

6-18-91

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 18, 1991

MEMORANDUM

SUBJECT: Transmittal of EFED List B Review for Endothall (Case # 2245; Chemical # 038901 (dicarbolic acid); Chemical # 038903 (disodium salt); Chemical # 038904 (dipotassium salt) and Chemical # 038905 (monosalt)

FROM: Amy Rispin, Chief *Amy Rispin*
Science Analysis and Coordination Staff
Environmental Fate and Effects Division

TO: Jay Ellenberger, Chief
Generic Chemical Support Branch
Special Review and Reregistration Division

Attached please find the following documents for the completed EFED review of Endothall its salts.

1. EFGWB review and data requirements table, as amended
2. EEB review and data requirements table
3. SACS Reregistration Summary Report

If you have any questions concerning this case, please contact Ruth Allen at 557-8296.

cc (with SACS Reregistration Summary Report attached)

Anne Barton Hank Jacoby
List B File
List B Cover Memo File

Jim Akerman

HJ
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SACS REREGISTRATION SUMMARY REPORT
for Phase IV

FROM: Ruth Allen, Ph.D., M.P.H.

Date May 15, 1991
(EEB update 6-18-91
re: bridging data)

THROUGH: Amy Rispin, Chief SACS

TO: Ernie Dobbins, SRRD

Active Ingredient: Endothall (and salts) # 2245; Chemical #
038901/903/904/905

List B

1. Intro/History

The chemical, also known as, 7-oxabicyclo [2,2,1]heptane-2,3-dicarboxylic acid and sodium, potassium or amine salt is a pre, postemergence herbicide, defoliant, desiccant, aquatic algicide, and growth regulator. It is listed as a granular in the '91 Farm Chemical Handbook and chapters, but not in the LUIS report which lists formulation unknown several times. The chemical has a complicated use pattern that is summarized below.

This memo on the chemical has been amended, as follows after the policy on the use of bridging data was clarified by EFED management. Pending the receipt, review and concurrence of bridging data by EFGWB that demonstrates that the dipotassium and sodium salts of endothall rapidly dissociate in water, the data marked by "x" are no longer required for EEB. Terrestrial and plant testing would still be required on endothall and its salts.

2. Use Pattern (Sites) and Application Rate.

The endothall (#038901) has no uses listed in LUIS.

The disodium salt of endothall (#038903) has the following uses listed in LUIS: terrestrial non-food crop, terrestrial non-food+outdoor residential, and outdoor residential. These uses include golf course turf and ornamental lawns and turf. This chemical has geographic limitations and it is disallowed in three states: NH, OR, and WA. It is used seasonally as a soluble concentrate liquid, and the application type is broadcast. There is a restriction that states do not apply this product through any type of irrigation system.

The dipotassium salt of endothall (#038904) has the following uses: terrestrial food+feed crop, aquatic food crop, aquatic non-food outdoor, and aquatic non-food industrial. It is formulated as a

granular and as a soluble concentrate liquid. This chemical is used in agricultural drainage systems, irrigation systems, lakes/ponds/ reservoirs with human or wildlife use, on sugar beets, in streams/ rivers/ channeled water and swamps/ marshes/ wetlands/ stagnant water aquatic sites.

This chemical has geographic limitations and is disallowed in AL, CA, FL, OR, TN, and TX. A restricted entry interval is given for one sugar beet use grown for seed only. There are restrictions for aquatic sites stating that fish from treated waters should not be used for feed or food for a specified interval. Also, avoid treating areas within 300 feet of potable water, and do not swim in treated water for 24 hours.

Application rates vary and are listed in LUIS as high as 9.3 lb ai/A (terrestrial use) or 32.7 lb ai/A (aquatic use). Aircraft and boats are used to apply the chemical.

The mono salt (alkyl amine) (#038905) has the following uses: terrestrial food crop, terrestrial food+feed crop, aquatic food crop, and aquatic non-food industrial. This chemical has use sites similar to above, but also includes alfalfa, cotton, hops, potatoes, and rice.

It is applied as a soluble concentrate liquid, and liquid-ready to use. Some product forms are homeowner restricted use chemicals. This chemical form has numerous state registrations for following types of uses: herbicide, algicide, defoliant, desiccant, and/or plant regulator.

There are geographic limitations and the chemical is disallowed in the following states: AL, AZ, CA, FL, ID, IN, NM, NV, OK, OR, TX, WA, WY. The chemical is allowed for aquatic food crops in irrigation systems for seven states. Use limitations and restricted entry intervals of 28 days preharvest are listed for various states, e.g., do not feed treated forage to dairy animals or animals being finished for slaughter; do not graze treated areas; do not use treated seed for feed, food or oil purposes; and, do not irrigate rice with treated water before it emerges above the surface of or after rice starts heading.

