

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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PM 31

662-73

JUN 10 1996

Basf Corporation
 Product Regulations Dept. cc.
 1609 Biddle Ave PO BOX 13528
 Wyandotte, MI 48192 Research Triangle Park, NC 27709

Attention: Thomas R. Nelsen
 Manager, Regulatory Affairs

Subject: GDA-50
 EPA Registration No. 662-73
 Your Submission Dated November 15, 1995.

The amendment (adding additional outdoor/indoor uses and removing "closed delivery systems only" restriction statement) referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable provided that you:

1. Submit and/or cite all data required for registration/reregistration of your product under FIFRA sec 3(c)(5) when the Agency requires all registrants of similar products to submit such data.

2. SUBMIT FDA CLEARANCE

Your product is not cleared under the Federal Food, Drug and Cosmetic Act for the Use pattern, as proposed on the label, that may come in contact with food, specifically paper and coatings.

A restriction statement has been added to the label.

In order to remove the restriction statement, submit a copy of an opinion letter from FDA that all the chemicals in your product are cleared for our review.

3. SUBMIT A REVISED CONFIDENTIAL STATEMENT OF FORMULA

According to our calculations, the revised Confidential Statement of Formula submitted (items 13a) equals only 995 pounds, not 1000 pounds as declared in item #17. Submit a revised CSF for our review.

CONCURRENCES							
SYMBOL							
SURNAME							
DATE							

4. SUBMIT A REVISED MATRIX

The matrix submitted is still incomplete. Incomplete matrices only delays the review and processing cycles. A cursory review of the submitted matrix is outlined below. (PM screen only).

a. Toxicology

(1) Guideline No. 82-1(a). Subchronic Feeding.

You cited only one study (a drinking water study in rat) with a permission from Union Carbide. This citation is incomplete.

NOTE: Union Carbide was requested that in lieu of the feeding study, that they conduct two drinking water studies (mice and rat).

(2) Guideline No. 82-3. Subchronic 90 day Dermal.

Your matrix response was a "waiver request" and your response to Reregistration was a "waiver request". Your previous waiver request was granted on the basis of a closed delivery system. Since your current amendment is requesting to delete the closed systems and add open systems, this data requirement must now be readdressed. The new waiver request submitted will not satisfy this data requirement. This required data requirement is based on the potential for repeated dermal exposure in commercial settings.

NOTE: Union Carbide was instructed that they must do the study.

(3) Guideline No. 83-1(b). Chronic (nonrodent).

Your matrix response was "Data Gap". This data requirement is required to be addressed. Based upon the Antimicrobial Data Call in and the Reregistration DCI, all products that are placed in high exposure category must conduct this study. The response of "data gap" is not an option to satisfy this data requirement. Submit a waiver request or the data or a data reference.

NOTE: Union Carbide submitted an acceptable waiver request.

(4) Guideline No. 83-2(b). Oncogeniity (Mouse).

Your matrix response was "Data Gap". This data requirement is required to be addressed. Based upon the Antimicrobial Data Call in and the Reregistration DCI, all products that are placed in high exposure category must conduct this study. The response of "data gap" is not an option to satisfy this data requirement.

NOTE: Union Carbide submitted an unacceptable waiver request. EPA is requiring Union Carbide to conduct the study.

(5) Guideline No. 85-1, 85-2. Metabolism & Dermal Penetration respectively.

Your matrix did not list these guideline numbers. A formal waiver request or data or data reference must be submitted by your company to address these data requirements.

NOTE: Union Carbide submitted a waiver request however the Agency decided that the data requirement can not be waived, but held these data requirements in reserved pending the further evaluation of the other toxicology data.

b. Fish & Wildlife

(1) Guideline No. 72-1(b), 72-1(d), 72-2(b). Bluegill, trout and invertebrate TEP respectively.

These are studies that are required to support Reregistration for formulated products. Your matrix response was "n.a." but your response to Reregistration was a waiver request. Both of these responses are not viable options. Please readdress these data requirements.

NOTE: Union Carbide was required to and did submit actual studies to address these data requirements.

(2) Guideline No. 72-3(d), 72-3(e), 72-3(f). Fish, mollusk, and shrimp TEP respectively.

These are studies that are required to support Reregistration for formulated products for use in pulp & paper mill sites. Your response of n.a. (Matrix) is not an option. Please readdress these data requirements.

NOTE: Union Carbide was required to and did submit actual studies to address these data requirements.

(3) Guideline No. 72-4, 72-5, 72-6, 72-7. Life stage, life cycles, aquatic accumulation, field aquatic respectively.

Your matrix response was "n.a." but your response to Reregistration was a waiver request. Your matrix must be adjusted to eliminate this discrepancy. Also submit a copy of your waiver request for our files.

