

10/18/2012

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Ms. Adora Clark  
Regulatory Product Manager  
Syngenta Crop Protection, LLC  
P.O. Box 18300  
Greensboro, NC 27419-8300

OCT 18 2012

Subject: Label Amendment – Removing Tumor Language as Allowed by the Second Cancer Assessment Review Committee (CARC) Report Dated November 3, 2005  
Product Name: Fomesafen Sodium Salt Aqueous Concentrate 48%  
EPA Registration Number: 100-1103  
Submission Date: August 9, 2012  
Decision Number: 468740

Dear Ms. Clark:

The label amendment proposing to remove the text that reads “This product contains fomesafen which has been determined to cause tumors in laboratory animals (mice). Risks can be reduced by closely following use directions and precautions and by wearing the protective clothing specified elsewhere in this label.” submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), is acceptable.

Products shipped after 18 months from the date on this notice or the next printing of the master label whichever occurs first, must bear the new label language. If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA. Your release for shipment of this product constitutes acceptance of these conditions. As required, you must submit one copy of the final printed label before the product is released for shipment. If you have any questions please contact Michael Walsh by phone at (703) 308-2972 or via email at “walsh.michael@epa.gov”

Sincerely,

A handwritten signature in black ink that reads "Kathryn V. Montague".

Kathryn V. Montague  
Product Manager (23)  
Herbicide Branch  
Registration Division (7505P)

Enclosure

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# Fomesafen Sodium Salt Aqueous Concentrate 48%

An Herbicide for Formulating Use Only

ACC

OCT 18 2012

Under the Federal Insecticide, Fungicide, and Rodenticide Act, this product is registered under EPA Reg. No. 100-1103

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.)

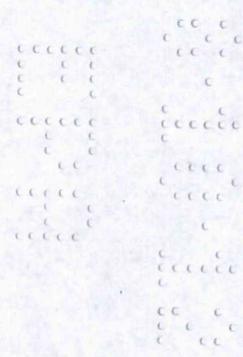
See additional precautionary statements and directions for use on label.

EPA Reg. No. 100-1103

EPA Est.

SCP 1103A

Net Contents: \_\_\_\_\_ pounds ( \_\_\_\_\_ kg )



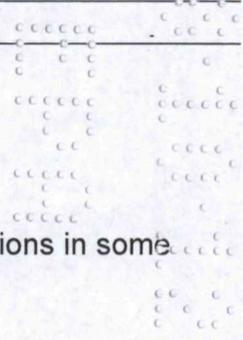
<b>FIRST AID</b>	
<b>If in eyes</b>	<ul style="list-style-type: none"> <li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li> <li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If swallowed</b>	<ul style="list-style-type: none"> <li>• Call a poison control center or doctor immediately for treatment advice.</li> <li>• Have person sip a glass of water if able to swallow.</li> <li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>If on skin or clothing</b>	<ul style="list-style-type: none"> <li>• Take off contaminated clothing.</li> <li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>If inhaled</b>	<ul style="list-style-type: none"> <li>• Move person to fresh air.</li> <li>• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth, if possible.</li> <li>• Call a poison control center or doctor for treatment advice.</li> </ul>
<b>NOTE TO PHYSICIAN</b>	
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.	
<b>HOT LINE NUMBER</b>	
For 24 Hour Medical Emergency Assistance (Human or Animal) or Chemical Emergency Assistance (Spill, Leak, Fire or Accident), Call <b>1-800-888-8372</b>	

**PRECAUTIONARY STATEMENTS**

**Hazards to Humans and Domestic Animals**

**DANGER**

Prolonged or frequently repeated skin contact may cause allergic reactions in some individuals.



**CORROSIVE. CAUSES IRREVERSIBLE EYE DAMAGE. DUE TO CORROSIVE NATURE, MAY BE HARMFUL OR FATAL IF SWALLOWED. HARMFUL IF INHALED OR ABSORBED THROUGH SKIN.** 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

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 wash waters. 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.

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**CONDITIONS OF SALE AND LIMITATION OF WARRANTY AND LIABILITY**

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**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 this 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.

## DIRECTIONS FOR USE

### Only for Formulation Into an Herbicide for Use On Soybeans

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 an herbicide for the following uses:

- *TERRESTRIAL - Food:* cotton, dry beans, peppers, potatoes, snap beans, soybeans and tomatoes.
- 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.

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## STORAGE AND DISPOSAL

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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

Nonrefillable 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, if allowed by state and local authorities by burning. If burned,

stay out of smoke. 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.

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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

SCP 1103A

FOM SOD SALT AQU CON 48% 1103 MAS 0211 AMEND AUG2012-clean - tb - 8-8-12  
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