

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

JUN 3 0 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

Ms. Rhonda M. Mannion Monsanto Company 600 13th Street, N. W. Suite 660 Washington, DC 20005

Dear Ms. Mannion:

Subject: MON 44951 Herbicide (Add Native Grass Sites and Revise Master Label)

EPA Registration No. 524-534 Application Dated April 16, 2003

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act as amended is acceptable, provided you make the following changes before you release the product for shipment.

- 1. Revise the last sentence of the second paragraph of your Environmental Hazards section to read "Do not contaminate water when **cleaning of equipment or** disposing of equipment washwaters.
- 2. Delete the phrase "to prevent transfer of this product onto desirable vegetation" from the last sentence of the Non-Agricultural Use Requirements box.

Submit three (3) copies of final printed labeling incorporating the above changes before you release the product for shipment. Amended labeling will supercede all previously accepted ones. A stamped copy of labeling is enclosed for your records.

Sincerely,

Junes A. Tompkins
Product Manager 25
Herbicide Branch
Registration Division (7505C)

MASTER LABEL FOR EPA REG. NO. 524-534

REGISTERED BRAND NAMES: Battalion® Turf Herbicide

MON 44951

ACCUPTED
with COMMENTS
In EPA Letter Dated:
JUN 3 0 2003

Under the Pederal Incomission, Fungicide, and Redunicide Arts, as amended, for the practicide registered under RPA Reg. No. 524-534

[INSERT BRAND NAME] herbicide is a selective herbicide for control of annual and perennial grass and broadleaf weeds in highly managed turf sites.

Complete Directions For Use

EPA Reg. No. 524-534

[year code]

Read the entire label before using this product.

Use only according to label instructions.

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

Not all products recommended on this label are registered for use in California. Check the registration status of each product in California before using.

Read the "LIMIT OF WARRANTY AND LIABILITY" before buying or using. If terms are not acceptable, return at once unopened.

THIS IS AN END-USE PRODUCT. MONSANTO DOES NOT INTEND AND HAS NOT REGISTERED IT FOR REFORMULATION. SEE INDIVIDUAL CONTAINER LABEL FOR REPACKAGING LIMITATIONS.

CONTENTS

1	1.0	ING	RED	IEN	ITS
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2 2.0 IMPORTANT PHONE NUMBERS

- 3 3.0 PRECAUTIONARY STATEMENTS
 - 3.1 Hazards to Humans and Domestic Animals
 - 3.2 Environmental Hazards
- 4 4.0 STORAGE AND DISPOSAL
- 5 5.0 GENERAL INFORMATION
- 6 6.0 MIXING
 - 6.1 Mixing with Water
 - 6.2 Tank Mixing Procedure
 - 6.3 Surfactants and Adjuvants
 - 6.4 Colorants and Dyes

7 7.0 APPLICATION EQUIPMENT AND TECHNIQUES

- 7.1 Ground Broadcast Equipment
- 7.2 Hand-Held or High-Volume Equipment
- 7.3 Equipment Cleaning

8 8.0 SITE AND USE RECOMMENDATIONS

- 8.1 Warm-Season Turfgrasses
 - a. Control of Sedges and Tall Fescue
 - b. Bermudagrass (Non-Overseeded Actively Growing, Dormant or at Green-Up)
 - c. Bermudagrass (Actively Growing, Prior to Overseeding to Perennial ryegrass)
 - d. Dormant Bermudagrass (Overseeded to Perennial Ryegrass)
 - e. Bermudagrass (For Removal of Overseeded Perennial Ryegrass Dormant or Actively Growing)
- 8.2 Cool-Season Turfgrasses
 - a. Poa trivialis Control in Established Creeping Bentgrass Fairways and Tees
- 8.3 Native Grasses
- 9 9.0 WEEDS CONTROLLED
- 10.0 LIMIT OF WARRANTY AND LIABILITY

1.0 INGREDIENTS

ACTIVE INGREDIENT:	
Sulfosulfuron,	75.0%
OTHER INGREDIENTS:	25.0%
	100.0%

This product is protected by U.S. Patent Nos. 5,017,212 and 5,534,482. No license granted under any non U.S. Patent(s).

