

# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460-0001

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

August 3, 2010

Mr. Mark Mongiovi, Product Compliance Specialist Safer®, Inc., a wholly owned subsidiary of Woodstream Corporation 69 North Locust Street, P.O. Box 327 Lititz, PA 17543-0327

Subject:

Revised Master Label, Addition of ABNs and Response to PR Notices 98-10 & 2007-4

Safer® Brand O-SAP READY-TO-USE SPRAY II, EPA Reg. No. 59913-10

Your Submission Dated April 15, 2010

Dear Mr. Mongiovi:

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable with the following label revision provision(s):

#### General Comment(s):

- 1. The submitted alternate brand names (ABNs) are acceptable.
- Delete all text on the subject label that has been marked up with "strikethrough."
- 3. Delete all references to aerosol products that are marked up with "strikethrough" on the subject label, since the accepted basic CSF supporting the referenced registration/product will only support an RTU pump spray product. As an alternative, if Safer®, Inc. desires to continue marketing an aerosol product, you will need to submit an alternate CSF with a propellant listed.
- 4. Within the general statement found at the top of page 2 of 8, replace the word "pyrethrum" with the word "pyrethrum."

#### National Organic Program (NOP) Labeling Review comment(s):

5. The MP/source for the pyrethrins is EPA Reg. No. 1021-1805, which is formulated using MP/source EPA Reg. No. 1021-1067. EPA Reg. No. 1021-1067 contains an inert ingredient which is not allowed under the NOP. While the manufacturer from the source claims that the manufacturing process for EPA Reg. No. 1021-1805 removes the referenced non-compliant inert ingredient, there is simply not enough information to validate this claim. Complete and unconditional approval of this product for its NOP claims would require you to either change to an NOP-compliant source product, or it would require the referenced manufacturer of the pyrethrins source to demonstrate that the referenced non-compliant inert ingredient is absent from their product, and that would require a formal amendment to the source CSF, which would need to make clear the removal of the non-compliant inert ingredient through distillation.

#### [Optional Logos/Marketing Claims section comment(s):

6. Delete the 2<sup>nd</sup> optional logo/marketing claim "[For Organic Production]" because this product is not a commercial product that would fall under an organic production standard as recognized by USDA.

## Precautionary Statements, Hazards to Humans and Domestic Animals section comment(s):

- 7. The section subheading "Hazards to Humans and Domestic Animals" should be the same font point size and should also be **bolded** and CAPITALIZED, similar to the section heading "**PRECAUTIONARY STATEMENTS**."
- 8. Revise the existing 3<sup>rd</sup> sentence to read "Wash hands thoroughly with plenty of soap and water after handling this product and before eating, drinking, chewing gum, using tobacco or using the toilet."

## First Aid Statement section comment(s):

9. Revise the 2<sup>nd</sup> sentence of the "**HOT LINE NUMBER**" subsection to read "For additional information on this product (including health concerns, medical emergencies or pesticide incidents), you may call 1-800-858-7378." <sup>1</sup>

#### Storage and Disposal [Ready To Use Pump Spray Products Only] section comment(s):

- 10. Revise the subsection heading "STORAGE:" to read "PESTICIDE STORAGE:"
- 11. Revise the subsection heading "DISPOSAL:" to read "CONTAINER HANDLING:"
- 12. Within the revised "CONTAINER HANDLING:" subsection, revise the 3<sup>rd</sup> sentence in the "If Empty:" statement to read "Offer for recycling, if available."

## Directions for Use [Ready To Use Pump Spray Products Only] section comment(s):

- 13. Within the existing "Use as provided on vegetables, including:" subsection, replace the word "control" with the word "kill."
- 14. Within the existing "<u>Use as provided on fruits and vegetable nuts, including:</u>" subsection, replace the word "control" with the word "kill."
- 15. Revise the existing "<u>Use as provided on lawns and turf grass:</u>" subsection to read "<u>Use as provided on lawns and turf grass:</u> to kill CHINCH BUGS, LAWN MOTH, SOD WEBWORM and ARMYWORMS."
- 16. Within the existing "<u>Use as provided on ornamental trees and shrubs, including:</u>" subsection, replace the word "control" with the word "kill."
- 17. Within the existing "<u>Use as provided on Flowers, including:</u>" subsection, replace the word "control" with the word "kill."
- 18. Within the existing "Use as provided on houseplants:" subsection, replace the word "control" with the word "kill."

