BIOPESTICIDES REGISTRATION ACTION DOCUMENT

L-Lactic Acid

U.S. Environmental Protection Agency
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division
June 2009

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BIOPESTICIDES REGISTRATION ACTION DOCUMENT TEAM

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I. EXECUTIVE SUMMARY:

Lactic acid has two optical isomers. One is known as L-(+)-Lactic acid and the other, its mirror image, is D-(-)-Lactic acid. L-(+)-Lactic acid is the biologically important isomer. L-Lactic acid, known by the IUPAC systematic name 2-hydroxypropanoic acid, is an organic acid belonging to the family of carboxylic acids. L-Lactic acid is a colorless liquid and very highly soluble in water. L-Lactic acid, also known as milk acid occurs naturally in several foods and is primarily found in fermented milk products, such as: sour milk, cheese, buttermilk and yogurt. Lactic acid also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil. L-Lactic acid was first isolated in 1780 by a Swedish chemist, Carl Wilhelm Scheele, and is produced commercially by fermentation of carbohydrates such as glucose, sucrose, or lactose. L-Lactic Acid is registered as a biochemical pesticide used as a mosquito attractant (in traps).

L-Lactic acid is a product of the anaerobic (without oxygen) phase of glucose metabolism (glycolysis) plant and animal cells use for energy. When insufficient oxygen is available for cells to derive maximum energy from glucose (e.g., bursts of spontaneous activity in muscle cells requiring more oxygen than is available) excess L-Lactic Acid is produced and diffuses out of the cells. L-Lactic acid is normally found in the blood and interstitial fluid of humans at a level of 10 mg/dl.(Ref. 4) It has also been noted in a previous Agency review that (Ref. 4):

> Many plants have the ability to accumulate large amounts of lactic acid; barley plants can have a typical concentration of pyruvic and lactic acid at 15 mg / 100 grams fresh weight. Lactic acid is found in man and other animals; the normal lactic acid concentration in arterial blood ranges from 5 to 20 mg / dl (100 ml).
>
> Normal human urine generally contains 50 to 200 mg of lactic acid per 24 hours (Ref. 4).

The previous Agency review (Ref. 4) also cited the FDA classification of lactic acid as Generally Recognized as Safe (GRAS; 21 CFR ,180.1061) for use in food as long as good manufacturing practices are maintained. An exemption from the requirement of a tolerance was granted for lactic acid when used as a plant growth regulator on May 4, 1988 (40 CFR 180.1090). L-lactic Acid is registered as an active ingredient in four end-use products and one manufacturing-use product. The manufacturing use product contains 80% L-Lactic Acid, and the end-use products contain between 6.5% and 35.4% L-Lactic Acid. All of the biochemical pesticide end-use products that are currently registered are in traps used for mosquitoes. L-Lactic Acid functions as a mosquito attractant. There is currently no L-Lactic Acid end use products for use on food or feed. The racemic mixture of lactic acid (the D and L isomers) is also approved for use as an inert ingredient. L-Lactic Acid is also classified by the Food and Drug Administration (FDA) as generally recognized as safe (GRAS) for use in food (21 CFR 180.1061).

L-Lactic Acid has a very low pH (<1) and is a severe irritant. The acute toxicity studies for the technical grade active ingredient are limited because the test substance (80% L-Lactic Acid) has a very low pH and it is a severe irritant. Acute toxicity studies for oral, dermal, inhalation, dermal irritation and skin sensitization demonstrate the low toxicity potential of L-Lactic Acid (Table 3).

All subchronic, and chronic toxicity and mutagenicity data requirements were waived in 1988 on the basis of the natural occurrence of L-Lactic Acid in plants and animals as well as its role in

glucose metabolism for cellular energy production. This reasoning is also appropriate for waiver of the developmental toxicity study typically required for the biochemical pesticide product uses such as the mosquito lures.

Toxicity studies were submitted to the Agency in 1984, 1987, 1988 and 1992. EPA has determined that there would be no human health concerns with the use of L-Lactic Acid in pesticide products (Refs. 1, 4, & 6). Concentrated lactic acid is a severe skin irritant (Toxicity Category I), but it is a ubiquitous metabolite in glycolysis and has no other toxic effects associated with its registered uses. Occupational and residential risks are expected to be minimal or non-existent. Exposure and risk are further reduced since all of the biochemical pesticide L-Lactic Acid end use products are used in traps for mosquito control, and by requiring protective clothing and eyewear labeling for the manufacturing use product label.

