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**To:** [P65Public Comments](#)  
**Cc:** [fcook@oldworldind.com](mailto:fcook@oldworldind.com)  
**Subject:** Comment on OEHHA Notice of Intent to List Ethylene Glycol  
**Date:** Wednesday, June 25, 2014 11:26:19 AM

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Dear OEHHA Assessment Team:

Old World Industries, LLC("Old World") is a leading marketer and distributor of antifreeze/coolant products in the US, products which of course contain ethylene glycol. Old World manufactures and sells to retailers, distributors and other third parties over 150 brands of antifreeze that are sold in the State of California.

As the manufacturer and distributor of antifreeze products ultimately sold in the State of California, Old World opposes the listing of Ethylene Glycol under Proposition 64 regulations for several reasons.

Old World submits the conclusions in the report relied upon by OWHHA, the NTP-CERHR (2004), (hereinafter the "Report") do not support the statement made by OWHHA that "an authoritative body formally identifies the chemical (Ethylene Glycol) as causing reproductive toxicity." Rather the Report clearly makes the following statements establishing quite the opposite:

*"No human reproductive toxicity data were identified." P. II-106*

*"There are no reproductive toxicity data in humans exposed to ethylene glycol" P. II-112*

*"Histopathological results in a reproductive toxicity screen (128) support the conclusion that ethylene glycol produces no major reproductive toxicity effects in males...Reproductive organ histopathology examined in subchronic and chronic toxicity studies (described in Section 2.2.2.1 and 2.4.2) found no treatment-related histopathology of reproductive organs including ovary, uterus, prostate, testis, seminal vesicles, or epididymis (34, 91) ...The Expert Panel concluded that data in mice are sufficient to demonstrate no effect on fertility of male or female mice following oral exposure of up to 2,826 mg/kg bw/day ethylene glycol for approximately 22 weeks." P. II-114*

*"There were no data identified that permit the evaluation of developmental toxicity in humans...There were insufficient data to determine whether ethylene glycol causes developmental toxicity by inhalation exposure in mice and rats. P. II-116*

Based upon the study data, the Expert Panel concluded in the Report as follows with respect to reproductive toxicity:

#### **"5.1.2 Reproductive Toxicity**

*There were no data identified that permit the evaluation of reproductive toxicity in humans. Ethylene glycol was tested for reproductive toxicity in rats and mice. There are sufficient data to conclude that ethylene glycol is not a reproductive toxicant in rats exposed orally to 1,000 mg/kg bw/day via diet. The study in mice was essentially negative at doses up to 2,826 mg/kg bw/day via drinking water. The studies available for review included a continuous breeding study in mice, a two-generation study in rats, and sub-chronic toxicity studies in rats.*

*The Expert Panel concluded that data in mice are sufficient to demonstrate no effect on fertility of male or female mice following oral exposure to up to 2,826 mg/kg bw/day ethylene glycol for approximately 22 weeks.*

*The Expert Panel concluded that the data are sufficient to demonstrate that ethylene glycol is not a*

*reproductive toxicant in male and female rats following dietary exposure with up to 1,000 mg/kg bw/day for 7 weeks prior to mating in parental rats or from the time of conception through mating in their offspring.*

*The Expert Panel is confident that these data are useful in judging hazard to humans because the doses tested far exceeded the doses relevant to humans based on knowledge of absorption, distribution, metabolism, and excretion in rats, mice, and humans. It was further noted that the pattern of general toxicity is similar in experimental animal studies and instances of human poisoning."*

P. II-118

The Expert Panel included the following statements in their Overall Conclusion:

### **"5.3 Overall Conclusions**

*The Expert Panel judges the likelihood of adverse developmental toxicity in the humans from such levels of exposure to be of negligible concern.*

*The Panel concludes that the lack of reproductive toxicity in experimental animal studies indicates there is negligible concern for reproductive effects in humans."*

P. II-119

Based upon the above findings and conclusions of the Report, Old World respectfully submits that statutory conditions of Section 25306(d), Title 27 Cal. Code of Regs. have not been satisfied by the Report data. As a result it would be unwarranted for ethylene glycol to be listed as a Proposition 65 chemical.

In addition, Old World would note that the safety of the public in the State of California is already well protected with respect to antifreeze products containing ethylene glycol under other state and federal regulations applicable to antifreeze/coolant products, including The Federal Hazardous Substances Act, Poison Prevention Packaging Act, Consumer Product Safety Standards and Fair Packaging & Labeling Act. As a result of these statutes and regulations and others, the typical label of a gallon of antifreeze sold in the State of California bears ample warning, guidance and first aid advice language to protect, inform and aid the consumer:

Moreover, more than half of the states in the US have established laws requiring that antifreeze/coolant products sold at the consumer level be embittered to avoid accidental consumption by humans or animals. The State of California has such an embittering requirement per CA Bus & Prof Code section 17582. These state embittering statutes afford consumers yet additional protections since all antifreeze/coolant products will operate to eliminate accidental ingestion of the product.

Finally, beginning in June 1, 2015, antifreeze/coolant product labeling will need to be compliant with OSHA regulations that will require that products containing hazardous chemicals (such as ethylene in antifreeze/coolant) be labeled in accordance with the Globally Harmonized System of Classification and Labeling.

Old World submits the myriad of federal, state (including California) and local laws and regulations sufficiently operate to protect the consumer from risks associated with the existence of ethylene glycol in antifreeze/coolant products. Since the Report does not scientifically support the conclusion reached by OEHHA regarding the risk of ethylene to human reproductivity, Old World respectfully submits that Ethylene Glycol not be added to the list of Proposition 65 chemicals. It is neither warranted under applicable law nor necessary to protect the consumer given existing laws and regulations.

Respectfully,

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