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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

July 1, 2021

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

Kristen R. Spotz
Senior Director, Regulatory Affairs
RISE, Responsible Industry for a Sound Environment

Gary Halvorson
Interim President
Council of Producers & Distributors of Agrotechnology

Komal K. Jain
Executive Director
Center for Biocide Chemistries

Dear Mr. McAllister, Ms. Spotz, Mr. Halvorson, and Ms. Jain:

This letter is in response to your letters dated March 30, 2021, informing the agency of a disruption in the supply chain for certain inert ingredients derived from ethylene oxide (EO) and propylene oxide (PO) feedstocks. Your letters noted that EO and PO production has been unexpectedly interrupted by weather events that occurred in the U.S. Gulf Coast in February 2021, with each letter including industry proposals for regulatory mechanisms that could be utilized by EPA to help alleviate these supply chain issues, which are characterized in the letters as urgent in nature. Additional information regarding the genesis and significance of this supply chain disruption to the pesticide industry was provided to the agency on April 23, 2021, in a document entitled "Supplemental Information on Shortage of Inert Ingredients Derived from Ethylene Oxide and Propylene Oxide Chemical Feedstocks."

Specifically, this letter is in response to the industry proposal identified as "Phase 2 – "Not In-Kind" Substitution Mechanism" as related to non-antimicrobial pesticide products. A separate response to the industry Phase 2 proposal will be provided for antimicrobial pesticide products.

Under your proposal, registrants would be allowed to substitute one or more pre-approved alternate inert ingredients for specified inert ingredients that are in short supply through a self-certification process. Based on the initial Phase 2 proposal and a subsequent email of April 7, 2021, in which the document "Assessment of Potential Substitutes for Propylene Glycol" was included, the specifics of the proposed substitution would be to permit registrants to substitute glycerin (CAS Reg. No. 56-81-5); diethylene glycol (CAS Reg. No. 111-46-6), ethylene glycol

(CAS Reg No. 107-21-1); and/or 1,3-propanediol (CAS Reg. No. 504-63-2) for the inert ingredient propylene glycol.

Your proposal would permit an end-use or manufacturing-use product registrant to substitute some combination of the substitutes listed above for propylene glycol, including cases where propylene glycol is directly added to the formulation or is part of a brand name mixture in which the full composition is known to the registrant. Additionally, the proposal included further constraints on the substitutions, including self-certifications that the substitute inert ingredients serve the same function in the product as propylene glycol, and that the change: 1) would not impact the validity of any product-specific data submitted in support of the registration; 2) would not change the product's acute toxicity category or physical/chemical characteristics such that label modifications are necessary; and 3) would not affect the product's fitness for its intended purposes in terms of efficacy, phytotoxicity, or otherwise.

Following a full consideration of the proposal, the agency has determined that, subject to certain prescribed limitations, a time-limited expedited process for formulation amendments. This analysis included a review of publicly-available acute toxicity data and physical/chemical characteristics data for propylene glycol and each of proposed substitute inert ingredients (glycerin, diethylene glycol, ethylene glycol, and 1,3-propanediol) in which it was determined that the overall acute toxicity profile and physical/chemical characteristics of the substitute inert ingredients was comparable to that of propylene glycol and therefore would not impact the validity of any product-specific data submitted in support of the affected registrations. The specific details of this process, including limitations, are given as an attachment to this letter.

Sincerely,

MARIETTA ECHEVERRIA

Digitally signed by MARIETTA ECHEVERRIA
Date: 2021.07.01 14:44:49 -04'00'

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

ATTACHMENT

Use of Streamlined Minor Formulation Amendment Process with Self Certification for Non-Antimicrobial Products—Changes from Propylene Glycol to Glycerin, Diethylene Glycol, Ethylene Glycol and/or 1,3-Propanediol

PR Notice 98-10, Section V. allows for the accelerated review of certain changes in product formulation via the submission of an application for amended registration identified as minor formulation amendments. The type of amendment that would fall under the category of minor formulation amendments is given in Section V.A.3 of PR Notice 98-10 and includes the following limitations:

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 180.1001(c), (d) or (e);
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.

PR Notice 98-10 further states that such formulation amendments will not be considered for accelerated review if they: 1) change the product's acute toxicity category or physical/chemical characteristics necessitating label modifications; or 2) 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 has determined that a change in product formulation proposed to address the supply disruptions involving propylene glycol that meet each of the following conditions would meet the criteria as given in PR Notice 98-10, Section V.A.3. Specifically:

1) The formulation change is specific to the substitution of the inert ingredient propylene glycol with a combination of one of more of the following inert ingredients: glycerin; diethylene glycol; ethylene glycol; and 1,3-propanediol;

2) The specific weight percentages of any of the propylene glycol substitutes given in paragraph (1) are clearly provided and the combined weight percentage of the propylene glycol substitutes does not exceed the concentration of propylene glycol as listed in the product’s CSF;

3) The product(s) that is/are the subject of an application for amended registration do not include antimicrobial pesticide products; and

4) The product(s) that is/are the subject of an application for amended registration is not a bait product labeled for use against pests included in the list of *Pests of Significant Public Health Importance.* https://www.epa.gov/insect-repellents/list-pests-significant-public-health-importance.

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 propylene glycol supply disruption, the agency has determined that for a period from the date of this letter through December 31, 2021, it will allow registrants of pesticide products containing propylene glycol as an inert 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 submission for amendment of multiple impacted products. The registration amendment submission should include an attachment to EPA Form 8570-1 specifically identifying the products (by EPA Registration No.) for which minor formulation amendments are being sought along with the following self-certification statement:

"*The change in formulation for EPA Registration No. [xxx-xx, etc.] is limited to a substitution of propylene glycol with a combination of one of more of the following inert ingredients: glycerin; diethylene glycol; ethylene glycol; and 1,3-propanediol and no other changes to the product formulation have been made. Additionally, this substitution: 1) does not materially affect the validity of any product-specific data submitted in support of the registration; 2) does not change the product's acute toxicity category such that label modifications are necessary; 3) does not change the product's physical/chemical characteristics such that label modifications are necessary; and 4) does not affect the product's fitness for its intended purposes in terms of efficacy, phytotoxicity, or otherwise. 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*."

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 granting or denying the amendment.

EPA intends to allow this expedited process for these minor formulation amendments until December 31, 2021. If a registrant has determined that, for any impacted product, they seek to

continue production/formulation with inert ingredients as described in paragraph (1) above, the registrant must submit an amendment for each impacted product, including an application (EPA Form 8570-1) and CSF for the proposed formulation to the agency for additional review prior to December 31,2021. Stocks of product approved under the present program that have been released for shipment by December 31, 2021, would be allowed to be sold and distributed after December 31, 2021.