

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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MEMORANDUM - December 3, 1996

TO: Pauline Wagner, Acting Branch Chief
 Environmental Fate and Ground Water Branch
 Environmental Fate and Effects Division

FROM: Kathleen Depukat, Section Chief
 Reregistration Section 1
 Accelerated Reregistration Branch
 Special Review and Reregistration Division

Kathleen Depukat

SUBJECT: Case 3148, Trimethoxysilyl Quats
 A.I. 107401, Trimethoxysilyl propyl dimethyl octadecyl ammonium chloride
 A.I. 169160, N,N-Didecyl-N-methyl-3-(trimethoxysilyl) propanaminium chloride
 Status of Reregistration Requirements

Per my discussion today with Karen Angulo and Mah Shamim, SRRD is trying to determine the status of this case for reregistration with respect to is EFGWB requirements.

The use pattern for A.I. 169160 is an antimicrobial (broad spectrum bacteriostat and fungistat) on textiles (e.g., human clothing and footwear), carpets or upholstery to control the growth of odor causing bacteria, to reduce deterioration and discoloration caused by fungus in the presence of moisture, and to control the growth of mold and mildew, etc. The use pattern for A.I. 107401 is identical expect that it is also registered for special industrial products. There are no food uses supported for either of these A.I.s

The following is the status of the EFGWB requirements:

GDLN	AI 169160	AI 107401
161-1 Hydrolysis (Phase 3 - The Agency requires a hydrolysis study for industrial microbiocides covered by an NPDES permit.)	The registrant submitted a LVMU waiver request with their 90-day response. The waiver was denied stating that the hydrolysis data is required because of discharge of waste water containing this chemical and a new due date of 5/31/96 was established for submission of this study. (See Attachment 1)	MRID 43578601 plus supplemental submissions. Analytical method inadequate. New method must be developed.

The following items are also attached:

- Attachment 2: Registrant letter of 11/11/94 requesting quick response for their proposal for the Agency to approve their proposed toxicity studies and provides preliminary results on the hydrolysis study and the 11/22/94 Agency response stating the inductively coupled plasma spectroscopy technique should be adequate but they had a few concerns related to the 11/11 write-up.
- Attachment 3: Registrant letter of 3/28/95 requesting to use results based on the nominal concentrations of 5772-Si based on the correspondence of 3/2/95 and 3/15/95 (also attached).
- Attachment 4: 6/16/95 Review of hydrolysis method and our letter to the registrant of 3/5/96.
- Attachment 5: Registrant letter of 5/17/96 requesting meeting with Agency because on continuing analytical method problems.
- Attachment 6: A copy of the registrant's Solubility of Q9-6346 silane study (GDLN 63-8) and RD's 5/31/95 review.

Additionally, for GDLN 63-13, Stability, the registrant submitted only thermostability data showing stability of the TGAI to elevated temperatures with slow decomposition reported at 125° C. Further, exposure to ambient light showed no changes in the test substance. No stability tests were conducted, however, for metals or metal ions since, according to the registrant, packaging and use of the product does not encounter metals or metal ions. GDLN 63-13 requirements are satisfied.

The following issues need to be resolved:

1. For A.I. 107401, the registrant has conducted a hydrolysis study and although the analytical method still has some issues to be resolved, the registrant has shown a good faith effort to resolve those issues and is requesting our help to resolve those issues. In speaking with Mah Shamim and Karen Angulo, they agreed that even though the study is not acceptable, the information provided may be adequate to fulfill the GDLN requirements for this study requirement. Therefore, can you please provide in writing a statement to that effect or guidance on how to resolve this issue for the registrant. e.g., schedule a meeting, etc.
2. Since the other registrant has requested a waiver, can analog data be used to satisfy the requirement for this A.I. also?

Both registrants are overdue on their studies, and need our help to resolve their

outstanding data requirements.

Your help in resolving this issue is appreciated. Both Karen and Mah have been very helpful in helping me work through this problem. Thanks again to all of you.

If you have any questions, please don't hesitate to call me at 308-8587. Thanks again for your help. A quick turnaround would be helpful.

cc: Karen Angulo
Mah Shamim

Attachments



13544

R107009

Chemical:	1-Octadecanaminium, N,N-dimethyl-N-(3-(t; 1-Octadecanaminium, N,N-dimethyl-N-(3-(t
PC Code:	169160; 107401
HED File Code	61200 SRRD CDC
Memo Date:	12/03/96
File ID:	00000000
Accession Number:	412-05-0097

HED Records Reference Center
06/07/2005