#### Optional Marketing/Advertising Claims section comment(s):

- 19. Delete the 1<sup>st</sup> optional marketing/advertising claim "For Organic Production" because this product is not a commercial product that would fall under an organic production standard as recognized by USDA.
- 20. Within the 5<sup>th</sup> optional marketing/advertising claim, revise the word "Pyrethrin" to read "Pyrethrins."
- 21. Delete the 27<sup>th</sup> optional marketing/advertising claim "Non-PBO\* formula. Does not contain PBO\* (\*Piperonyl Butoxide)". You cannot market a product due to the absence of another ingredient, as specified in 40 CFR §156.10(a)(5)(i) and Chapter 12, Section III of the Agency's Label Review Manual.
- 22. Revise the 28<sup>th</sup> optional marketing/advertising claim to read "Contains pyrethrins, a botanical insecticide derived from the *Chrysanthemum* flower."
- 23. Delete the 30<sup>th</sup>, 31<sup>st</sup>, 32<sup>nd</sup>, 33<sup>rd</sup> and 34<sup>th</sup> optional marketing/advertising claims since all references to aerosol products are being removed from the subject label as referenced in Item #3 above.

<sup>&</sup>lt;sup>1</sup> Please note that the "1-800-858-7378" number listed on the label must be available twenty-four (24) hours per day, seven (7) days per week for answering and responding to any medical emergencies or health concerns.

Optional Marketing/Advertising Claims section comment(s), continued:

- 24. Delete the 39<sup>th</sup> optional marketing/advertising claim, and revise the 41<sup>st</sup> optional marketing/advertising claim to read "Contains PyGanic™, a registered trademark of McLaughlin Gormley King Company."
- 25. Delete the 42<sup>nd</sup> and 43<sup>rd</sup> optional marketing/advertising claims since this information is already contained within the revised 28<sup>th</sup> optional marketing/advertising claim covered in Item #22 above.

Should you wish to add/retain a reference to the company's website on your label, please be aware that the website becomes labeling under FIFRA and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under section 12(a)(1)(E) of FIFRA. 40 CFR §156.10(a)(5) lists examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not be substantially differ from those claims approved through the registration process. Therefore, should the Agency find, or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to EPA's Office of Enforcement and Compliance Assurance (OECA). As an alternative, you may refer consumers to the company's phone number or e-mail address.

A copy of your label stamped "Accepted with Comments" is enclosed for your records. Please submit two (2) copies of the final printed labeling, incorporating the above changes, before releasing the product for shipment. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA. Your release for shipment of the product bearing amended labeling constitutes accepting of these conditions.

If you have any questions about this label review, please contact Mr. Carmen Rodia at (703) 306-0327 or via e-mail at <u>Rodia.Carmen@epa.gov</u>. If there are any questions regarding the NOP labeling review, please contact Mr. Chris Pfeifer at (703) 308-0031 or via e-mail at <u>Pfeifer.Chris@epa.gov</u>.

