



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

August 23, 2023

Kevin Finnegan
GSS Product Registration Manager
FMC Corporation
2929 Walnut Street
Philadelphia, PA 19104

Subject: Registration Review Label Amendments Incorporating Mitigation from the Fish and Wildlife Services (FWS) and the National Marine Fisheries Services (NMFS) Biological Opinions on the Effects of Malathion on Endangered and Threatened Species and Designated Critical Habitat
Product Name: Fyfanon EW Insecticide
EPA Registration Number: 279-3622
Application Dates: 6/27/2022 and 10/21/2022
Decision Numbers: 585500 and 588383

Dear Kevin Finnegan:

The Agency, in accordance with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended, has completed reviewing all the information submitted with your application to support the Registration Review of the above referenced product in connection with the FWS and NMFS' Biological Opinions on the effects of malathion on federally listed endangered and threatened species and designated critical habitat in accordance with section 7 of the Endangered Species Act (ESA) of 1973, as amended (16 U.S.C. 1531 et seq.). The Agency has concluded that your submission is acceptable. The label referred to above, submitted in connection with registration under FIFRA, as amended, is acceptable.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40

Page 2 of 2
EPA Reg. No. 279-3622
Decision No. 585500 and 588383

CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 12 months from the date of this letter. After 12 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

If you have any questions, please contact Carolyn Smith by phone at (202) 566-2273 or via email at smith.carolyn@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read "Kelly Sherman", with a long horizontal flourish extending to the right.

Kelly Sherman
Chief, Risk Management Implementation Branch 3
Pesticide Re-evaluation Division
Office of Pesticide Programs

Enclosure

FYFANON EW Insecticide

FYFANON EW INSECTICIDE

FOR USE ONLY BY FEDERAL, STATE, TRIBAL, OR LOCAL GOVERNMENT OFFICIALS RESPONSIBLE FOR PUBLIC HEALTH OR VECTOR CONTROL, OR BY PERSONS CERTIFIED IN THE APPROPRIATE CATEGORY OR OTHERWISE AUTHORIZED BY THE STATE OR TRIBAL LEAD PESTICIDE REGULATORY AGENCY TO PERFORM ADULT MOSQUITO CONTROL APPLICATIONS, OR BY PERSONS UNDER THEIR DIRECT SUPERVISION.

- [Kills mosquitoes]
- [Reduces mosquito populations]
- May be Applied Undiluted or Diluted with Water
- Low odor**

ACTIVE INGREDIENT:

Malathion*	40.9%
OTHER INGREDIENTS:	59.1%
TOTAL:	100.0%

*O,O-dimethyl phosphorodithioate of diethyl mercaptosuccinate.
 Contains 3.67 lbs malathion per gallon

[**U.S. Patent No. 6,121,478.]

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE [OTHER PANELS] [INSIDE] BOOKLET [BACK PANEL] FOR ADDITIONAL PRECAUTIONARY STATEMENTS AND USE DIRECTIONS

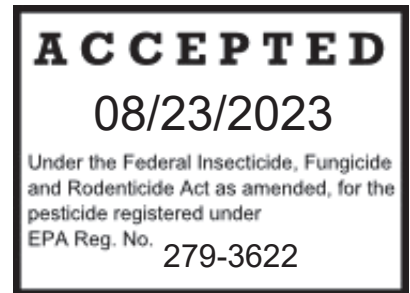
.EPA REG No 279-3622
 NET [Contents] [Weight]: _____

EPA Est. No: 4787-DNK-001



FMC Corporation
 2929 Walnut Street
 Philadelphia, PA 19104

Product of Denmark
 Fyfanon is a registered trademark of FMC Corporation or an affiliate.



IN CASE OF A MEDICAL EMERGENCY INVOLVING THIS PRODUCT, CALL TOLL FREE,

DAY OR NIGHT, 1-800-331-3148

Note to PM, the following bracketed statements are individually optional depending on the packaging configuration and whether a booklet label design is used:

- a. [See First Aid statement on back panel of booklet.]
- b. [See First Aid statement on back panel.]
- c. [See additional precautionary statements and Directions for Use in booklet.]

FIRST AID	
CONTAINS AN ORGANOPHOSPHATE THAT INHIBITS CHOLINESTERASE.	
IF SWALLOWED:	<ul style="list-style-type: none"> • Call a poison control center or doctor immediately for treatment advice. • Have person sip a glass of water if able to swallow. • Do not induce vomiting unless told to do so by a poison control center or doctor. • Do not give anything by mouth to an unconscious person.
IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"> • Take off contaminated clothing. • Rinse skin immediately with plenty of water for 15-20 minutes. • Call a poison control center or doctor for treatment advice.
IF IN EYES:	<ul style="list-style-type: none"> • Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. • Call a poison control center or doctor for treatment advice.
MEDICAL HOTLINE NUMBER	
<p>Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-331-3148 for emergency medical treatment information.</p> <p>NOTE TO PHYSICIAN: This product is a cholinesterase inhibitor. Treat symptomatically. Atropine is antidotal.</p>	

For Technical Support or Information Regarding the use of this product, call 1-800-321-1FMC(1362).

