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

05 FEB 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Lactic Acid - Expedited Review of Proposed
Registration of New Chemical, in Registration
Standard Format - Final Revision

FROM: Allen W. Vaughan, Entomologist *Allen W. Vaughan*
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Hazard Evaluation Division (TS-769C)

THRU: Norman J. Cook, Head, Section II *Norman J. Cook*
Ecological Effects Branch *2.4.88*
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THRU: Henry T. Craven, Acting Chief *H. T. Craven*
Ecological Effects Branch *2.4.88*
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TO: Robert J. Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division (TS-767C)

The Ecological Effects Branch (EEB) has reviewed the proposed registration of lactic acid as a growth regulator for various crops. The EEB review has been completed in Registration Standard format. Attached material includes Topical Summary, Disciplinary Review, and Data Table, which have been substantially revised to reflect changes agreed upon in October of 1987. Specifically, EEB has determined that:

- 1) No additional data are required for nontarget organisms;
- 2) Standard requirements for nontarget plant testing are waived. In lieu of these requirements, the registrant should submit whatever efficacy data are available.

Attachments

cc: B. Lowery (SPSM/HED)
H. Jacoby (SIPS/HED)

205606
RECORD NO.

128929
SHAUGHNESSY NO.

REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 10/19/87 OUT 05 FEB 1988

FILE OR REG. NO. 9018-A

PETITION OR EXP. PERMIT NO. _____

DATE OF SUBMISSION 10/14/87

DATE RECEIVED BY HED 10/16/87

RD REQUESTED COMPLETION DATE 02/02/88

EEB ESTIMATED COMPLETION DATE 02/02/88

RD ACTION CODE/TYPE OF REVIEW 111

TYPE PRODUCT(S): I, D, H, F, N, R, S Plant Growth Regulator

DATA ACCESSION NO(S). _____

PRODUCT MANAGER NO. R. Taylor (25)

PRODUCT NAME(S) Propel SY-83 (Lactic acid)

COMPANY NAME Brea Agricultural Services, Inc.

SUBMISSION PURPOSE Submission of Data to Support Proposed
Registration of Use on a Variety of Crops

SHAUGHNESSY NO.	CHEMICAL & FORMULATION	% A.I.
<u>128929</u>	<u>Lactic Acid</u>	<u>80%</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____

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Lactic Acid (Propel, SY-83)

Ecological Effects Topical Summaries

Effects on Birds

Three studies in three documents were evaluated under this topic. All three studies were acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Beavers	1986	265647
Beavers	1986	265649
Beavers	1986	265650

In order to establish the toxicity of lactic acid to birds, the following tests are required using the technical grade material: Two subacute dietary studies on one species of waterfowl (preferably mallard duck) and one species of upland game bird (preferably bobwhite quail or ring-necked pheasant); an avian single-dose oral study on one species (preferably mallard duck or bobwhite quail).

The acceptable single-dose oral study for use in a hazard assessment is listed below:

<u>Species</u>	<u>% ai</u>	<u>LD₅₀ (mg/kg)</u>	<u>Author</u>	<u>Date</u>	<u>Accession Number</u>	<u>Fulfills Requirement</u>
Bobwhite quail	100	> 2250	Beavers	1986	265650	Yes

There is sufficient information to characterize lactic acid as practically nontoxic to birds on an acute oral basis. The avian single-dose oral Guideline requirement has been satisfied by the evaluated document.

The acceptable subacute dietary toxicity studies for use in a hazard assessment are listed below:

<u>Species</u>	<u>% ai</u>	<u>LC₅₀ (ppm)</u>	<u>Author</u>	<u>Date</u>	<u>Accession Number</u>	<u>Fulfills Requirement</u>
Bobwhite quail	100	> 5620	Beavers	1986	265647	Yes
Mallard duck	100	> 5620	Beavers	1986	265649	Yes

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There is sufficient information to characterize lactic acid as practically nontoxic to birds on a subacute dietary basis. The avian subacute dietary Guideline requirement has been satisfied by the evaluated documents.

