does not preclude a business from presenting scientific evidence to establish that a level of exposure to a listed chemical poses no significant risk.

<sup>3</sup> OEHHA is accepting public comments concerning the proposed NSRL for 4-Methylimidazole until the close of business on February 21, 2011.

Orrick attorneys have been representing clients in Proposition 65 litigation and other Proposition 65 related matters for over 20 years. For more information about [Orrick's Proposition 65 practice](#), please visit our website.