



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

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 21, 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

Keith J. Jones, Esq.  
Executive Director  
Biological Products Industry Alliance

Steven Bennett, Ph.D.  
Senior Vice President of Scientific Affairs  
Household & Commercial Products Association

Gary Halvorson  
Interim President  
Council of Producers & Distributors of Agrotechnology

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

This letter is in response to your letter dated November 8, 2018, in which you requested that the Agency expand the expedited process for minor formulation amendments (MFAs) described in our October 18, 2018 letter. Your proposal is a result of a temporary and unexpected disruption in the BIT supply and involves substitution of 1,2-benzisothiazolin-3-one (BIT) (CAS Reg. No. 2634-33-5) products for use as an inert ingredient (preservative) in pesticide formulations.

Your most recent specific request included the following proposals:

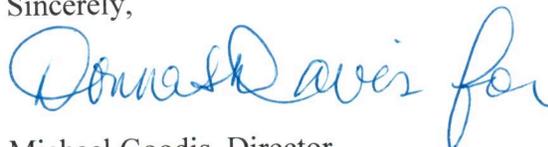
1. Expanding the listing of acceptable preservatives for use as BIT alternatives to include registered formulations of preservatives, including CIT/MIT; bronopol; cis-

isomer of 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane (also commonly known as adamantane or CTAC); sodium 2-phenylphenate (NaOPP); and 3-iodo-2-propynyl butyl carbamate (IPBC) (Tables A through D of your letter)

2. Use the expedited MFA process to remove BIT from formulations and replace BIT with water
3. Include addition of formulation adjustments to insure stability, such as the addition of acid(s), bases(s), or buffer(s) to adjust pH to the expedited MRA process
4. Expand the list of allowable substitutions to include preservatives not subject to FIFRA pesticide registration, but regulated as inert ingredients (Table E of your letter)

The Agency has considered your proposal and has determined that the expedited process for MFAs, described in the Agency's letter of October 18, 2018, can be expanded to include proposals 1 through 3 above. However, the Agency does not concur that proposal 4 be included in the expanded MFA process. The Agency believes that use of the preservatives listed in Table E, requires more careful evaluation, and is, therefore, not amenable to inclusion in the expedited MFA process. The details of the expanded processes for proposals 1 through 3 are given as an attachment to this letter.

Sincerely,



Michael Goodis, Director  
Registration Division  
Office of Pesticide Programs

Attachment

**Use of Streamlined Minor Formulation Amendment Process with Self Certification—  
Changes from BIT to other Preservatives**

A. PR Notice 98-10, Section V allows for registrant submission of an application for amended registration for certain minor formulation amendments. The specific criteria for review as a minor formulation amendment as given in PR Notice 98-10, Section V.A.3. are as follows:

3. Addition, deletion or substitution of one or more inert ingredients (other than fragrances or dyes) in a formulation:

- a. the nominal concentration of active ingredient does not change;
- b. the change does not invalidate any product-specific data submitted in support of the initial registration which causes additional data to be required;
- c. the identity of any proposed substitute inert ingredient is known by the registrant and is listed on EPA's Pesticide Inert Ingredient Lists 3 or 4;
- d. if the product is registered for food use, the inert ingredient is considered to be exempt from the requirement of a tolerance under [40 CFR 180.910, 180.920, and/or 180.950]
- e. any change is for inert ingredients used for the same purpose in the formulation (e.g., carrier, emulsifier, surfactant); and
- f. the product is not a bait or repellent and is not intended to be used to control pests of significance to public health.

Applications for the above kinds of amendments will not be considered for accelerated review if they will:

- change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or
- affect the product's efficacy so that supporting data are required (such as for vertebrate control products, tin-based antifoulant paints, food-contact surface sanitizers, and liquid or aerosol insecticides intended for household use).

The Agency reviewed the potential changes in inert ingredients proposed in your letter of November 8, 2018 and has determined that a change meeting each of the following conditions listed below would meet the criteria for review as a MFA 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 preservative is solely selected from those products specifically listed in paragraph (B) below or alternately, BIT is removed from the formulation and is replaced by water;
- Use of any product listed in paragraph (B) must be consistent with the label use directions, including any limitations associated with concentrations for use as a preservative in pesticide product formulations;
- Any specific concentration limits for preservative ingredients in pesticide formulations registered for food use that are expressed in the relevant tolerance exemptions (40 CFR §§180.910, 920, 930 & 950) are observed;

- Except as indicated in paragraph (B), the pesticide product is for pre-harvest or nonfood use only; and
- No other changes to the product formulation other than (1) and/or (2) below are permitted:
  - (1) Adjustment in the concentration of water in the product to account for minor changes in nominal concentration of alternative preservatives.
  - (2) Only in those cases where the pH or viscosity of the product may be impacted by a change in preservative, use or adjustment in the concentration of EPA-approved pH adjustment agents or viscosity modifiers, not to exceed a total of 1.0% by weight in the product formulation.