Avian reproduction tests are required for an end-use product when birds may be subjected to repeated or continuous exposure, the product is stable in the environment, stored or accumulated in plant or animal tissues, or reproduction in terrestrial vertebrates may be adversely affected based on information from mammalian reproduction studies. As none of the above criteria are met under the proposed registrations, avian reproduction testing is not required.

Precautionary Labeling

Labeling is not required at this time.

Effects on Fish

Two studies in two documents were evaluated under this topic. Both studies were acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Forbis, et al.	1984	265651
Forbis, et al.	1984	265652

The minimum lactic acid data required for establishing the acute toxicity to fish are the results from two 96-hour studies with the technical grade material. The studies should be performed on one coldwater species (preferably rainbow trout) and one warmwater species (preferably bluegill sunfish).

The acceptable toxicity studies for use in a hazard assessment are listed below:

<u>Species</u>	<u>% ai</u>	<u>LC₅₀ (ppm)</u>	<u>Author</u>	<u>Date</u>	<u>Accession Number</u>	<u>Fulfills Requirement</u>
Bluegill	100	130	Forbis, et al.	1984	265651	Yes
Rainbow trout	100	130	Forbis, et al.	1984	265652	Yes

There is sufficient information to characterize lactic acid as practically nontoxic to fish. The Guideline requirement for the technical grade active ingredient (TGAI) has been satisfied.

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Fish Early Life Stage

Data from a fish early life stage test may be required if the product is expected to be transported to water from the intended use site. The rapid degradation of lactic acid in the environment precludes the need for this test.

Precautionary Labeling

Based on one above data, precautionary statements for fish are not required.

Effects on Freshwater Invertebrates

One study in the document was evaluated under this topic. The study was acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Forbis, et al.	1984	265648

The minimum data required to establish the acute toxicity of lactic acid to freshwater invertebrates is a 48-hour aquatic study with the technical material. The test organisms should be first instar Daphnia magna or early instar amphipods, stoneflies, or mayflies.

The acceptable acute toxicity data on the technical material for use in a hazard assessment are listed below.

<u>Species</u>	<u>% ai</u>	<u>LC50 (ppm)</u>	<u>Author</u>	<u>Date</u>	<u>Accession Number</u>	<u>Fulfills Requirement</u>
<u>Daphnia magna</u>	100	750	Forbis, et al.	1984	265648	Yes

There is sufficient information to characterize lactic acid as practically nontoxic to aquatic invertebrates.

The Guideline requirement for a 48-hour EC50 for freshwater invertebrates has been satisfied.

Aquatic Invertebrate Life Cycle

Data from an aquatic invertebrate life cycle test may be required if the product is expected to be transported to water from the intended use site. The rapid degradation of lactic acid in the environment precludes the need for this test.

Precautionary labeling

No toxicity statement is required.



Effects on Estuarine and Marine Organisms

No studies were evaluated under this topic. Data on the acute toxicity to estuarine and marine organisms are required to support the registration of an end-use product intended for direct application to the estuarine or marine environment or if it is expected to enter this environment in significant concentrations because of its expected use or mobility pattern. As lactic acid does not meet these criteria, testing on estuarine and marine organisms is not required.

Effects on Beneficial Insects

One study in one document was evaluated under this topic. The study was acceptable for use in a hazard assessment.

<u>Author</u>	<u>Date</u>	<u>Accession No.</u>
Dingledine	1985	265646

The minimum data required to establish the acute toxicity of lactic acid to honey bees is an acute contact LD50 study with the technical material.

The acceptable toxicity study is outlined below:

<u>Species</u>	<u>% ai</u>	<u>LD50 (ug/bee)</u>	<u>Author</u>	<u>Date</u>	<u>Accession Number</u>	<u>Fulfills Requirement</u>
Honey bee	100	> 100.4	Dingledine	1985	265646	Yes

There is sufficient information to characterize lactic acid as practically nontoxic to honey bees. The Guideline requirement for acute toxicity testing with honey bees has been fulfilled.

Precautionary Labeling

Based on the above data, no toxicity statement is required.

Plant Protection

No studies were evaluated under this topic.

The registrant's response to the original standard was that Tier I Plant Protection studies should not be required, since lactic acid: is a natural constituent of all plant systems; does not pose phytotoxicity problems at the label rate on any crop; will not be used in forests or natural grasslands; does not meet triggers for plant protection testing.

