EEB REVIEW

DATE IN: 9-5-91   OUT:  

CASE #: 818944
SUBMISSION #: S401099
ID #: 056002

DATE OF SUBMISSION  7-2-91

DATE RECEIVED BY EFED 9-4-91

SRRD/RD REQUESTED COMPLETION DATE 10-5-91

EEB ESTIMATED COMPLETION DATE

SRRD/RD ACTION CODE/TYPE OF REVIEW 614 DATA WAIVER REQUEST

MRID # (S)

DP TYPE 001 SUBMISSION RELATED DATA PACKAGE

PRODUCT MANAGER, NO. LARRY SCHNAUBELT 72

PRODUCT NAME(S) 1-NAPHTHALEANECETIC ACID

TYPE PRODUCT  F R I N H D PLANT GROWTH REGULATOR

COMPANY NAME AMVAC CHEM. CORP. AND CHAS H. LILLY CO.

SUBMISSION PURPOSE REGISTRANTS REQUEST WAIVER OF PLANT DATA REQUIREMENTS FOR USE ON APPLES, PEARS AND CITRUS

COMMON CHEMICAL NAME
MEMORANDUM

OCT 7 1991

SUBJECT: Chas H. Lilly Chemical Company Minor Use/Low Volume Data Waiver Request For The Potassium Salt Formulation Of napthaleneacetic acid (NAA)

FROM: Douglas J. Urban, Acting Chief Ecological Effects Branch Environmental Fate And Effects Division (H7507C)

TO: Larry Scaubelt, PM - 72, Reregistration Branch Special Review And Reregistration Division (H7508W)

The Ecological Effects Branch (EEB) has reviewed the minor use, low volume data waiver request submitted by Chas H. Lilly Chemical Company for their potassium salt formulation of NAA. Registered NAA use sites include apples, pears, olives, citrus, and ornamentals. Through the data call-in process, the EEB has officially requested the following NAA studies:

122-1 (a) Non-target plant study using the potassium salt form.

122-1 (b) Non-target plant study using the potassium salt form.

122-2 Non-target aquatic plant using Lemna gibba and Selenastrum capricornutum

Based on a review of currently registered use patterns and domestic usage, the EEB does not grant a waiver for the above listed studies. The potassium salt form is the most widely used NAA formulation and the use pattern includes aerial application. The cost of conducting these studies is not expected to exceed $20,000 to $25,000.

If you have any questions regarding this review, please contact Richard Petrie at 557-7358 (Room 1024G - CM2).

cc: Amy Rispin
MEMORANDUM

OCT 7 1991

SUBJECT: Amvac Chemical Company Minor Use/Low Volume Data Waiver Request For naphthaleneacetic acid and It's Salts, Esters, and Acetamide Formulations.

FROM: Douglas J. Urban, Acting Chief, Ecological Effects Branch, Environmental Fate and Effects Division (H7507C)

TO: Larry Schnaubelt, PM - 72, Reregistration Branch, Special Review and Reregistration Division (H7508W)

The Ecological Effects Branch (EEB) has reviewed the minor use, low volume data waiver request submitted by Amvac Chemical Company on 06/12/91 for naphthaleneacetic acid (NAA) and its various formulations. The registered uses covered by this request include apples, pears, olives, citrus and ornamentals. Through the data call-in process, the EEB has officially requested the following NAA studies:

71-2 (a) Acute Avian Dietary. Two studies are required (ethyl ester and amide formulations) -------$ 10,000

72-1 (a) Acute bluegill. One study is required (ethyl ester) -----------------------------$ 8,500

72-2 (a) Acute Daphnia magna. One study is required (ethyl ester) ------------------------$ 10,000

122-1 (a) Non-target plant. Six sets are required (acid, ethyl ester, ammonium salt, sodium salt, potassium salt, amide) -------------$ 54,000

122-1 (b) Non-target plant. Six sets are required (same 6 forms as 122-1.a above) ------ $ 36,000

122-2 Non-target aquatic plant. Six sets are required (same 6 forms as 122-1.a above) --$ 42,000 using Lemna gibba and Selenastrum capricornutum

TOTAL (Amvac Estimates) $ 160,500
Based on a review of currently registered use patterns and domestic usage of the various forms of NAA, the EEB will reduce the above listed data requirements to the following:

71-2 (a) Two studies using ethyl ester and amide forms. ------------------------$ 10,000
72-1 (a) One study using the ethyl form. ----------$ 8,500
72-2 (a) One study using the ethyl form. ----------$ 10,000
122-1 (a) Two studies using the potassium salt and the ammonium salt forms. ------------------------$ 18,000
122-1 (b) Two studies using the potassium salt and the ammonium salt forms. ------------------------$ 12,000
122-2 Two sets using the potassium salt and the ammonium salt forms. ------------------------$ 14,000

TOTAL (Amvac Estimates) $ 72,500

This reduction in data requirements would result in a total cost reduction, by Amvac estimates, of $ 88,000.

* The potassium salt, sodium salt, and ammonium salt forms are applied aerially. The potassium salt form has the highest domestic usage, the acid form the lowest. The ammonium salt label (5481-66) warns that ornamental plants must be covered with a plastic sheet to prevent injury from drift.

In the Amvac data waiver request, they stated that they may cancel the ethyl ester and ammonium salt forms of NAA. If the registrant were to cancel these forms, the EEB data requirements would be reduced further to the following:

71-2 (a) One study using the amide form. ----------$ 5,000
122-1 (a) One study using the potassium salt ----------$ 9,000
122-1 (b) One study using the potassium salt ----------$ 6,000
122-2 One study using the potassium salt ----------$ 7,000

TOTAL (Avmac Estimates) $ 27,000
If Amvac cancels the ethylester and ammonium salt formulations, the total test cost reduction (by Amvac estimates) would be $133,500. The EEB feels that this is a reasonable reduction in data requirements given the minor use status of NAA.

If you have any questions regarding this review, please contact Richard Petrie at 557-7358 (Room 1024G -CM2).

cc: Amy Rispin