

00397-1

6/6/2013

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511P)
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

EPA Registration Number: 88347-1

Date of Issuance: JUN 06 2013

NOTICE OF PESTICIDE:

X Registration
Reregistration
(under FIFRA, as amended)

Term of Issuance: Unconditional

Name of Pesticide Product: Phyllom SDS-502 MP

Name and Address of Registrant (include ZIP Code):

Phyllom, LLC
922 San Leandro Avenue, Suite F
Mountain View, CA 94043

Note: Changes in labeling, differing in substance from that accepted in connection with this registration, must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product, always refer to the above EPA Registration Number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA or the Act). Registration is in no way to be construed as an endorsement or recommendation of this product by the U.S. Environmental Protection Agency (EPA). In order to protect health and the environment, the Administrator, on his or her motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This registration does not eliminate the need for continual reassessment of the pesticide. If the EPA determines at any time that additional data are required to maintain in effect an existing registration, it will require submission of such data under section 3(c)(2)(B) of FIFRA.

This product is unconditionally registered in accordance with FIFRA section 3(c)(5) and is subject to the following terms:

- 1. On the final printed labeling, revise the EPA File Symbol to read as follows: "EPA Reg. No.: 88347-1."

Signature of Approving Official:

[Handwritten Signature]

Keith A. Matthews, Director
Biopesticides and Pollution Prevention Division (7511P)

Date:

06 June 2013

EPA Form 8570-6

CONCURRENCES

Table with 4 columns and 3 rows for concurrence tracking. Headers: BOL, NAME, E. Entries include initials and dates like 7511P, KAUSCH, 06/06/2013.

Form 1320-1A (1/90)

Printed on Recycled Paper

OFFICIAL FILE COPY

Phyllom, LLC  
EPA Reg. No. 88347-1

2. Producers of Phyllom SDS-502 MP will conduct the following production quality control measures to detect contamination or changes in the parent strain:
  - a) Spore preparations of *Bacillus thuringiensis* subspecies *galleriae* strain SDS-502 shall be produced by pure culture fermentation procedures with adequate quality control measures during production to detect any changes from the characteristics of the parent strain or contamination by other microorganisms.
  - b) Each lot of spore preparation, prior to the addition of other materials, shall be tested by subcutaneous injection of at least 1 million spores into each of 5 laboratory mice weighing 17 grams to 23 grams. Such test shall show no evidence of infection or injury in the test animals when observed for 7 days following injection.
  - c) Spore preparations shall be free of the *Bacillus thuringiensis*  $\beta$ -exotoxin when tested with the fly larvae toxicity test ("Microbial Control of Insects and Mites," R.P.M. Bond *et al.*, p. 280 ff., 1971). This specification can be satisfied either by determining that each master seed lot brought into production is a *Bacillus thuringiensis* strain that does not produce  $\beta$ -exotoxin under standardized manufacturing conditions or by periodically determining that  $\beta$ -exotoxin synthesized during spore production is eliminated by the subsequent spore-harvesting procedure.
3. Producers of Phyllom SDS-502 MP will maintain records of the production quality control measures described directly above (see #2a-2c) for a period of at least 5 years from the date each batch is released for production.
4. Submit the following data on Phyllom SDS-502 MP by the due dates specified below. These data must be determined by the EPA to be acceptable.

Study Type	Required Data	Due Date <sup>1</sup>
Storage Stability (Guideline No. 830.6317)	Please provide the results of a one-year storage stability study.	June 6, 2014
Corrosion Characteristics (Guideline No. 830.6320)	Please provide the results of a one-year corrosion characteristics study.	June 6, 2014
pH (Guideline No. 830.7000)	Please provide data on pH and the method used to determine this characteristic. For more information on how to conduct a pH test on a solid pesticide product that is water soluble, such as Phyllom SDS-502 MP, please consult the associated guideline on the EPA's website: <a href="http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm">http://www.epa.gov/ocspp/pubs/frs/publications/Test_Guidelines/series830.htm</a> .	December 6, 2013

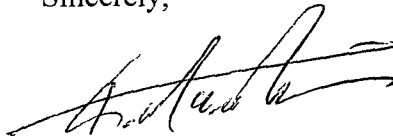
<sup>1</sup> The Office of Pesticide Programs' Document Processing Desk must receive (i.e., pin punch) the required data prior to or on the specified due date.

Phyllom, LLC  
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5. Submit two (2) copies of the final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

The December 18, 2012, April 30, 2013, and May 14, 2013 EPA Memoranda and a stamped, accepted copy of the product label are enclosed for your records.