L-Lactic Acid is practically non-toxic to birds, fish, aquatic invertebrates, and honey bees (Table 4). Based on use patterns in traps for biopesticide end-use products, low exposure levels, chemical's natural occurrence in the environment and living organisms and low toxicity potential of L-Lactic Acid, the Agency expects that the registered uses of L-Lactic acid will have "no effect" (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA) (Ref. 2). There are no concerns for non-target insects in regard to outdoor uses of L-Lactic acid in traps because this active ingredient is only attractive to blood-seeking insects, such as mosquitoes (Ref. 2).

The Biopesticides and Pollution Prevention Division (BPPD) reviewed data requirements for granting registration under Section 3(c)(5) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). It was determined that the data/information submitted adequately satisfy current guideline requirements (refer to 40 CFR Subpart U § 158.2000). Based on information in the Agency's database (public literature cited under MRID 458837-01) L-Lactic Acid is attractive to mosquitoes, L-Lactic acid emanations from human skin are a major factor in determining the relative attractiveness of different human hosts to mosquitoes, and the attractivity of L-Lactic Acid is concentration dependent.

For definitions of scientific terms, please refer to Appendix C Glossary of Terms and Abbreviations.

II. ACTIVE INGREDIENT OVERVIEW

Common Name: L-Lactic Acid

Chemical Names: 2-Hydroxypropanoic acid
(S)-2-Hydroxypropionic acid
L-(+)-alpha-Hydroxypropionic acid
Propanoic acid, 2-hydroxy-, (S)-
(S)-(+)-Lactic acid
Sarcolactic acid
L(+)-Lactic Acid

Trade & Other Names: (2S)-2-hydroxypropanoic acid
L (+)Lactic acid
Propel, SY-83

CAS Registry Number: 79-33-4

OPP Chemical Code: 128929

Type of Pesticide: Biochemical pesticide, currently L-Lactic Acid is used as a biting insect and mosquito attractant in traps.

Application rates and methods vary depending on the product. For specific information regarding the product*(s)* refer to Appendix B.

III. REGULATORY BACKGROUND

L-Lactic Acid was first registered as a pesticide in 1988 as a plant-growth regulator. There are currently no L-Lactic Acid end use pesticide products for use as a plant growth regulator.

An exemption from the requirement of a tolerance for residues of Lactic Acid when used as a plant growth regulator in or on all raw agricultural commodities has been established (40 CFR 180.1090; 53 FR 15286; May 4, 1988).

The Agency reassessed the active and inert tolerance exemptions for L-Lactic Acid in July, 2002 as an active and inert ingredient. The tolerances that were reassessed included both inert [40 CFR 180.930, 40 CFR 180.940(c), and 40 CFR 180.950] and plant growth regulator active ingredient (40 CFR 180.1090). In July 2002, the Agency concluded that "based on the Agency's review and evaluation of the available information, the Agency concluded that there was a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to L-Lactic Acid residues (U.S EPA 2002)."

In 2008 the Agency began the registration review process for L-Lactic Acid. On July 2, 2008, the Agency announced in the Federal Register (Volume 73; Number 128; FRL-8730-1), Registration Review of L-Lactic Acid and published for public comment USEPA L-Lactic Acid Summary Document Registration Review: Initial Docket June 2008 (Docket ID Number: EPA-HQ-OPP-2008-0383). This document contained the Preliminary Work Plan. No public

comments were received. On December 24, 2008, the Agency announce in the Federal Register (Volume 73; Number 248; FRL-8391-4) that the Final Work Plan and Proposed Registration Review Decision combined document was open for public comment, and no public comments were received. At the time of this writing, the Biopesticides and Pollution Prevention Division maintains the registrations for one manufacturing use product registration and four end-use product registrations. The end-use product registrations are all in traps for use against mosquitoes.