3. Registration Information

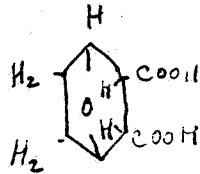
A. Kind of pesticide. (insecticide, herbicide, etc.)

Pre- and Post emergence herbicide

B. Target Pest.

These are not clear from LUIS, but the published uses in the '91 Farm Chemical Handbook are: for sugar beets, turf; hops sucker suppression; alfalfa, clover desiccant; cotton harvest aid; and potato vine killer.

D. Formulation Issues and Structure:



The active ingredient is manufactured as 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% endothall mono alkyl amine salts.

5. EEB Disciplinary Summary To highlight special issues

Because of the many use patterns, this chemical has the potential for widespread exposure to ecological systems. The data requirements are discussed in detail in the Phase IV EEB attachments separately for each of the four salts.

N.B. On 6-3-91 based on consultation with EEB on the question of bridging data, Dan Rieder provided the rationale for EEB to accept bridging data. (see attached memo) Subsequently, it was agreed that for the aquatic studies only, EEB data requirements apply on either disodium or dipotassium salts of endothall, pending the receipt and concurrence of bridging data by EFGWB that the acid and salt are identical in water.

The studies that would no longer be applied if bridging data are acceptable are and marked "x".

Bridging data for plants would be tier II phyto toxicity tests. Field data for any salt could not suffice for field testing with another salt.

For endothall (#038901), a manufacturing use product, the EEB data requirements are:

- 71-1 (a) Acute Avian Oral, Duck/Quail (if the MUP is a solid)
- 71-2 (a) or (b) Acute Avian Diet/ Quail & Duck
- 72-1 (a) Acute Fish Toxicity/Bluegill
- 72-1 (c) Acute Fish Toxicity/Rainbow Trout
- 72-2 (a) Acute Aquatic Invertebrate Toxicity

For disodium salt (#038903), the EEB data requirements are:

- 71-1 (a) Acute Avian Oral, Quail/Duck
- 71-2 (a) Acute Avian Diet/ Quail
- 71-2 (b) Acute Avian Diet/ Duck
- 72-1 (a) Acute Fish Toxicity/ Bluegill
- 72-1 (c) Acute Fish Toxicity/ Rainbow
- 72-2 (a) Acute Aquatic Invertebrate Tox

The following tests are required for products registered for use on golf courses, ornamental lawns, and turf:

- 72-3 (a), (b) & (c) Acute Estuarine/ Marine Toxicity-

Fish, Mollusc and Shrimp

The following study is required, and may be satisfied by the EFGWB fish bioaccumulation study:

72-6 Aquatic Org. Accumulation

The following studies are held in reserve for the reasons detailed in the attached EEB data requirements, and summarized below:

- 71-1 (b) Acute Avian Oral (TEP) [for granular formulations depending on acute toxicity of active ingredient]
- 71-4 (a) & (b) Avian Reproduction/ Quail & Duck [pending additional fate and use information; required for products registered for multiple treatments per season]
- 71-5 (a) & (b) Simulated & Actual Field [pending results of lower tier tests and more complete use and fate information]
- 72-1 (b) & (d) Acute Fish Tox/ Bluegill (TEP) & Rainbow Trout (TEP) and
- 72-2 (b) Acute Aquatic Inv. [pending acute toxicity test results, toxicity information on inerts, and additional use information that may suggest direct application to water is likely]
- 72-3 (d), (e) & (f) Acute Est/Mari Tox Fish (TEP) & Moll (TEP) & Shrimp (TEP) [pending additional use information, and information on the toxicity of active and inert ingredients]
- 72-4 (a) Early Life-Stage Fish and
- 72-4 (b) Life-Cycle Aquatic Invertebrate and
- 72-5 Life Cycle Fish and
- 72-7 (a) Simulated Aquatic Field Study and
- 72-7 (b) Actual Aquatic Field Study [pending results of lower tier tests, more complete use and fate information]
- 123-1 (a) Seed Germ./Seedling Emerg. and
- 123-1 (b) Vegetative Vigor [pending additional use or fate information indicating that transport to adjacent terrestrial or aquatic habitat is likely]
- 124-1 Terrestrial Field and
- 124-2 Aquatic Plant Growth [pending results of lower tier tests and more complete use information and environmental fate information]
- 141-2 Honey Bee Residue on Foliage
- 141-5 Field Test for Pollinators

For dipotassium endothall (#038904) the EEB data requirements are: 71-1 (a) Acute Avian Oral, Quail/ Duck

