



Bicarbonates
(Potassium Bicarbonate – PC Code 073508 and
Sodium Bicarbonate - PC Code 073505)

Proposed Interim Registration Review Decision
Case Number 4048

Approved by: FRANK ELLIS Digitally signed by FRANK ELLIS
Date: 2018.09.26
15:43:14 -04'00'
for Robert McNally, Director
Biopesticides and Pollution Prevention Division

Date: September 26, 2018

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I. Introduction

This document is the Environmental Protection Agency's (EPA or the Agency) *Proposed Interim Registration Review Decision* for Bicarbonates (Case Number 4048; PC Codes 073505 and 073508) and is being issued pursuant to 40 CFR sections 155.56 and 155.58. A registration review decision is the Agency's determination whether a pesticide meets, or does not meet, the standard for registration in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). The Agency may issue, when it determines it to be appropriate, an interim registration review decision before completing a registration review. Among other things, the interim registration review decision may: 1) require new risk mitigation measures; 2) impose interim risk mitigation measures; 3) identify data or information required to complete the review; and 4) establish schedules for submitting the required data, conducting the new risk assessment and completing the registration review. For further information on bicarbonates, additional documents can be found in EPA's public docket (EPA-HQ-OPP-2012-0407) at www.regulations.gov.

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 generally must be registered by the Agency based on scientific data showing that they will not cause unreasonable risks to human health or to the environment when used as directed on product labeling. The registration review program is intended to ensure that, as the ability to assess and reduce risk evolves and as policies and practices change, all registered pesticides continue to meet the statutory standard of no unreasonable adverse effects. Changes in science, public policy, and pesticide use practices will occur over time. Through the registration review program, the Agency periodically re-evaluates pesticides to ensure that as these changes occur, products in the marketplace can continue to be used safely. Information on this program is provided at www.epa.gov/pesticide-reevaluation. In 2006, the Agency implemented the registration review program pursuant to FIFRA section 3(g). The Agency will review each registered pesticide every 15 years to determine whether it continues to meet the FIFRA standard for registration.

Given that the Final Work Plan (FWP) did not anticipate requiring any new or additional data nor was an updated risk assessment needed, the Agency is issuing this *Proposed Interim Registration Review Decision for Bicarbonates*, pursuant to 40 CFR Sections 155.56 and 155.58.

This document is organized into five sections: the *Introduction*, which includes this summary and a summary of any public comments and the Agency's response; *Use and Usage*, which describes how and why bicarbonates is used and summarizes data on its use; *Scientific Assessments*, which summarizes the Agency's risk assessments, any revisions, and risk conclusions; *Proposed Interim Registration Review Decision*, which describes the regulatory rationale for the Agency's proposed interim registration review decision; and, last, the *Next Steps* and *Timeline* for completion of this registration review case.

A. Summary of Bicarbonates Registration Review

Pursuant to 40 CFR section 155.50, the Agency formally initiated registration review for bicarbonates (including potassium bicarbonate and sodium bicarbonate) (Case Number 4048). The following list highlights significant events that have occurred during the registration review of bicarbonates. Documentation of these events for bicarbonates can be found in the Agency's public docket, EPA-HQ-OPP-2012-0407 available at www.regulations.gov.

- July 06, 2012 – Publication of *Bicarbonates Preliminary Work Plan* (PWP) for a 60-day public comment period. The comment period closed September 10, 2012. The Agency did not receive any comments concerning this case.
- December 31, 2012 – Publication of the *Final Work Plan* (FWP) - The FWP confirmed that the most recent exposure and risk assessments still supported the registration of pesticide products containing bicarbonates. It was determined that no additional data were needed for the bicarbonates registration review because sufficient information was available to conduct a qualitative risk assessment, supporting a proposed interim registration review decision, pursuant to 40 CFR section 155.53(b).
- September 2018 – The Agency is now publishing the *Bicarbonates Proposed Interim Registration Review Decision* for a 60-day public comment period.

II. Use and Usage

Products containing bicarbonates are registered for use as fungicides on various raw agricultural food commodities, turf, flowers, and ornamentals. Bicarbonates have a nontoxic mode of action and disrupt the sodium and potassium ion balance within fungal cells, causing the cell walls to collapse. There are eleven (11) registered pesticide products containing bicarbonates as an active ingredient. Potassium bicarbonate is contained in three (3) manufacturing-use products (MP) and eight (8) end-use products (EP). The last registered product with sodium bicarbonate as an active ingredient was cancelled in July 2014.