A. Classification

On May 14, 1997 the Biochemical Classification Committee classified L-Lactic Acid a biochemical pesticide due to its non-toxic mode of action, natural occurrence in the environment, and history of exposure to humans and the environment demonstrating minimal toxicity.

In addition to being registered as a biochemical pesticide, L-Lactic acid is also registered as an antimicrobial pesticide. The antimicrobial pesticide registrations are administered by the Antimicrobials Division. L-Lactic Acid is used, as an antimicrobial pesticide, as a disinfectant, indirect food contact surface sanitizer, fungicide and virucide on hard, non-porous surfaces (EPA Federal Register Volume 67, Number 170, Pub. 9/3/2002). There are six antimicrobial pesticide registrations; all six are for end-use products used to sanitize surfaces in residences, public restrooms, hospitals, daycare centers, malls, schools, and nursing homes (Ref. 1).

B. Food Clearances/Tolerances

There are no registered uses for L-Lactic Acid on food or feed commodities and therefore a tolerance or exemption from the requirement of a tolerance is not relevant. However, it is important to note that a tolerance exemption for L-Lactic Acid has been established when used as a plant growth regulator in or on all raw agricultural commodities under 40 CFR 180.1090.

IV. RISK ASSESSMENT

A. Active Ingredient Characterization

L-Lactic acid, known by the IUPAC systematic name 2-hydroxypropanoic acid, is an organic acid belonging to the family of carboxylic acids. L-Lactic Acid, also known as milk acid occurs naturally in several foods and is primarily found in fermented milk products, such as: sour milk, cheese, buttermilk and yogurt. L-Lactic Acid also occurs naturally in meats, fruits, tomato juice, beer, wine, molasses, blood and muscles of animals, and in the soil. L-Lactic Acid was first isolated in 1780 by a Swedish chemist, Carl Wilhelm Scheele, and is produced commercially by fermentation of carbohydrates such as glucose, sucrose, or lactose. Lactic acid has two optical isomers. One is known as L-(+)-Lactic acid and the other, its mirror image, is D-(-)-Lactic acid. L-(+)-Lactic acid is the biologically important isomer. L-Lactic Acid is registered as a biochemical pesticide used as a mosquito attractant (in traps).

L-Lactic Acid is a product of the anaerobic (without oxygen) phase of glucose metabolism (glycolysis) plant and animal cells use for energy. When insufficient oxygen is available for cells to derive maximum energy from glucose (e.g., bursts of spontaneous activity in muscle cells requiring more oxygen than is available) excess L-Lactic Acid is produced and diffuses out of the cells.

The mode of action of L-Lactic Acid is to function as an attractant for biting insects and mosquitoes in traps.

All product chemistry data requirements for registration of L-Lactic Acid have been **satisfied**. Refer to Table 1 in Appendix A for the summary of product chemistry data requirements.

L-Lactic acid is a colorless liquid and very highly soluble in water. L-Lactic Acid has a very low pH (<1) and is a severe irritant. Refer to Table 2 in Appendix A for the summary of physical and chemical characteristics for L-Lactic Acid.

B. Human Health Assessment

1. Toxicology

For acute toxicity data requirements, toxicity categories are assigned based on the hazard(s) identified from studies and/or information on file with the Agency. The active ingredient is classified into Toxicity Category I, II, III or IV where Toxicity Category I indicates the highest toxicity and Toxicity Category IV indicates the lowest toxicity.
http://www.epa.gov/oppfead1/labeling/lrm/chap-07.htm#IIB

Adequate mammalian toxicology data/information are available to support registration review of L-Lactic Acid. Refer to Appendix A, Table 3. All toxicology data requirements for L-Lactic Acid have been **satisfied.**

a. Acute Toxicity

Acute toxicity testing is required to 1) determine systemic toxicity from acute exposure via the dermal, inhalation and oral routes, 2) determine irritant effects from exposure to the eyes and 3) determine the potential for skin sensitization (allergic contact dermatitis).

The acute toxicity studies are limited because the test substance (80% lactic acid) has a very low pH (<1). At high concentrations (e.g. 80%), L-lactic acid is a severe dermal irritant in rabbits (Tox Category I) but not a skin sensitizer; L-Lactic Acid has medium toxicity (Tox Category III) for dermal (rabbit) and oral (rat) and low toxicity via the inhalation route (Tox Category IV) of exposure. The eye irritation study was waived because of L-Lactic Acid's irritant properties in skin.