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Caution. Harmful if swallowed. Harmful if absorbed through skin. Causes moderate eye irritation. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet. Remove and wash contaminated clothing before reuse.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

Mixers, loaders, applicators, flaggers, and other handlers must wear:

- Long-sleeved shirt and long pants
- Chemical resistant gloves made of Barrier Laminate, Butyl Rubber ≥ 14 mils, Nitrile Rubber ≥ 14 mils, Neoprene Rubber ≥ 14 mils, Natural Rubber ≥ 14 mils, Polyethylene, Polyvinyl Chloride (PVC) ≥ 14 mils, or Viton ≥ 14 mils.
- Shoes plus socks

Follow manufacturer's instructions for cleaning and maintaining PPE. If no such instructions exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

User should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish and aquatic invertebrates. Drift and runoff may be hazardous to aquatic organisms in water adjacent to treated areas. Use care when applying in or to an area which is adjacent to any body of water, and do not apply when weather conditions favor drift from target area. Poorly draining soils and soils with shallow water tables are more prone to produce runoff that contains this product.

When applying as a wide area mosquito adulticide, before making the first application in a season, it is advisable to consult with the state or tribal agency charged with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.

This product is highly toxic to bees exposed to direct treatment on blooming crops or weeds. Do not apply or allow to drift onto blooming crops or weeds while bees are actively foraging in the treatment area, except when applications are made to prevent or control a threat to public and/or animal health determined by a state, tribal or local public health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort. When applying as a wide area mosquito adulticide, do not apply over bodies of water (lakes, rivers, permanent streams, natural ponds, commercial fish ponds, swamps, marshes or estuaries), except when necessary to target areas where adult mosquitoes are present, and weather conditions will facilitate movement of applied material away from the water in order to minimize incidental deposition into the water body.

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 EPA.

Reporting Ecological Incidents: To report ecological, including mortality, injury, or harm to plants and animals, call 1-(800)-321-1FMC(1362).

PHYSICAL OR CHEMICAL HAZARDS

FYFANON EW Insecticide

Do not use or store near heat or open flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling. For use by federal, state, tribal, or local government officials responsible for public health or vector control, or by persons certified in the appropriate category or otherwise authorized by the state or tribal lead pesticide regulatory agency to perform adult mosquito control applications, or by persons under their direct supervision.

FYFANON EW INSECTICIDE – PRODUCT DESCRIPTION

Fyfanon EW is a water-based malathion emulsion formulation for outdoor space-spray application to control mosquitoes. It contains proprietary formulation technology designed to reduce the odor of malathion.

Fyfanon EW is to be used for ground applications only and is approved for use in populated and rural areas.

Fyfanon EW may be used undiluted or diluted with water (only) – **it must not be diluted with oil-based solvents or diluents.**

Fyfanon EW is recommended to be part of a rotational program to reduce the occurrence of resistance developing in mosquito control programs – see RESISTANCE MANAGEMENT section below.

Endangered Species Protection Requirements:

It is a Federal offense to use any pesticide in a manner that results in an unauthorized “take” (e.g., kill or otherwise harm) of an endangered species and certain threatened species under the Endangered Species Act section 9. When using this product, you must follow the measures contained in the Endangered Species Protection Bulletin for the area in which you are applying the product. You must obtain a Bulletin no earlier than six months before using this product. To obtain Bulletins, consult <http://www.epa.gov/espp/>, call 1-844-447-3813, or email ESPP@epa.gov. You must use the Bulletin valid for the month in which you will apply the product.

Ecological Incidents Reporting

Reporting Ecological Incidents: To report ecological, including mortality, injury, or harm to plants and animals, call 1-(800)-321-1FMC(1362).

Pollinator Protection Language

To minimize hazard to bees, do not apply this product more than two hours after sunrise or more than two hours before sunset. This timing restriction prohibits applications when bees are most active (mid-day). This restriction does not apply when applications are made as a spot treatment or to prevent or control a threat to public and/or animal health determined by a state, tribal or local public health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito borne disease in animal or human populations, or if specifically approved by the state or tribe during a natural disaster recovery effort.

Calibrate and inspect nozzles at least once a year to ensure they are in good working condition.

