

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

November 19, 2020

Ms. Kristi Barnett U.S. Registration Specialist FMC Corporation 2929 Walnut Street Philadelphia, PA 19104

Subject: PRIA Label Amendment – Indoxacarb: New Non-Food Use on Tobacco Product Name: KN128 Technical EPA Registration Number: 279-9598 Application Date: October 21, 2019 Decision Number: 556884

Dear Ms. Barnett:

The application referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable under FIFR section (3)(c)(7)(B), subject to the following conditions:

- 1. You must submit and/or cite all data required for registration/registration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
- 2. You are required to comply with the data requirements described in the DCI identified below:
 - a. Indoxacarb GDCI-067710-1382

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1

 Be aware that proposed data requirements have been identified in a Work Plan. For more information on these proposed data requirements, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <u>http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1</u> Page 2 of 2 EPA Reg. No. 279-9598 Decision Nos. 556884

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 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 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.

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.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). If you have any questions, please contact Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327, or via email at *Rodia.Carmen@epa.gov*.

Sincerely,

Shanta Adeeb, Product Manager 10 Invertebrate-Vertebrate Branch 2 Registration Division (7505P) Office of Pesticide Programs

Enclosure: Stamped "Accepted" Master Label

KN128 Technical

FOR FORMULATION OF INSECTICIDES ONLY

ACTIVE INGREDIENT	By Weight
Indoxacarb: (S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl) [4-	
(trifluoromethoxy)phenyl]amino]-carbonyl]indeno[1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate	94%
OTHER INGREDIENTS	<u>6%</u>
TOTAL	100%

EPA Reg. No. 279-9598

EPA Est. No.

KEEP OUT OF REACH OF CHILDREN

WARNING

FIRST AID

If swallowed: 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 by the poison control center or doctor. Do not give anything to an unconscious person.

If in eyes: 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 to rinse the eye. Call a poison control center or doctor immediately for treatment advice.

If on skin: Remove contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor immediately for treatment advice.

If inhaled: Remove person to fresh air. If person is not breathing, call an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible. Call a poison control center or doctor immediately for treatment advice.

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For additional information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call **1-800-331-3148**, twenty-four (24) hours per day, seven (7) days per week.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Warning! May be fatal if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Avoid breathing dust, vapor, or spray mist. Harmful if absorbed through skin or if inhaled. Wash hands 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. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.

ENVIRONMENTAL HAZARDS

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other public 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 plant authority. For guidance contact your State Water Board or Regional Office of the EPA.





and Rodenticide Act as amended, for the pesticide registered under

EPA Reg. No. 279-9598

DIRECTIONS FOR USE

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

- Only for formulation into an insecticide for the following use(s): Terrestrial Food Crops—alfalfa, beans (dry), corn (field), corn (pop), corn (grown for seed), cotton, peanut, and soybean. Terrestrial Non-Food – tobacco.
- 2. Each formulator is responsible for obtaining EPA registration for their end-use product(s).
- 3. Uses for experimental purposes that are in compliance with U.S. EPA requirements. Consult FMC Corporation before using this product for formulating purposes.
- 4. This product may be used to formulate products for any additional uses not listed on the technical label if the formulator, user group, or grower has complied with U.S. EPA data submission requirements regarding the support of such uses.

STORAGE AND DISPOSAL

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

PESTICIDE STORAGE: Keep this product in its tightly closed original container. Store in a cool, dry (preferably locked) area away from other pesticides, fertilizer, food or feed that is inaccessible to children and animals.

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 HANDLING: Refer to the Net Contents section of this product's labeling for the applicable "Nonrefillable Container" or "Refillable Container" designation.