- 71-2 (a) & (b) Acute Avian Diet/ Quail & / Duck
- x 72-1 (a) & (c) Acute Fish Toxicity/ Bluegill & /Rainbow
- x 72-1 (b) & (d) Acute Fish Tox Bluegill (TEP) & /Rainbow (TEP) and
- x 72-2 (a) & (b) Acute Aquatic Invertebrate Toxicity & TEP [formulation testing for all TEP's applied directly to water]
- x 72-3 (a), (b) & (c) Acute Estuarine/Marine Toxicity- Fish, Mollusc and Shrimp [required for products registered for use on ditch banks and in bayous, marshes, streams and channels]
- x 72-3 (d), (e) & (f) Acute Estu/Mar Tox Fish (TEP), Moll (TEP) & Shrimp (TEP)
- x 72-6 Aquatic Org. Accumulation [bioaccumulation testing required by EFGWB will suffice for the requirement]

The following studies are in reserve:

- 71-1 (b) Acute Avian Oral (TEP) [required for granular formulations depending on acute toxicity of active ingredient]
- 71-4 (a) & (b) Avian Reproduction Duck/ & Quail [Required for products registered for multiple treatments per season]
- 71-5 (a) & (b) Simulated & Actual Terrestrial Field and
- 72-4 (a) Early Life-Stage Fish and
- 72-4 (b) Life-Cycle Aquatic Invertebrate and
- 72-5 Life-Cycle Fish and
- 72-7 (a) Simulated Aquatic Field Study and
- 72-7 (b) Actual Aquatic Field Study
- 124-1 Terrestrial Field
- 124-2 Aquatic Plant Growth [pending results of lower tier tests, more complete use information and environmental fate information]
- 141-2 Honey Bee Residue on Foliage
- 141-5 Field Test for Pollinators

For the mono salts (alkyl amine) (#038905), the EEB data requirements are:

- 71-1 (a) Acute Avian Oral, Duck/Quail
- 71-2 (a) & (b) Acute Avian Diet/ Quail & Duck
- 71-4 (a) & (b) Avian Reproduction/ Quail & /Duck [Required for products registered for multiple treatments per year, and may also be required depending on environmental fate information]
- 72-1 (a) & (b) Acute Fish Toxicity/Bluegill & TEP
- 72-1 (c) & (d) Acute Fish Toxicity/ Rainbow & TEP
- 72-2 (a) & (b) Acute Aquatic Inv. Toxicity and TEP [Formulation testing is required for TEP's applied directly to water]
- 72-3 (a), (b) & (c) Acute Estuarine/Marine Toxicity-

Fish, Mollusc and Shrimp [Required for products registered for use on ditch banks and in bayous, marshes, streams and channels]

72-3 (d), (e) & (f) Acute Estu/Mar Tox Fish (TEP), Moll (TEP) & Shrimp (TEP)

[Formulation testing for all TEP's applied directly to water]

72-6 Aquatic Org. Accumulation [bioaccumulation testing required by EFGWB will suffice for the requirement]

123-1 (a) Seed Germ./Seedling Emerg. and

123-1 (b) Vegetative Vigor

[TIER II terrestrial plant testing is required for aerial application that may permit drift to non-target habitat]

123-2 Aquatic Growth [TIER II testing for 5 species]

141-1 Honey Bee Acute Contact

The following studies are reserved for mono salts #038905:

71-1 (b) Acute Avian Oral (TEP) [may be required for granular formulations, depending on acute toxicity]

71-5 (a) & (b) Simulated & Actual Terrestrial Field [reserved pending results of lower TIER tests, additional environmental fate and use information]

72-4 (a) Early Life-Stage Fish and

72-4 (b) Life-Cycle Aquatic Invertebrate and

72-5 Life-Cycle Fish and

72-7 (a) & (b) Simulated and Actual Field Study [reserved pending results of lower tier tests, more complete use information and more complete environmental fate information]

6. EFGWB Disciplinary Summary To highlight special issues

The EFGWB reviewer notes that the following studies are still to be submitted and are therefore data gaps at this time:

160-5 Chemical Identity

161-1 Hydrolysis

161-2 Photodegradation in Water

161-3 Photodegradation in Soils

162-1 Aerobic Soil Metabolism

162-2 Anaerobic Soil Metabolism

162-3 Anaerobic Aquatic Metabolism

162-4 Aerobic Aquatic Metabolism [required to support aquatic use groups]

163-1 Leaching and Adsorption/Desorption

163-2 Laboratory Volatility

164-1 Terrestrial Field Dissipation

164-2 Aquatic (Sediment) Dissipation [required to support aquatic use groups]

165-1 Confined Rotational Crop

165-3 Accumulation in Irrigated Crops [required to support aquatic use groups]

165-4 Bioaccumulation in Fish

The following studies are reserved;

- 161-4 Photodegradation in Air
- 163-3 Volatility (Field)
- 164-5 Dissipation- Long Term Terr.
- 164-6 Dissipation- Long Term Aqua.
- 165-2 Accumulation Studies: Field Rot. Crops
- 165-5 Accumulation Studies: Aqua. Non-target Organ.
(Field)
- 166-1 Ground Water--Small Prospective
- 166-2 Ground Water--Small Retrospective
- 166-3 Ground Water--Large Retrospective
- 167-1 Surface Water--Field Runoff
- 167-2 Surface Water--Surface Water Monitoring
- 201-1 Droplet Spray Spectrum
- 202-1 Drift Field Evaluation

The EFGWB reviewer notes that all data requirements listed for the endothall acid will also be required for the salts of endothall, unless the registrant provides bridging data that quantifies the dissociation or ionization of endothall salts in comparison with the active ingredient. Additionally, the environmental fate assessment of the mono alkyl amine may be needed to support registration.