In view of the above, EEB has determined that the registrant should submit whatever efficacy data are available. These data may be sufficient to satisfy the requirements for nontarget plant testing.

Lactic Acid - Ecological Effects Disciplinary Review

I. ECOLOGICAL EFFECTS PROFILE

A. Manufacturing Use

1. Avian Studies

An LC₅₀ of > 5620 ppm was reported for the bobwhite quail, Colinus virginianus (Beavers 1986, Accession No. 265647). An LC₅₀ of > 5620 ppm was also reported for the mallard duck, Anas platyrhynchos (Beavers 1986, Accession No. 265649). Lactic acid can be characterized as practically nontoxic to birds on a subacute dietary basis.

An LD₅₀ of > 2250 mg/kg was reported for the bobwhite quail (Beavers 1986, Accession No. 265650). Lactic acid can be characterized as practically nontoxic to birds on an acute oral basis.

2. Aquatic Studies

For bluegill, Lepomis macrochirus, and rainbow trout, Salmo gairdneri, the 96-hour LC₅₀ value was reported to be 130 ppm (Forbis et al., 1984, Accession Nos. 265651 and 265652). Lactic acid can be characterized as practically nontoxic to freshwater fish.

An LC₅₀ of 750 ppm was reported for Daphnia magna (Forbis et al. 1984, Accession No. 265648). Lactic acid can be characterized as practically nontoxic to freshwater aquatic invertebrates.

3. Nontarget Insect Studies

An acute contact LD₅₀ of > 100.4 ug/bee was reported for the honey bee, Apis mellifera (Dingledine 1985, Accession No. 265646). Lactic acid can be characterized as practically nontoxic to honey bees.

B. Formulated Product

No data were available on formulated product testing.

II. ECOLOGICAL EFFECTS HAZARD ASSESSMENT

Lactic acid, as a plant growth regulator, has the following proposed uses: almonds, apples, beans (green and dry), broccoli, cabbage, cauliflower, cherries, citrus, corn (sweet and field), cotton, grapes, lettuce, peppers (green and chili), pineapples, prunes, strawberries, sugarcane,

tomatoes, and walnuts. Depending on the crop involved, the purpose of lactic acid application is to increase fruit size, increase fruit set, hasten ripening, compress maturity, etc.

Rates of application range from 1.0 to 4.0 lb ai/A, with a typical application rate being 2.0 lb ai/A. One application is indicated for the following crops, to be made: during bloom (beans, corn [at tasseling], cotton [first squaring], peppers, and tomatoes); immediately following bloom (almonds, cherries, citrus, prunes, and walnuts); 1 to 3 weeks after thinning or transplanting (broccoli, cabbage, cauliflower, and lettuce). Two applications are indicated for apples (during bloom and 30 to 45 days prior to harvest), grapes (3 to 14 days postshatter and at veraison), and strawberries (30 days after transplanting and at midbloom). For pineapples, directions include a 500 ppm preplant dip for crowns and/or slips, followed 30 days later by foliar application, followed by a third application 30 to 45 days prior to harvest. Sugarcane use calls for a 500 ppm seed piece dip, followed by foliar application 30 days later, with a winter application to maintain stalk growth.

Ecological Effects Branch has no validated data from Exposure Assessment Branch on the fate of lactic acid in the environment. However, no environmental fate data will be required because of the volume of data on this compound and its natural occurrence in the environment.

The following information was taken from EEB files.

A. Toxicological Properties
[References from Toxicology Branch]

1. Acute Oral LD50

Rat (male)	4.9 g/kg	(formulation)
Rat (female)	3.5 g/kg	(formulation)

2. Acute Dermal LD50

Rabbit	>2.0 g/kg	(formulation)
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B. Wildlife

Lactic acid has been characterized by EEB as practically non-toxic to birds on subacute dietary and acute oral bases. Acute data for freshwater fish and aquatic invertebrates indicate that lactic acid is practically non-toxic to aquatic organisms, as well.

At the maximum application rate of 4.0 lb ai/A, the following residues could be expected immediately after application:

<u>Substrate</u>	<u>Residue (ppm)</u>
Short range grass	960
Long grass	435
Leaves and leafy crops	500
Forage	230
Pods containing seeds	48
Fruit	28

These values are well below the bobwhite quail and mallard duck LC₅₀'s (>5620 ppm), and would not be expected to adversely affect avian species.