Table 1. Bicarbonates Use and Usage Information	
Summary of Use	Biochemical pesticide registered for use as a fungicide to control powdery mildew, black spot, leaf spot, and scab
Use Sites	Turf, terrestrial and indoor ornamental plants, greenhouse and agricultural crops
Summary of Usage	N/A
Formulation Type	Soluble powder
Application Method	Spray
Technical Registrants	Church & Dwight Company, Inc. - 2 technical products registered Henry Manufacturing Limited – 1 technical product registered
No. of Registrations	11 FIFRA Section 3 products ¹
Restricted Use	No

III. Scientific Assessments

A summary of the Agency's human health, environmental and ecological risk assessments for bicarbonates is presented below. A comprehensive risk assessment was completed in 1999, in support of the Agency's *Biopesticide Reregistration Action Document* (BRAD) and *Fact Sheet*, which found no significant risk relative to potassium bicarbonate and sodium bicarbonate registered uses (U.S. EPA,

¹ FIFRA Section 3 product labels can be obtained from the Pesticide Product Label System (PPLS) website (<https://iaspub.epa.gov/apex/pesticides/f?p=PPLS:1>).

2012). For the detailed risk assessments, see the bicarbonates public docket (EPA-HQ-OPP-2012-0407) at www.regulations.gov.

A. Human Health Assessment

Hazard Characterization

The Agency has sufficient toxicological information (toxicity studies and published literature) about bicarbonates to adequately characterize the risks associated with its pesticidal use and the toxicological database is considered complete for characterizing hazard and assessing risk for bicarbonates. The toxicological database is considered complete for characterizing hazard and assessing risk for bicarbonates. There is no significant human health hazard associated with exposure to bicarbonates. There are no known acute toxicity, reproductive, developmental, mutagenic, neurotoxic, or oncogenic effects associated with exposure to bicarbonates (U.S. EPA, 2012).

Bicarbonates are not associated with adverse effects to humans or the environment. The Agency concluded that no adverse human health effects are expected when bicarbonates are used as pesticides given: (1) the compounds are ubiquitous in nature; (2) the substance is considered to be "generally recognized as safe" (GRAS) by the U.S. Food and Drug Administration (FDA); (3) the substance is naturally present in human food; (4) it is widely distributed in commerce; (5) bicarbonates are available to the general public for non-pesticidal uses; and (6) the compound is required for normal function in humans, animals, plants, and throughout ecosystems (U.S. EPA, 2012).

Dietary Exposure Assessment

A dietary (food and drinking water) exposure and risk assessment was not conducted based on the lack of toxicity of bicarbonates. Any potential pesticide residues of bicarbonates in drinking water are anticipated to be negligible and continued use of bicarbonates as a pesticidal active ingredient does not present any concern to the Agency (U.S. EPA, 2012).

Food Tolerances

In light of available toxicity and exposure data, the EPA concluded that there was a reasonable certainty that no harm would result to the U.S. population from aggregate exposure to residues of bicarbonates. Therefore, the EPA established a tolerance exemption for residues of the active ingredients potassium bicarbonate and sodium bicarbonate. The current tolerance exemptions for the active ingredients are stated as follows:

§180.1177 Potassium bicarbonate; exemption from the requirement of a tolerance. The biochemical pesticide potassium bicarbonate is exempted from the requirement of a tolerance in or on all raw agricultural commodities when applied as a fungicide or post-harvest fungicide in accordance with good agricultural practices [61 FR 67473, December 23, 1996].

§180.1176 Sodium bicarbonate; exemption from the requirement of a tolerance. The biochemical pesticide sodium bicarbonate is exempted from the requirement of a tolerance in or

on all raw agricultural commodities when applied as a fungicide or post-harvest fungicide in accordance with good agricultural practices. [61 FR 67473, December 23, 1996]

Residential and Occupational Exposure

Based on the lack of toxicity, the Agency has concluded that occupational and residential exposures and risks to bicarbonates are not of concern (U.S. EPA, 2012).

Human Incidents

A search of the Office of Pesticide Programs' (OPP) Incident Data System (IDS) (version 2.1.1) conducted on August 07, 2018, revealed five (5) reported incidents associated with bicarbonates. All reported incidents can be attributed to misuse. This database contains information dating back to the 1970s and is continuously updated as incidents are reported.

B. Ecological Risk Assessment

Bicarbonate compounds are ubiquitous in living and non-living environmental systems and are present in consumer products, soils, water, and rocks. The unique characteristics of these active ingredients, their non-toxic mode of action, and biodegradability into non-toxic components (low to no persistence) will minimize the risks to terrestrial and aquatic species from pesticidal use of bicarbonates. When applied according to label instructions, no direct or indirect toxic risk is expected to occur to terrestrial and aquatic organisms from exposure to bicarbonates in pesticide products. Published studies submitted to the Agency indicate that bicarbonates potential environmental/ecological effects are likely to be negligible (U.S. EPA, 2012).

