



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS

April 29, 2021

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

Kristen R. Spatz
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. Spatz, 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 addresses the set of industry proposals identified as “Phase 1 – “In-Kind Substitution Mechanism.” Those proposals included the following:

A. expanding the designation of inert ingredients already on the Environmental Protection Agency’s (EPA) Commodity Inert Ingredient List to include all non-food uses of List N-only inert ingredients; and

B. updating the Commodity Inert Ingredient List to include additional EO- and PO-based Alkoxylates beyond those already on the list; and

C. allowing registrants to substitute inerts on the Commodity Inert Ingredient List in food-use products, provided that appropriate self-certifications concerning data rights are made.

The agency has considered this set of proposals and determined that there is sufficient flexibility in our current regulatory scheme to allow for a temporary process to address these supply chain issues. The details of that process are given below.

Commodity Inert Ingredient List Designation. The agency has determined that an expansion of the designation of “For List N products only” to “For List N products and other nonfood-use products only” in the Commodity Inert List at <https://www.epa.gov/pesticide-registration/commodity-inert-ingredients> is appropriate and will adopt this proposal on a permanent basis by making the appropriate revision to the Commodity Inert List website. This determination is based upon the fact that the “For List N products only” designation in the Commodity Inert List was established to provide for additional flexibilities in the production of List N pesticides, specifically as related to the ability to source certain inert ingredients for these disinfectants used against the novel coronavirus. Since data rights obligations under FFDCA §408(i) do not apply, EPA is comfortable expanding the list, at this point, to “For List N products and other nonfood-use products only.” This expansion will not affect the interests of data submitters.


Use of Additional Sources of Certain EO- and PO-based Alkoxylates. While the proposal to expand the Commodity Inert Ingredient List to include additional EO- and PO-based alkoxylates has merit, as noted in our 4/9 email response to Ray McAllister, the process required to fully validate each proposed addition and to perform quality control needed to ensure proper chemical names and CAS Reg. Nos. associated with each addition is a resource-intensive process. This process likely would not be able to be completed in the timeframe needed to provide the full relief sought under this element of the proposal. However, PR Notice 98-10, Section III.B., does, under certain circumstances, allow registrants to change the source of inert ingredients in a formulation from the current source without notification to the agency. The agency has determined that, based on the supply-chain interruptions impacting EO and PO production, a change or addition of source for the inert ingredients listed in Attachment 1 can be accomplished without notification to the agency during this period of significant supply disruption. Therefore, for the period of time from the date of this letter until December 31, 2021, the agency has concluded that changes or additions of sources for the inert ingredients listed in Attachment 1 are permitted via non-notification.

Addition or Change in Suppliers of Inert Ingredients in Food-Use Pesticides. The industry proposal included a self-certification process for ensuring compliance with data compensation rights under FFDCA §408(i) and FIFRA §3(c)(1)(F) if sources of EO- and PO-derived ingredients are to be substituted in pesticide formulations that have food-use patterns. To be clear, the current process utilized by registrants and suppliers of inert ingredients for use of inert ingredients with associated data compensation rights is to: 1) source such inert ingredients from the data owner(s), or 2) provide the agency with documentation that an offer to pay for the use of

such data has been made to the appropriate data submitter/owner or agent thereof. As these current procedures for addressing inert ingredient data compensation rights do not require a registrant to obtain agency approval prior to sourcing inert ingredients with associated data compensation rights, a self-certification process to ensure compliance with data compensation rights is unnecessary. We believe that, along with the flexibilities provided above, the current process for ensuring inert ingredient data compensation rights addresses this aspect of the industry proposal and no further change is needed.

