

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

July 27, 2021

Susan Westra Product Registration Manager Chem Tech, Ltd. 620 Lesher Place Lansing, MI 48912

Subject: Notification per PRN 98-10 – reformatting label and label claims

Product Name: StandGuard Pour On Insecticide

EPA Registration Number: 47000-190

Application Date: 12/16/2020 Decision Number: 570277

Dear Ms. Westra:

The Agency is in receipt of your Application for Pesticide Notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Registration Division (RD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The label submitted with the application has been stamped "Notification" and will be placed in our records.

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.

If you have any questions, you may contact Hester Dingle at 703-347-8860 or via email at dingle.hester@epa.gov

Sincerely,

Jacquelyn Herrick, Product Manager 03 Invertebrate & Vertebrate Branch 1 Registration Division (7505P) Office of Pesticide Programs StandGuard Pour On Insecticide Page 1 of 7 December 16, 2020

NOTIFICATION

47000-190

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

07/27/2021

StandGuard Pour On Insecticide

For control of Horn Fly and Lice on Beef Cattle and Calves Season Long control of Lice with a single Application

Alternate Brand Name: Prozap[®] StandGuardTM Pour-On Insecticide

Squeeze N Measure Bottle (this will go on 30 fl. oz label only)
May be used with an automatic dosing system.

Treats 60 cattle at maximum application rate (on 30 fl. oz label)
Treats 120 cattle at maximum application rate (on 60 fl. oz label)
Treats 333 cattle at maximum application rate (on 5 liter label)

ACTIVE INGREDIENT:

Gamma cyhalothrin [CAS# 76703-62-3]	0.50%
INERT INGREDIENTS:	<u>99.50%</u>
TOTAL	100.0%

EPA Reg. No. 72642-5 47000-190

EPA Est. No. 70815 GA-001 47000-IA-01

KEEP OUT OF REACH OF CHILDREN CAUTION

SEE BACK PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENT

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

CONTENTS: 30 fl. oz (900ml) CONTENTS: 60 fl. oz (1.8 liter) CONTENTS: 1 gal. 41 fl. oz (5 liter)

Net Contents: 16 fl. oz (473ml) up to 55 gal. (208 L)

Elanco Animal Health
A Division of Eli Lilly & Company
2001 West Main Street
Greenfield, IN 46140
Manufactured by:
Chem-Tech, Ltd.
1006 Business Hwy 5
Pleasantville, IA 50225 U.S.A.

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

FIRST AID

If on skin or clothing:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

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.

Call a poison control center or doctor for treatment advice.

If swallowed:

Call a poison control center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow.

 Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything to an unconscious person.

Have product container label container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-800-428-4441 for emergency medical treatment information.

PRECAUTIONARY STATEMENTS HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if swallowed or absorbed through the skin. Causes moderate eye irritation. Avoid contact with skin, eyes, or clothing. Remove contaminated clothing and wash before re-use. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, or using tobacco. Wear rubber or non-permeable protective gloves when applying this product. Data indicate this product to be a contact allergenic. Do not apply this product to the face of cattle.

FIRST AID		
If on Skin or on Clothing:	 Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes. Call a poison control center or doctor for further treatment advice. 	
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 further treatment advice. 	
If Swallowed:	 Call a poison control center or doctor immediately for treatment advice or transport the patient to the nearest hospital. Have person sip a glass of water if able to swallow. 	

- Do not induce vomiting unless told to do so by the poison control center or doctor.
- Do not give anything by mouth to an unconscious person.

Have product container or label with you when calling a poison control center, 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).

ENVIRONMENTAL HAZARDS

This pesticide is extremely toxic to fish. Do not apply directly to water, or areas where surface water is present, or to intertidal areas below the mean water mark. Do not contaminate water when disposing of equipment wash waters. Apply the product only as specified on this label.

PHYSICAL AND CHEMICAL HAZARDS

Do not use or store near heat or an open flame.

DIRECTIONS FOR USE

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

READY TO USE. No dilution necessary. Do not apply to lactating or dry dairy cows. Do not apply this product to the face of beef cattle *and* calves.

Apply to:	Target Insect	Dosage
Beef cattle	Horn flies, lice	Apply product along the backline at the rate of:
		More than 600 lbs. 15 mLs (1/2 fl. oz)
		Less than 600 lbs: 10 mLs (1/3 fl. oz)

For horn flies, repeat treatment as needed, however do not apply more than once every two weeks and do not apply more than four times within any 6-month period.

