Office of Environmental Health Hazard Assessment

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Agency Secretary

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Arnold Schwarzenegger Governor

MEMORANDUM

TO: Gary T. Patterson, Ph.D., Chief

Medical Toxicology Branch

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FROM: Anna M. Fan, Ph.D., Chief

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DATE: December 19, 2003

SUBJECT: COMMENTS ON THE DEPARTMENT OF PESTICIDE REGULATION'S

DRAFT RISK CHARACTERIZATION DOCUMENT FOR THE ACTIVE

INGREDIENT HYDRAMETHYLNON

We have completed our review of the draft risk characterization document (RCD) for tetrahydro-5,5-dimethyl-2 (1H)-pyrimidinone {3[4-(trifluoromethyl) phenyl]-1-[2-(4-trifluoromethyl) phenyl] ethenyl]-2-propenylidene} hydrazone (hydramethylnon) prepared by the Department of Pesticide Regulation (DPR).

Hydramethylnon{tetrahydro-5,5-dimethyl-2 (1H)-pyrimidinone {3[4-(trifluoromethyl) phenyl]-1-[2-(4-trifluoromethyl) phenyl] ethenyl]-2-propenylidene} is an insecticide used to control ants (including imported fire ants and leafcutter ants), cockroaches and termites. Hydramethylnon is used on a single food crop (pineapple), on feed (rangeland grasses, and hay) and also has non-food uses (lawns, turfs, golf courses, non-bearing nursery stocks, right-of-ways, houses and other structures). The use of hydramethylnon on pasture and rangeland grass is not permitted in California. Hydramethylnon was first registered with the U.S. EPA in 1980. It belongs to a chemical class of chemicals known as the trifluoromethyl amidinohydrazones. It is listed as a reproductive and developmental toxicant under Proposition 65.

Overall, we support the procedures and approaches used for characterizing the health risk of hydramethylnon in the draft RCD for this chemical. We especially acknowledge efforts made to substantiate the choices of critical studies, discussions of issues that might be raised by reviewers, identification of numerous uncertainties pertinent to risk estimates, and comparison of

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risk estimates with those estimated by the U.S. EPA. While the current version of the draft RCD is quite thorough, it would benefit from clarifying certain issues and expanding the information provided.

A summary of our comments on the draft RCD for methyl hydramethylnon is found below. For more details please refer to the attachment.

- 1. While OEHHA supports DPR's choices of critical studies, toxicological endpoints and NOAELS used in the RCD for hydramethylnon, we note that seasonal (subchronic oral) exposures are not evaluated in the document. No support for this decision is provided in the RCD. We suggest that DPR either evaluate this exposure scenario or provide appropriate justification for not evaluating subchronic exposures.
- 2. OEHHA agrees that inhalation exposure to hydramethylnon is likely negligible, however, only limited discussion is provided in the RCD supporting this assumption. We note that the U.S. EPA performed this assessment, finding that exposure from the inhalation pathway is indeed negligible. We suggest either evaluating this route in the RCD or substantiating that the exposures evaluated by the U.S. EPA are similar enough to those expected in California and cite the federal assessment as additional support for this assumption.
- 3. We support the overall evaluation for carcinogenicity. The report includes several important analyses. The report would further benefit by discussing the value of applying an additional uncertainty factor for possible carcinogenicity for chronic exposures.
- 4. Even though a developmental toxicity endpoint was not used for calculating MOEs in the RCD, we suggest that DPR provide further justification for the selection of 10 mg/kg/day as the NOAEL for developmental toxicity instead of the value of 5 mg/kg/day as determined by the U.S. EPA.
- 5. No potentially sensitive subpopulations are discussed in the RCD other than children and infants. OEHHA recommends a brief discussion of other potentially sensitive subpopulations (elderly, medical conditions) be added to the document.
- 6. It is unclear if hydramethylnon is applied to pineapples in California. We suggest clarifying this in the RCD.
- 7. OEHHA recommends including in the RCD specific information regarding existing (or lack of) current exposure benchmarks such as the reference dose, maximum contaminant level, threshold limit value, and permissible exposure limits etc.

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Thank you for providing the document for our review. If you have any questions about our comments, please contact Dr. Jolanta Bankowska at (510) 622-3162 or Mr. Robert Schlag at (916) 323-2624.

Attachment