

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

January 3, 2018

Susan Westra Chem Tech, Ltd. 110 Hopkins Drive Randolph, Iowa 50225

Subject: Label Amendment – Submission of amendment in labeling in response to letter

dated 10/4/2016, which noted efficacy data wasn't sufficient and new citation of

data was submitted

Product Name: CT Permethrin 1% Pour-On EPA Registration Number: 47000-150

Application Date: 11/01/2016 Decision Number: 523275

Dear Ms. Westra:

The amended label referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, is acceptable. This approval does not affect any conditions that were previously imposed on this registration. You continue to be subject to existing conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one copy of the final printed labeling before you release the product for shipment with the new labeling. In accordance with 40 CFR 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR 152.3.

Should you wish to add/retain a reference to the company's website on your label, then please be aware that the website becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act 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 FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list 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 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 the EPA's Office of Enforcement and Compliance.

Your release for shipment of the product constitutes acceptance of these conditions. If these conditions are not complied with, the registration will be subject to cancellation in accordance

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with FIFRA section 6. If you have any questions, please contact Autumn Metzger at 703-919-7453, or Metzger.autumn@epa.gov.

Sincerely,

Elizabeth Fertich Product Manager 4 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs

Enclosure

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CT Permethrin 1% Pour-On

ACCEPTED

01/03/2018

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 47000-150

Ready to use

For use on lactating and non-lactating dairy cattle, beef cattle and calves to control lice, horn flies, horse flies, stables flies, mosquitoes, black flies, tick and sheep keds.

ACTIVE INGREDIENT:

Permethrin*	1.00%
OTHER INGREDIENTS:	99.00%
TOTAL	100.00%

- * (3-phenoxyphenyl)methyl (+/-) cis/trans 3-(2,2-dicholorethenyl)-2,2-dimethylcyclopropanecarboxylate cis/trans ratio: Min 35% (+/-) trans and Max 65% (+/-) cis.
- ** Contains Petroleum Distillates

EPA Reg. No. 47000-150

EPA Est. No. 47000-IA-01 EPA Est. No. 61282-WI-01 EPA Est. No. 66171-CA-001 EPA Est. No. 66171-TN-001

[(First letter of batch number indicates establishment)]

KEEP OUT OF REACH OF CHILDREN CAUTION

See [inside, side, front, back] [panels, booklet, leaflet] for [First Aid and] additional Precautionary Statements

Net Contents:

- 1 gallon (3.785L)
- 2.5 gallons (9.464L)
- 55 gallons (18.927L)
- 250 gallons (946.353L)

Manufactured by:

Chem-Tech, Ltd. 1006 Business Hwy 5 Pleasantville, IA 50225

{Note to Reviewer: Items in [brackets] represent optional language. Standard measurements may be abbreviated or written out. "[This product]" supports the addition of the product brand name, which must be formatted in a size consistent with the surrounding body text. For brand names used in body text, **bold**, *italic*, and/or ALL CAPITALS is also permitted. Additional/optional marketing statements are listed on the last page(s) of this label. Section headers may be centered or formatted for emphasis, consistent with general label layout.}

{Note to Reviewer: First Aid statement may be formatted without bullets or as paragraph(s)}

FIRST AID		
If on Skin or	Take off contaminated clothing.	
on clothing:	• Rinse skin immediately with plenty of water for 15-20 minutes.	
	Call a poison control center or doctor for further treatment advice.	
If Swallowed:	• Call a poison control center or doctor immediately for treatment advice or	
	transport the patient to the nearest hospital.	
	• Do not give any liquid to the patient.	
	• Do not administer anything by mouth.	
	• Do not induce vomiting unless told to do so by the poison control center or	
	doctor.	
	Move person to fresh air.	
If Inhaled:	• If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth, if possible.	
	• Call a poison control center or doctor for further treatment advice.	
NOTE TO PHYSICIAN: Contains petroleum distillate. May pose an aspiration pneumonia hazard.		
Have product container or label with you when calling a poison control center, or doctor, or		
going in for treatment.		
For 24-hour emergency information on this product, call		
1-800-498-5743 (US & Canada) or 1-651-523-0318 (all other areas)		

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed, inhaled or absorbed through skin. Avoid contact with skin, eyes or clothing. Avoid breathing vapor or spray mist.

