Reg # 55947-136

PM-18



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

JEFF W. POPP SANDOZ AGRO, INC. 1300 EAST TOUHY AVENUE DES PLAINES, IL 60018

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

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Subject: Label Amendment Submission of 06/29/93 in Response to PR Notice 93-7 EPA REG. NO. 55947-136 JAVELIN WG BIOLOGICAL INSECTICIDE

Dear Registrant:

The labeling cited above and submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is accepted. A copy of your proposed labeling stamped "ACCEPTED WITH COMMENTS" is enclosed.

WHAT THIS ACCEPTANCE MEANS:

Based on your certification, the Agency has accepted the labeling changes that are necessary to comply with the Worker Protection Standard (WPS) labeling requirements of 40 CFR part 156, subpart K, described in PR Notices 93-7 and 93-11. Any other labeling changes submitted in connection with this amendment application but not directly related to compliance with the WPS have not been reviewed or accepted by the Agency. If you wish to make such changes, you must submit a separate amendment application proposing them. If your product is currently suspended, the acceptance of this labeling amendment does not affect the suspension in any way.

WHAT YOU NEED TO DO NEXT:

Send to EPA one (1) copy of the final printed labeling:

BEFORE selling or distributing any product bearing the final printed labeling AND

■ WITHIN one year from date of this acceptance.



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Submit the final printed labeling via the U.S. Postal Service to:

Document Processing Desk (FIN-LABEL) Office of Pesticide Programs (7505C) U.S. Environmental Protection Agency 401 M Street, SW Washington, D.C. 20460-0001

Hand or courier deliveries of final printed labeling may be made to:

Document Processing Desk (FIN-LABEL) Office of Pesticide Programs Room 266A, Crystal Mall 2 1921 Jefferson Davis Highway Arlington, VA 22202

Sincerely, Jim Tompkins, Deputy Chief Registration Support Branch Registration Division (7505W)

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Attachment

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JAVELIN® WG BIOLOGICAL INSECTICIDE

For Control Of Insect Pests Of Vegetables, Fruit and Field Crops

ACTIVE INGREDIENT:

Potency of 52,863 Spodoptera Units (at least 60 million viable spores) per milligram*	. 6.4%
INERT INGREDIENTS:	<u>.93.6%</u> 100.0%

*Equivalent to 24.0 billion Spodoptera Units per pound (14.4 billion International Units per pound) ACCEPTED with COMMENTS In EPA Letter Dated

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Under the Federal Insecticide, Fundicide, and Rodenticide Act as ancesded, for the pesticide registered under EPA Reg. No. 55947-/36

KEEP OUT OF REACH OF CHILDREN

WARNING

AVISO

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

SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS

EPA REG. NO.: 55947-136 EPA EST. NO.: 55947-CA-2

Lot No.: Net Contents:

SANDOZ AGRO, INC. DES PLAINES, IL 60018



JAVELIN® WG BIOLOGICAL INSECTICIDE

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS (AND DOMESTIC ANIMALS) WARNING

Causes eye irritation. Do not get in eyes.

May cause skin irritation and skin sensitization reactions in certain individuals. Avoid contact with skin or clothing. Wear protective clothing (overalls and gloves) while using or handling this product. Remove contaminated clothing and wash before reuse. Discontinue use if reaction occurs.

STATEMENT OF PRACTICAL TREATMENT

<u>If in Eyes</u>: Immediately flush with plenty of water. Get medical attention. <u>If On Skin</u>: Wash with plenty of soap and water. Get medical attention, if irritation persists.

Personal Protective Equipment: Applicators and other handlers must wear: Coveralls over short-sleeved shirt and short pants Waterproof gloves Shoes plus socks Protective eyewear

Discard clothing and other absorbent materials that have been drenched or heavily contaminated with this product's concentrate. Do not reuse them a Follow manufacturar's instructions for cleaning/maintaining PPE with no such instructions for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering continis statements

When handlers use closed systems, enclosed cabs, or aircrait 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.



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User Satety Recommendations: Users should:	
 Wash hands before eating, drinking, chewing gum, using tobacco or using the tollet. 	
 Remove Clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing. 	Ĭ
Remove PPE immediately after handling this product. Wash the outside of glove pelore removing the scontes possible swash thoroughly and change into dean	2
Clothing.	

ENVIRONMENTAL HAZARDS

Do not contaminate water when disposing of equipment washwaters.