Nonrefillable Plastic and Metal Containers (Capacity Equal to or Less Than 50 Pounds): Nonrefillable container. Do not reuse or refill this container. 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 1/4 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 reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable Plastic and Metal Containers (Capacity Greater Than 50 Pounds): Nonrefillable container. Do not reuse or refill this container. 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 1/4 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. Turn the container over onto its other 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. Turn the container over onto its other 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. Turn the container over onto its other 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. Turn the container over onto its other 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. Turn the container over onto its other 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. Then offer for recycling if available, or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable Plastic and Metal Containers, e.g., Intermediate Bulk Containers [IBC] (Size or Shape Too Large to be Tipped, Rolled or Turned Upside Down): Nonrefillable container. Do not reuse or refill this container. Clean container promptly after emptying the contents from this container into application equipment or mix tank and before final disposal using the following pressure rinsing procedure. Insert a lance fitted with a suitable tank cleaning nozzle into the container and ensure that the water spray thoroughly covers the top, bottom and all sides inside the container. The nozzle manufacturer's instructions are not available, pressure rinse the container for at least 60 seconds using a minimum pressure of 30 PSI with a minimum rinse volume of 10% of the container volume. Drain, pour or pump rinsate into application equipment or rinsate collection system. Repeat this pressure rinsing procedure two more times. Then offer for recycling if available, or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Nonrefillable Paper or Plastic Bags, Fiber Sacks including Flexible Intermediate Bulk Containers (FIBC) or Fiber Drums With Liners: Nonrefillable container. Do not reuse or refill this container. Completely empty paper or plastic bag, fiber sack or drum liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application or manufacturing equipment. Then offer for recycling if available or dispose of empty paper or plastic bag, fiber sack or fiber drum and liner in a sanitary landfill, or by other procedures approved by state and local authorities.

Refillable Fiber Drums With Liners: Refillable container (fiber drum only). *Refilling Fiber Drum*: Refill this fiber drum with KN128 Technical containing indoxacarb only. Do not reuse this fiber drum for any other purpose. Cleaning before refilling is the responsibility of the refiller. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application or manufacturing equipment. *Disposing of Fiber Drum and/or Liner*: Do not reuse this fiber drum for any other purpose other than refilling (see preceding). Cleaning the container (liner and/or fiber drum) before final disposal is the responsibility of the person disposing of the container. Offer the liner for recycling if available or dispose of of liner in a sanitary landfill, or by incineration. Do not burn, unless allowed by state and local ordinances. If drum before final disposal, completely empty the fiber drum by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application or manufacturing equipment. Then offer the fiber drum for recycling if available or dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.

All Other Refillable Containers: Refillable container. *Refilling Container*: Refill this container with KN128 Technical containing indoxacarb only. Do not reuse this container for any other purpose. Cleaning before refilling is the responsibility of the refiller. Prior to refilling, inspect carefully for damage such as cracks, punctures, abrasions, worn out threads and closure devices. If damage is found, do not use the container, contact FMC at the number below for instructions. Check for leaks after refilling and before transporting. If leaks are found, do not reuse or transport container, contact FMC at the number below for instructions. *Disposing of Container*: Do not reuse this container for any other purpose other than refilling (see preceding). Cleaning the container before final disposal is the responsibility of the person disposing of the container. To clean the container before final disposal, use the following pressure rinsing procedure. Insert a lance fitted with a suitable tank cleaning nozzle into the container and ensure that the water spray thoroughly covers the top, bottom and all sides inside the container. The nozzle manufacturer generally provides instructions for the appropriate spray pressure, spray duration and/or spray volume. If the manufacturer's instructions are not available, pressure rinsing procedure two more times. Then offer for recycling if available, or reconditioning if appropriate or puncture and dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

Do not transport if this container is damaged or leaking. If the container is damaged, leaking or obsolete, or in the event of a major spill, fire or other emergency, contact CHEMTREC (Transportation and Spills) at 1-800-424-9300, day or night.

CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY

Seller warrants that the product in this container conforms to its chemical description contained hereon and is reasonable fit for its intended purpose when used in accordance with proper manufacturing practices and procedures and under normal conditions of use. To the extent consistent with applicable law, neither this warranty nor any other warranty of **MERCHANTABILITY** or of **FITNESS** for a particular purpose, express or implied, extends to use or handling of this product contrary to proper manufacturing practices and procedures, or under abnormal conditions not reasonably foreseeable to Seller, or to use by mixture, chemical reaction or formulation with other substances not specifically recommended in writing by Seller, and Buyer assumes all risk of any such use. To the extent consistent with applicable law, any damages arising from breach of warranty or negligence shall be limited to direct damages not exceeding the purchase price paid for this product by Buyer, and shall not include incidental or consequential damages such as, but not limited to, loss of profits or values.

Nonrefillable Container

Net: _____

OR

Refillable Container

Net: _____

Made in U.S.A.

TD-4301 071920