The Agency has further concluded that, in the case of MFAs meeting the criteria given above, a streamlined MFA 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 ending no later than October 18, 2020, we will allow registrants of pesticide products containing BIT as an inert or other ingredient (e.g., preservative) to use a streamlined self-certification process for the MFAs conforming to the criteria given above. In lieu of the standard review process for MFAs described in PR Notice 98-10, Section V.B., EPA will allow for a streamlined MFA 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 products (by EPA Registration No.) for which MFAs are being sought along with one of the following appropriate self-certification statements:

When replacing BIT with a preservative from Table B:

“[Registrant] is replacing the BIT preservative in EPA Registration No. [xxx-xx, etc.] with an alternative preservative product. *The source of the BIT alternative preservative in EPA Registration No. [ xxx-xx, etc.] is solely limited to one or more of the products listed in paragraph B of the attachment to the Agency letter dated 12/21/18 and no other changes to the product formulation other than those permitted in paragraph A of the attachment to the Agency letter dated 12/21/18 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.*”

When removing BIT and replacing it with water:

“[Registrant] is removing the BIT preservative from EPA Registration No. [xxx-xx, etc.] and replacing it with water. *No other changes to the product formulation other than those permitted in paragraph A of the attachment to the Agency letter dated 12/21/18 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.”

B. The table below lists the acceptable alternate registered preservative products.

EPA Reg. No.	Product Name	Company Name	Name(s) Active ingredient(s)	% Active Ingredient
39967-79	PREVENTOL P 91	LANXESS CORPORATION	CIT/MIT (3:1)	1.1
			Bronopol	9.97
39967-93	PREVENTOL D7 CF	LANXESS CORPORATION	CIT/MIT (3:1)	1.5
67071-1	ACTICIDE LG ACTICIDE CT ACTICIDE MV	THOR GMBH	CIT/MIT (3:1)	1.48
67071-5	ACTICIDE 14	THOR GMBH	CIT/MIT (3:1)	14.1
67071-50*	ACTICIDE 2605	THOR GMBH	CIT/MIT (3:1)	2.6
			Bronopol	5.3
67071-10	ACTICIDE RS	THOR GMBH	CIT/MIT (3:1)	1.48
67071-11	ACTICIDE SPX	THOR GMBH	CIT/MIT (3:1)	1.48
67071-16	ACTICIDE LA ACTICIDE LA1209	THOR GMBH	CIT/MIT (3:1)	1.13
			Bronopol	8.8
67071-18	ACTICIDE SR 2060 ACTICIDE GA ACTICIDE LA 1206	THOR GMBH	CIT/MIT (3:1)	1.13
			Bronopol	5.2
67071-91	ACTICIDE LA 1016	THOR GMBH	CIT/MIT (3:1)	0.96
			Bronopol	16.36
6836-241	ISOCIL IG	LONZA INC	CIT/MIT (3:1)	1.58
707-166	KATHON CG-ICP	DOW CHEMICAL COMPANY	CIT/MIT (3:1)	1.5
707-196	KATHON CG-ICP II	DOW CHEMICAL COMPANY	CIT/MIT (3:1)	1.5
82760-2	BCS 3024CF	BULK CHEMICAL SERVICES	CIT/MIT (3:1)	1.5
6836-259*	ISOCIL IG-C CMC- E	LONZA INC	CIT/MIT (3:1)	1.5
1258-1339*	PROXEL CMC	ARCH CHEMICALS INC	CIT/MIT (3:1)	1.5
5383-103*	MERGAL CM1.5	TROY CHEMICAL CORPORATION	CIT/MIT (3:1)	1.5
5383-141	MERGAL MC14	TROY CHEMICAL CORPORATION	CIT/MIT (3:1)	14.6
33753-20**	MYACIDE S30	BASF CORPORATION	Bronopol	30.0
464-685**	BIOBAN BP-30 PRESERVATIVE	DOW CHEMICAL COMPANY	Bronopol	30.0
67071-75**	ACTICIDE L 30	THOR GMBH	Bronopol	30.0

EPA Reg. No.	Product Name	Company Name	Name(s) Active ingredient(s)	% Active Ingredient
39967-64**	PREVENTOL P 30	LANXESS CORPORATION	Bronopol	30.0
39967-130**	PREVENTOL P 30 S	LANXESS CORPORATION	Bronopol	30.0
464-327	DOWICIL 150 ANTIMICROBIAL	DOW CHEMICAL COMPANY	CTAC	96
464-78	DOWICIDE A ANTIMICROBIAL	DOW CHEMICAL COMPANY	NAOPP	71.7
5383-55	POLYPHASE EC17	TROY CHEMICAL CORPORATION	IPBC	17
5383-118	POLYPHASE LA33	TROY CHEMICAL CORPORATION	IPBC	17
39967-153*	PREVENTOL BM5	LANXESS CORPORATION	MIT	2.5
			BIT	2.5
67071-29*	ACTICIDE MBS	THOR GMBH	MIT	2.5
			BIT	2.5
67071-56*	ACTICIDE MBS 2550	THOR GMBH	MIT	2.5
			BIT	5.0
67071-62*	ACTICIDE CBM 2	THOR GMBH	MIT/CIT	6
			BIT	10
67071-26	ACTICIDE M20 S	THOR GMBH	MIT	20
67071-46*	ACTICIDE MBL	THOR GMBH	MIT	2.5
			BIT	2.5
			Bronopol	8.0
1258-1290	PROXEL BN PRESERVATIVE	ARCH CHEMICALS INC	BIT	13.5
			Bronopol	6.5

\* Acceptable for use in nonfood use pesticide products only

\*\* Acceptable for use in pesticide products for both pre- and post-harvest food use

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

By no later than October 18, 2020, 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 Confidential Statement of Formula for the proposed formulation must be submitted to the Agency for review and acceptance. If no amendment is submitted, the product formulation must adhere to the formulation as given in the current accepted CSF.