DIRECTIONS FOR USE

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

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 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. 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 Coveralls over short-sleeved shift and short pants Waterproof gloves Shoes plus socks
BEST AVAILABLE COPY

Unless specifically stated, do not apply this product through any type of irrigation system.

JAVELIN[®] WG is a biological insecticide specific for the control of lepidopterous larvae (see Recommended Application Rates section).

JAVELIN® WG attacks the larval gut and must be ingested by the insect to be effective.

Since the active ingredient, <u>Bacillus</u> thuringiensis, is exempt from tolerance requirements, **JAVELIN® WG** may be applied up to and on the day of harvest.

GENERAL USE INSTRUCTIONS

For most consistent control, apply at first sign of newly hatched worms (1st and 2nd instar larvae). Instructions for specific crops are located in the Additional Information section in the Use Directions.

Reapply as necessary under a pest management program that includes close scouting.

If rapid knockdown of heavy worm or non-lepidopterous populations is necessary, include an effective contact insecticide in combination with JAVELIN® WG.

For heavy worm infestations, use the higher JAVELIN® WG rate. During situations of dense foliage and/or rapid growth, increasing water carrier volumes will provide better crop coverage and improve JAVELIN® WG performance.

Mixing:

Fill spray or mixing tank 3/4 full. Turn on agitation and pour JAVELIN[®] WG into water while maintaining continuous agitation. Add other spray material (if any) and add balance of water. Agitate as necessary to maintain suspension. Do not allow diluted sprays to remain in the tank for more than 48 hours. JAVELIN[®] WG is formulated to provide desirable coverage and adherence to leaf surfaces. Additional adjuvants, spreaders, or stickers may be added to improve product performance, especially under heavy dew or rainy conditions. Combinations with commonly used insecticides, fungicides, or other spray tank adjuvants are generally not deleterious to JAVELIN[®] WG if the mix is used promptly. Before mixing in the spray tank, it is advisable to test physical compatibility by mixing all components in a small container in proportionate quantities.

GROUND APPLICATION

Unless otherwise stated, use recommended amount of JAVELIN[®] WG in a minimum of 20 gallons of water per acre depending on type of crop and requirements of state regulations.

AERIAL APPLICATION

Use recommended amount of JAVELIN[®] WG in at least 3 gallons of water per acre. Applications at higher water volumes have demonstrated improved control of targeted pests. Apply early morning or evening when air is calm.

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VEGETABLE CROPS

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Artichokes	Artichoke Plume Moth	1/2-1 1/4	Apply in a minimum of 100 gal. of water per acre with a spray interval of 10 days or less.
			Apply 1 Ib/A in combination with ASANA XL, AMBUSH, or SUPRACIDE aerially to aid in resistance management of the artichoke plume moth. Use and follow all label directions of the tank mix partner regarding application, timing, gallonage, and schedules.
Artichokes			
Asparagus	Armyworm	1/2-1 1/2	Repeat as necessary
Beans			to maintain control.
(Green, Lima, Mung)			
Broccoli	Diamondback Moth	1/2-1 1/4	
Broccoli Raab (Rapp	oini)		
Brussel Sprouts	Green Cloverworm	1/4-1/2	
Cabbage Cardoon	Hornworms	1/8-1/2	
Carrots	Imported		
Cauliflower	Cabbageworm	1/4-1/2	
Celeriac	Loopers	1/4-1 1/4	
Celery			
Chick Peas			
Chinese Broccoli	• • • • •		
Chinese Cabbage	Salt Marsh	1/2-1	
Culturations	Caterpillar		
Dou Bulb Opions			
Englante	European Com	1.1 1/2	
Garlic	Rorer	101 1/2	
Green Onions	00.01		
Greens (Dandelion, Turnip, Mustard,	Tomato pinworm	3/4-1 1/4	
Herbs (Basil			
Cilantro, Dill.			
Oregano, Thyme. e	tc.)		
Horseradish	•		
Kale			
Kohl Rabi			
Leeks			

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RECOMMENDED APPLICATION RATES

DATE

VEGETABLE CROPS

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Lettuce (Endive, Romaine, Head			

Lettuce, Escarole Butter Crunch, Leaf, etc.) Melons (Cantaloupe, Crenshaw, Honeydew, Muskmelon, Watermelon, etc.) Okra Onions Parsley Parsnips Peas Peppers Potatoes **Pumpkins** Radishes Rutabaga Salsify Spinach Squash (Summer and Winter) Sweet Corn Sweet Potatoes **Swiss Chard** Table Beets **Tomatoes** Turnip Root Watercress Yams