An inadvertent direct application to 6 feet of water at this same rate would result in a concentration of 0.256 ppm. The LC₅₀ value for both bluegill sunfish and rainbow trout was 130 ppm, and for Daphnia the LC₅₀ value was 750 ppm. Based on these data, residues occurring in water following an application at 4.0 lb ai/A would not result in adverse acute effects on freshwater aquatic organisms. Calculated residues occurring from runoff or drift would, of course, be lower than those resulting from direct application, so hazard through these exposure routes would also be minimal.

Due to the fact that lactic acid is present in all living systems, is a natural constituent of soils, and is readily metabolized in the environment, chronic hazards to nontarget organisms are not anticipated.

Endangered Species

1. Avian

Using the endangered species trigger of 1/10 the LC₅₀ of the most sensitive test species (LC₅₀ >5620 ppm), and the EEC for short grass following application to apples at 4.0 lb ai/A (960 ppm), the level of concern could be exceeded.

There are several factors which mitigate the potential hazard to birds. First, the only crops subject to application at 4.0 lb ai/A are citrus and apples. Second, only one avian endangered species (Aleutian Canada Goose) has been identified with apples, and none with citrus. Finally, the LC₅₀ was only determined to be greater than 5620 ppm; i.e., it is very possible that the EEC for short grass may not exceed 1/10 the avian LC₅₀. In view of the above, acute hazard to endangered avian species is likely to be minimal. In addition, chronic hazards are not anticipated, due to the factors outlined under II.B., above.

2. Aquatic

For freshwater fish and aquatic invertebrates, the trigger value (1/20 the LC₅₀) would not be exceeded using acute data. With the 4.0 lb ai/A rate for apples and citrus,

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and an LC₅₀ of 130 ppm, the hazard ratio would be 0.04:

$$\begin{aligned} 1/20 \times 130 \text{ ppm} &= 6.5 \text{ ppm} \\ \text{EEC} &= 0.256 \text{ ppm} \\ 0.256 / 6.5 &= 0.04. \end{aligned}$$

Maximum expected residues from runoff would be 0.122 ppm and would result in a hazard ratio of 0.19:

$$\begin{aligned} 1/20 \times 130 \text{ ppm} &= 6.5 \text{ ppm} \\ \text{EEC} &= 0.256 \text{ ppm} \\ 0.122 / 6.5 &= 0.19. \end{aligned}$$

On the basis of the above calculations, acute hazards to endangered species of aquatic organisms are not anticipated from the proposed uses. Again, due to the nature of lactic acid and its natural presence in the environment, chronic hazards are not expected.

3. Plants

One endangered plant species (Solano grass) has been associated with corn in California. In the absence of data on the effect of lactic acid on nontarget plants, potential hazard to this species cannot be fully addressed. However, in view of the nature of lactic acid, EEB will not impose the standard nontarget plant data requirements. Rather, EEB has determined that the registrant should submit any available efficacy data. These data may be sufficient to satisfy the requirements for nontarget plant testing.

Precautionary Statements

Data reviewed to date do not indicate the need for any precautionary statements.

TABLE A
 GENERIC DATA REQUIREMENTS FOR LACTIC ACID

Data Requirement	Composition ¹ / Pattern ² / Use	Proposed Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Accession No.	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.145 Wildlife and Aquatic Organisms</u>					
<u>Avian and Mammalian Testing</u>					
71-1 - Avian Oral LD50	TGAI	A	Yes	265650	No
71-2 - Avian Dietary LC50					
a. Upland Game Bird	TGAI	A	Yes	265647	No
b. Waterfowl	TGAI	A	Yes	265649	No
71-3 - Wild Mammal Toxicity	TGAI	A	N/A ³ /		No
71-4 - Avian Reproduction	TGAI	A	No		No ⁴ /
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A	No		No ⁴ /
<u>Aquatic Organism Testing</u>					
72-1 - Freshwater Fish LC50					
a. Warmwater	TGAI	A	Yes	265651	No
b. Coldwater	TGAI	A	Yes	265652	No
72-2 - Acute LC50 Freshwater Invertebrates	TGAI TEP	A	Yes	265648	No
72-3 - Acute LC50 Estuarine and Marine Organisms	TGAI	A	No		No ⁴ /
72-4 - Fish Early Life Stage and Aquatic Invertebrate Life Cycle	TGAI	A	No		No ⁴ /

