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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

November 14, 2005

MEMORANDUM

SUBJECT: Risk Assessment and Science Support Branch (RASSB) Scoping Review of PHMB For Use As A Sanitizer [ID NO 1258-1253; 20 % Active Ingredient (AI); PC Code 111801]

FROM: Norm Cook, Chief
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Chemical: Poly(iminoimidocarbonyliminoimidocarbonyliminohexamethylene) (PHMB) (111801)

DP Barcode: D320916, D320917, D322475

PRIA Code: A44 (21 months)

Science Due Date: 11/2/06

Purpose

The purpose of this scoping memo is to identify science issues to the regulatory management staff, including potential data requirements for continued review of this action. ***However, for this submission RASSB recommends that we meet internally to discuss the science issues presented below before sending the issues and data requirements to the registrant.***

Background

The registrant, Arch Chemicals, Inc., is proposing use of Vantocil IB Microbiocide (containing 20 % PHMB) as a sanitizer in: food handling/storage establishments, premises and equipment, including food contact surfaces in public eating places; dairy processing equipment; and food processing equipment and utensils. The concentration of PHMB in sanitizing solutions

(1)

is to be at a maximum 550 ppm (PHMB). These solutions are applied, from once per hour to once per week, by spray, flood, or pour-on applications, followed by adequate draining and air drying, or by wiping to inanimate hard surfaces, equipment, and/or utensils, such as stainless steel, aluminum, ceramic, glass, and polymers such as polypropylene.[1]

Proposed Use Patterns versus Uses in Reregistration Eligibility Decision (RED) For PHMB

The registrant refers to the PHMB RED, with statements that a 560 ppm (or 550 ppm, as proposed) PHMB sanitizing solution should be acceptable to the Agency. They state that Agency dietary exposure and risk calculations (as found in the RED) for the use of PHMB as a disinfectant indicate minimal, to no, dietary risk concerns at 560 PHMB, based on a 10 % migration to food factor (*disinfectant solution of 5600 ppm PHMB X 10 % = 560 ppm PHMB*).[2] However, it must be noted that because of the uncertainties and limitations associated with the dietary exposure and risk assessments (and particularly with the 10 % migration to food factor), the Agency required confirmatory dietary residue data to support disinfectant PHMB uses.

Considering the above, RASSB has performed a scoping review of the proposed sanitizer use of PHMB at 550 ppm PHMB in: food handling/storage establishments, premises and equipment, including food contact surfaces in public eating places; dairy processing equipment; and food processing equipment and utensils. We conclude that the proposed use patterns, though now at a proposed level of 550 ppm PHMB sanitizing solution, and which involve re-treatment of surfaces, equipment, and utensils at a maximum interval of one application per hour, are significantly different from the uses evaluated in the PHMB RED. We believe that additional data are required before RASSB can continue review of the proposed use patterns and offer the following comments:

Dietary Exposure/Risk Issues Associated With Proposed Sanitizer Uses

As discussed above, we believe the proposed use patterns are significantly different from those reviewed in the PHMB RED based on the following considerations:

- **Disinfectant versus Sanitizing Uses**: The uses reviewed in the PHMB RED concern disinfectant solutions, which are followed by a potable water rinse. The proposed sanitizer rinse uses are followed by adequate (?) draining and air-drying, or by wiping inanimate hard surfaces, equipment, and/or utensils. We believe the sanitizer uses are significantly different from the disinfectant uses and may result in significantly different residues on surfaces and food items. We note that for the proposed use patterns, it is RASSB's understanding that we will need to: (1) assess dietary exposures for utensils using the recommended FDA surface area of 4000 cm^2; and (2) aggregate these dietary

1 Note that the proposed labeling does not provide mixing directions for the user to achieve a maximum sanitizing solution of 550 ppm PHMB. Such directions need to be added to the label.

