

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

April 16, 2004

Memorandum

SUBJECT: Metam Sodium: Dietary Risk Assessment of Antimicrobial Uses for the Reregistration Eligibility Decision Document. PC Code 039003 (Metam Sodium) and 068103 (MITC). DP Barcode

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Attached is a review of the dietary antimicrobial uses of metam sodium (excluding metam potassium). The use of metam sodium is for control of bacteria and fungi that cause loss of sucrose as well as contribute to slime and odors during manufacture of raw cane and beet sugar.

EXECUTIVE SUMMARY

The Antimicrobials Division (AD) assessed the indirect food use of metam sodium in sugar cane processing facilities. For a complete review of the metam sodium risk assessment and discussion on the degradates (e.g., MITC) the reader is referred to the HED risk assessment chapter (D284260). AD believes that sugar processing itself, because of the heating and liming process, greatly reduces the level of metam sodium/MITC that is added to the cane or beets that enter the milling process. However, as the available sugar processing residue study is an old study, it does not enable AD to conclude what level of residue may be present in the sugar, syrup, or molasses that would be produced from the use of metam sodium. Therefore, the registrant is requested to submit a new sugar processing study using either sugarcane or sugar beet and state of the art analytical procedures for analysis of MITC or other residues that are considered of toxicological concern.

1.0 Introduction

The Health Effects Division (HED) has prepared the risk assessment for the Agricultural uses of metam sodium and its degradate, methylisothiocyanate (MITC). The reader is referred to the HED risk assessment for an in depth analysis of the toxicological and residue chemistry of metam sodium and its degradates. This memorandum discusses the indirect food use of metam sodium in sugar cane processing. Metam sodium is used as a broad-spectrum microbicide to control bacteria and fungi during the manufacture of raw cane and beet sugar. For the sugar cane processing use, a single product (Busan 1016, EPA Reg. No. 1448-93) is registered.

No data have been submitted to the Agency in support of the metam sodium antimicrobial use in sugar cane processing. However, Buckman Laboratories previously submitted a petition to the Food and Drug Administration in support of this use.

2.0 Toxicological Endpoints of Concern

Toxicological endpoints were determined by the Health Effects Division's Hazard Identification Assessment Review Committee (HIARC) for both metam sodium and MITC. As noted in the HIARC document as well as the preliminary risk assessment (D284260), there were no dietary endpoints of concern for metam sodium or MITC on the basis that "the use pattern does not indicate potential for dietary exposure."

3.0 Conclusions

As noted above, dietary endpoints were not selected for either metam sodium or MITC. In the case of sugar cane processing, it is expected that the elevated temperatures and liming processes used in the processing of raw sugar cane will result in a reduction of any residues of metam sodium/MITC such that there are no finite residues of concern. Therefore, a dietary risk assessment for this use is not needed. However, as the sugar cane processing study cited in the FDA petition was an older study, AD is requesting that an updated processing study be performed as confirmatory data for the lack of residue expected.