



Registration Decision for the New Active Ingredient Oxalic Acid

Approved by: _____

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Date: _____

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Summary

This document announces the decision by the U.S. Environmental Protection Agency (EPA) to register the new active ingredient oxalic acid for use against the Varroa mite, a parasite on honeybees. EPA has concluded that oxalic acid meets the regulatory standard under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). One product is registered under Section 3(c)(5) of FIFRA, "Oxalic Acid." The application for this registration was submitted by the United States Department of Agriculture. Due to the significant problems this parasite poses for honeybees, the EPA review of the application was conducted under a greatly expedited process.

Background

1. Application for Registration

The Varroa mite, *Varroa destructor*, is a serious and devastating pest of honeybee colonies. Varroa mites are parasites that feed on developing bees (larvae and pupae; brood) leading to brood mortality and the reduction of the lifespan of workers that were parasitized during development. Varroa can affect hypopharyngeal gland development of nurse bees and decrease brood/royal jelly production affecting nutrition in developing brood and queens. Varroa also serves as a vector of numerous honeybee viruses. Thus, the health of a colony can be critically impacted by an infestation of Varroa, if the colony is not treated, it will likely die.

EPA has long been aware of the need for products to control Varroa mites. In numerous meetings and discussions with university researchers, beekeepers, and state-level policymakers, EPA learned that oxalic acid exhibits efficacy against Varroa mites and that it is currently registered in Europe and Canada.

Oxalic acid (CAS # 144-62-7) was previously registered as an antimicrobial pesticide and EPA's Office of Pesticide Programs (OPP) issued a Reregistration Eligibility Decision (RED) in 1992. Although oxalic acid is no longer registered as a pesticide, OPP has data in-house that describes the human health effects of the compound, the environmental fate and ecotoxicology.

On November 14, 2014 EPA received the application for registration of oxalic acid from the USDA, Agricultural Research Service, Bee Research Lab (USDA/ARS/BRL). Under the Pesticide Registration Improvement Act (PRIA) the time frame for EPA to complete the review of the application for registration of a new active ingredient and make a decision is 24 months. The PRIA due date for the oxalic acid application is December 8, 2016.

In his June 20, 2014 memorandum to Heads of Executive Departments and Agencies, President Obama created a federal strategy to promote the health of honeybees and other pollinators. The president highlighted specific instructions for the EPA to expedite review of registration applications for new products targeting pests harmful to pollinators. The expedited review and

approval of the oxalic acid registration falls entirely in line with the Presidential direction set forth in the June 2014 memorandum.

EPA was able to expedite the evaluation of the application, in part due to a NAFTA “work share” agreement in which EPA’s counterparts at Health Canada’s Pest Management Regulatory Agency (PMRA) provided EPA risk assessors and risk managers with their data reviews. Oxalic acid was registered in Canada as an in-hive control of Varroa mites in 2010.

2. Evaluation

Oxalic acid dihydrate (the crystalline form) is a dicarboxylic acid, which is a relatively strong organic acid. Oxalic acid is ubiquitous in the environment being found naturally in many plants and vegetables, as well as in honey. It occurs naturally as the potassium or calcium salt in sap, notably in plants of the *Oxalis* and *Rumex* families. It is also a product of the metabolism of mold.

In the U.S., oxalic acid is marketed for a range of non-pesticidal uses. On the general consumer market, it is commonly known as wood bleach. As mentioned, oxalic acid was first registered as a pesticide (disinfectant/sanitizer) in 1957. When oxalic acid was evaluated for reregistration the Agency concluded in the RED that the pesticide uses of oxalic acid would not result in unreasonable adverse effects to human health or the environment and that all registered products containing oxalic acid were eligible for reregistration. The registrants of these products, however, decided to voluntarily cancel them in 1994.

The information on the evaluation of oxalic acid provided to EPA by PMRA included an updated review of the toxicity, dietary exposure, environmental fate and transport, and product chemistry data. A dietary assessment, and an occupational assessment for the proposed use were also forwarded by PMRA. EPA concurs with the conclusions and registration decision made by our Canadian colleagues.

Assessment of Risk to Human Health

The use pattern for this compound is in beehives when honey supers are not present. Dietary exposure from the proposed use as an in-hive application will be indistinguishable from naturally occurring levels of oxalic acid. In fact, oxalic acid is a natural constituent of honey and is commonly found in the range of 1 mg/kg to 800 mg/kg. Moreover, EPA has established an exemption from the food tolerance requirement for oxalic acid under 40 CFR 180.910. Oxalic acid is ubiquitous in the environment and exposures from use in honeybee hives will be minimal, therefore the contribution to aggregate risk from this use will be insignificant relative to the total exposure from other sources.