NOTE: Union Carbide submitted a waiver request and was granted a waiver for these data requirements.

(4) Guideline No. 71-2(b), 72-1(a). Avian & bluegill respectively.

These are studies that are required to support reregistration for formulated products. Your matrix response was "n.a." with MRID numbers for informational purposes but your response to Reregistration were MRID numbers. Your response of n.a. (Matrix) is not an option. Adjust the matrix accordingly.

NOTE: Union Carbide was required to and did submit actual studies to address these data requirements.

c. Environmental Fate

(1) Guideline No. 161-2. Photodegradation water.

This study is required to support Reregistration for formulated products. Your matrix response was "n.a." with MRID numbers for informational purposes but your response to Reregistration was a MRID number. Your response of n.a. (Matrix) is not an option. Adjust the matrix accordingly.

NOTE: Union Carbide was required to and did submit an actual study to address this data requirement.

(2) Guideline No. 162-1, 162-2, 162-3, 162-4, 163-1, 144-1, 164-2, 164-5, 165-3, 165-4, 165-5. Aerobic soil, anaerobic soil, anaerobic aquatic, aerobic aquatic, leach, terrestrial field, aquatic field, soil dissipation, accumulation, bioaccumulation-irrig, bioaccumulation-fish, bioaccumulation-aquatic respectively.

Your matrix response was "n.a." but your response to Reregistration was a waiver request. Your waiver request was granted. Since this office is not aware of the nature of your previous waiver request to reregistration, and since you are adding uses under your current amendment, a new waiver request must be submitted. Your matrix must be adjusted to eliminate this discrepancy. Also submit a copy of this new waiver request for our files.

NOTE: Union Carbide submitted a waiver request and was granted a waiver for these data requirements.

d. Plant Protection

(1) Guideline No. 122-1, 122-2, 123-1, 123-2, 124-1, 124-2, 132-1, 133-3, 133-4. Seed germ, vegetative, plant growth, seed germ, vegetative, plant growth, terrestrial, aquatic, foliar, soil, passive dosimet respectively.

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Your matrix response was "n.a." but your response to Reregistration was a waiver request. Your waiver request was granted on the basis of a closed delivery system. Since your current amendment is requesting an open system, a new waiver request must be entertained. Your matrix must be adjusted to eliminate this discrepancy. Also submit a copy of this new waiver request for our files.

NOTE: Union Carbide submitted a waiver request and was granted a waiver for these data requirements.

5. NOTE TO FILE: It will also be the responsibility of BASF to immediately contact Reregistration and request that the report card be updated to reflect the additional data requirements which will result from this amendment.

6. Note that even though this amendment is being accepted at this time, his amendment submission did fail the PM screen, no information will be routed for formal review until all the issues have been addressed. Incomplete submissions are not routed for review.

7. Just a reminder that after a review of the above requested information, additional data and/or information may be required to support your amendment for the declared new uses.

8. Make the following labeling changes below before you release the product for shipment bearing the amended labeling.

a. Revise the statement: "Remove an launder contaminated clothing before reuse" to read:

"Remove contaminated clothing and wash before reuse."

b. The address of record for company number 662 is:

Basf Corporation
1609 Biddle Ave
Wyandotte, MI 48192

c. Include the heading: Net Contents

d. The following statement must be retained on the label:

Formulators using this product are responsible for providing data for the EPA registration for their products.

e. Revise the statement: "A manufacturers use product for formulation of..." to read: "For use by manufacturers only in formulating..."

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f. Revise the following sentence in the Environmental Hazards section:

Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit.

to read:

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge.

g. The following statement must also be added to the label:

"Formulators using this product must put the following restriction statement on their labels:

This product is not cleared under the Federal Food, Drug and Cosmetic Act for the Use pattern: paper and coatings that may come in contact with food."

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). A release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions.

A stamped copy of the labeling is enclosed for your records.

If you have any questions concerning this letter, contact me at 703-305-6757.

Sincerely,

Marion J. Johnson, Jr.
Product Manager (31)
Antimicrobial Program Branch
Registration Division (7505C)

BASF

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May 8, 1995

GDA-50

Formulators using this product must put the following restriction statement on their labels:
This product is not cleared under the Federal Food, Drug and Cosmetic Act for the Use pattern: paper and coatings that may come in contact with food.

A Manufacturers Use Product for formulation of microbicides for controlling slime forming bacteria, sulfate reducing bacteria, fungi, yeast and algae in paper mills and paper mill process water systems, water based coatings for paper and paperboard, air washers, recirculating cooling water systems, heat transfer systems, drilling muds, workover fluids and oil well water floods.