Sincerely yours,

Richard J. Gebken

Product Manager (10)

Insecticide Branch

Registration Division (7504P)

Enclosure: Copy of label stamped "Accepted with Comments" 059913-00010 D433453

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MASTER LABEL-FRONT PANEL (Page #1 of 1)

# SAFER® BRAND O-SAP READY-TO-USE SPRAY II

## [Additional Brand Names]

Houseplant Insect Killer-Safer® Brand
Tomato & Vegetable Insect Killer<sub>II</sub>-Safer® Brand
Yard & Garden Insect Killer<sub>II</sub>-Safer® Brand
Concern® Tomato & Vegetable Insect Killer II
Concern® Rose & Flower Insect Killer II
Concern® Multi-Purpose Insect Killer II
SureFire Tomato & Vegetable Insect Killer
Houseplant Insect Killer
Tomato & Vegetable Insect Killer<sub>II</sub>
Yard & Garden Insect Killer<sub>II</sub>
Safer® Brand Tomato & Vegetable Insect Killer<sub>II</sub>
Safer® Brand Yard & Garden Insect Killer<sub>II</sub>

ACCEPTED
With COMMENTS
In EPA Letter Dated:
Augus + 3, 2010
Under the Federal Insecticide, Fungicide and Rodenticide Act, As amended, for the pesticide Registered under EPA Reg. No:
59913-10

## [Optional Logos/Marketing Claims]

Houseplant Insect Killer<sub>III</sub>

Safer® Brand Houseplant Insect Killerm

•	Safer® Brand	-[optional brand logo]
	[For Organic Production]	
	fror organio riognotion]	Tohman rogol
	[For Organic Gardening]	
		[obtionar togo]
	JOMPIN Listed Organic Materia	c Review Institute] [ontional local]

- Kills: Beetles, Caterpillars, Aphids, Whiteflies, Sawflies, Scale Insects, Spider Mites, Mealybugs, Thrips, Ants, Billbugs, Chinch Bugs, Japanese Beetles, Sod Webworms, Sowbugs, Earwigs and other listed pests.
- Kills Insects Including Beetles, Caterpillars & Aphids

For use on houseplants, flowers, herbs, berries, fruits, vegetables, shade trees, evergreens, ornamentals, cacti and succulents, and lawns, grown in and around the home and in home greenhouses and other interior plantings. Use up to day of harvest.

ACTIVE INGREDIENTS:	BY WT.
Pyrethrins	0.012%
Potassium Salts of Fatty Acids	1.015%
OTHER INGREDIENTS:	<u>98.973%</u>
TOTAL	100.000%

## KEEP OUT OF REACH OF CHILDREN

**CAUTION** (See back panel for additional precautionary statements and first aid.)

Net Contents: 8 fl. oz., 10 fl. oz., 24 fl. oz., 32 fl. oz.

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General: Safer ® Brand O-SAP READY-TO-USE SPRAY II is a patented formula that utilizes insecticidal soap to desiccate the cuticle of the insect, plus pyrethrins to attack the insect's nervous system. The combination of these ingredients is synergistic (the effect of the two ingredients together is greater than either used individually): The result is a more reliable insecticide with the benefit of immediate kill from pyrethrum.

## PRECAUTIONARY STATEMENTS

Hazards to Humans and Domestic Animals

**CAUTION:** Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wash thoroughly with soap and water after handling.

#### FIRST AID

# If in eyes:

- 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 eye.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-858-7378 for emergency medical treatment.

## -PHYSICAL OR CHEMICAL HAZARDS [Aerosol Products Only]-

Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130° F may cause bursting.

-Incincration of container may cause explosion.

## **ENVIRONMENTAL HAZARDS**

This product is toxic to fish. For terrestrial uses, 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 washwaters. Remove or cover fish aquaria in the area being treated.

## STORAGE AND DISPOSAL [Ready To Use Pump Spray Product]

STORAGE: Store only in original container in a cool, dry area inaccessible to children and pets. Protect from freezing. If frozen, thaw and shake well. Keep container tightiy closed to prevent evaporation.

## **DISPOSAL:**

If Empty: Non-refillable container. Do not reuse or refill this container. Place in transor-offer for recycling if available.

If Partly Filled: Call your local solid waste agency for disposal instructions. Never place unused product down any indoor or outdoor drain.

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STORAGE AND DISPOSAL [Aerosol Products Only]

STORAGE: Protect from freezing. If frozen, thaw and shake well. Store in a cool, dry place (preferably locked) inaccessible to children and pets, and away from heat, open flame or other sources of ignition.