2 Using this approach the Agency determined that the most conservative chronic dietary value (i.e., % dietary residues of cPAD for a child) was 37 %.

exposures with countertop estimates, which used a 2000 cm^2 surface area. We also note that the American Chemistry Council's (ACC's) dietary tiering proposal may assist us in determining dietary residues for food items contacting surfaces such as countertops (but not utensils). However, in order to address dietary aggregation issues and reduce uncertainties in the dietary risk assessment, we conclude that confirmatory dietary residue data are needed. Additionally, considering that the Agency required dietary residue data for disinfectant solutions, we believe similar data are required to support sanitizing solution uses;

- **New Use Patterns**: Under the proposed use patterns the registrant is proposing application of PHMB sanitizing solutions to: dairy processing equipment, and food processing equipment and utensils. These use patterns were not evaluated in the PHMB RED and do not appear to be registered for PHMB disinfectant solutions. They are new use patterns, and considering that the PHMB RED refers to disinfectant solution labels that state, "Do not use on glasses, dishes, or utensils", they are significantly different use patterns, for which the PHMB RED residue estimates are not appropriate.

Data Required To Continue Agency Science Review of PHMB Petition

Considering the discussion above, RASSB concludes that the following data/information are required before we can continue science review of the PHMB petition for sanitizing solution applications:

- **Modification of proposed labeling**: As discussed above, the proposed labeling does not provide mixing directions for the user to achieve a maximum sanitizing solution of 550 ppm PHMB. Such directions need to be added to the label.

- **Dietary exposure (residue chemistry) data**: To support the proposed sanitizing solution use patterns, involving multiple re-treatments, pertinent surface and food residue data are required. Such data should be developed for representative, but conservative (e.g., maximum daily re-treatments), scenarios for: food handling/storage establishments, premises and equipment, including food contact surfaces in public eating places; dairy processing equipment; and food processing equipment and utensils. We are particularly interested in PHMB food item residues, but surface residues are required as well to validate the food residue data and to assist in the determination of migration to food factors. The registrant is referred to the two FDA references (FDA, 2003a and 2003b) found in the PHMB RED and also to guideline, OPPTS 860.1460 (copy attached). Additionally, we recommend that in support of the petition the registrant submit an analytical method in support of the petition since we believe that with multiple daily re-treatments residues of PHMB in food items may occur.

In closing, the above represents RASSB's scoping review of the proposed new sanitizing solution uses of PHMB. We believe the above issues require further discussion among AD management unless RMB-II believes the data requirements and issues outlined are appropriate

for release to the registrant. Lastly, we'd like to point out one other science issue, which may require further discussion since repeat applications have not been previously addressed in prior Agency reviews of sanitizer or disinfectant uses:

- **Multiple (Repeat) Applications**: The proposed label, which needs to include adequate directions for mixing PHMB solutions to achieve a sanitizing solution of 550 ppm PHMB, recommends re-treatment at the shortest interval of one application per hour. Considering that environmental fate data for PHMB indicate a hydrolysis half-life of > 30 days, multiple applications of PHMB sanitizing solutions to surfaces may result in surface, and dietary, residues > 550 ppm. We recognize that using the Agency's previous PHMB RED calculations, 10 applications/day, may result in a maximum surface residue of 5500 ppm, which is similar to the Agency's 5600 ppm value used for the 0.56 % product. However, the PHMB RED required dietary residue data, which also would assist us in determining the percent migration to food factors (presently estimated as 10 %). Considering that for sanitizer solutions we also do not know what actual dietary residues, or percent migration to food factors, may be, we conclude that additional dietary residue data are in order to support the proposed sanitizing solution uses.

  If there are any questions on what is presented above, please contact RASSB.

Attachment

cc: D. Edwards
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T. Leighton
N. Shamim
J. Slotnick
B. Quick

References

FDA, 2003a. "Guidance For Industry: Preparation of Food Contact Notifications and Food Additive Petitions for Food Contact Substances: Chemistry Recommendations. Final Guidance." US Food and Drug Administration. April, 2003. http://www.cfsan.fda.gov/~dms/opa2pmnc.html. Last accessed June 9, 2003.

FDA, 2003b. "Sanitizing Solutions: Chemistry Guidelines for Food Additive Petitions." US Food and Drug Administration. January, 1993. http://www.cfsan.fda.gov/~dms/opa-cg3a.html. Last accessed June 9, 2003.

EPA 712-C-96-181. 1996. **Residue Chemistry Test Guidelines**. OPPTS 860.1460 - Food Handling. August 1996. 4pp.

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5