Active Ingredient:	
Glutaraldehyde	50%
Inert Ingredients:	50%
TOTAL	100%

EPA Reg. No. 662-73

EPA Est. No. 7969-WG-01

**KEEP OUT OF REACH OF CHILDREN.
DANGER**

**CORROSIVE; CAUSES EYE AND SKIN DAMAGE.
HARMFUL OR FATAL IF SWALLOWED.**

Statement of Practical Treatment

In case of contact with eyes, immediately wash with running water for 15 minutes. Call a doctor at once. *In case of contact with skin*, wash affected areas with soap and water. Remove an launder contaminated clothing before reuse. Call a doctor at once. *If swallowed*, give milk, or water to dilute. Do not induce vomiting. Never give fluids or induce vomiting if the victim is unconscious or having convulsions. Call a doctor at once. *If inhaled*, immediately move to fresh air. Aid in breathing, if necessary, and call a doctor at once.

Note To Physician: Probable mucosal injury may contradict the use of gastric lavage. See back panel for additional precautionary statements.

Environmental Hazards

This pesticide is toxic to fish. Do not discharge effluent containing this active ingredient into lakes, streams, ponds, estuaries, oceans or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product into sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your state water board or regional office of the EPA. Do not apply in marine and/or estuarine oil fields. Do not contaminate water when disposing of equipment washwaters.

Instructions in Case of Spills or Leaks: Wear goggles or face shield, rubber gloves, and protective clothing. Absorb spills and leaks with inert material such as sand, clay, or vermiculite. Shovel into a sealable container and dispose of in an authorized EPA disposal facility.

In Case of Fire: Use water, CO₂, dry chemical (e.g., sodium bicarbonate) extinguishing medias. Fire fighters should be equipped with self-contained breathing apparatus and turnout gear.

In Case of Chemical Emergency: Call CHEMTREC day or night for assistance and information concerning spilled material, fire, exposure, and other chemical accidents.
800-424-9300

Net Wt. 500 lbs. (227 kg)

BASF Corporation
Specialty Products

3000 Continental Drive-North
Mount Olive, New Jersey 07828-1234

RECEIVED
AND COMPANY
in EPA Letter Delet

JUN 10 1996

Under the Federal Insecticide, Fungicide, and Rodenticide Act as amended for the reason stated under EPA Reg. N

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PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Do not get in eyes, on skin, or clothing. Wear eye goggles or face shields, rubber gloves, and protective clothing when handling this product. Wash thoroughly with soap and water after handling.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Storage and Disposal

GDA 50 solutions are corrosive to many commonly used materials of construction such as steel, galvanized iron, aluminum, tin, and zinc. These solutions can be stored and handled in baked phenolic-lined steel, stainless steel, or reinforced epoxy equipment. This product freezes at approximately -7°C. Therefore, unless the storage tank is inside or underground, heating and insulation may be required. If heating is needed, exposure to high temperatures should be avoided. For short storage (one month), temperatures up to 100°F can be tolerated; however, the preferred maximum storage temperature is

approximately 80°F. Keep away from fire and open flames. A stainless steel centrifugal pump is suggested for transfer service. Asbestos is suitable for gaskets and packing.

Prohibitions: Do not contaminate water, food, or feed by storage or disposal.

Pesticide Disposal: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal law. If these wastes cannot be disposed of by use according to label instructions, contact your state pesticide or environmental control agency, or the hazardous waste representative at the nearest EPA regional office for guidance.

Container Disposal: Triple-rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

General: Consult Federal, state, and local authorities for approved alternative procedures. RCRA Hazardous Waste Code - D002.

CONDITIONS OF SALE AND WARRANTY

The Directions for Use of this product reflect the opinion of experts based on field use and

tests. The directions are believed to be reliable and should be followed carefully. However, it is impossible to eliminate all risks inherently associated with use of this product. Ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or use of the product in a manner inconsistent with its labeling, all of which are beyond the control of BASF CORPORATION ("BASF") or the Seller. All such risks shall be assumed by the Buyer. BASF warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes referred to above. **BASF MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. IN NO CASE SHALL BASF OR THE SELLER BE LIABLE FOR CONSEQUENTIAL, SPECIAL OR INDIRECT DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.** BASF and the Seller offer this product, and the Buyer and User accept it, subject to the foregoing Conditions of Sale and Warranty which may be varied only by agreement in writing signed by a duly authorized representative of BASF.

ACCEPTED
with COMMENTS
in EPA Letter Dated
JUN 10 1996

Under the Federal Insecticide, Fungicide, and Herbicide Act (as amended) for the pesticide registered under EPA Reg. No. 662-73