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NCIC HPV
Sent by: Mary-Beth Weaver

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To: NCIC HPV, moran.matthew@epa.gov
cc:
cc:
Subject: Environmental Defense comments on Methane Sulfonic Acid (CAS# 75-75-2)

Richard_Denison@environmentaldefense.org on 06/02/2003 02:21:04 PM

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To: oppt.ncic@epamail.epa.gov, hpv.chemrtk@epamail.epa.gov, Rtk Chem/DC/USEPA/US@EPA, Karen Boswell/DC/USEPA/US@EPA, ann.tveit@atofina.com
cc: MTC@mchsi.com, kflorini@environmentaldefense.org, rdenison@environmentaldefense.org

Subject: Environmental Defense comments on Methane Sulfonic Acid (CAS# 75-75-2)

(Submitted via Internet 6/02/03 to oppt.ncic@epa.gov, hpv.chemrtk@epa.gov, boswell.karen@epa.gov, chem.rtk@epa.gov, MTC@mchsi.com, and ann.tveit@atofina.com)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for Methane Sulfonic Acid (CAS# 75-75-2).

ATOFINA Chemicals, Inc. and Chevron Phillips LP, in response to EPA's High Production Volume (HPV) Challenge Program, have submitted a Robust Summary/Test Plan for methane sulfonic acid (MSA). The Test Plan consists of only a one-page table listing each SIDS elements, data values or test results, a numerical score for data reliability, an indication of whether the sponsor believes there is a need for further study and references. This Test Plan thus fails to meet a primary objective of the EPA HPV Challenge Program to provide the public with background information on chemicals of highest production. No information is provided on the quantity of MSA produced, methods of production, uses, transport or sources of potential human and environmental exposure, which are basic to a SIDS package. Further, virtually all the references provided in the Test Plan are internal company documents that are not available to the public. Given the fact there is a wealth of peer-reviewed information on MSA in the open literature, we feel this is inexcusable.

The Robust Summary submitted for MSA consists of a long list of internal company reports of varying quality. Some of these studies are judged "without reliability", while others are judged as "invalid". Thus, it is not surprising that these studies contain conflicting and confusing data. EPA guidance for preparing Robust Summary/Test Plans clearly state that companies should choose one or more "adequate" studies to address each SIDS element. It is entirely inappropriate to include, as has been done in some cases, multiple inadequate studies in the Robust Summary and extract data from only one such study to include in the Test Plan matrix.

Additional comments on the Robust Summary/Test Plan are listed below.

1. In Table 1 of the Test Plan:

a. Water solubility is given as 1000 g/ml. Since that would mean the solute out-weighs the solvent by more than 999 to 1, we would suggest water solubility be given as "miscible".

b. Acute toxicity to algae is given simply as 14. We would assume this is 14 mg/l, but the units should be provided.

c. Repeated dose toxicity is given as 0.026 mg/'1. This would suggest the

study was an inhalation study, but that is not stated. It is stated in the letter of submission that a new repeated dose study will be conducted. It is not obvious why an additional study is necessary if this study is judged to be of the highest reliability.

d. The species tested should be given along with the LD50 values.

e. The NOAEL for developmental toxicity is given as >400 mg/kg2. We assume kg2 is a typo, which should be corrected. If not, it should be explained.

2. Robust Summary

a. On page 2 it is reported that animals tolerated doses up to 1800 mg/kg/day for seven days and no deaths were observed. This is not consistent with the oral LD50 of 649 listed in Table 1 of the Test Plan.

b. It is noted on page 3 that MSA causes burns on contact with skin. Much of the toxicity reported throughout the Robust Summary appears to be the result of chemical burns. Whereas some of these tests may have been required in the past, we would hope they are no longer being conducted. Their reporting here serves little purpose here other than to emphasize that they should no longer be conducted.

c. The descriptions of many studies list the Test Substance as "other TS". In some cases Test Substance is mentioned a second time and properly identified as methane sulfonic acid. In many cases, however, Test Substance is not identified as anything other than "other TS". Perhaps this is a result of directly transcribing internal company reports into the Robust Summary. In any case, it should be corrected and Test Substance should be correctly identified in each study.

d. In some studies it is not possible to determine if the acid or the salt was used. Given that at one point the Robust Summary states the acid was 20-fold more toxic than the salt, this information is critical to interpretation of the data, and should be clearly indicated for each study.

e. The Test Substance under Vapor Pressure is not identified.

f. The headings of columns of numerous Tables in the Robust Summary are in French. The heading should be translated into English.

g. Data cited for biodegradation are conflicting and in our view the selective data provided in the Test Plan are misleading. That is, reports in the Robust Summary indicate biodegradation proceeds rapidly if the bacteria are preconditioned to MSA, but much less rapidly if tested in "naive" bacteria. The only data presented in Table 1 of the Test Plan were those obtained using preconditioned bacteria. If only one set of values is to be provided, we think it more appropriate to include data for biodegradation by bacteria that have not been previously conditioned to the test substance. These data would be more representative of the expected behavior in the event of an accidental release of MSA into the environment.

h. Data cited in the Robust Summary indicate variously that the LD50 for daphnia is as high as 260 mg/l to as low as 1.7 mg/l. Yet the Test Plan cites only the 260 mg/l value without any justification provided for excluding the other data.

i. On page 50, results of dermal toxicity studies include the use of the term "few faces". We are not familiar with this term and assume it is a typographical or translation error.

j. On page 69 it is stated that 400 mg/kg was the NOAEL for maternal toxicity and developmental toxicity. (The Test Plan matrix gives a value of >400 mg/kg, which does not seem consistent with the reported LD50 of 649

mg/kg.) However, on page 70, in the description of a study of developmental toxicity, it is stated that treatment-related clinical signs were observed in 100, and 200 mg/kg dosed groups. This seems more reasonable. At any rate, these discrepancies should be resolved or at least addressed by the sponsor.

In summary, this Robust Summary/Test Plan represents an inadequate effort to summarize and present data available on MSA. The fact that it consists almost exclusively of a collection of poorly prepared and often conflicting internal company reports, and contains no background data on production, use or human or environmental exposure, is inexcusable when the literature contains over 4000 peer-reviewed reports. Thus, we consider this Robust Summary/Test Plan to fall far short of meeting the requirements of the EPA HPV Challenge Program. We note that, since MSA is an acid and, as such, would be expected to corrode any tissues contacted, we would not recommend additional animal studies. Rather, the ample data currently available in the literature should be thoroughly reviewed, summarized and presented in a completely new Robust Summary/Test Plan.

Thank you for this opportunity to comment.

Hazel B. Matthews, Ph.D.
Consulting Toxicologist, Environmental Defense

Richard Denison, Ph.D.
Senior Scientist, Environmental Defense