

December 8, 2020

Mr. Stephen Savage
Antimicrobials Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted via regulations.gov

RE: Pesticide Registration Review; Draft Human Health and Ecological Risk Assessments for Several Pesticides for Several Isothiazolinones; Notice of Availability. 85 FR 28944. May 14, 2020. Dockets EPA-HQ-OPP-2014-0159 and EPA-HQ-OPP-2015-0736.

Dear Mr. Savage:

CropLife America (CLA),¹ RISE (Responsible Industry for a Sound Environment)^{®, 2} and the Council of Producers and Distributors of Agrotechnology (CPDA)³ appreciate the opportunity to comment on the Draft Human Health and Ecological Risk Assessments for Several Pesticides for Several Isothiazolinones (ITs). Our comments focus on the benefits of selected uses of ITs for preservation of pesticide products for crop protection and specialty uses.

There are three principal formulation types for large-volume pesticide products: (a) water-based, (b) solvent-based, and (c) dry/solid (e.g., broadcast granules, wettable powders, water dispersible granules). The choice of formulation type for a given product depends on chemical properties of the active ingredient(s); intended uses of the formulated product; and other considerations, as described within this document. Recent innovations in pesticide formulation have significantly increased the use of water-based formulations.

¹ CLA, established in 1933, represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the crop protection and biotechnology products used by American farmers.

² RISE represents more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the U.S., including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health.

³ CPDA is the premier advocate for agricultural adjuvant and inert ingredient suppliers. CPDA also provides legislative and regulatory support to formulators, distributors and manufacturers of post-patent pesticide products and biorationals. CPDA members produce and sell tank-mix adjuvants, inert ingredients, pesticides and other agrotechnology products across the United States and range in size from small businesses to large, publicly traded companies. Approximately 80% of the inert ingredients used in agricultural production products throughout the U.S. are provided by CPDA members.

Here we enumerate several benefits of water-based formulations; explain why they require preservative ingredients or “packages”; and spell out the importance of isothiazolinone (IT) chemistry in those packages.

The IT ingredients used as preservatives in agricultural and specialty products include:

- 5-chloro-2-methyl-4-isothiazolin-3-one, 2-methyl-4-isothiazolin-3-one (CMIT/MIT)
- 1,2-benzisothiazolin-3-one (BIT)

Benefits of Aqueous Formulations

1. Water-based formulations generally and broadly demonstrate lower impact on agricultural workers, pesticide applicators, and the environment.
2. For many situations, solvent based formulations are technically impractical or impossible. Dry/solid formulations may likewise be impractical or impossible.
3. Water for water-based formulations is obtained from local, readily available, and inexpensive sources, and can be transported and stored, as necessary, with little to no risk.
4. To the extent that water can replace organic solvents in formulations, it significantly reduces the higher expense and certain risks associated with solvent-based formulations, such as:
 - Purchase and/or manufacture of the solvents;
 - Transportation of solvents by road or rail to formulation facilities;
 - Protection of solvents from flammability hazards;
 - Leakage or spillage of solvents must be prevented;
 - Handling and storage of solvents may require special precautions to limit exposure to personnel.
5. Good stewardship and response to public advocacy supporting improved alternatives generally favors continued conversion to water-based formulations.
6. Customers often prefer water-based formulations.
7. Water-based formulations reduce regulatory burdens related to the following, among others:
 - compliance with state regulation of volatile organic carbon (VOC);
 - air permits;
 - pesticide application in non-attainment areas (with respect to ambient air quality standards);
 - California Prop 65.
8. Water-based formulations overcome the impracticality of applying granular formulations on large-scale farms that are typical in the United States (US), because handling of liquid concentrates is inherently preferable, compared to large-scale handling of solid products.
9. Application of agricultural and specialty pesticides overwhelmingly involves dilution of the formulated product in water for spraying. Water-based formulations can be readily diluted into water for application.
10. Water-based formulations reduce the introduction of solvents and surfactants into soil and the environment.
11. While many modern pesticide active ingredients (AIs) are generally safer and more effective, their intrinsic lower solubility in the more common solvents tends to require stronger solvents and/or more restricted packaging options to achieve practical formulations. In the balance, the most practical formulation alternative, then, is aqueous suspension.
12. Biologically based pesticide-alternative products (including options for organic agriculture) inherently require or strongly favor water-based formulations.
13. Likewise, pesticidal seed-treatments have multiple advantages for crop protection. The vast majority of seed-treatment products are water-based formulations, in order to protect seed safety.

14. Cost performance of water-based formulations over solvent-based formulations is generally advantageous.
15. Lower odor is an additional benefit of low-solvent/non-solvent, water-based specialty pesticide products.
16. Aqueous specialty products match preferences and requirements of applicators, distributors, retailers, homeowners, and facility operators.
17. Water-based formulations offer inherent safety benefits, particularly to non-certified and/or non-expert applicators, such as homeowners.
18. Water-based ready-to-use (RTU) formulations are commonly sold directly to consumers and applicators. RTU formulations are impractical to develop using solvent-based technology.

