UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

DP Barcode: D394355
Chemicals: N,N-methylenebismorpholine
PC Codes: 054702

September 22, 2011

Memorandum:

Subject: Status of Environmental Fate Data Requirements for N,N-methylene bismorpholine (Contram ST-1)

PC Code(s): 054702	DP Barcode(s)/No(s): D394355
Decision No.: 400806	Registration No(s).: 52484-G Contram ST-1;
Petition No(s).: 52484	Regulatory Action: Project Registration, Section 3 Review of Fate Studies
Risk Assess Type: Single Chemical	Case No(s).: None
TXR No.: NA	CAS No(s): 5625-90-1
MRID No(s).:	41555820, 41555821, 48064802, 48064803, 48064804, 47571313, 47555828

To: Marshall Swindell, Risk Manager 33
Regulatory Management Branch I
Antimicrobials Division (AD)

From: James Breithaupt, Agronomist
Risk Assessment and Science Support Branch (RASSB)
Antimicrobial Division (7510P)

Peer Review: Siroos Mostaghimi, Ph.D.
Risk Assessment and Science Support Branch (RASSB)
Antimicrobial Division (7510P)

Thru: Nader Elkassabany, Chief
Risk Assessment and Science Support Branch (RASSB)
Antimicrobial Division (7510P)

Hydrolysis (161-1, 835.2120)

In the 9/14/11 memorandum from James Breithaupt (D357908, D378130), the conclusion for hydrolysis was that the five hydrolysis studies involved in the subject product's application together satisfy the 835.2120/161-1 data requirement for Contram ST-1. None of the studies were completely acceptable, although there was one study (MRID 47555820) which did not address material balance or degradate identification but which was found to be supplemental but not acceptable because of the lack of any material balance and degradate identification. The absence of either material balance or degradate identification can be a basis for outright rejection of the study and a classification of such a study as being unacceptable to satisfy the 835.2120/161-1 data requirement. Environmental fate studies require a material balance of 90-110 % of applied radiolabeled substances and 70-120 % of applied non-radiolabeled substances. Degradates at or above 10 % of applied substance require identification. However, in this case, due to the reasons identified and explained below and in the attached document, information on material balance and degradates has been determined to be impractical to obtain for hydrolysis testing of this subject substance.

In light of information which has become available to the Agency since 9/14/11 and subsequently reviewed, the hydrolysis study (MRID 47555820) is now classified as acceptable and satisfies the hydrolysis data requirement (835.2120, 161-1), when combined with the attached 9/20/11 "Expert Statement" signed by D F White, Supervisor of Physico-Chemical Properties of Harlan Laboratories (formerly SafePharm Laboratories). The "Expert Opinion" is located in Appendix A. According to the attached "Expert Statement," material balance was not technically feasible in the subject substance's hydrolysis testing because the extremely short half-life of <1 day created the inability to detect any parent compound. The absence of degradate identification was based on matrix interference from the buffer compounds that prevent pH change in the solutions being tested. The buffer compounds would have absorbed the UV/Visible light from detectors and the detected response from buffer compounds could be greater than from any degradates of Contram ST-1. Based on the apparent degradation pathway, the degradates would be morpholine and formaldehyde in the ratio of 2:1. The factors affecting measurement feasibility in this case, which stem from the nature of the subject substance, adequately justify not requiring the aforementioned material balance and degradate identification information in this instance.

Activated Sewage Sludge Isotherm (835.1110)

Data on activated sewage sludge isotherm are not required at this time for Contram ST-1, contrary to the 9/14/11 memorandum. These data are not required under 40 CFR Part 161; the activated sewage sludge isotherm study is contained in proposed 40 CFR Part 158W but it is not a current data requirement under the existing data requirements regulation.

Table 1 below contains the current status of environmental fate data requirements.

Table 1. Environmental Fate and Transport Properties of Contram

Property	Value	Comments/Reference
Hydrolysis (835.2120)	Half-life of 3.6 months in oil-based metalworking fluids (intended use) Rapid degradation in guideline and other non-guideline studies with half-lives of <6 seconds to 1 day.	Guideline study is acceptable when combined with 9-20-11 "Expert Statement" discussed above and attached to this memo. Non-guideline studies provide additional information. Data requirement satisfied by MRID 47555820. MRIDs, 47555821, 48064802, 48064803, and 48064804 provide additional information.
Leaching-adsorption-desorption (835.1230)	Koc value of 18 ml/g	MRID 47555820 Satisfied
Ready Biodegradability (OECD 301, 835.3110)	Contram ST-1 was readily biodegradable Biodegradation reached 93 % after 28 days	Satisfied MRID 47571313
Sewage Sludge Respiration Inhibition (OECD 309, 835.6800)	NOAEC by 3 hours of 32 mg/l, EC50 values of 800 and 340 mg/l by 30 minutes and 3 hours EC20 of 133 mg/l for both times EC80 concentrations not reached	MRID 47555828 Satisfied
Activated Sewage Sludge Isotherm (835.1110)	No	Not required as explained above.

If there are any questions, please contact Jim Breithaupt at 703-305-5925 or at breithaupt.james@epa.gov.

Appendix A. September 20th, 2011 Expert Opinion from Harlan Laboratories

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EXPERT STATEMENT – HYDROLYSIS

TEST MATERIAL	:	OS 157340
PROJECT NUMBER	:	525/335
SPONSOR	:	The Lubrizol Corporation 29400 Lakeland Boulevard Wickliffe OHIO 44092-2298 UNITED STATES OF AMERICA
DATE	:	20 September 2011

A hydrolysis study was performed on the test material OS157340 (e.g., Contram ST-1) following Method C7 of Commission Directive 92/69/EEC (which constitutes Annex V of the Council Directive 67/548/EEC) and Method 835.2110 of the OPPTS Guidelines. This study was performed by SafePharm Laboratories (which is now Harlan) and was completed in July 2001.

Due to the extremely fast hydrolysis at all pHs investigated, no test material was detected at any of the time points. This study identified two hydrolysis products. From the reaction mechanism pathway given in the report, the only possible hydrolysis products are morpholine and formaldehyde in the ratio 2:1.

Based on the study methodology, it was not technically feasible to further quantify the amount of each hydrolysis product present since: :

a) Only a qualitative approach was used for the identification of aldehydes (for the formaldehyde).
b) No GC-MS comparison of the hydrolysis products was made to an external standard as part of this study.

Even if quantification of the degradation products was attempted, it would not have been successful due to the different response factors given with the different detector types (for the morpholine product). In addition, the determination of formaldehyde would not be definitive as it would not be possible due to the different sample matrices. An ultraviolet/visible spectroscopy method may have been applied, however, this would yield significant interference from the buffer solutions used.

In my opinion, the chemical structure of test material OS157340 will only yield morpholine and formaldehyde in the ratio of 2:1. The rapid and complete hydrolysis of the test material to yield just two products, one of which was confirmed to be an aldehyde provides confirmation that the yield was morpholine and formaldehyde in the only possible ratio, *i.e.*, 2:1.

Signed: ..... Date: 20 SEP 2011

D F White
Supervisor
PHYSICO-CHEMICAL PROPERTIES