2.0 IMPORTANT PHONE NUMBERS

1. FOR PRODUCT INFORMATION OR ASSISTANCE IN USING THIS PRODUCT, CALL TOLL- FREE,

1-800-332-3111.

2. IN CASE OF AN EMERGENCY INVOLVING THIS PRODUCT, OR FOR MEDICAL ASSISTANCE, CALL COLLECT, DAY OR NIGHT,

(314) 694-4000

3.0 PRECAUTIONARY STATEMENTS

3.1 Hazards to Humans and Domestic Animals

Keep out of reach of children.

CAUTION!

CAUSES MODERATE EYE IRRITATION.

Avoid contact with eyes or clothing. Wash thoroughly with soap and water after handling

FIRST AID			
 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. Call a poison control center or physician for treatment advice. 			

- center or physician, or going for treatment.
- In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.
- This product is identified as [INSERT BRAND NAME], EPA Reg. No. 524-534.

Personal Protective Equipment (PPE)

Applicators and other handlers must wear: long-sleeved shirt and long pants and 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.

When handlers use closed systems or enclosed cabs in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.240 (d) (4-6)], the handler PPE requirements may be reduced or modified as specified in the WPS.

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.

3.2 Environmental Hazards

This chemical demonstrates the properties and characteristics associated with chemicals detected in ground water. The use of this chemical in areas where soils are permeable, particularly where the water table is shallow, may result in ground water contamination.

This pesticide is highly toxic to non-target plants. Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Drift and runoff may be hazardous to plants in neighboring areas. Do not contaminate water when disposing of equipment washwaters or rinsate.

The use of any pesticide in a manner that may kill or otherwise harm an endangered species or adversely modify their habitat is a violation of Federal Laws.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling. This product can only be used in accordance with the Directions For Use on this label or in separately published Monsanto Supplemental Labeling.

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.

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 12 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:

- Coveralis
- Shoes plus socks
- Chemical-resistant gloves, such as nitrile rubber, neoprene rubber or polyethylene. For more options, follow the instructions for Category A (dry and water-based formulations) on an EPA chemical resistant category selection chart.

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 (40 CFR Part 170) for agricultural pesticides. The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries or greenhouses.

Keep people and pets off treated areas until spray solution has dried to prevent transfer of this product onto desirable vegetation.

4.0 Storage and Disposal

Do not contaminate water, foodstuffs, feed or seed by storage or disposal.

Storage: Store under cool, dry conditions (below 120°F). Do not store under moist conditions.

DISPOSAL: Wastes resulting from the use of this product that cannot be used or chemically reprocessed should be disposed of in a landfill approved for pesticide disposal or in accordance with applicable Federal, state or local procedures.

See individual container label for DISPOSAL information.

[Disposal Information for Plastic Bottle Packaging]

Do not reuse container. Triple rinse container, then 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.

[Disposal Information for Foil Pouch Packaging]

Emptied foil pouch retains vapor and product residue. Observe all labeled safeguards until foil pouch is destroyed. Do not reuse foil pouch. Completely empty foil pouch into application equipment. Then dispose of empty foil pouch in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

5.0 GENERAL INFORMATION

Product Description: This product is a preemergence and postemergence systemic herbicide. It controls many annual and perennial sedges, grass and broadleaf weeds on sod farms, highly managed turf and native grasses sites. It is a selective herbicide and can be used over-the-top of many warm-season perennial turf grasses, including: bermudagrass, St. Augustinegrass, zoysiagrass, centipedegrass and kikuyugrass. [INSERT BRAND NAME] can be used in creeping bentgrass turf to control *Poa trivialis*. Refer to the appropriate sections of this label for approved turf species. It can also be used to control johnsongrass in the following native grasses: big bluestem, bushy bluestem, little bluestem, buffalograss, indiangrass, blue oats grama, side oats grama, lovegrass and switchgrass. It is formulated as a water dispersible granule (WDG).

