



Department of Pesticide Regulation



Paul E. Helliker
Director

MEMORANDUM

Gray Davis
Governor
Winston H. Hickox
Secretary, California
Environmental
Protection Agency

TO: Anna M. Fan, Ph.D., Chief **HSM-02005**
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FROM: Charles M. Andrews, Chief [original signed by C. Andrews]
Worker Health and Safety Branch
(916) 445-4222

DATE: January 23, 2002

SUBJECT: RESPONSE TO COMMENTS ON METAM-SODIUM EXPOSURE
ASSESSMENT DOCUMENT (HS-1703)

On December 8, 1999, the Office of Environmental Health Hazard Assessment (OEHHA) provided comments to Dr. Joyce Gee of the Medical Toxicology Branch on the Department of Pesticide Regulation's (DPR) draft risk characterization document (RCD) for the active ingredient metam-sodium. In the same memorandum, OEHHA provided comments on the metam-sodium exposure assessment document (HS-1703; March 24, 1999).

Recently, Dr. Thomas Thongsinthusak had the opportunity to revise the exposure document. This revision incorporated comments from OEHHA, updated information on usage, product labels, and illness/injury data, calculated dermal exposure of metam-sodium ($\mu\text{g}/\text{cm}^2$), added the exposure appraisal section, and responded to comments from the Metam Sodium Task Force. Attached are responses to comments from OEHHA.

I apologize for a late response to comments from OEHHA. If you have any questions regarding the response, please contact me.

Attachment

cc: Joseph P. Frank, D.Sc., Senior Toxicologist
Susan Edmiston, B.S., Senior Environmental Research Scientist





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TO: Charles M. Andrews, Chief
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VIA Joseph P. Frank, Senior Toxicologist
Worker Health and Safety Branch

FROM: Thomas Thongsinthusak, Staff Toxicologist
Worker Health and Safety Branch
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(M-S/OEHHA-Respond to comments)



Attachment

Response to Comments on Metam-Sodium Exposure Assessment

A. Comments on the draft RCD for metam-sodium pertinent to exposure assessment:

Comment 1: Page 3. Need clarification of illnesses/injuries caused by metam-sodium and/or MITC alone or in combination with other pesticides.

Response: The current revised exposure document indicates illnesses/injuries were attributed to exposure to metam-sodium/MITC or metam-sodium/MITC in combination with other pesticides. The word "alone" in the context of metam-sodium/MITC alone is no longer used.

Comment 2: Page 3. The dose should be "mg/kg" instead of "mg/mL."

Response: The current exposure document shows the unit as "mg/kg" in Table 10.

Comment 3: Page 6. A justification for the selection of sodium tetrathiocarbonate as a surrogate would be helpful.

Response: The current revised exposure document indicates that this surrogate study was selected because both metam-sodium and the surrogate chemical, sodium tetrathiocarbonate, are salt and water-soluble. Both chemicals are applied to soil. After application, sodium tetrathiocarbonate will release carbon disulfide, whereas metam-sodium will release MITC and other degradates. Foliar applied pesticides are not suitable surrogate chemicals because of the difference in methods of application and the purpose of the use.

Comment 4: Page 6. The quantitative scientific evidence provided to support the use of a 50 percent correction for degradation of metam-sodium after deposition on skin is inadequate.

Response: A 50 percent correction for degradation of metam-sodium was arbitrarily used after considering some chemical and physical properties of metam-sodium. Since the 50 percent reduction could not be verified, exposure estimates in the revised exposure assessment document were not adjusted. The information related to discussion on exposure reduction was taken out.

B. Detailed comments on the exposure assessment document (HS-1703, March 24, 1999):

Comment 1: This exposure assessment was limited to metam-sodium exposure, with MITC exposure from metam discussed in a separate document (MITC Risk Characterization). This one chemical at a time evaluation process may make it more difficult to evaluate total occupational hazard, which may result from co-exposure to these two chemicals plus exposures to other metam degradation products including MIC. The aggregate risk from all of the degradation products may be particularly relevant for this pesticide, since several of these chemicals cause skin and eye irritation, which may result in additive or synergistic effects.