For more information regarding the acute toxicity data requirements, refer to Table 3 in Appendix A.

b. Subchronic Toxicity

All subchronic data requirements have been waived on the basis of the natural occurrence of L-Lactic Acid in plants and animals as well as its role in glucose metabolism for cellular energy production.

c. Developmental Toxicity and Mutagenicity

All mutagenicity data requirements have been waived on the basis of the natural occurrence of L-Lactic Acid in plants and animals as well as its role in glucose metabolism for cellular energy production. This reasoning is also appropriate for waiver of the developmental toxicity study typically required for residential uses such as the mosquito lures described in Table 5, Appendix B.

d. Chronic Toxicity (Tier II/Tier III information)

All chronic data requirements have been waived on the basis of the natural occurrence of L-Lactic Acid in plants and animals as well as its role in glucose metabolism for cellular energy production.

e. Effects on the Endocrine System

EPA is required under the Federal Food, Drug, and Cosmetics Act (FFDCA), as amended by the Food Quality Protection Act (FQPA), to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate." Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there was scientific basis for including, as part of the program, the androgen and thyroid hormone systems, in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, the Agency will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require the wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP).

The Agency is not requiring information on the endocrine effects of L-Lactic Acid at this time. The Agency has considered, among other relevant factors, available information concerning whether the active ingredient may have an effect on humans similar to an effect produced by naturally-occurring estrogen or other endocrine effects. There is no known metabolite that acts as an endocrine disrupter produced by this active ingredient. Based on the low potential exposure level associated with the proposed use (i.e., traps), the natural occurrence of L-Lactic Acid in plants and animals, and as well as its role in glucose metabolism for cellular energy production the Agency expects no incremental adverse effects to the endocrine or immune systems.

2. Dose Response Assessment

Although the toxicity database for L-Lactic Acid is limited, the toxicity profile indicates no significant systemic toxicity even at high dose levels. Therefore, a quantitative assessment is not being conducted and no human health toxicity endpoints for the active ingredient L-Lactic Acid have been selected.

3. Drinking Water Exposure and Risk Characterization

Currently the only biochemical pesticide end-use products that L-Lactic Acid is used in traps for mosquito control. Because of the low toxicity associated with L-Lactic Acid, its ubiquity in the environment, and its existing tolerance exemption, any risk of dietary exposure from drinking water is not of concern (i.e use in traps). Therefore, drinking water exposure and risk will not be assessed for L-Lactic Acid.

4. Occupational, Residential, School and Day Care Exposure and Risk Characterization

a. Occupational Exposure and Risk Characterization

Occupational exposure to workers who mix, load, and apply L-Lactic Acid is anticipated; however, a risk assessment is not needed based on the low toxicity. The Agency will require the appropriate signal word and precautionary statements to mitigate any risk from exposure.

b. Residential, School and Day Care Exposure and Risk Characterization

Based on the registered uses of L-Lactic Acid, in traps for mosquitoes, potential residential exposure is anticipated. However, because of the dilution and low toxicity of L-Lactic Acid, adverse effects from L-Lactic Acid are not expected. No school, or day care uses currently appear on any L-Lactic Acid labels.

5. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

There is reasonable certainty that no harm to the US population will result from aggregate exposure to L-Lactic Acid. This includes all exposures for which there is reliable information. The Agency arrived at this conclusion based on the toxicity profile indicates no systemic toxicity even at high dose levels. The risks from aggregate exposure via oral, dermal and inhalation exposure are negligible.

6. Cumulative Effects

Based on the information available to the Agency, there is no indication that toxic effects associated with exposure to L-Lactic Acid are cumulative. Because of L-Lactic Acid's low toxicity, cumulative effects with other substances that share a common mechanism of toxicity are not expected.

7. Risk Characterization

The Agency considered human exposure to L-Lactic Acid in light of the relevant safety factors in FQPA and FIFRA. A determination has been made that no unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, will result from the use of L-Lactic Acid when label instructions are followed.