DISPOSAL:

Do Not Puncture or Incinerate!

If empty: Place in trash or offer for recycling if available.

If partly filled: Call you local solid waste agency for disposal instructions.

**DIRECTIONS FOR USE** [Ready To Use Pump Spray Products Only] It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Plant Uses:

[Pump Sprayer A]

SHAKE WELL BEFORE USING. Turn sprayer nozzle to one of the open positions. Hold sprayer 12 to 18 inches from the surface and spray to achieve thorough coverage. Use with caution on new, tender foliage, and avoid spraying plants in full sun.

[Pump Sprayer B]

SHAKE WELL BEFORE USING. To unlock trigger, turn locking tab clockwise, then push down into open position. Hold sprayer 12 to 18 inches from the surface and spray to achieve thorough coverage. Sprayer works in all directions. Spray upside down to reach pests under the plant leaves. Use with caution on new, tender foliage, and avoid spraying plants in full sun.

Use as provided on vegetables, including: asparagus, beans, broccoli, Brussels sprouts, cabbage, kale, and oriental vegetables, herbs, lettuce, eggplant, peppers, tomatoes, potatoes, cucumbers, melons and squash to control ASPARAGUS BEETLES, BEAN BEETLES, COLORADO POTATO BEETLES, CUCUMBER BEETLES, FLEA BEETLES, CATERPILLARS (including CABBAGE LOOPERS, IMPORTED CABBAGEWORM, ARMYWORMS, HORNWORMS, DIAMOND BACK MOTH LARVAE), LEAF HOPPERS, PLANT BUGS, PSYLLIDS, APHIDS AND WHITEFLIES. Use up to day of harvest.

Use as provided on fruits and nuts, including: apples, avocados, citrus (grapefruit, lemons, oranges, tangerines, limes), peaches, nectarines, apricots, pears, almonds, pecans, walnuts, kiwi fruit, blackberries, loganberries, raspberries, strawberries and grapes to control JAPANESE BEETLES, FLEA BEETLES, WEEVIL ADULTS, CATERPILLARS (including NAVAL ORANGE WORM, BAGWORMS, LEAFTIFRS,

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CODLING MOTH, and TENT CATERPILLARS), APHIDS, LEAFHOPPERS, PSYLLIDS, SCALE CRAWLERS, and SAWFLY LARVAE. Use up to day of harvest.

<u>Use as provided on lawns and turf grass:</u> to control CHINCH BUGS, LAWN MOTH, SOD WEBWORM, ARMYWORMS, and other miscellaneous posts.

<u>Use as provided on ornamental trees and shrubs, including:</u> azaleas, camellias, cacti, dogwood, rhododendrons, evergreens, and broad-leaved shade trees to control APHIDS, BEETLES, CATERPILLARS (including GYPSY MOTH LARVAE, TENT CATERPILLARS, WEBWORMS, BAGWORMS, and LEAFTIERS), LACE BUGS, BOX ELDER BUGS, LEAFHOPPERS, PSYLLIDS, SAWFLIES, SCALES and WOOLY ADELGIDS.

ATTENTION: Do not use on Japanese maple, horse chestnut, or mountain ash.

<u>Use as provided on Flowers, including:</u> asters, carnations, chrysanthemums, geraniums, marigolds, petunias, and roses to control APHIDS, BEETLES, (including FLEA BEETLES and JAPANESE BEETLES), CATERPILLARS, PLANT BUGS, and WHITEFLIES.

ATTENTION: Do not spray blooms or partially open flower buds. Do not use on bleeding heart or gardenias. Test on fuschias and impatiens for varietal sensitivity.

<u>Use as provided on houseplants:</u> to control APHIDS, CATERPILLARS and WHITEFLIES. Apply when insects or signs of damage are first sighted. Thoroughly moisten all plant surfaces. Repeat treatment at 7 to 10 day intervals or as needed. ATTENTION: Do not use on Crown of Thorns, jade plant, or delicate ferns. Test on begonias, fuschias and impatiens for varietal sensitivity.