FRUIT, NUT, & VINE CROPS

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Apples and Pears	Fruittree Leafroller	1/2-1	Apply when newly hatched larvae appear and before leaves are rolled. Continue
	Gypsy Moth	1/2-1	applying as a part of the normal cover spray program until pest is adequately
	Reabanded Leafroller Tufted Apple	1/2-1	controlled.
	Budmoth Variegated	1/2-1	
	Leafroller Omnivorous	1/2-1	
	Tent Caterpillar	1/2-1	Apply when caterpillars are actively feeding (2nd-4th instars).
	Peach Twig Borer Oriental Fruit Moth	1-3 1-3	
	Navel Orangeworm Codling Moth	1-3 1-4	
Avocados	Loopers Orange Tortrix	1-1 1/4 1/2-1	Apply as necessary to maintain control.
	Omnivorous Leafroller	1/2-1	Begin treatment as soon as possible after hatching and before larvae are protected by leaf folds.
	Amorbia	1	Suppression only.
Bananas	Banana Skipper	1/2-1	Hawaii only. Use calibrated ground equipment with adequate water to apply to point of runoff.
Citrus	Citrus Cutworm	1/2-1 1/2	Use 50-600 gallons of water per acre when using ground equipment and 10
	Fruittree Leafroller	1/2-1	gallons of water minimum per acre by air.
	Orangedog	1/4-1/2	
	Amorbia	1-1 1/2	Suppression only.

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Blueberries Caneberries	Blueberry Leafroller	1/2-1	Apply by ground equipment only. Begin treatment as soon as possible after
Currants	Cherry Fruitworm	1/4-1/2	hatching. For leafrollers, apply before larvae are protected by leaf folds
Kiwi	Fruittree Leafroller Gypsy Moth Green Fruitworm Loopers Orange Tortrix Omnivorous Leafroller Blueberry spanworm	1/2-1 1/2-1 1/4-1/2 1/2-1 1/2-1 1/2-1 1/2-1	
Grapes	Grape Leaffolder Grapeleaf Skeletonizers Omnivorous Leafroller Orange Tortrix Saltmarsh Caterpillar	1/2-1 1/4 1/2-1 1/4 1/2-1 1/4 1/2-1 1/4 1/2-1 1/4	Apply by ground equipment in up to 200 gallons total spray per acre to obtain thorough coverage of leaf surfaces. Start treating as soon as possible after hatching and before larvae are protected by leaf folds.

FRUIT, NUT, & VINE CROPS

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FRUIT, NUT, & VINE CROPS

Almonds Fall Webworm Apricot Filbert Webworn	1/2-1 m 1/2-1	For leafrollers, start treating as soon as possible after hatching and before larvae are protected
CherriesOmnivorousFilbertsLeafrollerNectarinesCitrus CutwormPeachesRedhumpedPecansCaterpillarPersimmonsRoughskinnedPlumscutworm	1/2-1 1/2-1 1/4 1/2-1 1/4-1/2	by leaf folds.
Pomegranate Prunes Tent Caterpillar Walnuts	1/4-1/2 1/2-1	Apply when caterpillars are actively feeding (2nd to 4th instar).
Pecan nut casebearer Peach Twig Bo Oriental Fruit M	3/4-1 1/4 rer 1-3 loth 1-3	Application timing is very important for good casebearer suppression. Consult your local university or extension agent for information concerning specific modeling that predicts egg lay, typical application dates, and scouting techniques for your area. JAVELIN® WG must be present at egg hatch for best control. Make application when the majority of eggs are in the pink stage. For best control make two applications 7 days apart. If only one application is made, a minimum of 1 lb should be applied
Navel Orangew Codling Moth	rorm 1-3 1-4	

FRUIT, NUT, & VINE CROPS

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Melons (Also see Veget	Rindworm Complex ables)	1/2-3/4	Apply at first sign of hatch before larvae enter fruit. Repeat as necessary to maintain control.
Strawberries	Armyworm Gypsy Moth Looper Roughskinned Cutworm	1/2-1 1/2 1/2-1 1/4-1/2 1/2-1	Apply as necessary to maintain control. Use 20 gallons water minimum per acre when using ground equipment and 5 gallons water minimum per acre by aircraft.
			In a tankmix with contact insecticides, rates as low as 1/2 lb. of JAVELIN® WG may be used for the control of armyworm.

