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

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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

MEMORANDUM

SUBJECT: Review of Phase 4 Package for Endothall and Salts

EFGWB Number: 91-0166, 91-0167, 91-0168 and 91-0234

Chemical Barcode: 038901 (Endothall), 038903 (Disodium endothall, 038904 (Dipotassium endothall) and 038905 [Mono (N,N-dimethyl alkyl amine)] endothall

DP Barcode: D157729, D157735, D157744 and D157750

Case Number: 2245

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Environmental Fate and Effects Division (H7507C)

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Endothall (7-oxabicyclo (2,2,1)heptane-2,3-dicarboxylic acid) is an active ingredient manufactured as a 75% technical grade chemical used to formulate 11.25% and 19.2% endothall disodium salts, 10.1 and 40.3% endothall dipotassium salts and 11.2, 15.9 and 53.0% endothall mono alkyl amine salts. The various formulations-granular, soluble concentrate and liquid-ready to use-are registered as pre- or postemergence herbicides for use on sugar beets, ornamental lawns and turf. They are also registered for use as an aquatic weed control herbicide and for defoliation and desiccation of cotton, alfalfa, potatoes and hops. A Label Use Information System (LUIS) report was not



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included with the package; however, the LUIS report containing the "General Chemical Report," "Aggregate Report Showing Maximum Rate Per Site" and the "Detailed Report" was received on 2/6/91.

The Phase 4 review package, less the LUIS report, for the list B chemical Endothall was provided to EFGWB on 11/19/90 and 12/4/90. EFGWB has reviewed the use pattern and maximum application rates information as gleaned from the LUIS report. Based on this information and comparing it with the data requirements as listed in 40 CFR Section 158.290, EFGWB concludes that the use patterns being supported are terrestrial food+feed, terrestrial non-food, aquatic food, aquatic non-food outdoor, aquatic non-food industrial and outdoor and indoor residential. The maximum application rates, taken from the LUIS detailed reports, vary depending upon the salts used and may be as high as 9.306 lb ai/A for terrestrial uses and 32.73 lb ai/A for aquatic uses.

Although 7-oxabicyclo (2,2,1)heptane-2,3-dicarboxylic acid (endothall) is the active herbicide moiety in all registered formulations of this chemical, the acid is not the formulated end-use product. The end-use product, as stated above, can be a soluble concentrate, granular or liquid-ready-to-use formulation of the disodium or dipotassium inorganic or mono alkyl amine organic salts of the parent compound. Since several chemical forms are available as end-use products, a single set of data requirements on the parent endothall acid may not provide a sufficient environmental fate profile for all registered products.

Only after the parent chemical dissociates or ionizes to the acid form will general data be applicable and then only for the acid moiety. Environmental fate bridging data is required to quantify the extent and rate of ionization or dissociation of the various endothal salts which cause subsequent formation of endothall acid. The bridging data that define the rate and completeness of the dissociation or ionization reactions of the various salts are essential to the understanding of the environmental fate of endothall. The process or processes and the rate at which the reactions occur as well as any substantial side reactions are needed to satisfy the environmental fate data requirements. Additionally, the environmental fate assessment of the mono alkyl amine moiety may be needed to support registration.

Furthermore, with the exception of the acid form of endothall, the field dissipation studies probably should not be initiated until basic bridging data and laboratory studies have been reviewed and been judged as satisfying the data requirements. These studies will allow EFGWB to suggest which endothall salts should be studied in the field.

The Phase 4 package received by EFGWB contained no summaries, product chemistry information or new studies. The chemical identity data are incomplete. Solubility, vapor pressure, pK_a and K_{ow} data are required to support the environmental fate assessment for endothall and its salts, disodium-, dipotassium- and mono alkyl amine endothall.

