UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 4
ATLANTA FEDERAL CENTER
61 FORSYTH STREET
ATLANTA, GEORGIA 30303-8960

APR 16 2012

Mr. David A. Korn
Chief Compliance Officer
Zep, Inc.
1310 Seaboard Industrial Blvd.
Atlanta, Georgia 30318

Re: Case No: FIFRA-04-2012-3265
Stop Sale, Use, or Removal Order
ZEP Formula 165

Dear Mr. Korn:

Region 4 obtained a sample of ZEP Formula 165 bearing EPA Reg. No. 49403-6-1270 for testing in the U.S. Environmental Protection Agency's Antimicrobial Testing Program (ATP). As you may know, the EPA informed the basic registrant, Lanxess Corporation, of your ATP laboratory results in February 2012. You will find these laboratory results enclosed. Due to your product's ATP test failure, the EPA has also enclosed a Stop Sale, Use, or Removal Order (SSURO) that the EPA is issuing to Zep, Inc., pursuant to the authority set forth in Section 13 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. § 136k. This Order is effective immediately.

This Order prohibits all further sale and distribution of the pesticide ZEP Formula 165, EPA Reg. No. 39967-81-1270, or former EPA Reg. No. 49403-6-1270, under the control or custody of Zep, Inc. The company should identify and be prepared to notify EPA of the locations of all quantities of ZEP Formula 165, EPA Reg. No. 39967-81-1270, or former EPA Reg. No. 49403-6-1270, distributed within the past 12 months, and the amount of such pesticide product at each location. Please take notice that any violation of the terms or provisions of the Order may result in imposition of civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136*l*. Also, a civil penalty of up to $7,500 for each violation that is the subject of this SSURO may be assessed for violations of FIFRA. Prior to the assessment of any penalty, however, you will be given the opportunity to request a hearing and/or provide information that may mitigate any penalty amount.

Based on the accepted label claims for this product as a hospital disinfectant effective against *Mycobacterium tuberculosis* and the laboratory testing failures, we recommend that your company take immediate steps to voluntarily withdraw this pesticide product from the market. Specifically:

1. Zep, Inc. should consider a request for the return of all quantities of the pesticide product to your company from all such product locations as part of a voluntary recall effort; and

2. Prior to initiating any voluntary recall action, Zep, Inc. should inform the EPA of its intent to issue a recall action so that the attached SSURO can be amended to reflect removal of the product from the stream of commerce. Zep, Inc. should then inform the

EPA of: (a) all steps the company has taken in connection with the voluntary recall of this pesticide product, and (b) the completeness of the voluntary recall action.

Draft recall letters are enclosed for your convenience, which you may use. Each letter contains the acceptable language for a voluntary recall of this nature. Enclosure #1 is a letter which may be sent to your primary and secondary distributors. Enclosure #2 is a memorandum which may be sent by your primary and secondary distributors to their customers (*e.g.*, health care professionals). Enclosure #3 is a Recall Effectiveness Checklist, which may be included with Enclosure #2.

Please contact Ms. Molly Miller at (404) 562-9684 within 10 calendar days of receipt of this SSURO. At that time, you should be prepared to indicate the amount of affected product under the control or custody of Zep, Inc. You should also indicate what actions have been taken to insure that the product is not released for sale.

The EPA developed an information sheet entitled "U.S. EPA Small Business Resources" to help small businesses understand federal and state environmental laws and rights under the Small Business Regulatory Enforcement Fairness Act. The information sheet can be found on the internet at: www.epa.gov/compliance/resources/publications/incentives/smallbusiness/ smallbusresources.pdf. If you do not have internet access and would like to request the document in hard copy, please contact Ms. Miller at the phone number listed above.

Sincerely,

Jeaneanne M. Gettle
Chief
Pesticides & Toxic
Substances Branch

Enclosures

cc: Tommy Gray
Georgia Dept. of Agriculture

Enclosure #1

(REGISTRANT'S LETTERHEAD)

[date]

VIA CERTIFIED MAIL

[Separate letter to each distributor.]

Re: Voluntary Recall of **ZEP Formula 165**

Dear [name of distributor's representatives]:

(Registrant Name) is conducting a voluntary recall of all **ZEP Formula 165** shipped in the United States in the last 12 months. Distributors and users of this product should cease selling and using it. At this time, the United States Environmental Protection Agency believes that deficiencies in this product cause it to be an ineffective **hospital disinfectant** and that it's continued use may result in serious health consequences.

Please notify your customers to return to your warehouse their unused **ZEP Formula 165** by sending them a copy of the attached Memorandum and Effectiveness Check form. If you or your customers have any stocks of **ZEP Formula 165** from the above-mentioned lot numbers, advise **(Registrant's recall contact)** of the quantity and location.

