



U.S. ENVIRONMENTAL PROTECTION AGENCY

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

EPA Reg. Number:

11556-142

Date of Issuance:

11/2/23

NOTICE OF PESTICIDE:

☒ Registration
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

K9 Advantix II Medium Dog

Name and Address of Registrant (include ZIP Code):

J. Todd Frank
Senior Regulatory Affairs Consultant
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140

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:

Elizabeth Fertich, Product Manager 04
Invertebrate-Vertebrate Branch 1
Registration Division (7505P)
Office of Pesticide Programs

Date:

11/2/23

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 07/20/2021 contains appropriate mitigation measures. Further, the Agency has reviewed a sample of enhanced reporting using EPA's standardized templates, as described in Condition 2 of the letter dated 03/31/2021 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 amendment letter dated 01/19/2011 and amended in the letter dated 03/31/2021 to require continued use of the standardized templates.
3. Please note that the product is still subject to all other previously required conditions of registration. Your company is required to adhere to the spot-on label mitigation information as stated in the amendment letter dated 01/19/2011 and to submit annual reports of enhanced incident and sales using EPA's standardized templates as stated in the letter dated 03/31/2021.
4. You are required to comply with the data requirements described in the DCI Order identified below:
 - a. Imidacloprid GDCI-129099-951
 - b. Imidacloprid GDCI-129099-1516
 - c. Pyriproxyfen GDCI-129032-1299

You must comply with all of the data requirements within the established deadlines. If you have questions about the Generic DCI Order listed above, you may contact the Chemical Review Manager in the Pesticide Reevaluation Division:

<http://iaspub.epa.gov/apex/pesticides/f?p=chemicalsearch:1>

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). A stamped copy of the label is enclosed for your records.

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

- Basic CSF dated 11/21/2019

If you have any questions, please contact Beth Fertich by phone at 202-566-2674, or via email at Fertich.elizabeth@epa.gov.