C. ENVIRONMENTAL ASSESSMENT

1. Ecological Hazards

Adequate non-target toxicology data/information are available to support registration of L-Lactic Acid. All non-target toxicology data requirements for L-Lactic Acid have been **satisfied.** L-Lactic Acid is considered to be non-toxic to birds, fish, aquatic invertebrates, and bees. For more information regarding the non-target toxicity data requirements, refer to Table 4 in Appendix A.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data was not triggered because results of the acute toxicity studies did not trigger any additional Tier I studies.

3. Ecological Exposure and Risk Characterization

As stated above, L-Lactic Acid is considered to be non-toxic to birds, fish, aquatic invertebrates, and bees. The use of L-Lactic Acid is not expected to cause adverse effects to non-target organisms including endangered species based on available ecotoxicity data which demonstrate that L-Lactic Acid is practically non-toxic, and because of the natural occurrence of lactic acid. Therefore an environmental risk assessment was not performed for L-Lactic acid. Further, based on use patterns and low exposure levels, the Agency does not anticipate the need for new data or the need to conduct an environmental risk assessment.

4. Endangered Species Assessment

L-Lactic Acid is practically non-toxic to non-target organisms while the exposure levels from the registered use pattern, which is in, the biopesticide product, mosquito traps is low. In addition the chemical naturally occurs in the environment and living organisms. Based on the low toxicity, low exposure potential from the biopesticide use, and the natural occurrence in the environment and living organisms, the Agency expects that the registered uses of L-Lactic Acid will have “no effect” (NE) on endangered or threatened terrestrial or aquatic species, or their designated critical habitats, as listed by the U.S. Fish and Wildlife Service (USFWS) and the National Oceanic and Atmospheric Administration (NOAA). There are no concerns for non-target insects in regard to outdoor uses of L-Lactic acid in traps because this active ingredient is only attractive to blood-seeking insects, such as mosquitoes.

D. PRODUCT PERFORMANCE DATA (EFFICACY)

Submission of product performance data (OPPTS 810.3000) is listed as a requirement for all pesticide products. Customarily, the Agency requires efficacy data to be submitted for review only in connection with the registration of products directly pertaining to the mitigation of

disease bearing human health organisms and certain designated quarantine pests, i.e., ticks, mosquitoes, fleas, Mediterranean fruit flies, gypsy moths, Japanese beetles, etc. For a list of organisms considered by the Agency as "public health pests", please refer to Pesticide Registration Notice 2002-1 (http://www.epa.gov/PR_Notices/pr2002-1.pdf).

Based on information in the Agency's database (public literature cited under MRID 458837-01) lactic acid is attractive to mosquitoes, L-Lactic Acid emanations from human skin are a major factor in determining the relative attractiveness of different human hosts to mosquitoes, and the attractivity of L-Lactic Acid is concentration dependent (Ref. 8). The public literature that is cited in MRID 458837-01, are listed below:

Acree, F., et al. 1968. L-Lactic Acid: A mosquito attractant isolated from humans. Science 161: 1948.

Shirai, Y. et al. 2000. Proboscis amputation facilitates the study of mosquito (Diptera: Culicidae) attractants, repellents, and host preference. J. Med. Entomol. 37(4): 637-639.

Smith, C.N., et al. 1970. L-Lactic acid as a factor in the attraction of *Aedes aegypti* (Diptera: Culicidae) to human hosts Ann. Entomol. Soc. Amer. 63(3): 760-770.

Steib, B.M., et al. 2001. The effect of lactic acid on odour-related host preference of yellow fever mosquitoes. Chem. Senses 26: 523-528.

V. Risk Management Decision

A. Determination of Eligibility for Registration Review

FIFRA, as amended by the Food Quality Protection Act (FQPA) of 1996, mandated the continuous review of existing pesticides. All pesticides distributed or sold in the United States must generally be registered by EPA, based on scientific data showing that they will not cause unreasonable risks to human health, workers, or the environment when used as directed on product labeling. The Registration Review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects to human health or the environment. Changes in science, public policy, and pesticide use practices will occur over time. Through the new registration review program, the Agency periodically reevaluates pesticides to make sure that as change occurs, products in the marketplace can be used safely. Information on this program is provided at: http://www.epa.gov/oppsrrd1/registration_review/.