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RECOMMENDED APPLICATION RATES

FIELD CROPS

CROP	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Alfalfa (Hay and Seed) Sudan Grass Hay Crops & Other Forage Crops	Alfaifa Caterpillar Armyworm Loopers	1/4-1/2 1/2-1 1/2 1/4-1	Under conditions of rapid plant growth and rapidly increasing armyworm populations (10 worms or greater per 180° sweep), use the highest rate. Against heterogenous worm populations, where 4th and 5th instars are present, and continuous egg-laying, applications may provide variable control. Under these conditions, the addition of a contact insecticide in combination with JAVELIN• WG is recommended.
			The addition of a spreader sticker to JAVELIN® WG may provide improved performance.
Small Grains	Armyworm	1-1 1/2	Apply as necessary to maintain control.
Hops	Loopers Omnivorous Leaftier	1/4-1 1/2-1	Apply as necessary to maintain control.
	Spotted Cutworm Oblique Banded Leafroller	1/2-1 1/2-1	Begin treatment as soon as possible after hatching and before larvae are protected by leaf folds.
Canola Evening primrose	Armyworm Diamondback	1/2-1 1/2	Apply as necessary to maintain control.
	Moth Imported	1/2-1 1/4	
	Loopers	1/4-1/2 1/4-1	
	Hornworms	1/8-1/4	

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RECOMMENDED APPLICATION RATES

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FIELD CROPS

CROP	INSECT	RATE LBS./ACRE	
Field Corn Pop Corn Seed Corn	Armyworm	1/2-1 1/2	Make initial application when economically damaging populations exist. Repeat as necessary to maintain control. Applications must be made to early instars prior to entering the ear or plant.
	Southwestern Corn Borer	1-1 1/2	Aids in control.
	European Corn Borer	1-1 1/2	
Jojoba	Looper (Anacamptodes spp.)	1/2-1	Apply in a minimum of 50 gallons of water per acre by ground equipment or a minimum of 10 gallons of water by aerial equipment. Thorough coverage foliage is essential and dictates the minimum spray volumes necessary.
Dry Beans and Peas Lentils	Armyworms Green Cloverworm	1/2-1 1/2 1/4-1/2	Apply as necessary to maintain control.
Mint Peanuts Rice Safflower	Loopers Salt Marsh Caterpillar	1/2-1 1/2-1	
Soybeans Sugar Beets Sunflower	Velvetbean Caterpillar <u>Helicoverpa</u> spp.	1/4-1/2 3/4-1 1/4	
Sorghum	(<u>Heliothis</u> spp.) Cutworm	1/2-1 1/2	
Tobacco	Looper Tobacco Hornworm Tobacco Budworm	1/2-1 1/8-1/2 1/2-1 1/4	Apply as necessary to maintain control.

TIMING	INSECT	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Early	Tobacco Budworm Bollworm	1/4-1 1/4	For early season management of <u>Helicoverpa</u> and <u>Heliothis</u> species. Initiate applications when 50% of plants are at pinhead square cotton stage, independent of <u>Helicoverpa</u> and <u>Heliothis</u> egg and larval counts, or at 1st egg lay, whichever occurs earlier. Continue applications on 5-day spray interval up to synthetic pyrethroid spray window.
			For added control of <u>Helicoverpa</u> and <u>Heliothis</u> , tankmixing of JAVELIN® WG with a labeled ovicide, such as, methomyl (0.125 lb. a.i./acre), profenofos (0.25 lb. a.i./acre), or thiodicarb (0.125-0.25 lb. a.i./acre) is recommended.
			Read and follow all precautions and restrictions on tankmix product labels.

COTTON - INCLUDING CA AND AZ

TIMING		RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Early and Mid-Season	Armyworm Cotton Leaf Perforator Cotton Leafworm Loopers Saltmarsh Caterpillar	1/2-1 1/2 1/2-1 1/2-1 1/2-1 1/4 1/2-1	Repeat as necessary throughout season to maintain control. If egg laying frequency indicates future moderate to heavy worm populations, time application spray to coincide with the 2nd instar larvae. During periods of high temperatures, worms will progress through 1st and 3rd instars very rapidly and early application timing is necessary for control.
			To be effective, JAVELIN [®] WG spray must be deposited at the larval feeding site. When plant cover is dense and worms are feeding in the lower 2/3 portion of the plant, aerial application of JAVELIN [®] WG may not provide adequate control.
	Bollworm Tobacco Budworm	1/2-1 1/2 1/2-1 1/2	For the suppression of light to moderate infestations, apply at first sign of egg-laying or newly-hatched w o r m s (1 s t instar larvae).