Time to Symptoms: [INSERT BRAND NAME] is absorbed by both the roots and the foliage of plants, rapidly inhibiting the growth of susceptible weeds. By 2 to 3 weeks after application to weeds, leaf growth slows and the growing points turn reddish-purple. Within 4 to 6 weeks of application, leaf veins and leaves become discolored, and the growing points subsequently die. Warm and moist conditions following application will accelerate herbicidal activity. Cold, dry conditions will delay herbicidal activity. Weeds stressed by drought are less susceptible to [INSERT BRAND NAME].

Rainfastness: Heavy rainfall soon after application (less than 2 hours) may wash this product off of the foliage and a repeat application may be required for adequate control.

Annual Maximum Use Rate: The combined total of all treatments must not exceed 2.66 ounces of this product per acre per year.

IMPORTANT: Do not allow this product to contact roots or foliage of desirable vegetation, areas where roots of desirable vegetation may extend, or areas where

this product may be washed or moved into contact with roots of desirable vegetation.

Desirable plants may be injured if planted into treated areas.

Do not use on feed or food crops.

ATTENTION

AVOID DRIFT. Care must be used when applying this product to prevent injury to desirable plants and crops. Do not allow the herbicide solution to mist, drift, or splash onto desirable vegetation or soil areas where sensitive crops will be planted since minute quantities of this product can cause severe damage or destruction to plants on which treatment was not intended. The likelihood of injury occurring from the use of this product increases when winds are gusty, as wind velocity increases, when wind direction is constantly changing or when there are other meteorological conditions that favor spray drift. When spraying, avoid combinations of pressure and nozzle type that will result in splatter or fine particles (mist) which are likely to drift. AVOID APPLYING AT EXCESSIVE SPEED OR PRESSURE. Drift control agent additives should be used for ground broadcast applications. When a drift control additive is used, read and carefully observe the precautionary statements and all other information appearing on the additive label.

6.0 MIXING

Thoroughly clean equipment prior to mixing spray solution.

6.1 Mixing with Water

This product mixes readily with water. Mix spray solutions of this product as follows: Fill the spray tank to about three-fourths of the desired volume. Add the recommended amount of this product. Complete the filling process while maintaining agitation. Use caution to avoid siphoning back into the carrier source. Use approved anti-back-siphoning devices where required by state or local regulations. Add nonionic surfactant near the end of the filling process where required.

6.2 Tank Mixing Procedure

For tank mixtures, add individual formulations to the spray tank in the following sequence: water, water soluble bags, dry flowables, emulsifiable concentrates, drift control additive, water soluble liquids followed by a nonionic surfactant.

6.3 Surfactants and Adjuvants

Use a nonionic surfactant at 0.25 to 0.5 percent by volume (1 to 2 quarts per 100 gallons of spray solution) where specified in SITE AND USE RECOMMENDATIONS. Use only nonionic surfactants which contain at least 90 percent active ingredient. Use a methylated seed oil at 1.0 percent by volume where specified in SITE AND USE RECOMMENDTIONS.

Do not use nonionic surfactants or other additives that alter the pH of the spray solution below pH 5.

6.4 Colorants and Dyes

Agriculturally-approved colorants or marking dyes may be added to this product. Colorants or dyes used in spray solutions of this product may reduce performance, especially at higher rates or dilution. Use colorants or dyes according to the manufacturer's recommendations.

7.0 APPLICATION EQUIPMENT AND TECHNIQUES

SPRAY DRIFT MANAGEMENT

AVOID DRIFT. CARE MUST BE USED WHEN APPLYING THIS PRODUCT TO PREVENT INJURY TO DESIRABLE PLANTS AND CROPS.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determine the potential for spray drift. The applicator is responsible for considering all these factors when making decisions.

Do not apply product through any type of irrigation system.

Apply these spray solutions in properly maintained and calibrated equipment capable of delivering desired volumes.

Do not allow the herbicide solution to mist, drift, or splash onto desirable vegetation or soil areas where sensitive crops will be planted since minute quantities of this product can cause severe damage or destruction to plants on which treatment was not intended.