Pursuant to 40 CFR Sec. 155.50, the Agency formally initiated Registration Review for L-Lactic Acid with the following timeline:

- June 2008 – publication of a Preliminary Work Plan (PWP) in the initial docket for L-Lactic Acid (EPA-HQ-OPP-2007-1040). During the 90 day comment period that closed on September 2, 2008, the Agency received no comments from the public.
- December 2008 – Issuance of a Final Work Plan and Proposed Registration Review Final Decision stating that the most recent exposure and risk assessments still supported the registration of pesticide products containing L-Lactic Acid and meet the requirements of

registration review. During the 60 day comment period that closed on February 27, 2009, the Agency received no comments from the public.

- June 2009 – Issuance of a Final Registration Review Decision.

The Agency's Final Decision is that no additional data are required at this time to support the continued registration of L-Lactic Acid. The Agency has considered L-Lactic Acid in light of the standard for registration and safety factors in FIFRA and FFDCA as amended by FQPA. EPA has found that there are not likely to be any unreasonable adverse effects to the U.S. population in general, and to infants and children in particular, or to non-target organisms, from the use of products containing L-Lactic Acid when currently required label instructions are followed. The Final Decision Document for L-Lactic Acid is not expected to require further data requirements for currently registered pesticide products containing L-Lactic Acid. However, if additional information is submitted that warrants further risk assessment, the Agency will then conduct any necessary risk assessment(s) prior to issuing the Final Registration Review Decision.

The data and information evaluated to support L-Lactic Acid (case 6062) as published in the PWP (June 2008) continue to support this pesticide registration as summarized herein and in the Registration Review Final Decision which is available on *http//www.epa.gov/oppsrrd1/registration review/ review/.*

B. Regulatory Decision

The data submitted fulfill the requirements of registration review for use in traps as a mosquito attractant. Refer to Appendix B for product-specific information.

C. Environmental Justice

EPA seeks to achieve environmental justice - the fair treatment and meaningful involvement of all people, regardless of race, color, national origin, or income - in the development, implementation, and enforcement of environmental laws, regulations, and policies. At this time EPA does not believe that use of pesticide products containing L-Lactic Acid will cause harm or a disproportionate impact on at-risk communities. In the Preliminary Work Plan dated June 25th, 2008, and L-Lactic Acid Final Work Plan and Proposed Registration Review Final Decision Registration Review Case 6062 dated December 2nd, 2008, the Agency sought comment on environmental justice issues regarding L-Lactic Acid. No comments were received.

For additional information regarding environmental justice issues, please visit EPA's website at: http://www.epa.gov/compliance/environmentaljustice/index.html.

VI. ACTIONS REQUIRED BY REGISTRANTS

The Agency evaluated all of the data submitted in connection with the registration review of L-Lactic Acid and determined that these data are sufficient to satisfy current registration data requirements. No additional data are required to be submitted to the Agency at this time. For new uses and/or changes to existing uses, additional data may be required.

Not withstanding the information stated in the previous paragraph, it should be clearly understood that certain, specific, data are required to be reported to the Agency as a requirement for maintaining the Federal registration for a pesticide product. A brief summary of these types of data are listed below.

A. Reporting of Adverse Effects

Reports of all incidents of adverse effects to the environment must be submitted to the Agency under the provisions stated in FIFRA, Section 6(a)(2).

B. Reporting of Hypersensitivity Incidents

Additionally, all incidents of hypersensitivity (including both suspected and confirmed incidents) must be reported to the Agency under the provisions of 40 CFR Part 158.2050(d).

VII. Appendix A. Data Requirements (40 CFR Part 158-Subpart U)

*NOTE: MRID numbers listed in the following tables are representative of supporting data for the original registration of the product containing this active ingredient. Subsequent to this registration, there may be additional MRIDs that support registration of other products containing this active ingredient.

TABLE 1. Product Chemistry Data Requirements for L-Lactic Acid (40 CFR § 158.2030)

OPPTS Guideline No.	Study	Results *(below are example results)*
830.1550 to 830.1670	Product identity; Manufacturing process; Discussion of formation of unintentional ingredients	Submitted data satisfy the requirements for product identity, manufacturing process, and discussion of formation of impurities.
830.1700	Analysis of samples	Submitted data satisfy the requirements for analysis of samples.
830.1750	Certification of limits	Limits listed in the CSF are adequate / acceptable.
830.1800	Analytical method	Acceptable.