SPECIAL NOTE: StandGuard Pour On Insecticide is not recommended for veal calves. StandGuard Pour On Insecticide is not effective in controlling cattle grubs. Therefore, this product can be used on cattle at any time of the year without fear of host-parasite reactions commonly associated with grub treatments.

StandGuard Pour On Insecticide should be used in an integrated pest management system which may involve repeat treatments and the use of other pest control practices. Continual exposure of horn flies to a single class of insecticide (eg. pyrethroids or organophosphates) may lead to the development of resistance to that class of insecticide. In order to reduce the possibility of horn flies developing resistance, it is important to rotate, on a seasonal basis, the class of insecticide used and/or the method of horn fly control. For advice concerning current control practices with relation to specific local conditions, consult resources in resistance management programs, your

Cooperative Agricultural Extension Agent or your Elanco Animal Health Representative at 1-800-428-4441. Neogen Representative at 1-800-477-8201.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal Notice: Shake well before use. Avoid Freezing.

Pesticide Store in original container, tightly close in a secure place. Keep out of the

Storage: reach of children and domestic animals. In case of leak or spill, contain

material and dispose as waste.

Container Non refillable container. Do not reuse or refill this container. Offer for

Disposal: recycling if available.

Clean container promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or mix tank drain for 10 seconds after the flow begins to drip. Fill the container ½ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or mix tank or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility. Triple rinse empty container. Then dispose of empty bag/container in a sanitary landfill, or, if allowed by state and local authorities, by burning, if burned, stay out of smoke.

TERMS AND CONDITIONS OF USE

If terms of the following Warranty Disclaimer, Inherent Risks of Use and limitation of Remedies are not acceptable, return unopened package at once to the seller for a full refund of purchase price paid. Otherwise, use by the buyer or any other user constitutes acceptance of the terms under Warranty Disclaimer, Inherent Risks of Use and limitation of Remedies.

WARRANTY DISCLAIMER

Elanco warrants that this product conforms to the chemical description on the label and is reasonably fit for the purposes stated on the label when used in strict accordance with the directions, subject to the inherent risks set forth below. ELANCO ANIMAL HEALTH MAKES NO OTHER EXPRESSED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER EXPRESS OR IMPLIED WARRANTY.

INHERENT RISKS OF USE

It is impossible to eliminate all risks associated with the use of this product. Lack of performance or other unintended consequences may result because of such factors as use of the product contrary to label instructions, abnormal conditions, presence of other materials, the manner of application, or other factors which are beyond the control of Elanco Animal Health or the seller. All such risks are assumed by the buyer.

LIMITATION OF REMEDIES

The exclusive remedy for losses or damages resulting from this product (including claims based on contract, negligence, strict liability, or other legal theories), shall be limited to, at Elanco Animal Health's election, one of the following:

- (1) Refund of purchase price paid by the buyer or user of the product bought, or
- (2) Replacement of the amount of product used

Elanco Animal Health shall not be liable for losses or damages resulting from the handling or use of this product unless Elanco Animal Health is promptly notified of such loss or damage in writing. To the extent permitted by law, Elanco Animal Health shall not be liable for consequential or incidental damages or losses.

The terms of the Warranty Disclaimer above and this limitation of Remedies cannot be varied by any written or verbal statements or agreements. No employee or sales agent of Elanco Animal Health or the seller is authorized to vary or exceed the terms of Warranty Disclaimer of this Limitation of Remedies in any manner.

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. To the extent permitted by applicable law, Seller does not 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 permitted 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, or 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.

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**

Optional Marketing Statements/Graphics:

Label Code (RR.NA.) RE.EN.

Treats _____cattle [head of cattle] [head] greater than 600 lbs. {Number of cattle will be calculated based on label application rate of 15 mLs (1/2 fl. oz) and package size}

Insecticide For Cattle

Treats _____cattle [head of cattle] [head] less than 600 lbs. {Number of cattle will be calculated based on label application rate of 10 mLs (1/3 fl. oz) and package size}

Ready-To-Use Pour-On

Use as a component to your integrated pest management program (IPM)

Squeeze-N-Pour Bottle (30 fl. oz. label only)

May be used with an automatic dosing system.

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

Prozap[®] is a Registered Trademark of Neogen Corporation.

Contains [With] Gamma cyhalothrin

[Manufactured][Made] in the U.S.A.

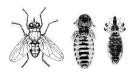
<American Flag graphic>



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<Graphics/silhouettes of listed insects>

Examples of listed insects:



<Graphics/silhouettes of listed animals>

Examples of listed animal graphics:



- <Chem-Tech logo>
- <Neogen logo>
- <Neogen Corporation logo>
- <Neogen flask logo>

Example Company Logos:







