

US EPA ARCHIVE DOCUMENT

11-28-95
CAS FILE



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

NOV 28 1995

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Acephate Technical: Request for "Me-Too" Registration

DP Barcode No. D220106	Submission No. S489248
Case No. 007405	P.C. Code No. 103301
EPA ID No. 051036 - EUA	Tox. Chem. No. 002A
CAS Registry No. 30560-19-1	

TO: Robert Forrest/Marilyn Moutz, PM Team 14
Registration Division (7505C)

FROM: Krystyna K. Locke, Toxicologist
Section I, Toxicology Branch I
Health Effects Division (7509C)

Krystyna K. Locke 11/27/95

THRU: Roger I. Gardner, Section Head
Section I, Toxicology Branch I
Health Effects Division (7509C)

Roger Gardner 11/27/95

Karl Baetcke, Branch Chief
Section I, Toxicology Branch I
Health Effects Division (7509C)

Karl Baetcke 11/24/95

Requested Action

Macro Flo Company, Lakeland, Florida has applied for registration of Acephate Technical, a product similar to the already registered Valent U.S.A. Corporation's Acephate Technical. Regarding this "me-too" registration, Toxicology Branch/HED has been asked by the Registration Division to answer the following questions:

1. What is the significance of the differences between the new source and the registered source (of acephate) ?
2. Could HED (TOX) studies conducted with the registered source be used to support registration/reregistration of the new source ?
3. Are there any HED (TOX) studies to be conducted on the new source that may be needed to support registration of this new source ?



Recycled/Recyclable
Printed with Soy/Canola Ink on paper that
contains at least 50% recycled fiber

Response from Section I, Toxicology Branch I, HED

Question 1. From the toxicological viewpoint, the differences between the two sources of Acephate Technical are insignificant. The active ingredient (Acephate or O,S-Dimethyl acetylphosphoramidothioate) content of Acephate Technical from both sources is 97% and the inert ingredient content is 3%. The inert ingredients in both products are similar, but not identical. With one exception, the differences are essentially quantitative: for example, a typical Valent's acephate may have 0-0.1% of component a and 0.01-0.5% of component b, whereas a Micro Flo's acephate may have 0-0.005% of component a and 0.1-0.3% of component b. Unlike Valent's Acephate Technical, Micro Flo's Acephate Technical contains component c (1st impurity in CSF, dated 4/7/95). However, component c occurs in very small amounts and has low toxicity (mild irritant, according to THE MERCK INDEX). Both Acephate Technicals have the same CAS Registry Number.

Question 2. Yes, studies conducted with the registered Acephate Technical could be used to support the registration/reregistration of the Micro Flo's Acephate.

Question 3. Yes. Had the registered (Valent's) Acephate come up for the reregistration now (it was reregistered in September, 1987), two neurotoxicity studies with rats, Acute (81-8 SS) and Subchronic (90-Day, 82-5b), would have been required. Therefore, these studies are also required for the registration/reregistration of Micro Flo's Acephate Technical. However, both studies have already been requested from Valent U.S.A. Corporation in October, 1992. Also, in March, 1993, Dr. William F. Sette, Science Analysis Branch/HED, has instructed Valent what parameters should be tested in these studies (personal communication with Dr. Sette on November 22, 1995). Although not having these studies should not interfere with the registration of Micro Flo's Acephate Technical, Toxicology Branch/HED would appreciate hearing from the Registration or Reregistration Division what is the current status of these studies.