

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

MAR 15 1996

Karen Warkentien
 Manager, Regulatory Affairs
 Grace Biopesticides
 W.R. Grace & Co.
 7500 Grace Drive
 Columbia, MD 21044

Dear Ms. Warkentien:

Subject: Revised labeling
 Neemguard
 EPA Reg. No. 11688-9
 Your submission dated February 20, 1996

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable, subject to the comments listed below:

At the time of next label printing or within the next nine months, whichever occurs first, you must make the following label changes:

1. The label must mention intended use/sites on the front panel. Please specify landscape use in terms of what areas (around buildings, ornamental gardens, parks etc.) where this product is intended to be used, in addition to nursery and greenhouse use. Also, broadly specify target pests.
2. The label must mention pounds of active ingredient per gallon of product on the front panel, beneath the ingredient statement.
3. There must be a Statement of Practical Treatment on front panel, beneath signal word "Caution" for toxicity category III exposure routes.
4. Add the following as first sentence to the Environmental Hazard statement: "This product may be hazardous to fish and aquatic invertebrates."

CONCURRENCES

SYMBOL	7511W	7501W					
SURNAME	K. Warkentien	S. S. S.					
DATE	3/11/96	3/14/96					

5. In order to provide continuity for the text for fungicide use directions, the Agricultural Use Requirements box should be moved to previous page, above the Fungicide Use header.

6. Part of the "General Information" list of bullets is repetitive. Eliminate repetitive statements and list remaining statements as follows:

Do not use on food crops

Not for use in food handling areas

Shake well before using

For best results, maintain constant agitation in spray equipment

Sonification equipment is not recommended because it may cause the emulsion to separate

For optimal performance, do not mix with cold water

Broad spectrum Insecticide/Fungicide/Miticide

Kills larval stages of insects

For indoor/outdoor use

7. Please note that we are currently evaluating the use of terms such as "Botanical" and "organic" on product labels, and depending upon the outcome of our evaluation, you may be asked to remove the term "botanical" from this label.

8. We have noted that you have homeowner use directions on this commercial use label. We would prefer that you have a separate registration for homeowner use of this product. Until that is done, you need to have a separate "Non-agricultural Use Requirements" box with the following language:

Non-Agricultural Use Requirements

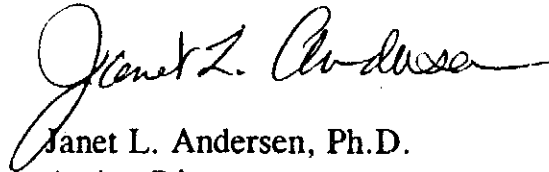
The requirements in this box apply to uses of this product that are not within the scope of the Worker Protection Standard for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep unprotected persons out of treated areas until sprays have dried.

This box may appear underneath the Agricultural Use Requirements box.

A stamped copy of the label is enclosed for your records. Questions regarding this letter may be directed to Rita Kumar at (703) 308-8291.

Sincerely yours,

A handwritten signature in cursive script that reads "Janet L. Andersen". The signature is written in black ink and is positioned above the typed name.

Janet L. Andersen, Ph.D.
Acting Director
Biopesticide and Pollution
Prevention Division (7501W)

NEEMGUARD™

Botanical Insecticide/Fungicide

ACTIVE INGREDIENT:		
Clarified Hydrophobic Extract of Neem Oil		90%
INERT INGREDIENTS:		<u>10%</u>
	TOTAL	100%

KEEP OUT OF REACH OF CHILDREN

CAUTION

MANUFACTURED BY:

W.R. GRACE & CO.—CONN.
7379 Route 32
Columbia, MD 21044

EPA Reg. No. 11685-9

EPA Est. No. _____

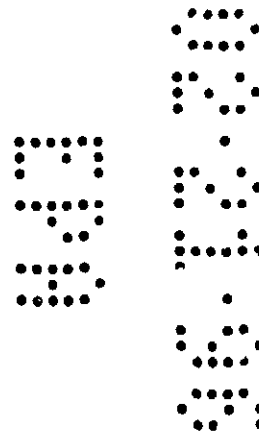
Net Contents: _____ gal

See Back Panel for Additional Precautionary Statements

**ACCEPTED
with COMMENTS
in EPA Letter Dated**

MAR 15 1968

Under the Federal Insecticide,
Fungicide, and Rodenticide Act
as amended, for the pesticide
registered under EPA Reg. No.
11685-9



PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND
DOMESTIC ANIMALS

CAUTION:

Harmful if absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Wash thoroughly with soap and water after handling.