RESISTANCE MANAGEMENT

For resistance management, Fyfanon EW Insecticide contains a Group 1B insecticide. Any insect population may contain individuals naturally resistant to Fyfanon EW Insecticide and other Group 1B insecticide. The resistant individuals may dominate the insect population of this group of insecticides are used repeatedly in the same areas. Appropriate resistance-management strategies should be followed. Examples of strategies:

- Rotate the use of Fyfanon EW Insecticide or other Group 1B insecticides within an application season with different groups that control the same pests.
- Use tank mixtures with insecticides from a different group that are equally effective on the target pest when such use is permitted. Do not rely on the same mixture repeatedly for the same pest population. Consider any known cross-resistance issues for mosquitoes between the individual components of a mixture. In addition, consider the following recommendations provided by the Insecticide Resistance Action Committee (IRAC).
- Individual insecticides selected for use in mixtures should be highly effective and be applied at the rates at which they are individually registered for use against the mosquitoes.
- Mixtures with components having the same IRAC mode of action classification are not recommended for insect resistance management.
- When using mixtures, consider any known cross-resistance issues between the individual components for the target pest.
- Mixtures become less effective if resistance is already developing to one or both active ingredients, but they may still provide pest management benefits.
- The insect resistance management benefits of an insecticide mixture are greatest if the two components have similar periods of residual insect activity. Mixtures of insecticides with unequal periods of residual insecticide activity may offer an insect resistance management benefit only for the period where both insecticides are active.
- Adopt an integrated pest management program for insecticide use that includes scouting, uses historical information related to pesticide use, crop rotation, record keeping, and which considers cultural, biological and other chemical control practices.
- Monitor after application for unexpected target pest survival. If the level of survival suggests the presence of resistance, consult with your local university specialist or certified pest control advisor.
- Contact your local or state mosquito management authorities for more pesticide resistance-management strategies and/or IPM recommendations.

Ultra-Low Volume Applications

Mandatory Spray Drift Management

- Apply when ground wind speeds are equal to or greater than 1 mph.
- All types of applications should be conducted when temperatures at ground level are at or above 50°F.

For Ground Applications:

- Create an optimum swath when possible. An optimum swath width can be achieved when Fyfanon EW Insecticide is applied from a truck that is being driven perpendicular to the wind direction. Direct the spray head of equipment to ensure even distribution of the spray cloud throughout the area.
- FOR BEST RESULTS treat when mosquitoes or insects are most active and weather conditions are conducive to keeping the spray cloud in the air column close to the ground.

- An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning is recommended.

RESTRICTIONS

- Do not apply more than 0.23 lb AI/Acre/day.
- Do not re-treat a site more than 3 times in any one week. However, more frequent treatments may be made to prevent or control a threat to public and/or animal health determined by a federal, state, tribal or local health or vector control agency on the basis of documented evidence of disease causing agents in vector mosquitoes or the occurrence of mosquito-borne diseases in animal or human populations, or if specifically approved by the state or tribe during a natural disaster effort.
- Apply when wind speed is equal to or greater than 1 mph.
- Not for aerial application
- Not for use on crop-land
- This product is for outdoor use only

GENERAL PREPARATION

- Fyfanon EW is only to be applied as an outdoor space-spray for wide-area adult mosquito control.
- Before making the first application in a season, it is advisable to consult with the state or tribal agency with primary responsibility for pesticide regulation to determine if other regulatory requirements exist.
- For best results, apply when mosquitoes are most active and meteorological conditions are conducive to keeping the spray cloud in the air column close to the ground. An inversion of air temperatures and a light breeze is preferable. Application during the cooler hours of the night or early morning may be recommended depending on target species. Use of technology to improve accuracy of treatments is recommended; this may include GPS mapping, weather monitoring or onboard or land based predictive drift modeling systems.
- Ensure Fyfanon EW (diluted or undiluted) is thoroughly agitated before use. Avoid prolonged storage of diluted product in application equipment.

OPERATING EQUIPMENT PREPARATION

Correct Droplet size: Each cold aerosol generator must be adjusted to produce the correct droplet spectrum for optimal mosquito control. Calibrate spray equipment so that the Volume Median Diameter (VMD) of the aerosol is less than 30 microns ($D_v 0.5 < 30\mu\text{m}$) and 90% of the volume is in droplets less than $50\mu\text{m}$ ($D_v 0.9 < 50\mu\text{m}$). Directions from the equipment manufacturer, insecticide vendor or a test facility can be used to establish the correct droplet size spectra

Maintenance: Equipment manufacturer's recommendations for cleaning and maintenance of the aerosol unit must be followed. The unit must be inspected before use to correct any malfunctions and to verify that the flow rate is correct. For truck mounted sprayers, use the table below to determine the application volumes required at each vehicle speed. Vehicle should not travel greater than 20 mph. Shut off spray equipment when vehicle is stopped.

APPLICATION INSTRUCTIONS

Truck Mounted Sprayer Applications – non-thermal/cold aerosol generator

Base acreage calculations on manufacturer’s directions and recommended swath width.

For control of adult mosquitoes, apply Fyfanon EW at the rate of 0.03 to 0.06 lb ai / A (1.05 to 2.1 fluid ounces Fyfanon EW per acre).

Truck Mounted Application - Rates for FYFANON EW INSECTICIDE (300 foot swath)						
lb ai/Acre	Dilution ratio (with water)	Application Rates Fluid Ounces per Minute at Vehicle Speeds				FL. OZ. Finished Spray per Acre
		5 mph	10 mph	15 mph	20 mph	
0.03 – 0.06*	Undiluted	3.2 - 6.3	6.3 - 12.6	9.5 - 18.9	12.6 – 25.2	1.05 – 2.1
	1:1	6.3 – 12.6	12.6 – 25.2	18.9 – 37.8	25.2 – 50.4	2.1 – 4.2

* Where dense vegetation or a public health emergency is present, the use of the highest label rate is recommended.

Hand-held Portable or Backpack Application

Apply through non-thermal/cold aerosol application equipment. Target application of Fyfanon EW is 1.05 – 2.1 fl.oz/Acre (0.03 – 0.06 lb ai/Acre). Application calculations assume a 50 foot swath and a walking speed of 2.9 ft/second – at this speed it will take 300 seconds (5 minutes) to walk 870 ft which (by using a 50 ft spray swath) covers one acre.

1 fl.oz/minute output: Sprayer calibrated to deliver 1 fl.oz finished spray per minute (5 fl.oz finished spray delivered per acre): Dilute Fyfanon EW 1 part concentrate + 3.7 parts water to deliver 0.03 lb AI/Acre. Dilute Fyfanon EW 1 part concentrate + 1.4 parts water to deliver 0.06 lb AI/Acre.

2 fl.oz/minute output: Sprayer calibrated to deliver 2 fl.oz finished spray per minute (10 fl.oz finished spray delivered per acre): Dilute Fyfanon EW 1 part concentrate + 8.8 parts water to deliver 0.03 lb AI/Acre. Dilute Fyfanon EW 1 part concentrate + 3.7 parts water to deliver 0.06 lb AI/Acre.

Dilution table for handheld/backpack sprayer for 2.9 ft/second walking speed & 50ft swath				
Finished spray per acre (fl.oz)	0.03 lb AI/Acre		0.06 lb AI/Acre	
	Fl.oz Fyfanon EW for quantity of finished spray required		Fl.oz of Fyfanon EW for quantity of finished spray required	
	For 1 Gallon	For 2 Gallons	For 1 Gallon	For 2 Gallons
5 fl.oz (1 fl.oz/minute spray rate)	27 fl.oz	54 fl.oz	54 fl.oz	108 fl.oz
10 fl.oz (2 fl.oz/minute spray rate)	13 fl.oz	27 fl.oz	27 fl.oz	54 fl.oz

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Fyfanon EW Insecticide should be stored in the original unopened container in a secure, dry place. Do not contaminate with other pesticides or fertilizers. Avoid excess heat. Fyfanon EW Insecticide should never be heated above 55°C (131°F), and should not be stored for long periods of time at a temperature in excess of 25° C (77° F).

PESTICIDE DISPOSAL: To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

CONTAINER HANDLING:

Refillable containers: Refill this container with pesticide only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean the container before final disposal, empty the remaining contents from this container into application equipment or mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable containers (equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank and drain for 10 seconds after the flow begins to drip. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable containers (greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty the rinsate into application equipment or a mix tank or store rinsate for later use or disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Conditions of Sale and Limitation of Warranty and Liability:

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions beyond the control of FMC. All such risks shall be assumed by User, and User agrees to hold FMC harmless for any claims relating to such factors.

FMC warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the Directions for Use when used in accordance with the directions under normal conditions of use. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, FMC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THE SELECTION, PURCHASE, OR USE OF THIS PRODUCT. Any warranties, express or implied, having been made are inapplicable if this product has been used contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to (or beyond the control of) FMC, and user assumes the risk of any such use.

To the extent permitted by law, FMC or seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER, AND THE EXCLUSIVE LIABILITY OF FMC FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF FMC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

This Conditions of Sale and Limitation of Warranty and Liability may not be amended by any oral or written agreement.

20230222