Sincerely,



Keith A. Matthews, Director  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs

Enclosures (5):

- Phyllom SDS-502 MP Stamped, Accepted Label
- A-79 Enclosure
- December 18, 2012 EPA Memorandum
- April 30, 2013 EPA Memorandum
- May 14, 2013 EPA Memorandum

# Phyllom SDS-502 MP

A Primary Powder (TGAI) For Manufacturing Use Only

**ACTIVE INGREDIENT:**

*Bacillus thuringiensis* subsp. *galleriae*, Strain SDS-502 fermentation solids, spores, and insecticidal toxins\*.....90.0% w/w

**OTHER INGREDIENTS:**.....10.0% w/w

**TOTAL:** .....100.0% w/w

\*Contains a minimum of  $1 \times 10^{10}$  CFU per gram.

**KEEP OUT OF REACH OF CHILDREN  
CAUTION**

See back or side panels for additional precautionary statements and directions for use.

Net Weight: \_\_\_\_\_ Lbs \_\_\_\_\_ Kg

Batch Number: \_\_\_\_\_

EPA Reg. No.: 88347-R

EPA Est. No.: 70051-CA-001 or 69592-MEX-001 or 70127-VA-001

Manufactured for:

Phyllom, LLC

922 San Leandro Avenue, Ste. F

Mountain View, CA 94043

(650) 322-5000

johnlibs@phyllom.com

**ACCEPTED**

JUN 06 2013

Under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, for the pesticide registered under EPA Reg. No. 88347-1

<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 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 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 by a poison control center or doctor.</li> <li>• Do not give anything by mouth to an unconscious person.</li> </ul>
<b>HOT LINE NUMBER</b>	
<p>Have the product container or label with you when calling a poison control center or doctor, or when going for treatment. For emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 seven days a week, 6:30 am to 4:30 pm, Pacific Time (NPIC Web site: <a href="http://www.npic.orst.edu">www.npic.orst.edu</a>). During other times, call your poison control center at 1-800-222-1222.</p>	

<b>PRECAUTIONARY STATEMENTS</b>
<b>HAZARDS TO HUMANS AND DOMESTIC ANIMALS</b>
<b>CAUTION</b>
<p>Causes moderate eye irritation. Harmful if absorbed through the skin or swallowed. 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.</p> <p>When handling this product, wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.</p>
<b>ENVIRONMENTAL HAZARDS</b>
<p>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.</p>

### DIRECTIONS FOR USE

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

Phyllom SDS-502 manufacturing-use pesticide product (MP) is for formulation into microbial pesticide end-use products for use on turf, ornamentals, and crops, and in forestry for general and experimental purposes that are in compliance with the Federal Insecticide, Fungicide, and Rodenticide Act and/or the Federal Food, Drug, and Cosmetic Act. End-use pesticide products formulated with Phyllom SDS-502 MP must be registered with the EPA or under a EUP if used on more than 10 acres. This product may be used to formulate pesticide products for any additional uses not listed on this label if the formulator, user group, or grower has complied with the EPA's data submission requirements regarding the support of such use(s).

<b>STORAGE AND DISPOSAL</b>	
Do not contaminate water, food or feed by storage or disposal.	
<b>PESTICIDE STORAGE:</b>	Re-close containers of Phyllom SDS-502 MP. Store product sealed, in a cool, dry place, and out of direct sunlight. In the case of leak or spill, wear chemical-resistant gloves and clean up leak or spill with a paper towel or other appropriate leak/spill equipment. Dispose of paper towel and any other waste as indicated in the Pesticide Disposal section directly below.
<b>PESTICIDE DISPOSAL:</b>	Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.
<b>CONTAINER HANDLING:</b>	<p><i>For 100-lb fiberboard drums with a polyethylene liner:</i> Nonrefillable container. Do not reuse or refill this container. Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residues into manufacturing equipment. Then, offer for recycling if available, dispose of empty 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 the manner required for its liner.</p> <p><i>For 50-lb polyethylene-lined paper bags:</i> Nonrefillable container. Do not reuse or refill this container. Completely empty bag into manufacturing equipment. Then, offer for recycling if available, dispose of empty bag in a sanitary landfill or by incineration or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.</p>

<b>WARRANTY AND LIMITATION OF DAMAGES</b>
Read all directions carefully. All statements concerning the use of this product apply only when used as directed. Phyllom, LLC warrants that this material conforms to the specifications on this label and is reasonably fit for the intended purpose on this label. To the extent consistent with applicable law, Phyllom, LLC makes no other express or implied warranty of merchantability for a particular purpose or any other express or implied warranty.