Sincerely,

MARIETTA
ECHEVERRIA

 Digitally signed by MARIETTA
ECHEVERRIA
Date: 2021.05.03 08:49:22 -04'00'

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs

Anita Pease, Director
Antimicrobials Division
Office of Pesticide Programs



ATTACHMENT 1

A. α -alkyl- ω -hydroxypoly (oxypropylene) and/or poly (oxyethylene) polymers where the alkyl chain contains a minimum of six carbons

(CAS RN 9002-92-0, 9004-95-9, 9005-00-9, 26183-52-8, 34398-01-1, 52292-17-8, 66455-14-9, 66455-15-0, 68002-97-1, 68131-39-5, 68131-40-8, 68154-96-1, 68213-23-0, 68439-45-2, 68439-46-3, 68526-94-3, 68439-50-9, 68439-49-6, 68551-12-2, 68951-67-7, 71243-46-4, 97043-91-9, 9043-30-5, 60828-78-6, 61827-42-7, 24938-91-8, 68439-54-3, 69011-36-5, 78330-20-8, 78330-21-9, 106232-83-1, 127036-24-2, 160875-66-1, 9004-98-2, 68920-66-1, 61804-34-0, 61791-28-4, 71060-57-6, 26468-86-0, 31726-34-8, 52609-19-5, 61791-20-6, 68155-01-1, 69013-19-0, 69364-63-2, 70879-83-3, 78330-19-5, 97953-22-5, 157627-86-6, 34398-05-5, 72905-87-4, 84133-50-6, 61702-78-1, 27306-79-2, 169107-21-5, 61791-13-7, 39587-22-9, 85422-93-1; 68154-98-3, 61725-89-1, 68002-96-0, 68154-97-2, 68439-51-0, 68551-13-3, 68603-25-8, 68937-66-6, 68987-81-5, 69227-21-0, 70750-27-5, 103818-93-5, 166736-08-9, 120313-48-6, 68213-24-1, 68458-88-8, 68551-14-4, 69013-18-9, 69227-22-1, 72854-13-8, 73049-34-0, 78330-23-1, 37311-02-7, 64366-70-7, 37251-67-5, 9087-53-0, 196823-11-7, 57679-21-7, 111905-54-5, 61827-84-7, 172588-43-1)

B. Alkyl Alcohol Alkoxylate Phosphate and Sulfate Derivatives

1. α -Alkyl (minimum C6 linear, branched, saturated and or unsaturated)- ω -hydroxypolyoxyethylene polymer with or without polyoxypropylene, mixture of di- and monohydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; minimum oxyethylene content is 2 moles; minimum oxypropylene content is 0 moles.

(CAS RN 9046-01-9, 37280-82-3, 39464-66-9, 42612-52-2, 50643-20-4, 52019-36-0, 58318-92-6, 60267-55-2, 61837-79-4, 67711-84-6, 68070-99-5, 68071-35-2, 68071-17-0, 68130-47-2, 68186-37-8, 68186-36-7, 68311-02-4, 68425-73-0, 68458-48-0, 68511-37-5, 68610-65-1, 68585-36-4, 68649-29-6, 68815-11-2, 68908-64-5, 68891-13-4, 73038-25-2, 78330-24-2, 108818-88-8, 154518-39-5, 317833-96-8, 873662-29-4, 936100-29-7, 936100-30-0)

2. [α]-Alkyl(C6-C15)-[ω]-hydroxypoly(oxyethylene) sulfate, and its ammonium, calcium, magnesium, potassium, sodium, and zinc salts, poly(oxyethylene) content averages 2-4 moles.

(CAS RN 3088-31-1, 9004-82-4, 9004-84-6, 13150-00-0, 25446-78-0, 26183-44-8, 32612-48-9, 50602-06-7, 62755-21-9, 68424-50-0, 68511-39-7, 68585-34-2, 68611-55-2, 68891-38-3, 73665-22-2)

C. Alkyl Amine Polyalkoxylates

1. N,N-Bis- α -ethyl- ω -hydroxypoly(oxy-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl) content is 2-60 moles

(CAS RN 10213-78-2, 25307-17-9, 26635-92-7, 26635-93-8, 288259-52-9, 58253-49-9, 61790-82-7, 61791-14-8, 61791-24-0, 61791-26-2, 61791-31-9, 61791-44-4, 68155-33-9, 68155-39-5, 68155-40-8, 70955-14-5, 73246-96-5)

2. N,N-Bis-a-ethyl-w-hydroxypoly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) C8-C18 saturated and unsaturated alkylamines; the poly(oxy-1,2-ethanediyl/oxy(methyl-1,2-ethanediyl) content is 2-60 moles

(CAS RN 68213-26-3, 68153-97-9, 75601-76-2)