7.1 Ground Broadcast Equipment

Apply [INSERT BRAND NAME] uniformly with properly calibrated ground equipment in 10 to 50 gallons of water per acre. Select spray volumes that ensure thorough and uniform weed coverage. Use equipment which is capable of continuous agitation. Choose nozzles which provide optimum spray distribution and uniform coverage at the appropriate spray pressure. Avoid streaking, skips, overlaps and spray drift during applications.

7.2 Hand-Held and High-Volume Equipment

Hand-held spray guns, backpacks, or other similar sprayers may be used to apply this product. Apply to foliage of vegetation to be controlled. For applications made on a spray-

MON 44951 Master Label Approved 13 Dec 2001, Amendment Submitted 04/15/2003 to-wet basis, spray coverage should be uniform and complete. Do not spray to the point of runoff. Use coarse sprays only.

7.3 Equipment Cleaning

Thoroughly clean application equipment immediately after using this product. Prepare a tank cleaning solution which consists of a 1 percent solution of ammonia (1 quart of ammonia for every 25 gallons of rinse water). Use sufficient cleaning solution to thoroughly rinse all surfaces and to flush all hoses. Repeat the procedure with the ammonia solution. Complete the cleaning process by rinsing with clean water.

If visible residue is present in the spray tank, a solution consisting of 1 percent ammonia plus 0.25 percent nonionic surfactant (0.25 quart per 25 gallons of water) is recommended for adequate cleansing.

8.0 SITE AND USE RECOMMENDATIONS

[INSERT BRAND NAME] may be used for general weed control on sod farms and in highly managed turf sites and ornamental native grasses. [INSERT BRAND NAME] may be applied to commercial and residential turf and other non-crop sites including: cemeteries, golf course fairways, golf course roughs, golf course tees, or other areas of a golf course (excluding greens), sod or turf seed farms, and other similar sites. **Do not apply to golf course greens or within 4 feet of these sites.**

8.1 Warm-Season Turf Grasses

8.1.a Control of Sedges and Tall Fescue

Ground Broadcast Application. For the selective control of sedges (including purple nutsedge, yellow nutsedge, *Kyllinga* spp., annual sedges) and tall fescue in common or hybrid bermudagrass, zoysiagrass, centipedegrass, St. Augustinegrass or kikuyugrass turf, apply [INSERT BRAND NAME] at 1.33 oz. per acre. A sequential application of 1.33 ounces per acre may be made 21 to 28 days after initial treatment if needed. Some chlorosis or stunting of the desirable turf may occur following application. Use of a nonionic surfactant is required.

Hand-Held and High-Volume Equipment Application. Add 0.1 ounces of [INSERT BRAND NAME] per 10 gallons of water. Add 6 ounces of a nonionic surfactant per 10 gallons of spray solution.

8.1.b BERMUDAGRASS (NON-OVERSEEDED - ACTIVELY GROWING, DORMANT or at GREEN-UP)

[INSERT BRAND NAME] may be used for control of *Poa annua* or to control or partially control other annual and perennial weeds in highly managed bermudagrass sites.

Ground Broadcast Application

Apply [INSERT BRAND NAME] at 0.67 to 1.33 ounces per acre..

Use the higher recommended rates of this product for control of large established weeds or when weed growth is heavy or dense. Best results are obtained when weeds are in the early stage of growth and are not disturbed by mowing. Use of a nonionic surfactant is required.

Fall applications for Poa annua control can begin as early as September 1. Time first application to just before *Poa annua* germination. Reapply [INSERT BRAND NAME] when Poa annua reappears but no more frequently than every 21 days.

Tank Mixtures.

FOR USE IN DORMANT BERMUDAGRASS ONLY. Tank mixtures of this product with Roundup Pro herbicide may be used to increase the spectrum of vegetation controlled. When tank mixing, read and carefully observe the label directions, precautionary statements and all information on the label of Roundup Pro herbicide. Any recommended rate of this product may be tank mixed with 8 fluid ounces of Roundup Pro herbicide. Refer to the Roundup Pro product label for approved application sites. Always apply tank mixtures according to the most restrictive label of the products used.

