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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: Cover Memorandum for Lactic Acid

FROM: Henry Jacoby, Chemist
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Hazard Evaluation Division

Henry Jacoby

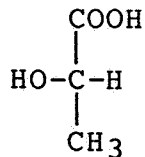
TO: Robert J. Taylor, Product Manager 25
Fungicide/Herbicide Branch
Registration Division

THRU: Amy S. Rispin, Chief
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Amy S. Rispin

Lactic acid is submitted for registration as a growth regulator. It is intended to increase nut and fruit set on almonds, walnuts, apples, beans (green and dry), broccoli, cabbage, cauliflower, cherries, citrus, corn (sweet and field), grapes, lettuce, peppers (green and chili), pineapples, prunes, strawberries, sugarcane, tomatoes, and cotton. The petitioner is proposing an exemption from the requirement of a tolerance for residues of lactic acid in or on all raw agricultural commodities.

Propel (lactic acid) has not been given any American National Standards Institute, Inc. (ANSI), British Standards Institution (BSI), or International Organization for Standardization (ISO) name. The structure of Propel is depicted below:



The chemical name for Propel is 2-hydroxypropionic acid or alpha hydroxypropionic acid. The compound is also known as SY-83.

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Other identifying characteristics and codes are:

Empirical Formula:	C ₃ H ₆ O ₃
Molecular Weight:	90.08
CAS Registry No.:	79-33-4
Shaughnessy No.:	128929
Caswell No.:	None Available

Lactic acid is a natural constituent of plants and animals. The metabolism of lactic acid in animals and plants is adequately described in open literature. In animals, lactic acid is formed from pyruvic acid in a glycolytic process (Embden-Meyerhof pathway). The primary metabolic pathway for pyruvic acid is the tricarboxylic acid cycle in which the acid is converted to carbon dioxide and water. However, under conditions that exist during strenuous exercise when energy must be made available in excess of that which can be provided by oxidative processes, pyruvic acid in the presence of the enzyme lactate dehydrogenase is reversibly converted to lactic acid with concurrent oxidation of nicotinamide adenine dinucleotide (NADH) to NAD⁺. Once formed, lactic acid can be further metabolized only by reconversion to pyruvic acid and through the pathway of pyruvate metabolism. In contrast to the phosphorylated intermediates of glycolysis, lactic and pyruvic acids readily diffuse from the cells in which they are produced (largely muscle) and pass into the circulation, from which they are removed by the liver and reconverted to glucose and glycogen. The reactions of glycolysis have been investigated most thoroughly in microorganisms and in tissues of animals, but there is good evidence for occurrence of similar if not identical chains of reactions in the cells of higher plants.

The submitted data, except for the two data gaps, namely inhalation LC₅₀ and nontarget plant phytotoxicity, are adequate to support registration. Available public information adequately addresses the occurrence and fate of lactic acid in soil, animals, and plants. Leaching, spray drift, or exposure to agricultural workers is not a cause for concern.

Previously the Agency has approved the use of lactic acid as an inert ingredient for application to plants (40 CFR 180.1001(c)). Thus, residues of lactic acid were exempted from the requirement of a tolerance when lactic acid was used in accordance with good agricultural practices as inert or occasionally applied as an active ingredient in pesticide formulations to growing crops or to raw agricultural commodities after harvest.

Product Chemistry

- 63-1: Color -- Colorless.
- 63-3: Physical State -- Nonvolatile liquid.
- 63-4: Odor -- Odorless to weakly acid.
- 63-5: Melting Point -- 190°C (760 mmHg)
- 63-7: Density -- 1.195 (at 85.3%) grams/mL
- 63-8: Solubility (25°C) -- Ether - infinite.
Ethanol - infinite.
- 63-9: Vapor Pressure -- 1.3 ml Hg at 90°C
- 63-10: Dissociation Constant -- pKa = 3.87
- 63-11: Octanol/Water Partition Coefficient -- Not applicable.
- 63-12: pH -- 0.6
- 63-13: Stability -- Material is stable at normal temperatures.

Nature of the Residue in Plants

No metabolism data were submitted. As noted above the nature of the residue in plants is adequately understood. The residue data submitted show that residues of lactic acid from the proposed uses will not exceed normal physiological levels of lactic acid in raw agricultural commodities.

Environmental Fate

Lactic acid naturally occurs in soils as a fermentation byproduct of anaerobic degradation of organic material. It will also degrade rapidly in environmental systems due to microbial action. There is voluminous data in the literature on the formation and degradation of lactic acid in soils and plants. Because of the volume of data available on this compound and its natural occurrence in the environment, no environmental fate data is required.

Toxicology

No metabolism data were submitted. As noted above the metabolism of the lactic acid in animals is adequately understood. The available data indicates lactic acid demonstrates relatively low acute toxicity via the oral and dermal routes of exposure (Category III). However, it is considered to be a severe dermal and eye irritant (Category I based on pH). The chemical is not considered to be a skin sensitizer.

The precautionary labeling must comply with statements required for Category I skin and eye irritants.

The inhalation LC50 is considered a data gap. This study must be submitted unless adequate justification is provided in of particle size.

No subchronic or chronic toxicity data are required because, as noted above, 1.) lactic acid is a normal constituent of plants and animals; 2.) lactic acid residues resulting from the uses will not exceed normal physiological lactic acid levels in new agricultural commodities; and 3.) resulting residues of lactic acid will not be higher than is presently allowed in food production, and/or from inert ingredient applications.

Ecological Effects

Lactic acid is considered to be non-toxic to birds, fish, aquatic invertebrates, and bees. No endangered species labeling is required for these species. However, one endangered plant species (Solano grass) has been associated with corn in California. Concern about the effects of direct applications of lactic acid to this species requires the submission of Tier I Nontarget Area Phytotoxicity.