Personal Protective Equipment:

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical-resistant category selection chart.

Applicators and other handlers must wear:

- Long-sleeved shirt and long pants.
- Chemical-resistant gloves, such as barrier laminate or butyl rubber or nitrile rubber or neoprene rubber or polyvinylchloride (PVC) or Viton.
- Shoes plus socks.

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

User Safety Recommendations:

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
- Remove clothing 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 by cleaning of equipment or disposal of equipment washwaters.

BEE HAZARD

This product is toxic to bees exposed to direct treatment. Do not apply this product while bees are actively visiting the treatment area.

PHYSICAL & CHEMICAL HAZARDS

Do not use or store near heat or open flame.

STORAGE & DISPOSAL

STORAGE: Keep in original container. Store in a cool, dry place away from direct sunlight, feed, or foodstuffs. Keep container tightly sealed when not in use. Do not store below 55°F (10°C) or above 95°F (35°C).

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: Triple rinse. Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

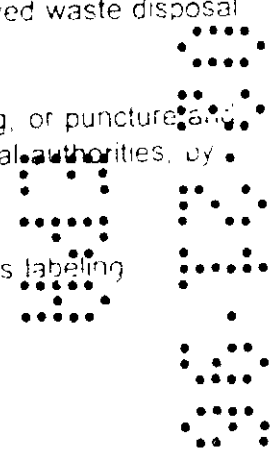
DIRECTIONS FOR USE

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

Do not apply this product through any type of irrigation system.

General Information

Do not use on food crops.



Not for use in food handling areas.

Shake well before using.

For best results, maintain constant agitation in spray equipment.

Sonification equipment is not recommended because it may cause the emulsion to separate.

For optimal performance, do not mix with cold water (less than 55°F).

For effective control of black spot on roses.

Broad spectrum disease control.

Disease preventative.

Effective botanical disease control.

Prevents and controls black spot on roses, anthracnose, rust, and powdery mildew.

All-Purpose Insecticide/Fungicide/Miticide

Multi-Purpose Insecticide/Fungicide/Miticide

Broad Spectrum Insecticide/Fungicide/Miticide

Broad Spectrum Organic/Botanical Insecticide/ Fungicide/Miticide

Kills Insects and their Eggs

For Indoor/Outdoor Use

Kills larval stages of insects

Organic Active Ingredient

Organic Insecticide/Fungicide/Miticide

Organic Insect Control

Formulated for Interiorscape Use

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the agency responsible for pesticide regulation.

FUNGICIDE USE

[Consumer Use Directions]

APPLICATION INSTRUCTIONS:

NeemGuard™ is an effective fungicide for the prevention and control of various fungal diseases, including black spot on roses, powdery mildew, downey mildew, anthracnose, rust, leaf spot, Botrytis, needle rust, scab, and flower, twig, and tip blight.



As a preventative, NeemGuard™ should be applied on a 7 to 14 day schedule until the potential for disease development is no longer present

To control disease already present, apply NeemGuard™ on a 7 day schedule until disease pressure is eliminated. Then continue spraying on a 14-day schedule to prevent the disease from reoccurring

To prevent rust, leaf spot diseases, anthracnose, and scab, begin applications at the first sign of spring budding

To prevent powdery mildew, apply in mid-summer or when disease is first detected. Applications should continue until disease pressure no longer exists.

BLACK SPOT ON ROSES

Applications should begin at first bud emergence in spring. Apply NeemGuard™ on a 14-day preventative schedule through the spring and fall to prevent disease emergence.

MIXING INSTRUCTIONS

Mix NeemGuard™ at the rate of 2 tablespoons (1 oz.) per gallon of water. Thoroughly mix solution and spray all plant leaf surfaces (including undersides of leaves) until completely wet. Frequently mix solution as you spray.

AGRICULTURAL USE REQUIREMENTS

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE), and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

PPE required for early entry to treated areas that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil, or water is:

- Coveralls.
- Chemical-resistant gloves, such as barrier laminate or butyl rubber or nitrile rubber or neoprene rubber or polyvinylchloride (PVC) or Viton.
- Shoes plus socks.