8.1.c BERMUDAGRASS (ACTIVELY GROWING, PRIOR to OVERSEEDING to PERENNIAL RYEGRASS)

[INSERT BRAND NAME] may be used for control of *Poa annua* or to control or partially control other annual and perennial weeds in highly managed bermudagrass sites prior to overseeding of perennial ryegrass.

Ground Broadcast Application

Apply [INSERT BRAND NAME] at 1.33 to 2.0 ounces per acre. Use the higher recommended rates of this product if there is potential that *Poa annua* has already germinated.

Fall applications for *Poa annua* control should be made 7 to 10 days prior to overseeding.

8.1.d DORMANT BERMUDAGRASS (OVERSEEDED TO PERENNIAL RYEGRASS)

[INSERT BRAND NAME] may be used for control of *Poa annua* or to control or partially control other annual and perennial weeds in dormant, highly managed bermudagrass sites overseeded to perennial ryegrass.

Ground Broadcast Application

Apply [INSERT BRAND NAME] 0.125 to 0.25 ounces per acre.. In the southeastern U.S., do not apply this product prior to February 15 to perennial ryegrass seeded the previous fall. In the southwestern U.S., wait at least 120 days after overseeding to perennial ryegrass before applying this product.

OPTIONAL STATEMENT: Do not use this product in the southwestern U.S.

Best results are obtained when weeds are in the early stage of growth and are not disturbed by mowing.

Repeat applications should be made at a 21 day or longer intervals for improved safety to weed control and safety to ryegrass. Some chlorosis or stunting of the desirable turf may occur following application. Use of a nonionic surfactant or methylated seed oil is required.

8.1.e BERMUDAGRASS (FOR REMOVAL OF OVERSEEDED PERENNIAL RYEGRASS - DORMANT or ACTIVELY GROWING)

[INSERT BRAND NAME] may be used to remove overseeded perennial ryegrass or to control or partially control other annual and perennial weeds in dormant, highly managed bermudagrass sites at or around the time of bermudagrass greenup or when bermudagrass is actively growing.

Ground Broadcast Application

Apply [INSERT BRAND NAME] at 1.33 ounces per acre. A sequential application of 1.33 ounces per acre may be made 14 to 21 days after initial treatment. Best results are obtained when weeds are not disturbed by mowing. Use of a nonionic surfactant is required.

Spring applications for perennial ryegrass control should begin up to 4 weeks before perennial ryegrass removal is desired.

8.2 Cool-Season Turfgrasses

8.2.a Poa trivialis Control in Established Creeping Bentgrass Fairways and Tees

Ground Broadcast Application. For suppression or control of <u>Poa trivialis</u> in established creeping bentgrass turf on golf course fairways and tees, apply 0.25 to 0.50 ounces per acre of this product. Make applications after creeping bentgrass and <u>Poa trivialis</u> have resumed growth in the spring, are actively growing and after at least one mowing. Two to four sequential applications of 0.25 ounces per acre of this product at 14 to 21 day intervals are needed for control. <u>Poa trivialis</u> is more easily controlled in the spring. Discontinue applications in the fall when night time air temperatures reach 40° F and lower. Some chlorosis or stunting of the desirable turf may occur following application. When severe <u>Poa</u>

<u>trivialis</u> infestations are controlled, open turf spaces may occur. If this or turf discoloration occurs, skip or delay sequential applications to allow turf to close or recover to a desirable quality. Observe maximum annual dosage limits. Use of a nonionic surfactant or methylated seed oil is required.

These applications will also provide suppression or control of seedling annual bluegrass (*Poa annua*) before the tiller stage.

8.3 Native Grasses

[iNSERT BRAND NAME] may be used postemergence to control johnsongrass, yellow nutsedge, purple nutsedge, tall fescue and other weeds listed in the "WEEDS CONTROLLED" section of this label in the following perennial native grasses: big bluestem, little bluestem, bushy bluestem, blue oats grama, side oats grama, buffalograss, indiangrass, lovegrass and switchgrass.

Use the higher recommended rates of this product for control of large established weeds or when weed growth is heavy or dense. Best results are obtained when weeds are in the early stage of growth and are not disturbed by mowing or other factors for 12 days prior to, or 12 days after application.

Ground Broadcast Application. Apply [INSERT BRAND NAME] at 0.75 to 2.0 ounces per acre. Do not exceed 2.66 ounces of this product per acre per year. Follow-up applications should be made after suitable re-growth of weeds and no sooner than 30 days after the previous application. Use of a nonionic surfactant is required.

Hand-Held and High-Volume Equipment Application. Add 0.1 ounces of [INSERT BRAND NAME] per 10 gallons of water. Add 6 ounces of a nonionic surfactant per 10 gallons of spray solution.

WEEDS CONTROLLED

Barley, volunteer Hordeum vulgare Bedstraw, catchweed Galium aparine Bluegrass, annual Poa annua Bluegrass, roughstalk Poa trivialis Bluegrass, bulbous Poa bulbosa Buttercup Ranunculus arvensis Chamomile, mayweed Anthemus cotula Chickweed, common Stellaria media Green Kyllinga Kylliinga brevifolia Henbit

Lamium amplexicaule

Johnsongrass Sorghum halepense Mustard, tumble Sisymbrium altissimum Mustard, wild Sinapis arvensis Pennycress, field Thlaspi arvense **Purple Nutsedge** Cyperus rotundus Sedges, annual Cyperus spp. Shepherd's-purse Capsella bursa-pastoris Yellow Nutsedge Cyperus esculentus

LIMIT OF WARRANTY AND LIABILITY

Monsanto Company warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes set forth in the Complete Directions for Use label pamphlet ("Directions") when used in accordance with those Directions under the conditions described therein. NO OTHER EXPRESS WARRANTY OR IMPLIED WARRANTY OF FITNESS FOR PARTICULAR PURPOSE OR MERCHANTABILITY IS MADE. This warranty is also subject to the conditions and limitations stated herein.

Buyer and all users shall promptly notify this Company of any claims whether based in

Buyer and all users shall promptly notify this Company of any claims whether based in contract, negligence, strict liability, other tort or otherwise.

Buyer and all users are responsible for all loss or damage from use or handling which results from conditions beyond the control of this Company, including, but not limited to, incompatibility with products other than those set forth in the Directions, application to or contact with desirable vegetation, unusual weather, weather conditions which are outside the range considered normal at the application site and for the time period when the product is applied, as well as weather conditions which are outside the application ranges set forth in the Directions, application in any manner not explicitly set forth in the Directions, moisture conditions outside the moisture range specified in the Directions, or the presence

of products other than those set forth in the Directions in or on the soil, crop or treated vegetation.

THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE LIMIT OF THE LIABILITY OF THIS COMPANY OR ANY OTHER SELLER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT (INCLUDING CLAIMS BASED IN CONTRACT, NEGLIGENCE, STRICT LIABILITY, OTHER TORT OR OTHERWISE) SHALL BE THE PURCHASE PRICE PAID BY THE USER OR BUYER FOR THE QUANTITY OF THIS PRODUCT INVOLVED, OR, AT THE ELECTION OF THIS COMPANY OR ANY OTHER SELLER, THE REPLACEMENT OF SUCH QUANTITY, OR, IF NOT ACQUIRED BY PURCHASE, REPLACEMENT OF SUCH QUANTITY. IN NO EVENT SHALL THIS COMPANY OR ANY OTHER SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES.

This Company does not warrant any product reformulated or repackaged from this product except in accordance with this Company's stewardship requirements and with express written permission from this Company.

Upon opening and using this product, buyer and all users are deemed to have accepted the terms of this LIMIT OF WARRANTY AND LIABILITY which may not be varied by any verbal or written agreement. If terms are not acceptable, return at once unopened.

Battalion and Roundup Pro are registered trademarks of Monsanto Technology LLC.

EPA Reg. No. 524-534

In case of an emergency involving this product, Call Collect, day or night, (314) 694-4000.

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Formulated in the United States Using Active Ingredient Made in Japan.