The following studies, including MRIDs, were listed in the summary of registrant's Phase 2 response as a previously submitted acceptable studies in which raw data was available. However, the registrant must have withdrawn the studies for review by EFGWB, since, in the Phase 3 response, they indicated they would provide a new study and did not submit a summary:

CHEMICAL IDENTITY--160-5 (MRID 35434, 67762, 96703)
HYDROLYSIS--161-1 (MRID 298901)
TERRESTRIAL FIELD DISSIPATION--164-1 (MRID 162921)
CONFINED ROTATIONAL CROP--165-1 (MRID 113953, 113971, 114502)
ACCUMULATION IN IRRIGATED CROPS--165-3 (MRID 99882, 96704, 94704, 71249)
BIOACCUMULATION IN FISH--165-4 (MRID 99882, 99884, 96703, 94704)
BIOACCUMULATION IN AQUATIC NON-TARGET ORGANISMS--165-5 (MRID 99882, 71249, 71035)

The following studies are required to support terrestrial use groups:

CHEMICAL IDENTITY--160-5
HYDROLYSIS--161-1
PHOTOLYSIS IN WATER--161-2
PHOTOLYSIS ON SOIL--161-3
AEROBIC SOIL METABOLISM--162-1
ANAEROBIC SOIL METABOLISM--162--2
ANAEROBIC AQUATIC METABOLISM--162-3
LEACHING AND ADSORPTION/DESORPTION--163-1
LABORATORY VOLATILITY--163-2
FIELD DISSIPATION FOR TERRESTRIAL USES--164-1
CONFINED ACCUMULATION IN ROTATIONAL CROPS--165-1
ACCUMULATION IN FISH--165-4

In addition to the above, the following studies are required to support aquatic use groups:

AEROBIC AQUATIC METABOLISM--162-2
AQUATIC FIELD DISSIPATION--164-2
ACCUMULATION IN IRRIGATED CROPS--165-3

The following studies are reserved:

PHOTOLYSIS IN AIR--161-4

FIELD VOLATILITY--163-3
LONG-TERM SOIL DISSIPATION--164-5
LONG-TERM AQUATIC DISSIPATION-164-5
FIELD ACCUMULATION IN ROTATION CROPS--165-2
BIOACCUMULATION--AQUATIC NON-TARGET--165-5
GROUND WATER--SMALL PROSPECTIVE--166-1
GROUND WATER--SMALL RETROSPECTIVE--166-2
GROUND WATER--LARGE RETROSPECTIVE--166-3
SURFACE WATER--FIELD RUNOFF-167-1
SURFACE WATER--SURFACE WATER MONITORING--167-2
DROPLET SIZE SPECTRUM--201-1
DRIFT FIELD EVALUATION--202-1

The registrant requested a waiver from the accumulation in fish (165-2) and aquatic non-target organisms (165-5) studies for endothall and its salts. The waiver requests were based on their statement that the studies were not required since the K_{ow} of endothall was close to zero and that it cannot be partitioned out of water with any organic solvent. Until EFGWB has reviewed acceptable chemical identity data, including K_{ow} , the studies are required.

The summary table of the status of environmental fate data requirements for endothall and its salts is attached.

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR ENDOTHALL AND SALTS
[DISODIUM, DIPOTASSIUM AND MONO (N,N-DIMETHYL ALKYL AMINE)]*

Chemical Code : 038901, -04, -05 Reviewer: Richard J. Mahler, EFGWB

Pesticide Type: Herbicide, algicide

Date: 3/7/91

Uses: Terrestrial Food, Feed and Non-food Crop
 Aquatic Food and Non-food (outdoor) Crop

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
<u>PRODUCT CHEMISTRY</u>				
160-5. Chemical ID	35434, 67762	Studies Withdrawn ^a		SWBSubmitted ¹
b	96703			
<u>DEGRADATION-LAB:</u>				
161-1. Hydrolysis	298901	Study Withdrawn ^a		SWBSubmitted ²
<u>Photodegradation:</u>				
161-2. In Water	None ^c	None		SWBSubmitted ³
161-3. On Soil	None	None		SWBSubmitted ⁴
161-4. In Air	None	None		Reserved ⁵ _d
<u>METABOLISM-LAB:</u>				
162-1. Aerobic Soil	None	None		SWBSubmitted ⁶
162-2. Anaerobic Soil	None	None		SWBSubmitted ⁷
162-3. Anaerob. Aquat.	None	None		SWBSubmitted ⁸
162-4. Aerobic Aquatic	None	None		SWBSubmitted ⁹

* Unless the registrant provides bridging data that quantifies the dissociation or ionization of endothall salts to the active ingredient, all the data requirements listed below for endothall acid will also be required for the salts of endothall.