[Commercial Use Instructions]

TANK MIXING:

NeemGuard™ Botanical Insecticide/Fungicide has been found to be compatible with many commonly used fungicides, insecticides, and fertilizers. Physical compatibility should first be checked by using the correct proportion of products in a small jar test. Growers should then test tank-mix combinations for phytotoxicity on a sample of plants prior to use. This is also recommended with combinations used before as environmental conditions can alter the interaction between compounds. *Due to the wide variation in climatic conditions, cultural practices, and other factors, the user assumes full*

BEST AVAILABLE COPY

responsibility for any crop damage or other liability resulting from the use of NeemGuard™ Botanical Insecticide/Fungicide in a tank mix combination.

ORNAMENTAL DISEASE CONTROL:

Landscape, Greenhouse, Nursery Ornamentals:

NeemGuard™ will provide a broad spectrum control of many fungal diseases affecting ornamental flowering plants, trees, shrubs, and foliage when used as a foliar spray. NeemGuard™ should be used at the rate of 1 gallon per 100-200 gallons of water, depending on the level of disease pressure. The lower rate (1:200) can be used when spraying as a preventative in a greenhouse while the higher rate (1:100) is needed for outdoor applications. Determine the best rate for your particular situation.

Greenhouse:

When NeemGuard™ is used as a preventative, the lower rate (1:200) will provide adequate control for most greenhouse situations. If disease pressure is evident, the higher rate (1:100) is recommended. Applications for disease prevention should be made on a 7-14 day schedule depending on the anticipated severity of the disease pressure. To control existing disease, NeemGuard™ should be applied on a 7-day schedule until the disease pressure is eliminated. A 14-day schedule should then be used to prevent disease pressure from returning. NOTE: Greenhouse roses should only be sprayed in a rotation program which includes NeemGuard™ once every 4 weeks.

Landscape Ornamentals:

In outdoor landscape applications, it is best to apply NeemGuard™ at the 1:100 rate. This will provide the necessary control under the extreme outdoor conditions. When using NeemGuard™ as a preventative, applications should be made on a 14-day schedule. If disease is present, a 7-day application schedule should be used to control the disease and prevent further damage from occurring.

MIXING INSTRUCTIONS:

Add NeemGuard™ to one-half (1/2) full tank under agitation containing water of 55°F or greater before filling to desired level. If water temperature is below 55°F, premix NeemGuard™ at a 1:10 ratio with tepid water to ensure good emulsification. Then dilute to final volume. Maintain agitation during spray application. Do not use if this oil does not emulsify.

APPLICATION INSTRUCTIONS:

Apply to runoff at 25-40 psi with hand sprayer or 100-200 psi with power sprayer as a fine spray to both leaf surfaces. Excessive application is unnecessary and should be avoided.

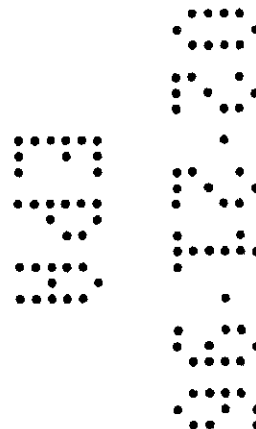
Do not add any adjuvants (spreaders, stickers, extenders, etc.) to NeemGuard™.

Do not apply to wilted or otherwise stressed plants, or to newly transplanted materials prior to root establishment.

Do not apply to known sensitive plant species without prior testing.

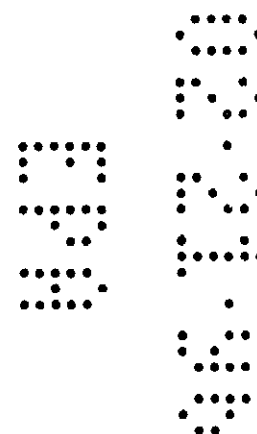
Known Sensitive Plants

Do not apply to impatiens flowers.