Need for Preservation of Water-based Formulations

19. Some components of water-based pesticide formulations are vulnerable to microbial degradation. Bacterial and fungal contamination can severely curtail their effectiveness on target pests in the field.
20. Production, distribution, and use of pesticide products under aseptic conditions to prevent such degradation is impractical or impossible. Consequently, use of chemical preservatives in water-based products is an absolute requirement.
21. In wettable-powder and dispersible-granule formulations, preservatives are needed primarily (but not exclusively) to protect the rheological modifier (e.g., xanthan gum and related bio-based polymers) required to effectively suspend the active ingredients.
22. Accurate metering and application of the formulated product requires uniform and stable formulations that do not settle and have a uniform distribution of the active ingredient throughout the bulk of the product as sold and as diluted for use in the field.
23. Effective preservation is essential to field application of pesticides, to avoid plugging of nozzles and fouling of application equipment.
24. Protection of application mixtures ensures that diluted product that is not applied immediately, does not spoil, which would require equipment cleaning and waste disposal, and lead to financial loss. If preservation is inadequate, microbial degradation can render such treatment mixtures unusable, before they can be applied.
25. Effective preservation avoids damage to packaging (due to swelling), hence avoiding leakage, spillage, and exposure of workers to spilled product.
26. Effective preservation likewise avoids lost production; avoids the need for disposal of unrecoverable/spoiled product; reduces waste; extends product shelf life; and minimizes impact on the environment.
27. Preservatives eliminate and/or control the bioburden potential in agricultural biological products, thus enhancing product shelf life and quality.
28. Effective preservation is particularly necessary in inherently vulnerable, nutritive/food-based or water-based bait matrices and water-gel formulations used in attract-and-kill products. Such formulations minimize environmental and health impact by employing targeted applications of pesticides.
29. The COVID-19 pandemic is contributing to proliferation of invasive pests (e.g., rodents) in urban areas, increasing the need for rodent control, which inherently relies on attract-and-kill products. Such products contain foodstuffs as attractants and hence require effective preservation to avoid spoilage. The preservatives must not be repellent to the target pests, and extensive testing is required to demonstrate efficacy.
30. Minimization of microbial and pathogen contamination shows clear safety benefits, protecting workers and the public.

Importance of IT Chemistry

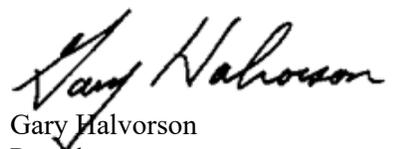
31. There are very limited options for preservation of formulated agricultural and specialty pesticide products.
32. CMIT/MIT and BIT are particularly suited for preservative use in pesticide formulations because of the broad spectrum of activity and longevity of control in this environment.
33. All active and inert ingredients of formulated pesticides registered for application to food crops, whether preplant, pre-harvest, or post-harvest, must have residue tolerances or exemptions from a tolerance. CIT/MIT and BIT are the only preservative ingredients having the requisite tolerance exemptions, listed in 40 CFR §180.920. They can also be used in products formulated for nonfood-uses.
34. Presently, there are no known safe and effective alternatives to the ITs, nor are there any on the horizon.
35. The ITs have an unparalleled, strong safety and efficacy profile.
36. A high degree of microbial resistance to some preservatives has emerged. However, this has not been a problem with the ITs.
37. Any loss of preservative efficacy due to resistance development eliminates potential ingredients needed to maintain product safety and quality in combination preservative packages. Hence the broadest portfolio of preservatives must be retained.
38. Only very limited options are available for preservative packages that are globally acceptable. Loss of IT-based options would have a cascading impact by limiting international trade and the opportunity to export products that are developed and produced in the US.
39. Conversely, the loss of IT-based options available in the US would limit the availability of imported pesticides to US users/growers/applicators. Given the overlap of regulations among nations, few globally acceptable alternates exist – BIT is essentially the only one.
40. Major retail sustainability programs screen product ingredients for consumer safety and environmental impact. BIT is a preferred preservative in consumer pesticide products based on its overall safety profile and broad spectrum of activity.
41. The importance of the IT chemistries to the agricultural and specialty pesticide sectors was emphasized during the worldwide BIT shortage in 2018, caused by regulatory restrictions and industrial accidents that disrupted BIT production in China. The situation required short-term regulatory modifications by EPA to find acceptable temporary substitutes.
42. The BIT shortage highlights the limited number of antimicrobial tools available for pesticide formulation. The only alternatives having the tolerance exemptions that permit use on food crops are the other IT products: CMIT/MIT and MIT. Additional restrictions on this class of chemicals would devastate the agricultural sector, since there are literally no other cost-effective antimicrobial alternatives that have the necessary tolerance exemptions.

Therefore, isothiazolinones (IT) are essential to supporting innovation in pesticide formulations, enabling development and introduction of water-based formulations for products used by growers, professional applicators and consumers in the United States (US). Their loss would be devastating to this market sector and would adversely impact the overall availability, safety, and quality of pest control products in the US.

Respectfully submitted,


Ray S. McAllister
Senior Director, Regulatory Policy
CropLife America


Megan Provost
President
Responsible Industry for a Sound Environment

A handwritten signature in black ink that reads "Gary Halvorson". The signature is written in a cursive style with a large, stylized initial "G".

Gary Halvorson

President

Council of Producers & Distributors of
Agrotechnology