Endangered Species Assessment

Based upon the active ingredients' biodegradability in the environment, lack of toxicity, and non-toxic mode of action, the Agency has come to a "No Effect" determination for bicarbonates under the Endangered Species Act (ESA) for all listed endangered or threatened species and their designated critical habitat. The Agency anticipates conducting no further analysis of potential risks to endangered or threatened species, unless data or information are obtained during the registration review process that would indicate such an assessment would be needed to inform the Agency's decision (U.S. EPA, 2012).

Ecological Incidents

A search of OPP's Environmental Incident Information System (EIIS) conducted on August 7, 2018, revealed no reported ecological incidents associated with bicarbonates. This database contains information dating back to the 1970s and is continuously updated as incidents are reported.

C. Endocrine Disruptor Screening Program

As required by the Administrator under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(p), the Agency has developed the Endocrine Disruptor Screening Program (EDSP) and has begun to implement the screening program that is to be used to test all pesticides in order to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or

wildlife similar to an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.”

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife like an effect produced by a “naturally occurring estrogen, or other such endocrine effects as the Administrator may designate.” The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2012, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. The Agency has reviewed all the assay data received for the List 1 chemicals and the conclusions of those reviews are available in the chemical-specific public dockets. A second list of chemicals identified for EDSP screening was published on June 14, 2013² and includes some pesticides scheduled for Registration Review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Bicarbonates is not on either list. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.³

Additionally, FFDCA section 408(p)(4) authorizes the Administrator, by order, to exempt from the requirements of the Estrogenic Substances Screening Program a biologic substance or other substance if a determination is made that the substance is not anticipated to produce any effect in humans similar to an effect produced by a naturally occurring estrogenic substance.

In this proposed interim decision, the Agency is making no human health or environmental safety findings associated with the EDSP screening of bicarbonates. Before completing this registration review, the Agency will make an EDSP FFDCA section 408(p) determination.

D. Benefits Assessment

By definition, biochemical pesticides are naturally-occurring substances (or substances structurally-similar and functionally identical to naturally-occurring substances) with a history of exposure to humans and the environment demonstrating minimal toxicity. Benefits of biochemical pesticides, such as bicarbonates, as compared to conventional pesticides typically include lower toxicity profiles for humans and nontarget organisms, and faster degradation in the environment.

² See <http://www.regulations.gov/#!documentDetail;D=EPA-HQ-OPPT-2009-0477-0074> for the final second list of chemicals.

³ <http://www.epa.gov/endo/>

IV. Proposed Interim Registration Review Decision

In accordance with 40 CFR §155.56 and 155.58, the Agency is issuing this *Proposed Interim Registration Review Decision*. Except for the EDSP component of this case, the Agency has made the following Proposed Interim Decision: (1) no additional data are required at this time; and (2) no changes to the affected registrations and their labels are needed at this time. In this proposed interim decision, the Agency is making no human health or environmental safety findings associated with the EDSP screening of bicarbonates. The Agency's final registration review decision for bicarbonates will be made following completion of an EDSP FFDCA §408(p) determination.

V. Next Steps and Timeline

In accordance with 40 CFR § 155.56 and 155.58, the Agency is issuing this *Proposed Interim Registration Review Decision* for bicarbonates (Case Number -4048), and posting it in the bicarbonates registration review docket (EPA-HQ-OPP- 2012-0407). A Federal Register Notice will announce a 60-day comment period for this *Proposed Interim Registration Review Decision*. The Agency's final decision on the bicarbonates registration review case will occur following an EDSP FFDCA §408(p) determination.

Activities	Estimated Month/Year*
Opening the Docket/Case Development	
Open Docket and 60-Day Public Comment Period for Bicarbonates	July 2012
Close Public Comment Period	September 2012
Issue Final Work Plan	December 2012
Proposed Interim and Final Registration Review Decision	
Open 60-Day Public Comment Period for Proposed Interim Registration Review Decision	September 2018
Close Public Comment Period	November 2018
Interim Registration Review Decision	June 2019
Final Decision	TBD

* This schedule is subject to revision should unforeseen issues arise during the registration review process. In the event an issue arises, such as the failure to acquire an EDSP exemption, an amended Final Work Plan will be issued at that time that will set forth a new timeline and, if applicable, any new data requirements will be included in the amended document and a Data Call-In Notice will be issued.

References

- U.S. EPA, 1999. Sodium and Potassium Bicarbonate Fact Sheet. U.S. Environmental Protection Agency Office of Pesticide Programs. Available at:
https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_G-135_01-Oct-04.pdf
- U.S. EPA, 2012. Preliminary Work Plan and Summary Document for Bicarbonates. U.S. Environmental Protection Agency Office of Pesticide Programs. Available at:
<https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0407-0005>