WHAT IT IS: Safer® Brand O-SAP READY-TO-USE SPRAY II is a specially formulated combination of insecticidal soap and botanical pyrethrins which kills insects on contact yet is gentle on plants.

WHAT IT KILLS: Aphids, Asparagus Beetles, Bag Worms, Bean Beetles, Cabbage Loopers, Caterpillars, Colorado Potato Beetles, Cucumber Beetles, Diamond Backed Moth Larvae, Earwigs, Flea Beetles, Gypsy Moth Larvae, Imported Cabbageworm, Japanese Beetles, Leafhoppers, Mealybugs, Plant Bugs, Scales, Spider Mites, Thrips, Tomato Hornworm, and Whiteflies.

WHERE TO USE IT\*: Asparagus, Beans, Broccoli, Brussels sprouts, Cabbage, Cauliflower, Cucumbers, Eggplant, Herbs, Kale, Lettuce, Peppers, Potatoes, Squash Tomatoes, Roses, Flowers, Vegetables, Herbs, Houseplants, Ornamental Trees and Shrubs (Ornamentals).

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**HOW TO USE IT:** Shake well. Use at first sighting of insects. Thoroughly moisten all plant surfaces where insects are feeding or resting. Apply every 7 to 10 days when insects are present or as needed to prevent damage. CAN BE USED UP TO THE DAY OF HARVEST.

\*NOTE: Use with caution on tender new foliage. DO NOT USE on Crown of Thorns, jade plant or delicate ferns. TEST for varietal sensitivity on begonias, fuschias, and impatiens. If uncertain about a plant's sensitivity, test in an inconspicuous area then wait 24 hours before full coverage.

## Coverage:

8 oz. will treat approximately 5 plants, 2' high by 2' diameter.

12 oz. will treat approximately 8 plants, 2' high by 2' diameter.

16 oz. will treat approximately 10 plants, 2' high by 2' diameter.

24 oz. will treat approximately 15 plants, 2' high by 2' diameter, or 1 tree, 10' high by 4' diameter.

32 oz. will treat approximately 20 plants, 2' high by 2' diameter, or one tree, 10' high by 4' diameter.

64 oz. will treat approximately 40 plants, 2' high by 2' diameter, or 3 trees, 10' high by 4' diameter.

1 gallon will treat approximately 80 plants, 2' high by 2' diameter, or 6 trees, 10' high by 4' diameter.

## **DERECTIONS FOR USE** [Aerosol Products Only]

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

SHAKE BEFORE USING. Hold sprayer 12 to 18 inches from surface and spray to achieve thorough coverage. Apply when insects or their damage first appears. Spray to thoroughly moisten all plant surfaces where insects are feeding or resting. Repeat treatment every 7 to 10 days when insects are present or as needed to prevent damage. Use with caution on new, tender foliage. Do not use this product in or around electrical equipment due to the possibility of shock hazard.

Use on Houseplants: to control [kill] aphids, [(spider) (red) mites, mealybugs, thrips, scales,] caterpillars and whiteflies. Apply when insects or their damage first appears. Spray to thoroughly moisten all plant surfaces where insects are feeding or resting. Repeat treatment every 7 to 10 days when insects are present as needed to prevent damage. ATTENTION: Do not use on Crown of Thorns, jade plant or delicate ferns. Test on begonias, fuchsias and impatiens for varietal sensitivity.

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Use on Ornamental Trees and Shrubs: including asters, azaleas, begonias, camellias, carnations, chrysanthemums and roses to control [kill] aphids, leafhoppers, whiteflies, [(spider) (red) mites, mealybugs, thrips, scales,] Japanese beetles, flea beetles, gypsy moth larvae, tent caterpillars, bagworms, leaftiers and other caterpillars. (ATTENTION: Do not use on Crown of Thorns, jade plant or delicate ferms. Test on begonias, fuchsias and impatiens for varietal sensitivity.)