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to aquatic organisms including fish and invertebrates. To protect the environment, do not allow pesticide to enter or run off into storm drains, drainage ditches, gutters, or surface waters. Applying this product in calm weather when rain is not predicted for the next 24 hours will help to ensure that wind or rain does not blow or wash pesticide off the treatment area.

This product is highly toxic to bees and other pollinating insects exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees or other pollinating insects are foraging the treatment area.

Personal Protective Equipment (PPE):

Mixers, loaders, applicators, and other handlers must wear:

- Long-sleeved shirt and long pants,
- Shoes plus socks,
- Chemical-resistant gloves (barrier laminate, nitrile rubber, neoprene rubber, or Viton),
- Chemical-resistant apron for mixers, loaders, persons cleaning equipment, and for handlers performing animal dip operations.

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User Safety Requirements

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

User Safety Recommendations

Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.

Users should remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.

Users should 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.

DIRECTIONS FOR USE

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

READ THIS LABEL: Read this entire label and follow all use directions, use restrictions and precautions.

USE RESTRICTIONS

Entry Restrictions

Except when applying to livestock, do not enter or allow others to enter treated area until sprays have dried.

Application Restrictions

- Except when applying to livestock, do not apply this product in a way that will contact workers or other persons, either directly or through drift.
- Except when applying to livestock, only protected handlers may be in the area during application.
- Do not breathe vapors or spray mist.
- Do not water the treated area to the point of run-off. Do not make applications during rain.
- All outdoor applications must be limited to spot or crack-and-crevice treatments only, except for the following permitted uses:
 - 1. Treatment to soil or vegetation around structures,
 - 2. Applications to lawns, turf, and other vegetation,
 - 3. Applications to building foundations, up to a maximum height of 3 feet
- Other than applications to building foundations, all outdoor applications to impervious surfaces such as sidewalks, driveways, patios, porches, and structural surfaces (such as windows, doors and eaves) are limited to spot and crack-and-crevice application only.
- Application is prohibited directly into sewers or drains, or to any area like a gutter where drainage to sewers, storm drains, water bodies, or aquatic habitation can occur. Do not allow the product to enter any drain during or after application.
- When used in dairy barns or facilities:

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Close milk bulk tank lids to prevent contamination from spray and from dead or falling insects. Remove or cover milking utensils before application. Wash teats of animals before milking.

• Do not use sponge to apply.

APPLICATION DIRECTIONS

Apply To:	Target Insects:	Application Instructions:
Lactating Dairy Cattle,	Lice, Horn Flies.	Apply ½ fl. oz. (15cc) per 100 lbs. body
Non-Lactating Dairy	Aids in control of Horse	weight of animal, up to a maximum of 5 fl. oz.
Cattle,	Flies, Stable Flies,	for any one animal over a 14 day period.
Beef Cattle,	Mosquitoes, Black Flies, and	POUR-ON: Pour along back line and down
Calves	Ticks.	face.
		BACKRUBBER USE:
		Mix one pint per gallon of #2 diesel or mineral
		oil. Keep rubbing device charged. Results are
		improved by daily forced use.
Sheep	Keds	Pour along back line and down face. Apply 1/4
		fl. oz. (7.5cc) per 50 lbs. body weight of
		animal, 3 fl. oz. for any one animal over a 14
		day period.
Premises:	Horse Flies, Stable Flies,	For use as a ready-to-use spot spray or
In and around Horse,	Face Flies, Gnats,	premise spray:
Beef, Swine, Sheep, and	Mosquitoes, Black Flies,	Use undiluted in a mist sprayer. Apply
Poultry Premises, Animal	Fleas, Little House Flies	directly to surface to leave a residual
Hospital Pens and	(Fannia spp.).	insecticide coating, paying particular attention
Kennels, and outside Meat	Aids in control of	to areas where insects crawl or alight. One
Processing Facilities	Cockroaches, Ants, Spiders,	gallon will treat approximately 7,300 square
	and Crickets	feet.

