



U.S. ENVIRONMENTAL PROTECTION AGENCY

Office of Pesticide Programs
Registration Division (7505P)
1200 Pennsylvania Ave., N.W.
Washington, D.C. 20460

EPA Reg. Number:

83399-15

Date of Issuance:

08/20/20

NOTICE OF PESTICIDE:

Registration
 Reregistration
(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

C780.0 (Vectra Cat Plus Tick)

Name and Address of Registrant (include ZIP Code):

Katy Hernandez
Regulatory Specialist
Ceva Animal Health, LLC
8735 Rosehill Road
Lenexa, KS 66215

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A). You must comply with the following conditions:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product under FIFRA when the Agency requires all registrants of similar products to submit such data.

Signature of Approving Official:

Sincerely,

Gene Benbow, Product Manager 7
Invertebrate & Vertebrate Branch 3
Registration Division (7505P)
Office of Pesticide Programs

Date:

08/20/20

2. Consistent with the guidance on [Pet Spot-On Enhanced Reporting Implementation \(updated Aug. 2019\)](#), the Agency has reviewed your request to remove the two-year registration expiration date and has found your company to be in compliance with the terms and conditions for the subject product. The last stamped accepted label dated 08/30/18 contains appropriate mitigation measures. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 3. hereafter, and concluded that the use of the standardized templates for enhanced reporting for this product will considerably improve pharmacovigilance and thus the continued safety of this product. Therefore, the Agency is removing the two-year registration expiration date for this product. The product remains subject to all other previously required conditions of registration, including the submission of enhanced incident reports and sales information as stated in an Agency letter dated 09/08/15 and amended below to require continued use of the standardized templates and submission of the data through the Agency's CDX pet spot on portal.
3. The Agency has reviewed your request to change the terms of your registration from quarterly to annual submission of enhanced incident and sales reports using EPA's standardized templates. Based on an initial screening of sample enhanced reports, the sample submission was determined to be adequate and the templates were successfully used. Therefore, the condition of quarterly submission of enhanced incident and sales reports is hereby amended to annual submission with continued use of these standardized templates. You must submit enhanced incident and sales reports for this product to the Agency every 12 months from the date the product is first released for shipment, or from the end date in the last quarterly enhanced reporting submission. The initial released-for-shipment date must be provided to the Product Manager, once known. The enhanced reporting submission should be addressed to the Product Manager's attention and must use the standardized, electronic templates available on the EPA website through the following links: [Enhanced Incident Reporting Template](#), [Sales Reporting Template](#). Submissions must be received by the Agency through CDX pet spot on portal no later than 60 days following the completion of the 12-month period. If the product is not marketed or sold, you must submit to the Product Manager a letter to this effect every 12 months in lieu of the enhanced incident and sales reports. Please follow appropriate procedures and flag any Confidential Business Information as such.
4. You are required to comply with the data requirements described in the DCI identified below:
 - a. Dinotefuran GDCI-044312-1147
 - a. Fipronil GDCI-129121-1305
 - b. Pyriproxifen GDCI-129032-1299

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division: <http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

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 fail to satisfy these terms and conditions, EPA will consider appropriate regulatory action including, among other things, cancellation under FIFRA section 6(e).

Please note that the record for this product currently contains the following CSF:

- Basic CSF dated 06/12/19

If you have any questions, please contact Gene Benbow by phone at 703-347-0235, or via email at Benbow.Gene@epa.gov.