D. α -[p-(1,1,3,3-tetramethylbutyl)phenyl]- ω -hydroxypoly (oxyethylene) produced by the condensation of 1 mole of p-(1,1,3,3-tetramethylbutyl)phenol with a range of 1-14 or 30-70 moles of ethylene oxide: if a blend of products is used, the average range number of moles of ethylene oxide reacted to produce any product that is a component of the blend shall be in the range of 1-14 or 30-70

(CAS RN 9036-19-5, 9002-93-1)

E. Methyl poly(oxyethylene)C8-C18 alkylammonium chlorides where the poly(oxyethylene) content is n=2-15 and where C8-C18 alkyl is linear and may be saturated or unsaturated

(CAS RN 3010-24-0, 18448-65-2, 70750-47-9, 22340-01-8, 67784-77-4, 64755-05-1, 61791-10-4, 28724-32-5, 28880-55-9, 68187-69-9, 68607-27-2, 60687-90-3)

F. Nonylphenol Ethoxylates, Phosphates, and Sulfate Derivatives

1. α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and mono hydrogen phosphate esters and the corresponding ammonium, calcium, magnesium, monoethanolamine, potassium, sodium, and zinc salts of the phosphate esters; the nonyl group is a propylene trimer isomer and the poly(oxyethylene) content averages 4-14 moles or 30 moles CAS RN 51811-79-1, 59139-23-0, 67922-57-0, 68412-53-3, 68553-97-9, 68954-84-7, 99821-14-4, 152143-22-1, 51609-41-7, 37340-60-6, 106151-63-7, 68584-47-4, 52503-15-8, 68458-49-1)

2. α -(p-Nonylphenyl)- ω -hydroxypoly(oxyethylene) sulfate, ammonium, calcium, magnesium, potassium, sodium, and zinc salts; the nonyl group is propylene trimer isomer and the poly(oxyethylene) content averages 4 moles

(CAS RN 9014-90-8, 9051-57-4, 9081-17-8, 68649-55-8, 68891-33-8)

G. N,N,N,N-Tetrakis 2-hydroxy propyl ethylene diamine

(CAS RN 102-60-3)

H. Ethylene Oxide Adducts of 2,4,7,9 - Tetramethyl - 5 -Decyldiol

(CAS RN 9014-85-1)

I. Polyoxyethylene polyoxypropylene mono(di-sec-butylphenyl) ether

(CAS RN 69029-39-6)

J. Oxirane, polymer with methyloxirane, block

(CAS RN 106392-12-5)

K. Poly(oxyethylene) p-nonylphenol

(CAS RN 26027-38-3)



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

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

OFFICE OF PESTICIDE PROGRAMS

May 3, 2021

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

Kristen R. Spatz
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

Re: Addendum to the Phase 1 Response Letter dated April 29, 2021

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

This letter is an addendum to the Phase 1 response letter dated April 29, 2021.

In addition to the inert ingredients listed in Attachment 1 of that letter, changes or additions of sources for the inert ingredients listed below are also permitted via non-notification for the time period specified in that letter.

Poly(oxy-1,2-ethanediyl), α -sulfo- ω -(dodecyloxy)-, ammonium salt (CAS Reg. No. 32612-48-9)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -(dodecyloxy)-, potassium salt CAS Reg 50602-06-7)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -(dodecyloxy)-, magnesium salt (CAS Reg. No. 62755-21-9)
Fatty acids, tall-oil, C12-15-alkyl esters, sulfated, sodium salts (CAS Reg. No. 68424-50-0)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -hydroxy-, C12-15-alkyl ethers (CAS Reg. No. 68511-39-7)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -hydroxy-, C10-16-alkyl ethers, sodium salts ethers (CAS Reg. No. 68585-34-2)

Sulfuric acid, mono-C10-16-alkyl ester ethers (CAS Reg. No. 68611-55-2)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -hydroxy-, C12-14-alkyl ethers, sodium salts ethers (CAS
Reg. No. 68891-38-3)
Poly(oxy-1,2-ethanediyl), α -sulfo- ω -hydroxy-, C6-10-alkyl ethers, sodium salts ethers (CAS
Reg. No. 73665-22-2)

Sincerely,

Marietta Echeverria, Acting Director
Registration Division
Office of Pesticide Programs