The California Environmental Protection Agency’s Office of Environmental Health Hazard Assessment (OEHHA) intends to change the basis for the listing of carbaryl as known to the state to cause reproductive toxicity under the Safe Drinking Water and Toxic Enforcement Act of 1986¹.

Carbaryl was originally added to the Proposition 65 list as causing reproductive toxicity on August 7, 2009, pursuant to Labor Code Section 6382(d), which is incorporated by reference in Health and Safety Code Section 25249.8(a). Carbaryl was listed based on its identification as causing male reproductive and developmental toxicity in the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs). The TLVs were previously incorporated by reference into the federal Occupational Health and Safety Administration (OSHA) Hazard Communication Standards (Title 29, Code of Federal Regulations [C.F.R.] section 1900.1200), which is incorporated by reference into Labor Code Section 6382(d).

OEHHA is initiating this action based on changes to federal regulations that affect the basis for the original listing. Specifically, in March 2012, OSHA extensively amended the regulations contained in Title 29, C.F.R. section 1910.1200. Title 29, C.F.R. 1910.1200 (d)(3)(ii), which specifically referred to the ACGIH TLV list, was deleted in the 2012 version of the regulation. OEHHA has determined that these changes have eliminated the ACGIH TLVs as a definitive source for identifying chemicals that are known to cause reproductive toxicity.

However, OEHHA has determined that carbaryl meets the criteria for listing via the “authoritative bodies” listing mechanism² and is providing this notice of its intent to change the basis for listing the chemical based on identification of male and female reproductive and developmental endpoints. Carbaryl will not be removed from the Proposition 65 list as causing reproductive toxicity during this process.

¹ Commonly known as Proposition 65, the Safe Drinking Water and Toxic Enforcement Act of 1986 is codified in Health and Safety Code section 25249.5 et seq.
² See Health and Safety Code section 25249.8(b) and Title 27, California Code of Regulations, section 25306. All further references are to sections of Title 27 of the California Code of Regulations, unless indicated otherwise.
<table>
<thead>
<tr>
<th>Chemical</th>
<th>CAS No.</th>
<th>Reproductive Toxicity Endpoints</th>
<th>Reference</th>
<th>Chemical Uses</th>
</tr>
</thead>
</table>

**Background on listing via the authoritative bodies mechanism**: A chemical must be listed under Proposition 65 and its implementing regulations (Section 26306) when two conditions are met:

1. An authoritative body formally identifies the chemical as causing reproductive toxicity (Section 25306(d)(1)).
2. The evidence considered by the authoritative body meets the sufficiency criteria contained in the regulations (Section 25306(g)).

However, the chemical is not listed if scientifically valid data that were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met (Section 25306(h)).

The National Institute for Occupational Safety and Health (NIOSH) is one of several institutions designated as an authoritative body for the identification of chemicals as causing reproductive toxicity (Section 25306(l)).

OEHHA is the lead agency for implementation of Proposition 65. After an authoritative body has made a determination that a chemical causes cancer or reproductive toxicity, OEHHA evaluates whether listing under Proposition 65 is required using the criteria contained in the regulations.

**OEHHA’s determination**: Carbaryl meets the criteria for listing as known to the State to cause reproductive toxicity under Proposition 65, based on findings of NIOSH (NIOSH, 1976), as outlined below.

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Formal identification and sufficiency of evidence: OEHHA is relying on NIOSH’s conclusions that carbaryl causes developmental and male and female reproductive effects. These conclusions meet the formal identification requirement of Section 26306(d)(1)\textsuperscript{4} and are made in the following document:

\textit{NIOSH Criteria for a Recommended Standard: Occupational Exposure to Carbaryl} (NIOSH, 1976)

The NIOSH document states that:

“From the above studies [72, 73, 77, 78] it may be concluded that oral administration of carbaryl to rodents has an effect on several aspects of their reproduction.” (page 94, NIOSH, 1976)

The effects identified in those studies include:

- Developmental toxicity
  - decreased litter size (rats and gerbils)
  - reduced pup survival (rats and gerbils)
- Male reproductive toxicity
  - decreased spermatogenesis (rats)
  - decreased sperm motility (rats)
  - decreased fertility (rats)
  - histopathology of spermiogenic epithelium (rats)
- Female reproductive toxicity
  - decreased duration of estrus (rats)
  - decreased fertility (rats)
  - lengthened gestation periods (rats)
  - histopathology of ovarian follicles (rats)

This report meets the formal identification criterion in Section 26306(d)(2)(C)\textsuperscript{5}. OEHHA has reviewed the study reports identified by NIOSH (1976) as providing the basis for NIOSH’s conclusions regarding the male reproductive, female reproductive and developmental toxicity of carbaryl, relative to the criteria in Section 25306(g). The criteria for listing carbaryl as known to cause reproductive toxicity by the authoritative bodies mechanism have been met. Therefore, OEHHA has determined that carbaryl must stay on the Proposition 65 list.

Request for comments: OEHHA is requesting comments as to whether this chemical meets the criteria set forth in the Proposition 65 regulations for listings via the authoritative bodies mechanism (Section 25306), and should, therefore, remain on the list of chemicals known to the state to cause reproductive toxicity, with the additional endpoint of female reproductive toxicity.

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\textsuperscript{4} “the chemical…is the subject of a report which is published by the authoritative body and which concludes that the chemical causes...reproductive toxicity”

\textsuperscript{5} “[the document is] Published by the authoritative body in a publication such as, but not limited to, the federal register…”
In order to be considered, comments must be received by **OEHHA by 5:00 p.m. on Monday, December 9, 2013.** We encourage you to submit comments in electronic form, rather than in paper form. Comments transmitted by e-mail should be addressed to **P65Public.comments@oehha.ca.gov.** Please include “carbaryl” in the subject line. Comments submitted in paper form may be mailed, faxed, or delivered in person to the address below.

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P.O. Box 4010, MS-19B  
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1001 I Street  
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Comments received during the public comment period will be posted on the OEHHA web site after the close of the comment period. If you have any questions, please contact Ms. Oshita at **cynthia.oshita@oehha.ca.gov** or at (916) 445-6900.

**References**