TABLE 2. Physical and Chemical Properties of L-Lactic Acid (40 CFR § 158.2030)		
OPPTS Guideline No.	**Property**	**Description of Result**
830.6302	Color	Colorless to Light yellow
830.6303	Physical State	Non-volatile liquid. Liquid at room temperature
830.6304	Odor	Odorless to weakly acid Slightly acidic Taste: Mild acidic
830.6313	Stability to Normal and Elevated Temperatures, Metals and Metal Ions	Stable at normal temperatures. Heat stability: 190-220°C
830.6315	Flammability	Not applicable. Does not contain any combustible liquids. **Flash Points:** Closed Cup: Higher than 93.3°C (200°F).
830.6317	Storage Stability	Product does not deteriorate or degrade under storage conditions. Lactic acid is a normal plant and animal constituent. Adequate information exists in the open literature to show lactic acid is stable.
830.6319	Miscibility	Not applicable. Not meant for dilution with petroleum solvents.
830.6320	Corrosion Characteristics	Packaged in plastic container. Container is corrosion resistant unless heated above 140°F. DOT Classification: Class 8: Corrosive material. Corrosive liquid.
830.7000	pH	pH = 0.6
830.7050	UV/Visible Light Absorption	Not applicable
830.7100	Viscosity	28.50 cP at a lactic acid concentration of 85.3%
830.7200	Melting Point/Range	Not applicable. Product is a liquid.
830.7220	Boiling Point/Range	190ºC at 760 mm Hg 119-122 ºC at 12 mm
830.7300	Density	1.195 (at 85.3% purity) grams/ml 1.18~1.19@ 20ºC g/ml
830.7520	Particle Size, Fiber Length and Diameter Distribution	Not applicable the product is a liquid
830.7550 830.7560 830.7570	Partition Coefficient (n-Octanol/Water)	Not applicable Technical chemical is polar
830.7840	Water Solubility	Infinitely soluble in water at 25ºC Infinitely soluble in cold water Ether: Infinite @ 25ºC Ethanol: Infinite@ 25ºC
830.7950	Vapor Pressure	1.3 mm Hg at 90°C 0.0284 mm Hg at 25ºC (Source : EPI Suite)

Table 3. Human Toxicology Data Requirements for L-Lactic Acid (40 CFR § 158.2050)		
Study/OPPTS Guideline No.	**Results**	**Toxicity Category/Description**
Acute oral toxicity (rat) (870.1100)	LD_{50} = 4936 mg/kg (males) 3543 (females)	III
Acute dermal toxicity (rat) (870.1200)	LD_{50} > 2000 mg/kg (no deaths)	III
Acute inhalation toxicity (rat) (870.1300)	LC_{50} > 5 mg/l	IV
Primary eye irritation (rabbit) (870.2400)	Waived because L-Lactic Acid is a severe irritant due to low pH*	I
Primary dermal irritation (rabbit) (870.2500)	Severe irritant	I
Dermal sensitization (guinea pig) (870.2600)	Not a sensitizer	---
Hypersensitivity incidents (885.3400)	No incidents were reported for L-Lactic Acid's use as a biochemical pesticide. However 2 incidents were reported for its use as an antimicrobial pesticide.	

* Data requirement was waived in 1988 because the test material (80% L-Lactic Acid has a pH < 1, and is a severe irritant.