7. Integrating Paragraph to highlight special issues

This case contains four chemicals and includes an acid, which is not the formulated end-use product, and various salts. Since several chemical forms are available as end-use products, one set of data requirements on the parent may not provide sufficient environmental fate information for all registered products.

For EFGWB data requirements, bridging data conditions and the requirements for consideration of a waiver request are contained in the attached EFGWB chapter. Environmental fate bridging data are required to quantify the extent and rate of ionization or dissociation of various endothall salts.

Ecological Effects Branch data requirements were originally listed as separate requirements for each chemical. These requirements are summarized above and attached for reference, in case the toxicity data are not comparable for endothall and its salts. After the cover memo was signed, at SACS request and in order to integrate the science policy positions for both EFED Branches, EEB's reviewer reconsidered the question of bridging data and issued a memo to recommend specific terms and conditions for the use of bridging data to satisfy ecological effects data requirements (see attached memo). Subsequently, Division policy was reaffirmed that EEB will follow EFGWB on the use of bridging data, if the salts dissociate instantly in water to form the acid, and therefore have comparable toxicity, then redundant testing of salts is not required for aquatic tests only. Terrestrial and plant data requirements apply to both endothall and its salts.

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Both branches have a long list of qualifying footnotes that have been summarized above. The readers should still note the original list for details on the background and logic for a particular requirement.

On uses, the EFGWB chapter lists indoor residential as a use pattern, but this is not contained in LUIS. After consultation with the section chief and reviewer, it was determined that this difference did not alter the data requirements and no change was made to the chapter.

8. Ecotoxicity studies to be flagged for early review for tier or other decisions

See data requirement above marked by [].

9. Any data waivers, special considerations, or special study needs? (special information needed for data waivers)

The EFGWB reviewer, in footnotes 22 and 23, states that waiver decisions are pending the results of environmental fate data requirements. Waivers were requested for:

- 165-2 Accumulation in Fish
- 165-5 Aquatic Non-target Organism

The studies are required for endothall and its salts until EFGWB has reviewed acceptable chemical identity data.

For EEB, the question of a waiver for 72-6 bioaccumulation testing depends on EFGWB. If they only require bioaccumulation with one salt then EEB will concur. For plants, field testing with any salt could not suffice for field testing with another salt.

June 3, 1991

NOTE TO: Ruth Allen

FROM: *Dan Rieder*
Dan Rieder

SUBJECT: Use of Bridging Data for Endothal and Salts

The EEB has considered the use of bridging data for endothal and its salts. Bridging data, in the form of the 6 basic ecological effect studies¹ will be acceptable. These tests must be performed on endothal² and on each of the salts of endothal, including disodium endothal, dipotassium endothal and the mono salt (alkyl amine). If these tests show the various forms of endothal to be substantially similar in toxicity, it may be justification to waive the higher tier tests. This includes those that are required, and those reserved. Specifically, estuarine studies are required for the three salts of endothal because of their registered uses. If the bridging data show the salts to be similar in toxicity, estuarine testing would be required only for one salt. The waiver of the bioaccumulation testing (72-6) with all three of the salts depends on the EFGWB. If they only require bioaccumulation with one salt, then EEB will concur. *

The phyto-toxicity data, conversely, cannot be waived based on bridging data. Two primary reasons:

1. It is considered likely that these salts were developed to be efficacious on different types of plants under different conditions. Therefore, their toxicity is likely to be different.

2. "Bridging data" for plants would be the Tier II phyto-toxicity tests. The next Tier, if triggered, would be field studies. Since this would be performed using the particular end use products of concern, and each different salt is formulated into different end use products, bridging data could not provide scientific justification for a waiver. Field testing with any salt could not suffice for field testing with another salt.

If you have questions, please contact me.

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- ¹ Avian acute oral LD50
Avian dietary LC50 with an upland gamebird
Avian dietary LC50 with a waterfowl
Coldwater fish LC50
Warmwater fish LC50
Freshwater aquatic invertebrate EC50

² Since there are no registered uses of endothal and it is a manufacturing use product only, a reduced data set is required, see the Summary Report.

* amended 6-18-91

see EEB section of cover memo

(10)