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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 18, 2018

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Dear Mr. McAllister, Ms. Binns, Ms. Jain, Mr. Jones, Dr. Bennett, and Mr. Halvorson:

This letter is in response to your letter dated August 31, 2018, requesting the incorporation of further clarifications and additions to EPA's August 23, 2018, letter addressing disruptions in availability of 1,2-benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5) and providing for a streamlined self-certification process. Specifically, your August 31st letter requested that the Agency expand the listing of acceptable alternative sources of BIT to include the following:

1) For the active ingredient uses of BIT, to specifically allow all registered BIT technical products and MUPs as acceptable alternative sources of BIT for formulated BIT products.

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2) For the inert ingredient uses of BIT, to: a) include other registered BIT products in the 19 to 20.5% concentration range as part of the listing of previously approved BIT products, b) allow for the use of other BIT products outside the 19 to 20.5% active ingredient concentration range via the same self-certification process, and c) in addition to alternative BIT sources, allow substitution of 1,2-benzisothiazolin-3-one, 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one (BIT/CIT/MIT) combination products for BIT by self-certification.

Additionally, your letter asked that the Agency allow substitution of BIT-free products and other preservatives in lieu of the inert ingredient uses of BIT.

The Agency has considered your request and has determined that the batched notification process previously described in EPA's August 23, 2018, response can be expanded to include registered BIT technical products and MUPs, as well as additional registered BIT products. Additionally, the Agency has determined that an expedited process for formulation amendments involving substitution of BIT products for use as an inert ingredient (preservative) with BIT/CIT/MIT combination products can also be utilized, providing further relief. These products have been identified following an in-depth Agency review of all currently registered pesticide products containing BIT and consideration of the listing of BIT-containing products provided by CLA in an e-mail dated September 17, 2018. The specific details of these expanded processes are given as an attachment to this letter.

Lastly, the Agency awaits specific proposals from industry to address disruptions in the availability of BIT which address options such as use of BIT-free formulations and use of other, non-BIT preservatives (e.g., substitution of BIT with a CIT/MIT-only product). Further written guidance will be provided following Agency evaluation of any such proposals.

Sincerely,

Michael Goodis, Director
Registration Division

Anita Pease, Acting Director
Antimicrobial Division

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Attachment

A. Use of Batched Notification Process with Self-Certification

1. Changes of source of BIT in registered BIT product formulations.

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 selected from a currently-registered technical or manufacturing use product, 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. 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 a currently-registered technical or manufacturing use product containing BIT as the sole active ingredient and no other changes to the product formulation other than the use of an acceptable alternative source of BIT have 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.*"

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2. **Changes in source of BIT as an inert ingredient**

PR Notice 98-10, Section III.B. 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. Provided the new source of BIT is a registered source included in the lists 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 the BIT supplier for end-use products. Provided the change in source of BIT is to a registered product as provided in paragraphs (a) or (b) 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. The notification should include one of the two following self-certification statements:

a. For changes in source of BIT where the source product contains between 19 and 20.5% concentration of BIT

"*The source of BIT in EPA Registration No. [xxx-xx, etc.] is solely limited to one or more of the products listed in paragraph A(2)(a) of the attachment to the Agency letter dated 10/18/2018 and no other changes to the product formulation other than the use of an acceptable alternative source of BIT have 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 in the 19 to 20.5% concentration range.

EPA Reg. No.	Product Name	Company Name	% BIT
464-719	CANGUARD BIT 20 AS PRESERVATIVE	DOW CHEMICAL CO., THE	20
464-720	CANGUARD BIT 20 PRESERVATIVE	DOW CHEMICAL CO., THE	20

707-314	ROCIMA (TM) BT 2S	ROHM AND HAAS COMPANY	19
1258-1255	PROXEL GXL	ARCH CHEMICALS, INC.	19.3
1258-1260	PROXEL BD20	ARCH CHEMICALS, INC.	19.3
5383-121	MERGAL BIT20	TROY CHEMICAL CORPORATION	19.18
5383-144	MERGAL BIT20W	TROY CHEMICAL CORPORATION	19.18
5383-166	NUOSEPT 495	TROY CHEMICAL CORPORATION	19
9386-46	AMA-480WB	KEMIRA CHEMICALS, INC.	19
9386-47	AMA-80S	KEMIRA CHEMICALS, INC.	19
39967-55	BIOCHEK BIT 20	LANXESS CORPORATION	19
39967-56	BIOCHEK BIT 20D	LANXESS CORPORATION	19
39967-74	PREVENTOL BIT 20N II	LANXESS CORPORATION	20.5
39967-77	PREVENTOL BIT 20D II	LANXESS CORPORATION	20.5
39967-150	Preventol BIT 20N	LANXESS CORPORATION	19
39967-152	Preventol BIT 20D	LANXESS CORPORATION	19
67071-22	ACTICIDE B20	THOR GMBH	20
67071-23	ACTICIDE BW20	THOR GMBH	20
80285-2	PROMEX 20S	PROMCHEMIE AG	19
80285-3	PROMEX 20D	PROMCHEMIE AG	19
82760-7	BCS 3196	BULK CHEMICAL SERVICES, LLC	19.5
89110-12	BIONIX BIT20	ISOMERIC INDUSTRIES	19

b.) For changes in source of BIT where the source product containing a concentration of BIT other than in the range of 19 to 20.5% BIT.