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR ENDOTHALE AND SALTS (cont'd)

	Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
<u>MOBILITY STUDIES:</u>				
163-1. Leaching and Adsorp./Desorp.	None	None		SWBSubmitted ¹⁰
163-2. Volatil.(Lab)	None	None		Yes ¹¹
163-3. Volatil.(Field)	None	None		Reserved ¹²
<u>DISSIPATION-FIELD:</u>				
164-1. Terrestr.(Soil)	162921	Study Withdrawn ^a		SWBSubmitted ¹³
164-2. Aquat.(Sediment)	None	None		SWBSubmitted ¹⁴
164-3. Forestry	None	None		No ¹⁵
164-4. Combin./Tank Mix	None	None		No ¹⁶
164-5. Long Term Terr.	None	None		Reserved ¹⁷
164-5. Long Term Aqua.	None	None		Reserved ¹⁸
<u>ACCUMULATION STUDIES:</u>				
165-1. Conf. Rot. Crops	113953, 113971 114502	Studies Withdrawn ^a		SWBSubmitted ¹⁹
165-2. Field Rot. Crops	None	None		Reserved ²⁰
165-3. Irrigated Crops	99882, 96702 94704, 71249	Studies Withdrawn ^a		SWBSubmitted ²¹
165-4. Fish (Lab)	99882, 99884 96703, 94704	Studies Withdrawn ^a		Reserved ²²

PHASE IV ENVIRONMENTAL FATE SUMMARY TABLE FOR ENDOTHALL AND SALTS (cont'd)

Submitted Studies/ Addendums	DER/Addendum Review/Summary Identification	DER/Addendum Review/Summary Review Conclusions	Additional Data/Info Required?
<u>ACCUMULATION STUDIES: (cont'd)</u>			
165-5. Aqua. Non-target Organ. (Field)	99882, 71249 71035	Studies Withdrawn ^a	Reserved ²³
<u>GROUNDWATER MONITORING:</u>			
166-1. Small Prospect.	None	None	Reserved ²⁴
166-2. Small Retrospect.	None	None	Reserved ²⁴
166-3. Large Retrospect.	None	None	Reserved ²⁴
<u>SURFACE WATER:</u>			
167-1. Field Runoff	None	None	Reserved ²⁵
167-2. Surface Water Monitoring	None	None	Reserved ²⁵
<u>SPRAY DRIFT:</u>			
201-1. Droplet Spect.	None	None	Reserved ²⁶
202-1. Field Spray Drift Eval.	None	None	Reserved ²⁶

DEFINITIONS:

a. Study/Studies Withdrawn indicates that there are no DERs or summaries available for the study identified by MRID# in the first column/same row, but that the registrant has indicated in their Phase 3 response that another study will be submitted.

b. SWBSubmitted indicates that one or more studies will be submitted by the registrant as indicated in their Phase 3 response.

c. None indicates that the registrant did not list any studies or addendums in their Phase 2 and/or 3

responses for the data requirements. In addition EFGWB has no record of any studies or study/addendum combinations satisfying or partially satisfying the data requirements.

- d. Reserved indicates that the data requirement is being held in reserve since other information is needed to decide whether or not to impose the data requirements.

FOOTNOTES:

1. The chemical identity data are incomplete for Endothall and its salts. The following product chemistry data are required to support an environmental fate profile for Endothall and its salts.

	<u>Endothall Acid</u>	<u>Dipotassium Endothall</u>	<u>Disodium Endothall</u>	<u>Alkyl Amine Endothall</u>
Molec. Wt:	186.2	Not Provided	Not Provided	Not Provided
Empirical Form.:	$C_8H_{10}O_5$	"	"	"
Vapor Pressure:	Not Provided	"	"	"
Kow:	Not Provided	"	"	"
pK _a :	Not Provided	"	"	"
Solubility:	Not Provided	"	"	"

EFGWB notes that chemical identity studies were referenced in the Phase 2 response and listed as "Previously submitted acceptable study. Raw data are available;" however, the registrant apparently withdrew the studies since the Phase 3 response indicates registrant will submit new chemical identity studies.

2. A hydrolysis study was referenced in the registrant's Phase 2 response and listed as "Previously submitted acceptable study. Raw data are available;" however, the registrant apparently withdrew the study since the Phase 3 response indicates registrant will submit a new hydrolysis study.

3. The registrant indicated in the Phase 3 response that a new photodegradation in water study would be submitted.

4. The registrant indicated in the Phase 3 response that a new photodegradation on soil study would be submitted.

5. The photodegradation in air study is reserved pending results of the laboratory volatility study.

6. The registrant indicated in the Phase 2 response that a new aerobic soil metabolism study would be submitted.

7. The registrant indicated in the Phase 2 response that a new anaerobic soil metabolism study would be submitted. EFGWB notes that an acceptable anaerobic aquatic metabolism study can substitute for the anaerobic soil metabolism study; however, the opposite is not possible.