Additionally, in 2005 EPA confirmed the safety of oxalic acid for its use in pesticide formulations, *i.e.*, use as a calcium chelating hard water inhibitor in pesticides applied to growing crops and to raw agricultural commodities after harvest. Oxalic acid may be used in pesticide

formulations up to 2 lbs per acre (40 CFR §180.910). In assessing this use, EPA determined that there is a reasonable certainty that no harm to any population subgroup would result from aggregate exposure to oxalic acid. By contrast, the maximum application for oxalic acid in honeybee hives is 50 mL of 2.8% oxalic acid sugar solution which is far lower than 2 lbs of 98-100% oxalic acid per acre.

In evaluating the risk to applicators, EPA notes that oxalic acid is corrosive to the eyes and skin and has been placed in Toxicity Category I, indicating the highest degree of toxicity. It is also highly irritating and damaging to the respiratory system if inhaled. Thus, the product label will carry the "Danger" signal word. In addition to the standard beekeeping suit (veil, long-sleeved shirt, long pants and gloves) as personal protective equipment, a respirator and goggles are required.

Assessment of Ecological Risk

Although no data have been submitted directly to EPA to assess the likelihood of adverse effects on non-target organisms from the proposed use of oxalic acid to control Varroa mites on adult bees, the Agency believes that the likelihood of non-target exposure is low given that the compound is proposed for use in the honeybee colony; environmental exposure would occur primarily through accidental spillage or leakage during application. Following the entire label and preventing accidental spillage will minimize environmental exposures.

Oxalic acid is a naturally occurring compound that degrades rapidly in the environment. It readily dissolves in water because it has a high solubility. It occurs as the oxalate ion at environmentally relevant pHs where high mobility of the ion in soil is expected to occur (as with most anions).

While there are data to demonstrate that oxalic acid can be acutely toxic to adult bees, the proposed treatment rates have been established based on research demonstrating that oxalic acid will provide effective control of mites while minimizing adverse effects to adult bees. There is evidence to suggest oxalic acid is toxic to brood. However, based on the available information, the Agency does not have any evidence that the proposed use of oxalic acid will be detrimental to the colony especially given that the use of oxalic acid is intended to reduce mite loads that could otherwise be far more detrimental to individual bee and colony survival. Given the in-hive use of the product, and the absence of exposure to non-target organisms other than the honey bee, the Agency has determined that the proposed in-hive use of oxalic acid will have no effect (NE) on federally listed threatened or endangered species and will not modify their habitat.

Based on limited exposure, the chemical's natural occurrence and the likelihood for relatively rapid transformation under environmental conditions, the proposed use of oxalic acid is not expected to pose a significant risk to the environment.

Critical Need

The Varroa mite is a devastating pest of honeybees, vectoring disease and severely impacting the health of colonies throughout the U.S. Researchers have established extremely low thresholds for

treatment, commonly less than 3 mites per 100 bees. If an infested colony is not treated, it will likely die.

The scope of this nationwide problem is evidenced by the number and the extent of applications submitted by State Lead Agencies to EPA requesting the use of unregistered pesticide products to combat this parasite. From 1999 - 2014, EPA has issued FIFRA Section 18 Emergency Exemptions to State Lead Agencies to provide their beekeepers with use of these unregistered products, some of which contain unregistered active ingredients. Unfortunately, the Varroa mite has quickly developed resistance to most approved pesticide tools. Over these 16 years, the number of Section 18s issued totals 723. In some years over 40 states submitted Section 18 requests. The nationwide scope of these exemptions exceeds anything ever authorized for any other pest, agricultural or otherwise.

Concluding that these efforts were in the public interest, EPA assembled the necessary data, reached out to our NAFTA partner, Canada, and worked closely with USDA to put together the oxalic acid registration submission. As directed by President Obama through his June 20, 2014 memorandum, and in acknowledgement of the critical need to make every possible control tool available, EPA has expedited the review process and this registration decision.