Sincerely,

Enclosures

Enclosure #2

(REGISTRANT'S LETTERHEAD)

MEMORANDUM

FROM: **(Registrant - Company Official)**

TO: Health Care Professionals

SUBJECT: Voluntary Product Recall of **ZEP Formula 165**

(Registrant Name) is presently in the process of working with the United States Environmental Protection Agency with respect to the **hospital disinfectant** claims associated with **ZEP Formula 165.** While we are doing so, we request that you stop use of **ZEP Formula 165.**

Returns (whether opened or unopened) should be sent to your dealer. You will receive appropriate credit from your dealer. Also, please fill out the attached Effectiveness Checklist and return it to your dealer.

Attachment

Enclosure #3

VOLUNTARY PRODUCT RECALL
Effectiveness Checklist

PLEASE FILL OUT AND RETURN TO YOUR DEALER

VOLUNTARY RECALL: ZEP Formula 165

___ We do not have any stock of the above on hand.

___ We have ____ unopened units and ____ cases for a total of ____ units of the above on hand.

___ We have ___ opened units of the above on hand.

COMPANY NAME _____

ADDRESS _____

CITY _____ **STATE** _____ **ZIP** _____

UNITED STATES
ENVIRONMENTAL PROTECTION AGENCY
REGION IV
ATLANTA, GEORGIA

IN THE MATTER OF:	)	
	)	
Zep, Inc.,	)	**FIFRA**-04-2012-3265
	)	
Respondent.	)	
	)	

STOP SALE, USE OR REMOVAL ORDER

I. Nature of the Action

1. This is a Stop Sale, Use or Removal Order issued by the United States Environmental Protection Agency pursuant to Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act as amended (FIFRA), 7 U.S.C. § 136k(a).

II. Preliminary Statement

2. Section 13(a) of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended FIFRA, 7 U.S.C. § 136k(a), authorizes the Administrator of the EPA to issue an order prohibiting the sale, use, or removal of any pesticide or device by any person who owns, controls, or has custody of such pesticide or device whenever there is reason to believe that, *inter alia*, the pesticide or device is in violation of any provision of FIFRA, or the pesticide or device has been or is intended to be distributed or sold in violation of any provision of FIFRA. The Administrator of the EPA has delegated this authority under FIFRA to the Regional Administrators by EPA Delegation 5-12, dated May 11, 1994.

The Regional Administrator, Region 4 has redelegated this authority to the Director, Air, Pesticides and Toxics Management Division and to the Chief, Pesticides and Toxic Substances Branch, by EPA Region 4 Delegation 5-12, dated November 15, 1993. Pursuant to these delegations, the Chief, Pesticides and Toxic Substances Branch has the authority to issue a Stop Sale, Use and Removal Order in this matter.

3. The Respondent in this matter is Zep, Inc. (Respondent)

4. On or about May 26, 2011, EPA inspectors inspected Respondent's facility located at 1420 Seaboard Industrial Blvd., NW, Atlanta, GA 30318. The facility is assigned EPA Establishment Number 1270-GA-001.

5. During the inspection, the inspectors collected a physical sample of the pesticide product, "ZEP Formula 165," which bore the EPA Registration Number (Reg. No.) 49403-6-1270.

6. "ZEP Formula 165" was produced, distributed or sold by Respondent as those terms are defined in Sections 2(w) and 2(gg) of FIFRA.

7. 40 C.F.R. § 152.132 states that a registrant may distribute or sell his registered product under another person's name and address instead of (or in addition to) his own. Such distribution and sale is termed "supplemental distribution" and the product is referred to as a "distributor product." Clariant Corporation produced, distributed or sold the product labeled by Respondent as "ZEP Formula 165" under EPA Reg. No. 49403-6.

8. Prior to April 21, 2010, Respondent produced, distributed or sold "ZEP Formula 165" pursuant to a supplemental distribution agreement with Clariant Corporation under EPA Reg. No. 49403-6-1270.

9. 40 C.F.R. § 152.135(a) states that a registrant may transfer the registration of a product to another person.

10. On April 21, 2010, Clariant Corporation transferred the registration of EPA Reg. No. 49403-6, to Lanxess Corporation. The EPA assigned the new registration number EPA Reg. No. 39967-81 to the transferred product.

11. On January 10, 2012, Lanxess Corporation registered distributor product "ZEP Formula 165" under EPA Reg. No. 39967-81-1270.

12. "ZEP Formula 165" is a "pesticide" as defined in Section 2(u) of FIFRA, 7 U.S.C. § 136(u), in that it is a substance or mixture of substances intended for preventing, destroying, repelling, or mitigating a pest.

13. A "pest" is defined in Section 2(t) of FIFRA, 7 U.S.C. § 136(t) as any insect, rodent, nematode, fungus, weed, or any other form of terrestrial or aquatic plant or animal life or virus, bacteria, or other micro-organism (except viruses, bacteria, or other micro-organisms on or in living man or other living animals) which the Administrator declares to be a pest under Section 25(c)(1).

