Department of Pesticide Regulation

Brian R. Leahy
*Director*

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# M E M O R A N D U M

TO: Dr. Marylou Verder-Carlos
Assistant Director
Pesticide Programs Division

**HSM-16017**
**(No. assigned after issuance of memo)**

FROM: Lisa Ross, Ph.D.
Environmental Program Manager II
Chief, Worker Health and Safety Branch
(916) 324-4116

[*Original signed by L. Ross*]

DATE: July 14, 2016

SUBJECT: COMPLETION OF MITIGATION FOR DIETARY EXPOSURE TO ORTHO-PHENYLPHENOL AND ITS SODIUM AND POTASSIUM SALTS

The attached memorandum (Jones 2008) describes the findings of the Worker Health and Safety Branch (WHS) in regards to the need for mitigation of dietary exposure to ortho-phenylphenol (OPP) and its sodium salt, sodium ortho-phenylphenate (SOPP). The findings also are relevant to the potassium salt of OPP, potassium ortho-phenylphenate (POPP). All three active ingredients are used as antimicrobials, which for some products includes post-harvest treatment of certain fruits and vegetables.

In 2007, DPR's Risk Characterization Document (RCD) for OPP and SOPP (Kwok 2007) estimated exposures and risks for acute and chronic dietary exposure for the average U.S. population and fifteen subpopulation groups. Margins of Exposure were greater than 100 for all dietary exposures, and cancer risk was considered negligible at the upper bound value of $10^{-6}$.

In July 2016, in response to a question from WHS, scientists from DPR's Human Health Assessment Branch stated that POPP pesticide products would not be more toxic than SOPP products via the dietary route. The reason is OPP is the driver for dietary toxicity; both SOPP and POPP dissociate to OPP within the gut. Therefore, the HHA scientists consider that the conclusions of the dietary RCD (Kwok 2007) are also applicable to POPP.

Based on the absence of dietary risk estimates of concern for OPP and SOPP within the RCD, and on the applicability of the RCD to POPP, WHS finds that there is no need for further mitigation action with respect to potential dietary exposure for any of the three active ingredients: OPP, SOPP, and POPP. Your approval of this conclusion is requested.

cc: Shelley DuTeaux, Chief, Human Health Assessment Branch
Eric Kwok, Senior Toxicologist, Human Health Assessment Branch
Svetlana Koshlukova, Senior Toxicologist, Human Health Assessment Branch
Kevin Solari, Environmental Program Manager I, WHS Branch

APPROVAL

[*Original signed by M. Verder-Carlos*] July 15, 2016
Marylou Verder-Carlos, Assistant Director Date

**REFERENCES**

Kwok, E.S.C. 2007. *Ortho-Phenylphenol (OPP) and Sodium Ortho-Phenylphenate (SOPP) Risk Characterization Document Dietary Exposures*. California Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA. Available at: http://www.cdpr.ca.gov/docs/risk/rcd/opp.pdf (accessed June 27, 2016).

Jones, T. 2008. *Ortho-Phenophenol/Sodium Ortho-Phenophenol Risk Characterization Document for Dietary Exposures*. Memorandum to Chris Reardon dated May 22, 2008. California Department of Pesticide Regulation, California Environmental Protection Agency, Sacramento, CA.

Attachment: Copy of Jones (2008).

dpr Department of Pesticide Regulation

Mary-Ann Warmerdam
*Director*

Arnold Schwarzenegger
*Governor*

May 22, 2008

TO: Chris Reardon
Chief Deputy Director

FROM: Tobi Jones, Ph.D.
Assistant Director
Pesticide Programs Division

SUBJECT: ORTHO-PHENOPHENOL/ SODIUM ORTHO-PHENOPHENOL RISK CHARACTERIZATION DOCUMENT FOR DIETARY EXPOSURES

Attached is the final approved Risk Characterization Document (RCD) for dietary exposures for the active ingredients orthophenophenol (OPP) and the sodium salt of orthophenophenol (SOPP). This document was provided for review to the Office of Environmental Health Hazard Assessment (OEHHA), the U.S. Environmental Protection Agency and the registrants. Comments received from OEHHA and the registrants are addressed in this final document.

OPP and its sodium salt SOPP are broad spectrum antimicrobial agents used for post-harvest treatment of fruits and vegetables, and as disinfectants and preservatives in consumer products. They are treated together in this RCD because of their chemical and toxicological similarities

The attached memorandum from Gary Patterson outlines the findings on dietary risks for OPP/SOPP. Two acute oral endpoints were selected to address the acute dietary exposure: the No Observed Effect Level (NOEL) of 25 mg/kg/day for characterizing health risk in women of childbearing age (effect that only occurred during pregnancy), and 150 mg/kg/day for characterizing health risk in the general population including infants, children, and adult males. These critical endpoints were derived from studies in the rat. For chronic exposure, two critical NOELs were used: 39 mg/kg/day for characterizing health risk in males and 4.9 mg/kg/day for characterizing health risk in females. The rat studies from which these critical endpoints were derived showed different sensitive endpoints in males and females; this differential sensitivity is consistent with other animal studies exhibiting similar effects within a comparable dose range. OPP and SOPP were determined likely to be carcinogenic in humans based on several lines of evidence, and a potency factor was used to estimate cancer risk from dietary exposure.

Dietary exposures and subsequent risk estimates were estimated under acute and chronic scenarios for the average U.S. population and fifteen different subpopulation groups. Estimates were based on residue data (estimated and measured), and food consumption patterns from U.S. Department of Agriculture surveys.

Margins of exposure (MOEs) were greater than 100 for acute and chronic exposures, including subpopulation groups of infants and children 1-2 years of age that were identified as the group most highly exposed. MOEs ranged from ~$10^3$ to $10^4$ at the 95$^{th}$ to 99$^{th}$ percentiles for acute exposures, and greater than $10^4$ for chronic exposures for all population subgroups. Cancer risk was considered negligible at the upper bound value of 1 X $10^{-6}$.

**Recommended Risk Management**: Dietary exposures to OPP/SOPP do not require mitigation. At this time, an assessment of occupational and possible homeowner exposures is not planned. Branch managers will want to determine whether devoting resources to conducting an exposure assessment and developing a comprehensive risk assessment is warranted.

Attachment

cc: Dr. Gary Patterson, Dept. of Pesticide Regulation, Medical Toxicology Branch, (w/o Attachment)
Ms. Sue Edmiston, Dept. of Pesticide Regulation, Worker Health and Safety Branch, (w/o Attachment)
Ms. Anne Downs, Dept. of Pesticide Regulation, Pesticide Registration Branch, (w/o Attachment)