MANAGEMENT OF LANDSCAPE AND ORNAMENTAL DISEASES			
SPRAY TARGET	CONCENTRATION	SPRAY INTERVAL	PRECAUTIONS
Potted Plants (Greenhouses)	1:100 - 1:200 (1.0% - 0.5%)	14 Days	Trial first on open blooms
Flowering Bench Crops (Greenhouse)	1:100 - 1:200 (1.0% - 0.5%)	7-14 Days	Trial first on open blooms—not suggested for cut roses
Outdoor Flowering Plants	1:100 - 1:200 (1.0% - 0.5%)	7-14 Days	Do not spray impatiens flowers
Outdoor Woody Plants	1:50 - 1:100 (2.0% - 1.0%)	14 Days	

MANAGEMENT OF TURF DISEASES			
SPRAY TARGET	CONCENTRATION	SPRAY INTERVAL	PRECAUTIONS
Snow Mold	1:100-1:50 (1%-2%)	14 Days	In fall before first snow
Dollar Spot	1:100-1:200 (1%-0.5%)	14 Days	At first sign of disease
Brown Patch	1:100-1:200 (1%-0.5%)	14 Days	At first sign of disease



INSECTICIDE USE

[Commercial Use Instructions]

For use to control whiteflies, thrips, mealybugs, leafminers, loopers, caterpillars, beet armyworms, aphids, psyllids, webworms, hornworms, spruce budworms, pine sawflies, gypsy moths, crane flies, leafhoppers, fruit flies, elm leaf beetles, bagworms, tent caterpillars, mites, scales, Japanese beetles, midges, and grasshoppers on ornamentals, trees, and shrubs in and around greenhouses, commercial nurseries, and other commercial and residential structures.

NeemGuard™ should be used at the rate of 1-2 gallons per 100 gallons of water. The low rate (1%) can be used when pest pressure is low. The high rate (2%) should be used for high pest infestations or to control more troublesome pests, such as mites and scales. Determine the best rate for your particular situation.

Sprays should be made on a 7-14 day interval depending on the severity of the pest problem. The 7-day schedule should be used until the pest population is reduced. A 14-day interval should then be used for control.

Sprays should be made in early to mid-morning or late afternoon. This is important to ensure that the spray thoroughly wets the pests to be controlled, which are often sedentary on the foliage at these times, and also minimizes plant stress.

MIXING INSTRUCTIONS:

Add NeemGuard™ to one-half (1/2) full tank under agitation containing water of 55°F or greater before filling to desired level. If water temperature is below 55°F, premix NeemGuard™ at a 1:10 ratio with tepid water to ensure good emulsification. Then dilute to final volume. Maintain agitation during spray application. Do not use if this oil does not emulsify.

APPLICATION INSTRUCTIONS:

Apply to runoff at 25-40 psi with hand sprayer or 100-200 psi with power sprayer as a fine spray to both leaf surfaces. Thorough coverage of plant pests is necessary to ensure efficacy. However, excessive application is unnecessary and should be avoided.

[Consumer/Homeowner Use]

MIXING INSTRUCTIONS:

Mix NeemGuard™ at the rate of 2 tablespoons (1 oz.) per gallon of water. Thoroughly mix solution and spray all plant surfaces (including undersides of leaves) until completely wet. Frequently mix solution as you spray.

APPLICATION INSTRUCTIONS:

Apply NeemGuard™ at first sign of insects/mites. NeemGuard™ is most effective in controlling insects/mites when applied on a 7-14 day schedule. For heavy insect populations, apply on a 7-day schedule.

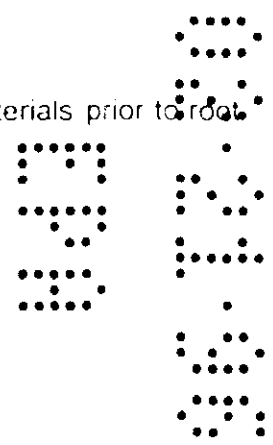
Do not add any adjuvants (spreaders, stickers, extenders, etc.) to NeemGuard™

Do not apply to wilted or otherwise stressed plants, or to newly transplanted materials prior to root establishment.

Do not apply to known sensitive plant species without prior testing.

Known Sensitive Plants

Do not apply toimpatiens flowers



Warranty

W.R. Grace & Co.—Conn. warrants that the material contained herein conforms to the description on the label and is reasonably fit for the purposes referred to in the directions for use. Timing and method of application, weather, watering practices, nature of soil, the insect problem, condition of the crop, incompatibility with other chemicals not specifically recommended, and other influencing factors in the use of this product are beyond the control of the seller. Buyer assumes all risks of use, storage or handling of this material not in strict accordance with directions given herein. NO OTHER EXPRESS OR IMPLIED WARRANTY OF THE FITNESS OR MERCHANTABILITY IS MADE.