TABLE 4. Non-Target Organism Toxicity Requirements for L-Lactic Acid (40 CFR § 158.2060)		
Study/OPPTS Guideline No.	**Results**	**Toxicity Category/Description**
Avian acute oral toxicity *Colinus virginianus* (850.2100)	LD_{50} =>2250 mg/kg	Practically non-toxic
Avian dietary toxicity *Colinus virginianus* (850.2200)	LC_{50} => 5620 ppm	Practically non-toxic
Avian dietary toxicity *Anas platyrhynchos* (850.2200)	LC_{50} =>5620 ppm	Practically non-toxic
Aquatic invertebrate acute toxicity (*Daphnia magna*) (850.1010)	48-hr EC_{50} = 750 mg/l NOEC: 320 mg/L	Practically non-toxic
Freshwater fish LC_{50} (*Oncorhynchus mykiss*) (850.1075)	96-hr LC_{50} = 130 mg/l NOEC: 56 mg/L	Practically non-toxic
Non-target insect testing (Honey Bee acute contact) (880.4350)	LD_{50}(ug/bee) = >100.4 ug/bee	Practically non-toxic

VIII. Appendix B.

TABLE 5. Products Containing the Biochemical Pesticide L-Lactic Acid

EPA Reg. No.	Product Name	Signal Word	Per Cent AI[d]
69132-1	PURAC® SANILAC (manufacturing use product - MUP)	Danger	80
72336-1	NOsquito Stinger 2-in-1 Power Bait	Caution	5.331[a]
72563-2	Lurex™	Caution	35[b]
72563-4	Lurex™-Cubed	Caution	35.40[c]

a. Also contains 6.531% 1-Octen-3-ol as a second active ingredient. The active ingredients and inert ingredients are in lures which are intended for use with Stinger Mosquito Killer and Stinger Mosquito Vacuum devices. Each lure contains 0.98 g lactic acid.
b. Unspecified amount of active ingredient in a container which is designed for use with Mosquito Magnet Biting Insect Equipment.
c. For use outdoors with Mosquito Magnet® Traps 18 g AI per lure. For indoor use with LureVac® containing 9 g per lure or cartridge. Label claims efficacy for 21 days.
d. Active Ingredient.

For further specific information, please refer to EPA Docket Number: EPA-HQ-OPP-0383.
(http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=EPA-HQ-OPP-2008-0383)

IX. Appendix C.

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9) U.S. EPA June 2009. USEPA L-Lactic Acid Final Registration Review Decision.

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GLOSSARY of TERMS & ABBREVIATIONS

ai	Active Ingredient
AR	Anticipated Residue
ASTM	American Society for Testing and Materials
AWPA	American Wood Preserver's Association
CFR	Code of Federal Regulations
cPAD	Chronic Population Adjusted Dose
CSF	Confidential Statement of Formula
CSFII	USDA Continuing Surveys for Food Intake by Individuals
DCI	Data Call-In
DEEM	Dietary Exposure Evaluation Model
DFR	Dislodgeable Foliar Residue
DNT	Developmental Neurotoxicity
DWLOC	Drinking Water Level of Comparison
EC	Emulsifiable Concentrate Formulation
EDWC	Estimated Drinking Water Concentration
EEC	Estimated Environmental Concentration
EPA	Environmental Protection Agency
EUP	End-Use Product
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FQPA	Food Quality Protection Act
FOB	Functional Observation Battery
GENEEC	Tier I Surface Water Computer Model
IR	Index Reservoir
LC_{50}	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD_{50}	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LOC	Level of Concern
LOAEL	Lowest Observed Adverse Effect Level
µg/g	Micrograms Per Gram
µg/L	Micrograms Per Liter
mg/kg/day	Milligram Per Kilogram Per Day
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MRID	Master Record Identification (number). EPA's system of recording and tracking submitted studies.
MUP	Manufacturing-Use Product
NA	Not Applicable
NAWQA	USGS National Ambient Water Quality Assessment
NPDES	National Pollutant Discharge Elimination System
NR	Not Required
NOAEL	No Observed Adverse Effect Level
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PAIRA	Pure Active Ingredient Radiolabelled
PCA	Percent Crop Area

PDP	USDA Pesticide Data Program
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRZM/EXAMS	Tier II Surface Water Computer Model
Q_1*	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RAC	Raw Agriculture Commodity
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RQ	Risk Quotient
SCI-GROW	Tier I Ground Water Computer Model
SAP	Science Advisory Panel
SF	Safety Factor
SLN	Special Local Need (Registrations Under Section 24(c)) of FIFRA)
TGAI	Technical Grade Active Ingredient
TEP	Typical End-Use Product
USDA	United States Department of Agriculture
UF	Uncertainty Factor
WPS	Worker Protection Standard