Application Methods and Labeling

Oxalic acid will be labeled for application by three different methods:

1. By Solution to Package Bees (Oxalic acid in sugar solution is applied as a spray to the package)
2. By Solution to Beehives (Oxalic acid in sugar solution is trickled between frames and other spaces)
3. Vapor Treatment of Beehives (Oxalic acid dihydrate is heated and the vapor sublimates in the hive)

The solution method and the vaporized applications are made in the late fall to early spring, when little brood is present. Additionally, honey supers are not present when applications to the hive are made. Packaged bees (small artificial swarms of broodless bees used for repopulating hives/colonies) can be treated any time before shipping or after receiving the bees before introducing them to the entire population (*i.e.*, when brood are not present). Treatment of package bees is intended to reduce the rate at which Varroa are spread around the country. Researchers at Penn State and individual beekeepers have reported directly to EPA staff that packaged bees shipped around the country contain high levels of Varroa mites. An effective tool, such as oxalic acid, used to spray package bees before shipping or before “hiving” will limit the proliferation of Varroa in the U.S.

With the solution-method of application, oxalic acid dihydrate is dissolved into a 1:1 sugar:water solution, which is directly applied to the space between frames of infested colonies. The bees can tolerate the concentration of oxalic acid in the applied solution, but the Varroa mites cannot. With the vaporization method of application, oxalic acid dihydrate crystals are heated using a

specialized application device until they liquefy and vaporize. Oxalic acid vapor fills the hive and all the bees and hive interior surfaces are covered with a very thin layer of oxalic acid dihydrate crystals during sublimation. While bees tolerate these fine crystals, they are toxic to the Varroa mites.

Efficacy and Mode of Action

Oxalic acid is shown to be a tool with high potential benefit for control of Varroa mite in honeybee colonies. Evaluated data demonstrated that Oxalic Acid Dihydrate can provide 90-99% control of Varroa mites in honeybee colonies when either the sugar solution treatment or vaporization application methods are used in the late fall to early spring, and for treating packaged bees to ensure that a beekeeper is not introducing phoretic mites into healthy hives. At this time, the mode of action of oxalic acid is not entirely understood. Most researchers, however, state that the mode of action is unknown and it has not been classified by the Insecticide Resistance Action Committee.

Since Varroa populations have quickly developed resistance to registered chemicals, the Agency required the following language on the label that advises pesticide users to manage applications effectively to minimize the likelihood of developing resistance to oxalic acid or any chemical used in hives to control Varroa mites.

Any Varroa mite population has the potential to become resistant to acaricides. Resistance development is affected by both the frequency of application and rate/dose of application. Continued reliance on a single class of miticide or single miticide with the same mode of action will select for resistant individuals which may dominate the mite population in subsequent generations. In order to prevent resistance development and to maintain the usefulness of individual acaricides it is important to adopt appropriate resistance management strategies.

To delay resistance:

- *When possible, rotate the use of miticides to reduce selection pressure as compared to repeatedly using the same product, mode of action or chemical class. If multiple applications are required, use a different mode of action each time before returning to a previously-used one.*
- *Base miticide use on Integrated Pest Management (IPM). This includes proper pest identification, monitoring for locality specific economic threshold and economic injury levels, record keeping, and utilizing all available control practices (cultural, biological and chemical).*
- *Maximize efficacy by following all label instructions including dosage and timing of application.*

Public Comments

On February 4, 2015 EPA published a Notice of Receipt (NOR) in the Federal Register of an application for the registration of oxalic acid and announced a public comment period of 30 days, a statutory requirement. During the 30 day comment period for the NOR, the Agency published the proposed regulatory decision for the unconditional registration of oxalic acid and announced a public comment period of 15 days, both comment periods closed on the same day, March 6, 2015. Comments from both the NOR and the proposed decision are summarized below and have been considered in formulating the Agency's final regulatory decision for oxalic acid.

Nearly 250 comments were received in support of the Agency's proposed decision to unconditionally register oxalic acid for use in honeybee hives to control Varroa mites. Six comments were submitted opposing the Agency's decision, however there were no compelling arguments or scientific evidence provided in these comments which influence the Agency's decision. One comment stated all chemicals are toxic and harmful to the environment (no evidence or data were submitted), one comment was from a hobbyist beekeeper who himself does not use chemicals in his hives and believes no one should, and four additional comments stated their opposition but provided no scientific evidence or regulatory basis opposing the Agency's decision.

Regulatory Decision

In cooperation with our regulatory partners in Canada, the evaluation of the application for registration of oxalic acid was completed as a work share. Considering the assessed risk to human health and the environment, the Agency concludes that oxalic acid meets the regulatory standard under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). There are no outstanding data requirements for oxalic acid. Therefore, the EPA is granting the unconditional registration of oxalic under Section 3(c)(5) of FIFRA.