Response: The author of the metam-sodium and MITC documents was instructed to prepare the two documents separately. The aggregate exposure/risk assessment may be feasible if laboratory animals were concurrently administered with metam-sodium, MITC, and other selected metam-sodium degradation products at the same or similar level of exposure experienced by workers or residents. A complex study design may be needed in order to detect additive or synergistic effects of those chemicals.

Comment 2: Page 6. Worker Illnesses/Injuries. Discussion of injuries from drift should distinguish between drift of aerosol droplets during spraying and drift of vapors later.

Response: The author presented summary of illness/injury data as they were received from the California Pesticide Illness Surveillance Program. This data set does not differentiate different illnesses caused by metam-sodium and MITC.

Comment 3: Tables 1, 2, 3 appear in the "Dermal Toxicity and Eye Irritation" section on page 7 rather than in the previous section, "Worker Illnesses and Injuries," where they would be more appropriately placed.

Response: Tables 1, 2, 3 are now shown in the section on "Illness/Injury Data" as suggested.

Comment 4: The discussion of dermal absorption on page 9 includes statements on the concentration-dependence of degradation of diluted metam-sodium, and that a particular concentration of product "should be representative of exposure experienced by agricultural workers. "We recommend strengthening this discussion by documenting the relative dilution of metam-sodium in use, in the spray apparatus, or in other application methods.

Response: Typically, dermal exposure to workers is normalized to the whole body or body regions, which in contrast to localized exposure to a spray dilution or mix. A discussion on the relative dilution of metam-sodium in use, in the spray apparatus, or in other application methods is not useful for a dermal absorption study.

Comment 5: Figure 1, "Proposed degradation/metabolic pathways for metam-sodium (1) and MITC (2)," which appears in the "Exposure Assessment" section, would be better placed in the previous section on "Animal Metabolism/Pharmacokinetics."

Response: Figure 1 is now shown in the section on "Animal Metabolism/Pharmacokinetics" as suggested.

Comment 6: The statement on page 16, second paragraph, that metam-sodium half-life at pH 9 is 4.5 days is inconsistent with the statement in the third paragraph that metam-sodium is very stable above pH 8.8.

Response: The information in these two paragraphs is no longer needed and was taken out because the information was previously used to justify 50 percent reduction of metam-sodium on the skin. The reduction is no longer applied in the revised exposure document. To clarify the comment, the metam-sodium half-life of 4.5 days at pH 9 is correct. However, the study was done using diluted metam-sodium solution (57 to 65 mg/L) at 25 °C and performed in the dark under sterile conditions. The study shown in the third paragraph was conducted using concentrated metam-sodium (32.7% metam-sodium and 67.3% water) at pH range above 8.8. The word "very" in "very stable" was not used in the submitted study.

Comment 7: The statement on page 17 that "at least 50 percent of metam sodium on skin will transform to its degradates in an 8-hour workday" and use of this assumption to decrease dermal absorption estimates appears to rely on the assumption of a prolonged residence time of metam-sodium on skin. However, this is inconsistent with the statement on page 10, second paragraph, that "metam-sodium and/or its degradates are absorbed rapidly into the skin," based on the observation that absorption in one hour is similar to that with longer times. The data support rapid dermal absorption, and we do not think that the 50 percent degradation assumption is or could be justified from the available data. The degradation of metam occurs in the diluted form applied to the skin, but the experimental results should already have accounted for this factor, which is presumably why absorption was only 2.5 percent at 0.1 mg/cm² compared to 4.2 percent at 10 mg/cm². The degradation correction appears inappropriate.

Response: The 50 percent exposure reduction was no longer applied to dermal exposure of metam-sodium because the reduction was based on some assumptions and could not be verified.

Comment 8: Some estimate of the range or distribution of potential exposures should be included. Such an estimate could be based on the variability found in other comparable studies, if the data from the study used in this case are not adequate.

Response: Most surrogate exposure data were determined from half of the limit of detection or limit of quantitation of a surrogate chemical. It may not be appropriate to show the range or distribution of potential exposures because there were no other appropriate comparable studies.