> "*The source of BIT in EPA Registration No. [xxx-xx, etc.] is solely limited to one or more of the products listed in paragraph A(2)(b) of the attachment to the Agency letter dated 10/18/2018 and no other changes to the product formulation other than the use of an acceptable alternative source of BIT and a corresponding adjustment in the concentration of water in the product to provide for the same nominal concentration of BIT in the EPA Registration No(s). listed above have 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 outside of the 19 to 20.5% concentration range.

EPA Reg. No.	Product Name	Company Name	% BIT
464-721	CANGUARD BIT 10 PRESERVATIVE	DOW CHEMICAL CO., THE	10
1258-1256	PROXEL DL	ARCH CHEMICALS, INC.	9
1258-1262	PROXEL XL 2	ARCH CHEMICALS, INC.	9
1258-1284	PROXEL AQ PRESERVATIVE	ARCH CHEMICALS, INC.	9.25
1258-1289	PROXEL UL 7 PRESERVATIVE	ARCH CHEMICALS, INC.	7
5383-107	MERGAL K10N	TROY CHEMICAL CORPORATION	9.5
5383-135	TROY EX1050	TROY CHEMICAL CORPORATION	10
5383-136	MERGAL 753	TROY CHEMICAL CORPORATION	44.9
39967-54	BIOCHEK BIT 10	LANXESS CORPORATION	9
67071-25	ACTICIDE B10	THOR GMBH	10

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67071-80	ACTICIDE SR 9069	THOR GMBH	9.5
68575-2	PALENE LN 710-C	TRUTEC INDUSTRIES INC	4.3
80285-1	PROMEX 10S	PROMCHEMIE AG	9
82760-6	BCS 3096W	BULK CHEMICAL SERVICES, LLC	9.25
89110-13	BIONIX BIT9	ISOMERIC INDUSTRIES	9.25

For notifications submitted under both (a) and (b) above, at the end of the 24-month period, or at such time as a registrant has identified a stable source of BIT, a new amended CSF for the affected product(s) must be submitted to the Agency for review and acceptance.

B. Use of Streamlined Minor Formulation Amendment Process with Self Certification—Changes from BIT to BIT/MIT/

For changes in source of BIT where the changed source of BIT is a product containing a combination of BIT/CIT/MIT as the active ingredients PR Notice 98-10, Section V. allows for registrant submission of an application for amended registration for certain minor formulation amendments. The Agency has determined that a change meeting each of the following conditions would meet the criteria as given in PR Notice 98-10, Section V.A.3:

- A change from a source of BIT for use as an inert or other ingredient (preservative) to an alternate source containing a combination of BIT/CIT/MIT as included in the list below;
- A corresponding adjustment in the concentration of water in the product to provide for a nominal concentration of BIT/CIT/MIT that is equivalent to the nominal concentration of BIT as listed on the current CSF; and
- The product(s) that is/are the subject of an application for amended registration is not labeled for post-harvest uses.

The Agency has further concluded that, in the case of minor formulation amendments meeting the criteria given above, a streamlined minor formulation amendment 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 for the minor formulation amendments conforming to the criteria given above. In lieu of the standard review process for minor formulation amendments described in PR Notice 98-10, Section V.B., EPA will allow for a streamlined minor formulation amendment process whereby such change may be submitted in the form of a single registration amendment which covers all the impacted products. The registration amendment should include an attachment to EPA Form 8570-1 specifically identifying the

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products (by EPA Registration No.) for which minor formulation amendments are being sought along with 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 BIT/CITMIT products listed in paragraph B(2) of the attachment to the Agency letter dated 10/18/2018 and no other changes to the product formulation other than the use of an alternative source of BIT and a corresponding adjustment in the concentration of water in the product to provide for the same nominal concentration of BIT in the subject EPA Registration No(s). listed have been made. This self-certification is consistent with the provisions of PR Notice 98-10 and no other changes have been made to the confidential statement of formula or labeling 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 combination BIT/CIT/MIT products.

EPA Reg. No.	Product Name	Company Name	% BIT/MIT/CIT
67071-62	ACTICIDE CBM 2	THOR GMBH	10, 5, 1
5383-137	MERGAL 758	TROY CHEMICAL CORPORATION	10.1, 0.16, 0.5
5383-149	MERGAL 760	TROY CHEMICAL CORPORATION	10.1, 0.53, 1.67
5383-181	NUOSEPT BMC 422	TROY CHEMICAL CORPORATION	10, 5.05, 0.15

Following receipt of such streamlined minor formulation amendments, the Agency will review the submission to ensure that the products are within the scope of the streamlined minor formulation amendment process described above, confirm that the self-certification statement is included, and provide a response in writing accepting the amendment.

At the end of the 24-month period, or when a registrant has identified a stable source of BIT, or BIT alternative, an amendment for each impacted product, including an application (EPA Form 8570-1) and CSF for the proposed formulation must be submitted to the Agency for review and acceptance.