8. The registrant indicated in the Phase 2 response that a new anaerobic aquatic metabolism study would be submitted.
9. The registrant indicated in the Phase 3 response the a new aerobic aquatic metabolism study would be submitted.
10. The registrant indicated in the Phase 3 response that a new leaching and adsorption/desorption study would be submitted.
11. The registrant indicated in the Phase 3 response that the laboratory volatility study was not required. However, they did not offer any explanation of why it was not required, nor did they request a waiver for the study. Therefore, the laboratory volatility study is required.
12. The field volatility study is reserved pending results from an acceptable laboratory volatility study.
13. A field dissipation study was referenced in the registrant's Phase 2 response and listed as "Previously submitted acceptable study. Raw data are available." However, the registrant apparently withdrew the study since the Phase 3 response indicated registrant would submit new terrestrial field dissipation studies.

Depending on the results of the bridging data linking the dissociation and ionization of endothall salts to the active ingredient, additional field dissipation data may be required using the endothall salts.

14. The registrant indicated in the Phase 2 response that a new aquatic field dissipation study would be submitted.
15. Not required since endothall or its salts have no forestry uses.
16. This study is not being imposed at this time.
17. The registrant indicated in the Phase 2 response that a long term field dissipation study was not required. However, they did not offer any explanation of why it was not required, nor did they request a waiver for the study. Therefore, the long term field dissipation study is reserved pending the receipt of acceptable field dissipation studies.
18. A long term aquatic field dissipation study is reserved pending receipt of an acceptable aquatic field dissipation study.
19. Three confined rotational crop studies were referenced in the registrant's Phase 2 response and listed as "Previously submitted acceptable study. Raw data available." However, the registrant apparently withdrew the studies since the Phase 3 response indicated that the registrant would submit a new study.

20. The registrant indicated in the Phase 2 response that the field rotational crop study was not required. However, they did not offer any explanation of why it was not required, nor did they request a waiver for the study. Therefore, the field rotational crop study is reserved pending results from an acceptable crop rotational study.

21. Four accumulation in irrigated crops studies were referenced in the registrant's Phase 2 response and listed as "Previously submitted acceptable study. Raw data are available." However, the registrant apparently withdrew the studies since the Phase 3 response indicated registrant would submit a new accumulation in irrigated crops study.

22. The registrant requested a waiver from the bioaccumulation in fish study for endothall and its salts. The waiver was based on their statement that "this study is not required if the octanol/water partition coefficient is less than 1000. The K_{ow} of Endothall is essentially zero; it cannot be partitioned out of water with any organic solvent." EFGWB notes that the K_{ow} is not the sole criterion for determination of the 165-4 study. Therefore, this study is reserved pending the results of acceptable environmental fate studies, particularly the chemical identity studies, which will include K_{ow} .

23. The registrant requested a waiver from the accumulation in aquatic non-target organisms (165-5) studies for endothall and its salts. The waiver requests were based on their statement that the study was not required since the K_{ow} of endothall was close to zero and that it cannot be partitioned out of water with any organic solvent. Until EFGWB has reviewed acceptable environmental fate data, including K_{ow} , the study is reserved.

24. Ground water monitoring studies are reserved pending review of acceptable environmental fate studies.

25. If projected aquatic residues, based on modeling scenarios, are of environmental concern, this study may be required.

26. In general, droplet spectrum and field spray drift information will be required if one of the following criteria are met:

1. Human exposure - The chemical is classified as being in Toxicity Category I or II for human acute inhalation or dermal effects studies;
2. Aquatic animal wildlife exposure - The chemical is used in close proximity to aquatic systems and five percent of the applied quantity yields a greater than ten percent mortality for aquatic animal species. This is based on the fact that about one to five percent of an applied pesticide can drift 100 yards (100 meters) in a ten knot (4.5 m/s) wind when applied about ten feet above the crop canopy. Terrestrial wild animal situations are based on human toxicity criteria given above; or
3. Wild and cultivated plant exposure - The chemical is used in close proximity to sensitive plants, as noted in phytotoxicity testing, including endangered and threatened species, that may be found within 100 to 500 yards (100 to 500 meters) downwind.