For pour-on and ready-to-use applications, repeat treatment as needed but do not exceed 5 fl. oz. for any one animal on cattle or 3 fl. oz. for any one animal on sheep during any 14 day interval. For optimum insecticidal effectiveness against lice, a second treatment at 14 day intervals is recommended.

NOTE: This product is not effective for grub control on cattle.

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed by storage or disposal.

PESTICIDE STORAGE: Store in a cool, dry and secure area. Store in original sealed container away from food or feed.

PESTICIDE DISPOSAL:

Wastes resulting from the use of this product may be disposed of on-site or at an approved waste disposal facility.

CONTAINER DISPOSAL: *Non-refillable container.* Do not reuse or refill this container.

If empty: Place in trash or 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.

DISCLAIMER

[DISCLAIMER:] To the extent permitted by applicable law, Seller makes no representation or warranty, either express or implied, for results due to misuse, improper handling, or improper storage of this material. Nor does Seller assume any responsibility for injury to persons, crops, animals, soil, or property arising out of misuse, improper handling, or improper storage of this material.

OR

LIMITED WARRANTY

To the extent permitted by applicable law, Neogen Corporation makes no warranty concerning uses which extend beyond the use of the product under normal conditions in accord with the statements made on this label. To the extent by applicable law, Neogen Corporation shall not be liable for (1) any consequential, incidental, or special damages related in any way to this product or its uses, or (2) any damages related in any way to resistance to pesticides.

OR

CONDITIONS OF SALE AND LIMITATIONS OF WARRANTY AND LIABILITY

NOTICE: Read the entire Directions for Use and Conditions of Sale and Limitations of Warranty and 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.

To the extent permitted by applicable law, Manufacturer and Seller warrant that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated in the Directions for Use, subject to the inherent risks referred to above, when used in accordance with directions under normal use conditions. To the extent permitted by applicable law, this warranty does not extend to the use of this product contrary to label instructions, under abnormal conditions, or under conditions not reasonably foreseeable to or beyond the control of Seller or Manufacturer, and Buyer and User assume the risk of any such use. To the extent permitted by applicable law, MANUFACTURER AND SELLER MAKE NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTY EXCEPT AS STATED ABOVE.

To the extent permitted by applicable law, in no event shall Manufacturer or Seller be liable for any incidental, consequential, or special damages resulting from the use or handling of this product. TO THE EXTENT PERMITTED BY APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF MANUFACTURER AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES, 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 THE MANUFACTURER OR SELLER, THE REPLACEMENT OF THE PRODUCT.

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Manufacturer and Seller offer this product, and Buyer and User accept it, subject to the foregoing Conditions of Sale and Limitations of Warranty and Liability, which may not be modified except by written agreement signed by a duly authorized representative of Manufacturer.

> For non-emergency (e.g., current product information), Call: 1-800-621-8829

[Code (RR.RT.) RR.RT]

[Chem-Tech, Ltd. is a wholly-owned subsidiary of Neogen Corporation]

Alternate Brand Names:

Prozap[®] Insectrin 1% Pour-On

Optional Marketing Statements/Graphics:

Ready-To-Use

Pour-On Insecticide

[Controls] [listed insects]

Kills Lice and Flies on Beef and Lactating Dairy Cattle, and Keds on Sheep

[Also for use] in and around Horse, Beef Cattle, Dairy Cattle, Swine, Sheep, and Poultry Premises

[Contains] Permethrin

For Back-Rubber Use

For [Cattle, Sheep, Swine, Poultry] and their Premises

- <Sheep Graphic>
- <Dairy Cow Graphic>
- <Beef Cow Graphic>
- <Barn Graphic>
- <Graphics of listed insects]</pre>

Manufactured in the U.S.A.

- <American Flag Graphic>
- <Chem Tech logo>
- <Neogen logo>
- <Neogen Corporation logo>
- <Neogen flask logo>

Example Company Logos:





