

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 20 2000

Ransom Hinton
Vinings Industries
245 Town park drive, Suite 200
Kennesaw, GA 30144

**RE: AMA-20
EPA Reg. No. 9386-28
Your Letter Dated 2/4/2000 and Original Amendment Dated 10/6/98**

The letter and the associated original Amendment referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, to receive approval for deleting one inert ingredient, and in its place, using two different inert ingredients, which will be used in the manufacture of paper and paperboard products that are incorporated into food packaging, **is acceptable, with the following comments.**

BACKGROUND

We understand that you believe "Genapol 26 L 60" and "Genapol UD 079" to be "ethoxylated alcohols" that are already approved in the FDA category called "**aliphatic polyoxyethylene ethers**" listed in 21 CFR 181.30 ("Substances used in the manufacture of paper and paperboard products used in food packaging"). We also believe that these two inerts are in the same chemical class as "**aliphatic polyoxyethylene ethers**". This seems to be a simple case of two agencies agreeing on chemical class terminology. However, we need some kind of concurrence from FDA.

COMMENT #1 – Within 180 calendar days of the date stamped on this letter, you must submit evidence to show that your two inert substances are already acceptable by FDA under 21 CFR 181.30 ("Substances used in the manufacture of paper and paperboard products used in food packaging"). We asked you to provide this information prior to this letter and you recently submitted an opinion from Keller & Heckman, but no opinion or evidence from FDA. We understand that FDA doesn't provide letters but according to page 2 of the attachment to your letter by Keller & Heckman, you may be able to receive some form of FDA concurrence or approval via their new 120 day Notification process under "The FDA Modernization Act of 1997". An FDA response will hopefully show their concurrence that both "Genapol 26 L 60" and "Genapol UD 079" are "ethoxylated alcohols" that not only fit into FDA's "**aliphatic polyoxyethylene ethers**" category listed in 21 CFR 181.30, but are deemed safe.

CONCURRENCES

SYMBOL							
SURNAME							
DATE							

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COMMENT #2 – For easier location, you must put the following restriction statement at the beginning of the “Clay, slurries, adhesives...” section,, rather than at the end where it is now.

“This product is not cleared for use in the manufacture of adhesives that may come into contact with food”.

COMMENT #3 – We have stamped the “Technical Data AMA-20” sheet but at your next regular scheduled label printing, you must add a statement on the main label that refers the reader to it (eg., “See *Technical Data AMA-20* sheet for further information”). .

A stamped copy of the main label and technical data sheet is enclosed for your records.

If you have any questions about the comments in this letter, please feel free to contact Tony Kish at 703-308-9443.

Sincerely,

Marshall Swindell,
Product Manager Team 33,
Regulatory Management Branch I
Antimicrobials Division (7510C)

CONCURRENCES

SYMBOL								
SURNAME								
DATE								

DIRECTIONS FOR USE:

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

PAPER MILL SLIME CONTROL: FOR THE CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA: AMA[®]-20 is added at a point in the system (raw stock chest; beater and/or refiner chest or machine chest - wire pit) where it will be uniformly mixed. Application may be continuous or intermittent for a certain number of hours per day or per shift, depending upon system characteristics. Add 5 to 20 fluid ounces of AMA[®]-20 per ton of paper produced.

INTERMITTENT FEED METHOD: Apply 12 to 20 fluid ounces of AMA[®]-20 per ton (dry basis) of pulp or paper produced for 2 hours every 8 hours. Badly fouled process systems must be cleaned before initial treatment.

CONTINUOUS FEED METHOD: Apply 5 to 15 fluid ounces of AMA[®]-20 per ton (dry basis) of pulp or paper produced on a continuous basis. Badly fouled process systems must be cleaned before initial treatment.

OIL FIELD DRILLING MUDS AND WORKOVER OR COMPLETION FLUIDS: FOR CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA: Determine the total volume of the circulating system. Calculate the number of gallons of AMA[®]-20 needed to produce a concentration of 2,080 ppm (0.73 lb/bbl) of AMA[®]-20 in the drilling mud circulating system. For example, 75 gallons of AMA[®]-20 per 1000 barrels of drilling fluid will produce the proper concentration. For best results, add AMA[®]-20 in a thin stream to the mud pit while the drilling fluid is circulating. As the total volume increases, due to greater well depth, add additional AMA[®]-20 to maintain the proper concentration. Because of the wide variation in drilling mud composition and bacterial contamination, greater or lesser amounts of the AMA[®]-20 may be prescribed.

OILFIELD WATER TREATMENT AND WATER FLOODS: FOR CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA: Calculate the total volume of water to be treated. Using this volume, calculate the number of gallons of AMA[®]-20 needed to produce a concentration of approximately 2,500 ppm AMA[®]-20. For example, 2.1 gallons of AMA[®]-20 per 1000 gallons of total volume will produce this dilution. 350 ppm of AMA[®]-20, added each week is recommended to maintain bacterial control. This may be accomplished by adding 0.30 gallons of AMA[®]-20 to each 1000 gallons of total volume. Because of the wide variation in waters found in the oil fields, greater or lesser amounts of AMA[®]-20 may be required in a particular location.

FOR THE PRESERVATION OF CLAY SLURRIES, ADHESIVES, COATINGS AND HIGH VISCOSITY SUSPENSIONS: For preservation of slurries and high viscosity suspensions, AMA[®]-20 should be added at a point in the processing system where there will be sufficient time and agitation for good mixing and dispersion. Add AMA[®]-20 at use levels of 0.04-0.40%, by weight, based on the total formulation in slurries of starch, clay, calcium carbonate or titanium dioxide; paper coatings; high viscosity suspensions (e.g. polymers; silica-polymer combinations); polyvinyl alcohol/polyvinyl acetate based adhesives; starch based adhesives; dextrin based adhesives. The exact amount of material to be added for the preservation of any given formulation will depend on the components and local storage conditions. Dosage rates should be determined by actual test. This product is not cleared for use in the manufacture of adhesives that may come in contact with food.

RECIRCULATING COOLING WATER SYSTEMS: FOR THE CONTROL OF ALGAE, FUNGI, AND SLIME FORMING BACTERIA: Dosages for industrial recirculating cooling water systems will depend on the conditions of the system prior to treatment initiation. Systems which are heavily contaminated should be cleaned first. Apply AMA[®]-20 to the cleaned system or when growth is first noticed according to the following schedule.

INITIAL DOSAGE: Apply 3.25-6.5 fluid ounces (30-60 ppm) of AMA[®]-20 per each 1000 gallons of water in the system. This dose may be as a continuous treatment or applied once, twice, or three times weekly or as required to control the growth of slime-forming organisms.

SUBSEQUENT DOSAGE: When microbial control is evident add 0.5 to 3.25 fluid ounces (5-30 ppm) of AMA[®]-20 per 1000 gallons of water in the system as a continuous treatment daily or every 3 days or as required to maintain control.

AMA[®]-20

ANTIMICROBIAL AGENT

Active Ingredient:	
Tetrahydro-3,5-dimethyl-2H-1,3,5-thiadiazine-2-thione	20%
Inert Ingredients:	80%
TOTAL	100%

(FOR INDUSTRIAL USE ONLY)

KEEP OUT OF REACH OF CHILDREN

CAUTION

STATEMENT OF PRACTICAL TREATMENT

- If on skin:** Wash with plenty of soap and water. Get medical attention if irritation persists.
- If in eyes:** Flush with plenty of water. Get medical attention.
- If swallowed:** Call a physician. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

EPA REG. No. 9386-28

EPA EST. No. 9386-GA-1

MANUFACTURED BY

ACCEPTED
with COMMENTS
in EPA Letter Dated:
MAR 20 2000

VININGS INDUSTRIES INC.

Under the Federal Insecticide,
Fungicide, and Rodenticide Act as
amended, for the pesticide,
registered under EPA Reg. No.

9386-28

1654 West Oak Drive

MARIETTA, GEORGIA 30062-2234

PRECAUTION

HAZARDS TO HUMAN

CAUTION. KEEP OUT OF REACH OF CHILDREN. Avoid contact with skin, eyes or clothing. Wear goggles or face shield when handling. Wear goggles or face shield if swallowed or absorbed through skin.

ENVIRONMENTAL HAZARDS: This product is not to be discharged into estuarine oil fields where drilling fluids are not discharged unless in accordance with the National Pollution Discharge Elimination System. This product has been notified in writing prior to discharge into sewer systems without previous authority. For guidance contact your local EPA.

PHYSICAL OR CHEMICAL HAZARDS: Do not use, spill, or inhale.

STORAGE

Do not contaminate water, soil, or food.

STORAGE: Protect from freezing and store in a container closed when not in use. If damaged, collect liquid with absorbent material and dispose in accordance with state and federal disposal regulations.

PESTICIDE DISPOSAL: Pesticide waste should be disposed of as food, or feed by storage or disposal. Disposal of a mixture, or rinsate is a violation of federal law. Use or contact your State Pesticide or Environmental Waste representative at the nearest EPA office.

CONTAINER DISPOSAL: Metal Containers should be recycled for recycling or reconditioning, or punctured and disposed of in other procedures approved by state and local authorities. Rinse (or equivalent). Then offer for disposal of in a sanitary landfill, or incinerate at a facility approved by local authorities, by burning. If burned, stay out of the fire.

LABEL DATE: 02/04/00

LOT#

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TECHNICAL DATA

AMA[®]-20

DESCRIPTION:

AMA[®]-20 is an effective, low cost, liquid antimicrobial agent.

COMPOSITION:

Active Ingredient:	Tetrahydro-3,5-dimethyl-2H-1,3,5-thiadiazine-2-thione	20%
Inert Ingredients:		80%
	TOTAL	100%

TYPICAL PROPERTIES:

Appearance:	White creamy liquid	Solubility:	Complete at use concentration
Flash Point:	> 200°F (Pensky-Martens)	Viscosity:	1900 cps (Brookfield)
pH:	8.2		
Density:	8.8 lb/gal		

EFFICACY:

AMA[®]-20 has been found to be an effective agent against many bacteria and fungi.

Following is a tabulation showing the ppm of AMA[®]-20 required to give complete inhibition at 96 hours:

<u>MICROORGANISM</u>	<u>PPM</u>	<u>MICROORGANISM</u>	<u>PPM</u>
1. Flavobacterium capsulatum	167	5. Aspergillus niger	333
2. Enterobacter aerogenes	1000	6. Penicillium expansum	500
3. Bacillus subtilis	333	7. Fusarium oxysporum	1000
4. Pseudomonas fluorescens	1000		

<u>COMBINATION OF BACTERIA</u>	<u>PPM</u>	<u>COMBINATION OF FUNGI</u>	<u>PPM</u>
1,2&4 (Bacterial Combination)	1000	5,6&7 (Fungal Combination)	500

SULFATE-REDUCING BACTERIA

Desulfovibrio desulfuricans	120-130
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DIRECTIONS FOR USE:

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PAPER MILL SLIME CONTROL: FOR THE CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA:

AMA[®]-20 is added at a point in the system (raw stock chest; beater and/or refiner chest or machine chest - wire pit) where it will be uniformly mixed. Application may be continuous or intermittent for a certain number of hours/day or per shift, depending upon system characteristics. Add 5 to 20 fluid ounces of AMA[®]-20 per ton of paper produced.

INTERMITTENT FEED METHOD: Apply 12 to 20 fluid ounces of AMA[®]-20 per ton (dry basis) of pulp or paper for 2 hours every 8 hours. Badly fouled process systems must be cleaned before initial treatment.

CONTINUOUS FEED METHOD: Apply 5 to 15 fluid ounces of AMA[®]-20 per ton (dry basis) of pulp or paper produced on a continuous basis. Badly fouled process systems must be cleaned before initial treatment.

Consult your Vinings' representative for technical advice concerning certain site problems.

RECIRCULATING COOLING WATER SYSTEMS: FOR THE CONTROL OF ALGAE, FUNGI, AND SLIME FORMING BACTERIA:

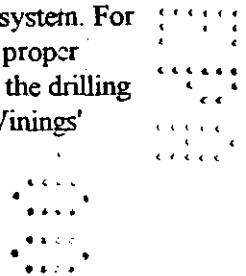
Dosages for industrial recirculating cooling water systems will depend on the conditions of the system prior to treatment initiation. Systems which are heavily contaminated should be cleaned first. Apply AMA[®]-20 to the cleaned system or when growth is first noticed according to the following schedule.

INITIAL DOSAGE: Apply 3.25-6.5 fluid ounces (30-60 ppm) of AMA[®]-20 per each 1000 gallons of water in the system. This dose may be as a continuous treatment or applied once, twice, or three times weekly or as required to control the growth of slime-forming organisms.

SUBSEQUENT DOSAGE: When microbial control is evident add 0.5 to 3.25 fluid ounces (5-30 ppm) of AMA[®]-20 per 1000 gallons of water in the system as a continuous treatment daily or every 3 days or as required to maintain control.

OIL FIELD DRILLING MUDS AND WORKOVER OR COMPLETION FLUIDS: FOR CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA:

Determine the total volume of the circulating system. Calculate the number of gallons of Vinings' AMA[®]-20 needed to produce a concentration of 2080 ppm (0.73 lb/bl) of Vinings' AMA[®]-20 in the drilling mud circulating system. For example, 75 gallons of Vinings' AMA[®]-20 per 1000 barrels of drilling fluid will produce the proper concentration. For best results, add Vinings' AMA[®]-20 in a thin stream to the mud pit while the drilling fluid is circulating. As the total volume increases, due to greater well depth, add additional Vinings'



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in EPA Letter Dated:

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AMA®-20 to maintain the proper concentration. Because of the wide variation in drilling mud composition and bacterial contamination, greater or lesser amounts of the AMA®-20 may be prescribed.

OILFIELD WATER TREATMENT AND WATER FLOODS: FOR CONTROL OF SLIME-FORMING AND/OR SPOILAGE BACTERIA: Calculate the total volume of water to be treated. Using this volume, calculate the number of gallons of AMA®-20 needed to produce a concentration of approximately 2,500 ppm AMA®-20. For example, 2.1 gallons of AMA®-20 per 1000 gallons of total volume will produce this dilution. 350 ppm of AMA®-20, added each week is recommended to maintain bacterial control. This may be accomplished by adding 0.30 gallons of AMA®-20 to each 1000 gallons of total volume. Because of the wide variation in waters found in the oil fields, greater or lesser amounts of AMA®-20 may be required in a particular location.

STORAGE AND DISPOSAL:

STORAGE: Protect from freezing and temperatures in excess of 140°F. Keep container closed when not in use. If contents are spilled or leaked due to container damage, collect liquid with absorbent material and dispose of in accordance with local, state and federal pesticide disposal regulations.

PESTICIDE DISPOSAL: Pesticide wastes are hazardous. Do not contaminate water, food, or feed by storage or disposal. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of federal law. Dispose of excess or waste pesticide by use or contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

CONTAINER DISPOSAL: Metal Containers - 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. Plastic Containers - Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

TECHNICAL ASSISTANCE:

Our technical staff is available to assist in the application of Vinings' products. You may request assistance through your sales representative or by contacting Vinings Industries at 800-347-1542.

PRECAUTIONARY STATEMENTS:

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION. KEEP OUT OF REACH OF CHILDREN. Causes eye and skin irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling. Wear goggles or face shield and rubber gloves when handling. Harmful if swallowed or absorbed through skin.

ENVIRONMENTAL HAZARDS: This pesticide is toxic to fish. Do not apply (or use) in estuarine oil fields where drilling fluids (muds) are discharged in the surface water. 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. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the Environmental Protection Agency.

STATEMENT OF PRACTICAL TREATMENT

- If on skin:** Wash with plenty of soap and water. Get medical attention if irritation persists.
- If in eyes:** Flush with plenty of water. Get medical attention.
- If swallowed:** Call a physician. Drink 1 or 2 glasses of water and induce vomiting by touching back of throat with finger. Do not induce vomiting or give anything by mouth to an unconscious person.

SHIPPING POINT:

Marietta, Georgia
Washougal, Washington

PACKAGING:

30 gallon drums
55 gallon drums
350 gallon portabins
Bulk

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