14. Respondent "distributes or sells" pesticides. The term "to distribute or sell" as defined by Section 2(gg) of FIFRA, 7 U.S.C. § 136(gg), includes to distribute, sell, offer for sale, hold for distribution, hold for sale, hold for shipment, ship, deliver for shipment, or release for shipment.

15. Respondent "produces" pesticides. The term "produce" as defined by Section 2(w) of FIFRA, 7 U.S.C. § 136(w), means to manufacture, prepare, compound, propagate, or process any pesticide.

16. Further, "ZEP Formula 165" is an "antimicrobial pesticide" as defined in Section 2(mm) of FIFRA, 7 U.S.C. § 136(mm), in that the product is intended to disinfect, sanitize, reduce, or mitigate growth or development of microbiological organisms.

17. "ZEP Formula 165" is an antimicrobial pesticide registered for use as a hospital disinfectant.

18. The registration documents accepted by the EPA for EPA Reg. No. 39967-81, state that it contains 1.25% of the active ingredient Para-tertiary-amyl phenol.

19. EPA laboratory testing of the sample of "ZEP Formula 165" collected during the inspection was conducted using the analytical method "SOP for the Analysis of Phenols and their Salts in Antimicrobial Products." Analytical results showed that the product contained 1.41% of the active ingredient Para-tertiary-amyl phenol, which exceeds the upper certified limit that was established for that ingredient as part of the registration for EPA Reg. No. 39967-81.

20. A copy of the Chemistry Review and Report of Analysis for the sample of "ZEP Formula 165" is attached to this SSURO as Attachment A.

21. Section 12(a)(1)(C) of FIFRA, 7 U.S.C. § 136j(a)(1)(C), states that it shall be unlawful for any person in any state to distribute or sell to any person any registered pesticide the composition of which differs at the time of its distribution or sale from its composition as described in the statement required in connection with its registration under Section 3.

22. The label on "ZEP Formula 165" provides directions for use to kill *Mycobacterium tuberculosis*.

23. EPA laboratory testing of the sample of "ZEP Formula 165" obtained during the inspection was conducted using the "Association of Official Analytical Chemists (AOAC) Confirmative In-Vitro Test" as part of the EPA Antimicrobial Efficacy Testing Program. Analytical results showed that it was ineffective against *Mycobacterium tuberculosis*, when used according to label directions for a contact time of 10 minutes.

24. A copy of the Biological Report of Analysis of the AOAC Confirmative In Vitro Test performed on the sample of "ZEP Formula 165" is attached to this SSURO as Attachment B.

25. Section 2(q)(1)(A) of FIFRA, 7 U.S.C. § 136(q) states "a pesticide is misbranded if its labeling bears any statement, design, or graphic representation relative thereto or to its ingredients which is false or misleading in any particular."

26. The label on "ZEP Formula 165," as packaged when offered for sale at the facility located at 1420 Seaboard Industrial Blvd., NW, Atlanta, GA 30318, was false and misleading regarding its effectiveness against *Mycobacterium tuberculosis*.

27. Section 12(a)(1)(E) of FIFRA, 7 U.S.C. § 136j(a)(1)(E), states that it shall be unlawful for any person in any state to distribute or sell to any person a pesticide that is misbranded.

III. ORDER

28. Respondent is hereby ordered NOT to distribute, sell, use, or remove the following pesticide product: "ZEP Formula 165," EPA Reg. No. 39967-81-1270, or former EPA Reg. No. 49403-6-1270.

29. This Order shall pertain to all quantities and sizes of "ZEP Formula 165" within the ownership, control or custody of Respondent, wherever located.

30. After receiving this Order, Respondent shall not commence any sale or distribution of "ZEP Formula 165," without prior written approval from the EPA. All communications should be directed to Ms. Molly Miller at the following address:

Molly Miller
Pesticides Section
Air, Pesticides and Toxics Management Division
U.S. Environmental Protection Agency
61 Forsyth Street, SW
Atlanta, Georgia 30303

31. Violation of the terms or provisions of this Order may subject the violator to civil or criminal penalties as prescribed in Section 14 of FIFRA, 7 U.S.C. § 136*l*.

32. The issuance of this Order shall not otherwise affect any liability of Respondent to the United States other than as expressed herein nor does it act as a waiver by the EPA of any right to bring an enforcement action against Respondent for any violation of any federal or state statute, regulation or permit, or to initiate an action for imminent and substantial endangerment, or to pursue criminal enforcement.

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IV. Effective Date

33. This Order shall be **EFFECTIVE IMMEDIATELY** upon receipt by Respondents.

4-16-2012
Date

Jeanne M. Gettle, Chief
Pesticides and Toxic
Substances Branch
Air, Pesticides and Toxics
Management Division