



# Department of Pesticide Regulation



Paul E. Helliker  
Director

## MEMORANDUM

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

TO: Joseph P. Frank, Senior Toxicologist  
Worker Health and Safety Branch **HSM-02018**

FROM: Thomas Thongsinthusak, Staff Toxicologist [original signed by T. Thongsinthusak]  
Worker Health and Safety Branch  
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DATE: July 16, 2002

SUBJECT: COMMENT ON METAM-SODIUM RISK CHARACTERIZATION  
DOCUMENT

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I have reviewed the metam-sodium risk characterization document (RCD) dated June 24, 2002 from the Medical Toxicology Branch. The RCD was well written by the author since it contains essential information for the risk assessment. A significant portion of the RCD deals with details and discussions on toxicology studies. Presentation of toxicology studies in the RCD was thorough and well organized. However, I feel that the document can be improved by providing more details on some points and making corrections on some typos. My other comments are as follows:

### General comments:

1. The author of the RCD provided adequate justification for the selection of appropriate toxicology endpoints for the risk assessment. However, some toxicology endpoints were obtained from the toxicology studies using oral administration, which is not typically experienced by agricultural workers. I assume that this is an acceptable practice at the Department of Pesticide Regulation as well as the U.S. Environmental Protection Agency.
2. "Metam" and "metam sodium" were used interchangeably throughout the document. Metam is a trade name and it should be capitalized when used unless metam is defined for use in place of metam-sodium.
3. What is the difference between acute NOEL and critical acute NOEL? Both terms were used in the document for the same NOEL.
4. Both Fischer's Exact Test and Fischer Exact Test were used. I think that the first one should be used.
5. LADD was defined as "Lifetime average daily dose" and "Lifetime adjusted daily dose" in many places. The first definition should be consistently used in the RCD.



Specific comments:

Page 9, Usage. The use of metam-sodium in 2000 is also available and should be included. The use information is also repeated in page 66, paragraph 1, which may be redundant. I do not believe that the statement “.9.2 million pounds per year of MITC was released into the air...” (Page 9. D. Usage, paragraph 2) is accurate because MITC can be degraded or bound in the soil.

Page 11, Table 3. The systemic illnesses in 1999 should be 161 cases. The average for respiratory and respiratory/eye cases should be 0.3, and the average of the total is 39.0

Page 18, number 5, line 1. Should it be “Following oral exposure to metam sodium (instead of MITC)?

Page 30. Footnote 1 is very long. It should be incorporated in the body of the text.

Page 52. Please explain or define the meaning of “Manus and pes” scores.

Page 78, paragraph 3 (also, page 52). I did not find clear evident showing the developmental effects was acute in nature. I do not know when was the onset of the developmental effect because metam-sodium was administered on gestation days 7-16.

Page 78, 2. Dermal irritation. I was wondering if skin irritation is reversible in a short time. If so, it may be unjustifiable to use it as a toxicology endpoint for risk assessment.

Page 85, Table 25 and subsequent tables, footnote “a” for “Work task”. The cited table should be Table 24.

Page 92, B.1. Acute systemic and local toxicity. The ENOEL was established at 1 mg/kg/day based on a default uncertainty factor of 10. Would it be possible that the factor could be 2 to 4 because the uncertainty factor was 4 (from LOEL to NOEL) for the Tinston’s study? A default uncertainty factor of 3 was used for the derivation of critical subchronic endpoint (Page 94, last paragraph).

Page 98, section 1.1, paragraph 2, line 5. It should read “Thus, the lifetime average daily MITC exposure...” Also, the text “...that exposure values determined over a single day were validly translated into daily exposure values occurring over a 40-year working career.” This summary statement may be misleading because we assume that the average annual exposure level stays the same. However, we have no long-term studies to verify this assumption. The procedure of calculating LADD may be overestimated because metam-sodium has a short half-life. As such, metam-sodium may not exhibit chronic or lifetime effects in humans unless the effects caused by a short-term exposure can last for a longer period of time.

Page 100, E., paragraph 2. What is “ve” for? Is it a typo?

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Page 3

Typos:

Page 1, paragraph 4, line 1. I assume that it is  $8.6 \mu\text{g}/\text{cm}^2$ , not  $\text{fg}/\text{cm}$ . The author should check the use of “fg” elsewhere too.

Page 3, paragraph 2, line 2. No space after the parenthesis.

Page 10, paragraph 1, line 3. Use  $\text{H}_2\text{S}$  instead of H2S.

Page 25, Robinson 1994b, the unit of LOEL should be  $\text{mg}/\text{kg}$ .

Page 30, No. 2. It should read 5 rats/sex/group (check unit elsewhere too); No. 3. Need a hyphen after rat.

Page 86. paragraph 2, line 2 from bottom. What is a[n]? I assume that it is a typo.

Please note that I did not verify the cited sections or Tables in the document if they are correct, such as the section shown in the parenthesis in page 88, *likelihood of dermal irritation*, last line (section IV.A.3).

(HSM-02018-M-S-MedTox)