

### UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

June 13, 2016

Ana Rodriguez-Koster Agent for Pulcra Chemicals, LLC Lewis and Harrison 122 C Street NW, Suite 505 Washington, DC 20001

Subject: Label Amendment – Addition of marketing claims against the Zika virus Product Name: SKINTEX MR III APPAREL EPA Registration Number: 86110-2 Application Date: 05/24/2016 Decision Number: 517793

Dear Ms. Rodriguez-Koster:

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, you may contact Elizabeth Fertich at 703-347-8560 or via email at fertich.elizabeth@epa.gov.

Sincerely,

Meridith M. Fry

Meridith M. Fry, Ph.D., Product Manager 4 Invertebrate & Vertebrate Branch 1 (IVB1) Registration Division (7505P) Office of Pesticide Programs

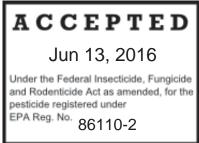
Enclosure

### Hang-tag on outside of item (removable by consumer) Text in [] is optional.

# Skintex MR III Apparel [Skintex MR III Insect Repellent Apparel] [Skintex MR III Insect Repellent Gear]

- Uses microencapsulation technology.
- This [garment] [item] has been treated with Skintex MR III encapsulated permethrin insect repellent.
- Repels [mosquitoes [that may carry West Nile Virus]] [ticks [that may carry Lyme disease]] [ants] [flies] [chiggers] [and] [or] [midges].
- Repels mosquitos that may carry (the) Zika (virus).
- Provides protection against mosquitoes that may carry (the) Zika (virus).
- Effective protection from mosquitoes that may carry (the) Zika (virus).
- Do not dry clean. Dry cleaning removes active ingredient.
- Repellency effectively remains for 25 washings for washable items: [apparel] [sleeping bag covers] [backpacks] [outdoor furniture covers] [outdoor furniture cushion covers] [netting] [ground cloths] [horse blankets] [pet bedding].
- Repellency effectively remains for 6 months of exposure to weathering for nonwashable items: [tents] [tarps] [awnings] [patio umbrella covers] [kennel covers] [stall covers].
- Do not re-treat [garment] [item] with other permethrin insect repellent products.
- To protect exposed skin, use in conjunction with an insect repellent approved for direct application to the skin.
- When washing, wash treated [garment] [item] separate from other clothing or washables.
- [Skintex MR III Apparel] [Skintex MR III Insect Repellent Apparel] [Skintex MR III Insect Repellent Gear] uses a durable carrier to bind the permethrin in to the [garment] [item]. [Skintex MR III Apparel] [Skintex MR III Insect Repellent Apparel] [Skintex MR III Insect Repellent Gear] does not change the [garment's] [item's] original hand and drape.

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



Proposed Label Dated 5/24/2016

STORAGE AND DISPOSAL

Do not contaminate water, food, or feed for storage or disposal. Disposal: Discard in trash when [clothing] [item] is worn out. Do not reuse [clothing] [item] for other purposes.

RETAIN THIS TAG FOR FUTURE REFERENCE ON PROPER HANDLING OF THIS [GARMENT] [ITEM]. THIS TAG NOT TO BE REMOVED EXCEPT BY CONSUMER.

EPA Reg. No. 86110-2 EPA Est. No. \_\_\_\_\_ Batch Code: \_\_\_\_\_



Pulcra Chemicals, LLC 474 Bryant Blvd. Rock Hill, SC 29732

### Permanent Garment/Item Label

## Skintex MR III Apparel [Skintex MR III Insect Repellent Apparel] [Skintex MR III Insect Repellent Gear]

- Do not dry clean
- Repels [mosquitoes] [ticks] [ants] [flies] [chiggers] [and] [or] [midges].
- Repels mosquitos that may carry (the) Zika (virus).
- Provides protection against mosquitoes that may carry (the) Zika (virus).
- Effective protection from mosquitoes that may carry (the) Zika (virus).
- [Repellency effectively remains for 25 washings for washable items: [apparel] [sleeping bag covers] [backpacks] [outdoor furniture covers] [outdoor furniture cushion covers] [netting] [ground cloths] [horse blankets] [pet bedding].]
- [Repellency effectively remains for 6 months of exposure to weathering for nonwashable items: [tents] [tarps] [awnings] [patio umbrella covers] [kennel covers] [stall covers].]

Active Ingredient: Permethrin 0.52% w/w EPA Reg. No. 86110-2 EPA Est. No. \_\_\_\_\_

Wash separately from other clothing. Dispose of [garment] [item] in trash. For more information, refer to hang tag.

Pulcra Chemicals, LLC cannot guarantee complete protection from insects, insect bites, or related reactions.