SHADE TREES, ORNAMENTALS (Including Roses)

PESTS	RATE LBS./ACRE	ADDITIONAL INSTRUCTIONS
Spring and Fall Capkonyorm	1/4 1/2	
Elm Spanworm	1/4-1/2	40% to 50% as infestation warr ants.
Test Caterpillar Gypsy Moth	1/4-1/2 1/4-1/2	If eggs hatch over a long period of time, or if reinfestation occurs, spray about 14 days after first applications.
Spruce Budworm	1/4-1/2	Apply when most larvae are 3rd-4th instar. Also consider the opening of the bud cap to ensure foliage exposure.
Jackpine Budworm Douglas Fir Tussock Moth Bagworm	1/4-1/2 1/4-1/2 1/4-1/2	
California Oak Moth	1/4-1/2	Apply after eggs have hatched and
Western Tussock Moth	1/4-1/2	early instar larvae are feeding on
Fruittree Leafroller	1/4-1/2	exposed foliage.
Mimosa Webworm	1/4-1/2	
Redhumped Caterpillar	1/8-1/2	
Fall Webworm	1/8-1/4	
Armyworm	1-1 1/4	
Omnivorous leafroller	1/2-1	

TURF AND GRASS SEED PRODUCTION

Tropical Sodwebworm	1	Repeat as necessary
Armyworm	1	throughout season to
Sodwebworm	1	maintain control.

STORED SOYBEANS, GRAINS

(Indian Meal Moth, Almond Moth)

To control and prevent Indian Meal Moth and Almond Moth infestations of stored soybeans and grains, prepara a spray mixture which includes 1 gallon of water for every 1.5 oz. by weight of **JAVELIN® WG**. The spray mixture may be applied either by treating the top 4 inches of grain as it is being augered into storage (applying 0.6 pint of mixture per bushel in the grain stream), or by treating the surface of grain after it is in the bin. The Table below can be used as a guide in determining the total amount of **JAVELIN® WG** needed according to the bin diameter or the number of bushels to be treated.

Bin Diameter (ft)	Surface Area 、 (sq. ft.)	Bushels (to 4 in. depth)	JAVELIN [®] WG Rate (by weight)	
			Grams	<u>oz.</u>
8	50	13	21	0.75
12	113	30	50	1.75
16	201	53	85	3.00
20	314	84	120	4.25
24	452	120	185	6.50
28	615	163	255	9.00
32	804	214	326	11.50

To insure thorough coverage when making applications to the grain surface after it is in the bin, apply spray mixture in three (3) applications. Mix the grain with a scoop or rake to a depth of four (4) inches after each application.

Stored grain may be treated anytime, but for best results, treat grain at the time it is placed into storage or shortly thereafter, or in the early spring prior to egg-laying. Full season control is normally experienced. Re-treat only if reinfestation occurs.

For the protection of bagged grain, apply spray mixture to entire grain mass, and mix thoroughly prior to bagging. JAVELIN[®] WG at 6 oz. by weight per 10 gallons of water will treat approximately 100 bushels.

Treated grain may be used at any time after treatment.

FLOWERS AND ORNAMENTALS

JAVELIN[®] WG may also be used on flowers and ornamentals outdoors and in the greenhouse at a rate of 1/4-1 1/2 lb. per 100 gallons of water for control of listed insects on this label.

GUIDE FOR SMALL SPRAY VOLUME MIXING

Rate	Conversion Rate*
Lbs./A	Teaspoons/Gallon
1/4	1/2
1/2	1
1	2

*Assumes Application to spray runoff.

LIMITATION OF WARRANTY AND LIMITATION OF LIABILITY

NOTICE: Read this Limitation of Warranty and Lin. itation of 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.

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 weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Sandoz or seller. All such risks shall be assumed by buyer or user.

Sandoz 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, under normal use conditions, subject to the risks described above. SANDOZ MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MER-CHANTABLILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

In no event shall Sandoz or seller be liable for any incidental, consequential or special damages resulting from the use or handling of this product. THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABLILITY OF SANDOZ OR SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJU-RIES 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 SANDCZ OR SELLER, THE REPLACEMENT OF THE PRODUCT.

Sandoz and seller offer this product, and buyer and user accept it, subject to the foregoing limitations of warranty and limitation of liability, which may not be modified by any oral or written agreement.