



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 23, 2018

Ray S. McAllister
Senior Director, Regulatory Policy
Crop Life America

Stephanie Binns
Regulatory Affairs Manager
RISE, Responsible Industry for a Sound Environment

Komal K Jain
Executive Director
Center for Biocide Chemistries

Dear Mr. McAllister, Ms. Binns, and Ms. Jain:

This letter is in response to your letter dated July 27, 2018, concerning a situation where an unforeseen foreign production site closure has led to disruptions in availability of 1,2-benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5). In that letter, you requested that the Agency approve a self-certification process, in lieu of submission of Confidential Statement of Formulation (CSF) for each of the impacted end-use products.

The Agency has considered your request and determined that there is sufficient flexibility in our current regulatory scheme to allow for a temporary process to address the issue during this period of supply chain uncertainty. BIT can be both an active ingredient and, when acting as a preservative in a pesticide product but not providing the intended pesticidal effect of that pesticide product, is considered as an inert or other ingredient in that product. We are providing the regulatory framework for both the active ingredient use, and preservative use of BIT, as well as details of both processes, in this letter.

If a product's current CSF lists BIT as an active: PR Notice 98-10, Section III.A., allows registrants to change the source of the active ingredient in a formulation from the current source to a new source by notification, provided the new source is registered for the same uses as the current source and the new source is similar to the current source (i.e., meets the criteria at 40 CFR 152.43(b)(1) and (2)). Given the current situation, the Agency has determined that a streamlined process of notification, provided the new source of BIT is a registered source included in the list below, temporarily provides sufficient information to satisfy the Agency's regulatory needs. Therefore, given the temporary nature of the BIT supply disruption, the Agency has

determined that for a period not to exceed 24 months, we will allow registrants of pesticide products containing BIT as an active ingredient to use a batched self-certification process to notify changes in BIT supplier for end-use products. As described in PR Notice 98-10, a Formulator's Exemption form (EPA Form 8570-27) must be submitted to the Agency for each product where BIT is the active ingredient. The details of the process are outlined further in this letter.

If a product's current CSF lists BIT as an inert: PR Notice 98-10, Section III.B. also allows registrants to change the source of inert ingredients in a formulation from the current source to a new source by notification, where EPA has required the identification of a source, as EPA regularly does on the CSF. Like described above, provided the new source of BIT is a registered source included in the list below, the Agency has determined that a streamlined notification process temporarily provides sufficient information to satisfy the Agency's regulatory needs. Therefore, given the temporary nature of the BIT supply disruption, the Agency has determined that for a period not to exceed 24 months, we will allow registrants of pesticide products containing BIT as an inert or other ingredient to use a streamlined self-certification process to notify changes in BIT supplier for end-use products. The details of the process are outlined further in this letter.

Process: Understanding the urgency of the issue, and the need to minimize resource expenditures to both registrants and the Agency, the following streamlined self-certification process will be allowed. Provided the change in source of BIT is to a registered product as listed below, in lieu of submission of amended CSFs for all impacted products, EPA will allow notification of the source change to be submitted in the form of a single letter which covers all the impacted products. In addition, for products where BIT is the active ingredient, , a Formulator's Exemption form (EPA Form 8570-27) for each product must be submitted to the Agency as described in PR Notice 98-10. The notification should include the following self-certification statement:

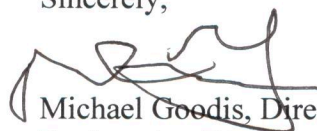
"The source of BIT in EPA Registration No. [xxx-xx, etc.] is solely limited to one or more of the products listed in the Agency letter dated 8/23/18 and that no other changes to the product formulation other than the use of an acceptable alternative source of BIT has been made. This self-certification is consistent with the provisions of PR Notice 98-10 and EPA regulations at 40 CFR 152.46, and no other changes have been made to the confidential statement of formula of this product. I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if this self-certification is not consistent with the terms of PR Notice 98-10 and 40 CFR 152.46, this product may be in violation of FIFRA and I may be subject to enforcement actions and penalties under section 12 and 14 of FIFRA."

The list below details the acceptable alternate registered sources of BIT.

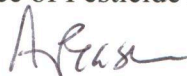
Tradename	Supplier Name	% BIT	EPA Reg. No.
Acticide B20	Thor Specialties, Inc. Shelton, CT	20%	67071-22
Acticide BW20	Thor Specialties, Inc. Shelton, CT	20%	67071-23
Proxel BD20	Arch Chemicals Alpharetta, GA	19.30%	1258-1260
Proxel GXL	Arch Chemicals Alpharetta, GA	19.13%	1258-1255
TROYGUARD B20F (also Mergal BIT20)	Troy Corporation Florham Park, NJ	19.18%	5383-144
TROYGUARD B20G (Mergal BIT20X)	Troy Corporation Florham Park, NJ	19.18%	5383-121
Mergal BIT20W	Troy Corporation Florham Park, NJ	19.18%	5383-144

At the end of this 24-month period, unless evidence is presented that there continues to be market instability, the Agency will require the submission of new or amended CSFs for any product for which the source of BIT has changed from what is listed in the current CSF. The Agency would expect that such submissions would be made within 90 days of August 23, 2020, or upon identification of stable source(s), whichever occurs earlier.

Sincerely,



Michael Goodis, Director
Registration Division
Office of Pesticide Programs



Anita Pease, Acting Director
Antimicrobial Division
Office of Pesticide Programs