Use on Asparagus, Beans, Broccoli-Brussel Sprouts, Cabbage, Cauliflower, Cucumber, Lettuce, Kale, Herbs, Eggplant, Pepper, Tomatoes, Potatoes, and Squash: to control [kill] asparagus beetles, bean beetles, Colorado potato beetles, cucumber beetles, flea beetles, cabbage loopers, imported cabbageworm, [(spider) (red) mites, mealybugs,] tomato hornworm, diamondback moth larvae, and other caterpillars, plant bugs, leafhoppers, aphids and whiteflies.

**Note:** Seller warrants that this product complies with the specifications expressed in this label. To the extent consistent with applicable law, Seller makes no other warranties, and disclaims all other warranties, express or implied, including but not limited to warranties of merchantability and fitness for the intended purpose. To the extent consistent with applicable law, Seller's liability or default, breach or failure under this label shall be limited to the amount of the purchase price. To the extent consistent with applicable law, Seller shall have no liability for consequential damages.

Manufactured For:
Safer®, Inc., a wholly owned subsidiary of Woodstream Corporation
69 North Locust Street
Lititz PA 17543
1-800-800-1819 for information

EPA Reg. No. 59913-10

EPA Est. No. 63416-MN-01

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# MASTER LABEL- OPTIONAL CLAIMS (Page # 1 of 2)

## [Optional Marketing/Advertising Claims]

- For Organic Production
- For Organic Gardening
- OMRITM Listed Organic Materials Review Institute
- Effective on hard and soft bodied insects (see back panel for listed insects)
- Pyrethrin and Insecticidal Soap
  - Kills aphids, whiteflies, scales, [(spider) (red) mites, mealybugs, thrips] and other listed pests.
  - For use on houseplants, flowers, herbs, ornamentals, shrubs, vegetables grown in and around homes and home greenhouses and other interior plantings.
  - For use in and around homes and home greenhouses and other interior plantings.
  - WATER-BASED
  - Quick knock-down
  - Nonflammable
  - Reliable
  - Kills bugs on contact!
  - Kills insects on contact (see back panel).
  - Unique, patented formula.
  - Easy to use
  - Fresh scent
  - Use up to day of harvest
  - Kills Japanese Beetles on Contact
  - Gentle on Most Plants
  - Multi-purpose
  - Broad spectrum
  - Dual Killing Action
  - Dual Action
  - Indoor and Outdoor
  - Water Based Products Since 1976
  - Non PBO\* formula. Does not contain PBO\* (\*Piperonyl butoxide)
- Made with botanical pyrethrins from Chrysanthemum flowers.
  - Broad-spectrum insect killer.
  - Contains no acrosol propellants. Powered by compressed air. [Acrosol Product-Only]
  - CONTAINS NO CFCs OR OTHER OZONE DEPLETING SUBSTANCES.
    - Federal-Regulations Prohibit CFC Propellants in Aerosols [Aerosol Product Only].
  - Sprays in any direction even upside down. [Aerosol Product Only]

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## MASTER LABEL- OPTIONAL CLAIMS (Page # 2 of 2)

- Gentle Mist [Aerosol Products Only]
  - Gentle Mist sprays from any angle [Aerosol Products Only]
    - Made in USA
    - Printed in USA
    - ALWAYS SHAKE WELL BEFORE USING
    - Contains Insect Killing Soap & Botanical Pyrethrins
  - ◆ Contains PyGanic™ (ORGANIC PYRETHRINS)
  - This product contains [PyGanic™ LOGO].
  - PyGanic is a registered trademark of McLaughlin Gormley King Company
  - Made with Organic Pyrethrins From Chrysanthemum flowers
- Contains Organic Pyrethrins From Chrysanthemum flowers
  - Kills 40 Insects!
  - 360° Sprayer [Ready to Use Pump Sprayer B only]
  - Spray upside-down [Ready to Use Pump Sprayer B only]
  - Sprays from any angle [Ready to Use Pump Sprayer B only]
  - www.saferbrand.com