



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 28, 2018

Montague Dixon
Senior Regulatory Manager
Syngenta Crop Protection, LLC
PO Box 18300
Greensboro, NC 27419

Subject: PRIA Label Amendment – New uses in or on Tuberous and Corm Vegetables (Crop Group 1C), Legume Vegetable (Crop Group 6), and Low Growing Berry (Except Cranberry) (Crop Group 13-07G)
Product Name: Fomesafen Sodium Salt Aqueous Concentrate 48%
EPA Registration Number: 100-1103
Application Date: 07/24/2015
Decision Number: 507772

Dear Mr. Dixon:

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

1. You must submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.
2. 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:
<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) 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 you fail to satisfy these data requirements, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e). If you have any questions, please contact Lisa Pahel by phone at (703) 347-0459, or via email at pahel.lisa@epa.gov.

Sincerely,

A handwritten signature in cursive script that reads "Rachel C. Holloman".

Rachel Holloman, Branch Chief
Fungicide and Herbicide Branch
Registration Division (7505P)
Office of Pesticide Programs

Enclosure: Human health risk assessments dated 10/24/16 and 08/14/2017, DP429681 and DP429103; Ecological risk assessment dated 06/23/2016, DP429105

Fomesafen Sodium Salt Aqueous Concentrate 48%

A Herbicide for Formulating Use Only

Active Ingredient:

Sodium salt of fomesafen

5-[2-chloro-4-(trifluoromethyl)phenoxy]-N-(methylsulfonyl)-2-nitrobenzamide:..... 50.4%*

Other Ingredients: 49.6%

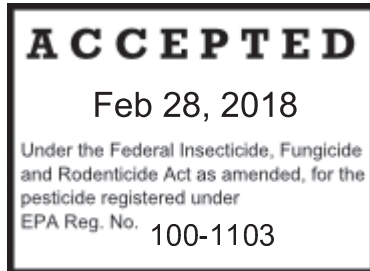
Total: 100.0%

*Contains the equivalent of 48.0% fomesafen active ingredient.

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

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle. (If you do not understand the label, find someone to explain it to you in detail.)

See additional precautionary statements and directions for use on label.



FIRST AID	
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.
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 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 inhaled	<ul style="list-style-type: none"> • Move person to fresh air. • If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible. • Call a poison control center or doctor for treatment advice.
NOTE TO PHYSICIAN	
Probable mucosal damage may contraindicate the use of gastric lavage.	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment.	

HOT LINE NUMBER

For 24-Hour Medical Emergency Assistance (Human or Animal)
or Chemical Emergency Assistance (Spill, Leak, Fire or Accident),
Call
1-800-888-8372

EPA Reg. No. 100-1103

EPA Est.

Net Weight: _____ pounds (_____ kg)

PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

DANGER/PELIGRO

CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN. Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals. Do not get in eyes, on skin or on clothing. Avoid breathing vapors or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco, or using the toilet.

Personal Protective Equipment (PPE)

Manufacturers and other handlers must wear:

- Coveralls
- Waterproof gloves
- Shoes plus socks
- Protective eyewear

User Safety Requirements

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this technical material. Do not reuse them.

User Safety Recommendations

Users 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

Do not apply directly to water, or to areas where surface water is present, or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate. Do not apply when weather conditions favor drift from target area.

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.

DIRECTIONS FOR USE

Only for Formulation Into Herbicides for Use On Approved Crops

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

Formulators using this product are responsible for obtaining EPA registration for their formulated products.

Only for formulation into a herbicide for the following uses:

- *TERRESTRIAL - Food:* Berry, low growing subgroup 13-07G, except cranberry; cantaloupe; cotton; cucumber; peppers; pumpkin; summer squash; tomatoes; vegetable, legume group 6; vegetable, tuberous and corm, subgroup 1C; watermelon; and winter squash.
- Uses for which USEPA has accepted the required data and/or citations of data that the formulator has submitted in support of registration; and
- Uses for experimental purposes that are in compliance with USEPA requirements.

STORAGE AND DISPOSAL

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

Pesticide Storage

Store above 32°F in original containers only. If product freezes, return to room temperature and agitate to reconstitute. Keep container closed when not in use. Do not store near food or feed. In case of spill or leak on floor or paved surfaces, soak up with sand, earth, or synthetic absorbent. Remove to chemical waste area.

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. Open dumping is prohibited.

Container Handling [fiber drums with liners]

Non-refillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into formulation equipment. Then offer for recycling if available or dispose of liner in a sanitary landfill, or by incineration, or by other procedures approved by state and local authorities. If drum is contaminated and cannot be reused, dispose of it in a manner required by its liner.

Do not refill or transport damaged or leaking container.

CONTAINER IS NOT SAFE FOR FOOD, FEED OR DRINKING WATER.

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 buying or 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, presence of other materials or other influencing factors in the use of the product, which are beyond the control of SYNGENTA CROP PROTECTION, LLC or Seller. To the extent consistent with applicable law, Buyer and User agree to hold SYNGENTA and Seller harmless for any claims relating to such factors.

SYNGENTA warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent consistent with applicable law: (1) this warranty does not extend to the use of the product contrary to label instructions, or under conditions not reasonably foreseeable to or beyond the control of Seller or SYNGENTA, and (2) Buyer and User assume the risk of any such use. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, SYNGENTA MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS WARRANTED BY THIS LABEL.**

To the extent consistent with applicable law, in no event shall SYNGENTA be liable for any incidental, consequential or special damages resulting from the use or handling of this product. **TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF SYNGENTA AND SELLER 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 SYNGENTA OR SELLER, THE REPLACEMENT OF THE PRODUCT.**

SYNGENTA and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitation of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of SYNGENTA.

For non-emergency (e.g., current product information), call
Syngenta Crop Protection at 1-800-334-9481.

Manufactured for:
Syngenta Crop Protection, LLC
P.O. Box 18300
Greensboro, North Carolina 27419-8300

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