TABLE A
 GENERIC DATA REQUIREMENTS FOR LACTIC ACID (cont'd)

Data Requirement	Composition ¹ / Pattern ²	Proposed Use	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Accession No.	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.145 Wildlife and Aquatic Organisms					
<u>Aquatic Organism Testing (cont'd)</u>					
72-5 - Fish Life Cycle	TGAI	A	No		No ⁴ /
72-6 - Aquatic Organism Accumulation	TGAI	A	No		No ⁴ /
72-7 - Simulated or Actual Field Testing Aquatic Organisms	TEP	A	No		No ⁴ /

TABLE A
 GENERIC DATA REQUIREMENTS FOR LACTIC ACID

Data Requirement	Composition ¹ / Pattern ² / Use	Proposed	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Accession No.	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
<u>§158.150 Plant Protection</u>					
121-1 - Target Area Phytotoxicity	TEP	A	N/A ³		No
<u>Non-target Area Phytotoxicity</u>					
<u>Tier I</u>					
122-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No ⁴ / -
122-1 - Vegetative Vigor	TGAI	A	No		No ⁴ / -
122-2 - Aquatic Plant Growth	TGAI	A	No		No ⁴ / -
<u>Tier II</u>					
123-1 - Seed Germination/ Seedling Emergence	TGAI	A	No		No ⁴ / -
123-1 - Vegetative Vigor	TGAI	A	No		No ⁴ / -
123-2 - Aquatic Plant Growth	TGAI	A	No		No ⁴ / -
<u>Tier III</u>					
124-1 - Terrestrial Field	TEP	A	No		No ⁴ / -
124-2 - Aquatic Field	TEP	A	No		No ⁴ / -

TABLE A
 GENERIC DATA REQUIREMENTS FOR LACTIC ACID

Data Requirement	Composition ¹ / Pattern ² / TGAI	Proposed Use Pattern ² / TGAI	Does EPA Have Data To Satisfy This Requirement? (Yes, No, or Partially)	Accession No.	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?
§158.155 Nontarget Insect					
<u>Nontarget Insect Testing - Pollinators</u>					
141-1 - Honey Bee Acute Contact LD50	TGAI	A	Yes	265646	No
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A	No		No ⁵ / _
141-4 - Honey Bee Subacute Feeding Study	[Reserved] ⁶ / _				
141-5 - Field Testing for Pollinators	TEP	A	No		No ⁵ / _
<u>Nontarget Insect Testing - Aquatic Insects</u>					
142-1 - Acute Toxicity to Aquatic Insects	[Reserved] ⁷ / _				
142-2 - Aquatic Insect Life Cycle Study	[Reserved] ⁷ / _				
142-3 - Simulated or Actual Field Testing for Aquatic Insects	[Reserved] ⁷ / _				
143-1 - Nontarget Insect thru Testing - Predators 143-3 and Parasites	[Reserved] ⁷ / _				

TABLE A
GENERIC DATA REQUIREMENTS FOR LACTIC ACID

Footnotes

- 1/Composition: TGAI = Technical Grade of the Active Ingredient; TEP = Typical End-Use Product.
- 2/The use patterns are coded as follows: A = Terrestrial, food crop; B = Terrestrial, nonfood; C = Aquatic, food crop; D = Aquatic, nonfood; E = Greenhouse, food crop; F = Greenhouse, nonfood; G = Forestry; H = Domestic outdoor; I = Indoor.
- 3/Not currently a requirement.
- 4/Due to the nature of lactic acid (low acute toxicity to nontarget organisms, natural occurrence in the environment, and rapid breakdown in soil), these data will not be required.
- 5/As data from the acute contact study indicate low toxicity to bees, no further testing is required.
- 6/Reserved pending development of test methodology.
- 7/Reserved pending Agency decision as to whether the data requirement should be established.