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# Pesticide Update

EPA's Office of Chemical Safety and Pollution Prevention

## EPA Requires Additional Mitigation Measures for Seresto Pet Collars

Today, the U.S. Environmental Protection Agency (EPA) is requiring the implementation of additional measures for Seresto pet collars. The new measures will alert veterinarians and consumers of potential risks and provide more information about how to prevent and report adverse reactions from Seresto collars. The new measures will also improve the quality of adverse incident data reported to EPA to aid in the continued review of this product.

EPA conducted an extensive analysis of incident and other data, with the assistance of the Food and Drug Administration (FDA). From this analysis, EPA concluded that these collars continue to meet EPA's standard under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). However, with the implementation of today's mitigations, EPA expects to receive higher quality data in the coming years. EPA has approved Seresto collar registrations for five years to allow for the continued evaluation of incident reports, which could result in further regulatory action in the future.

### Background

Seresto collars offer flea and tick prevention for dogs and cats, as well as lice control for dogs. This use is important because fleas and ticks are considered significant public health pests that can transmit many serious diseases, such as Lyme disease and Rocky Mountain spotted fever, to pets and humans.

Under FIFRA, EPA is required to consider the benefits, as well as the risks, of the use of a pesticide. In addition to its protection against several serious public health pests, Seresto works for up to 8 months per collar, is available without the need for a prescription, and is relatively easy to apply compared to other flea and tick products. For cats and dogs, there are very few flea and tick collar alternatives that can be used for such a prolonged time.

Over the past several years, EPA has been improving its method for considering pet product-incidents, such as those reported for Seresto collars, in the pesticide registration and re-evaluation process. As part of this effort, and due to the number of Seresto-related incidents reported to EPA, the Agency began an in-depth review of the incidents of Seresto collars in 2021.

EPA has reviewed an extensive set of data it required Elanco, the current registrant of Seresto collars, to submit and reviewed the many incidents reported to EPA's Incident Data System to determine whether the collars may contribute to an elevated number of pet-related incidents. Throughout the review process, EPA consulted with FDA, which regulates similar products for cats and dogs, including flea and tick products that are ingested. EPA used information gathered during this review process to make its determination about the product.

### **EPA's Risk Findings and New Measures to Reduce Risk**

EPA's scientific review of Seresto-related incident reports identified the need for more detailed incident reporting and public outreach. EPA analyzed all incidents that reported death for Seresto. This included 1,400 deaths reported to EPA from 2016-2020, which represent 2 percent of all Seresto incidents reported for these years. In many of the death-related incidents, critical details of the incident were often missing, preventing the Agency from determining the cause of the death.

The only reported deaths that were found to be "probably" or "definitely" related to Seresto product use were associated with mechanical strangulation or trauma caused by the collar, often associated with a failure of the release mechanism.

For all other deaths, EPA did not identify cases with a probable or definite association between collar use and death, often due to other factors impacting the animal, such as an existing medical condition. In addition, the rate of deaths reported for Seresto was similar to that for other pet products reviewed.

EPA also analyzed all non-lethal incidents, such as neurological symptoms. In some incidents with moderate or severe clinical sign removal of the collar seemed to alleviate symptoms and/or reapplication of the collar coincided with a reoccurrence of symptoms. Based on these findings, Elanco, the registrant of Seresto, has agreed to implement the following measures:

- **To alert veterinarians and consumers of potential risks**, the terms of continued registration require Elanco to include label warnings on Seresto products that describe common adverse effects that have been reported, along with instructions to remove the collar if those effects occur and instructions on how to report the incident. Elanco also must develop an outreach program to more effectively communicate with veterinarians and the public on the risks of using the product and other similar pesticides on pets.
- **To improve the quality of data reported when receiving reported incidents from consumers**, Elanco must pursue additional information to the greatest

extent possible to ensure that complete details of each event are captured. This information includes whether the pet had any pre-existing conditions or previous history of the reported condition. The Seresto collar registration has also been split into two registrations, one for cats and one for dogs, to make comparison of incident data across products easier in the future. Elanco must report incident and sales data to EPA on an annual basis.

- **To reduce the risk of strangulation**, Elanco must evaluate potential changes to the emergency release mechanism of Seresto collars to prevent death by strangulation or choking. The company must submit a report detailing the data and analysis collected and performed in pursuit of this effort within one year. Based on this evaluation, EPA may require a modified release mechanism for the Seresto collar.
- **To allow for the continued evaluation of reported incidents**, EPA has limited its current approval of Seresto collar registrations to five years. EPA will continue to evaluate Seresto incident data over that period.

Elanco must implement the new registration requirements by the next printing of Seresto pet collar labels, which must occur in the next 12 months. To learn more, read [EPA's decision document](#), [EPA's scientific review document](#), or [EPA's frequent Q&As](#).

### **EPA Denies Petition to Cancel and Suspend Seresto Pet Collars**

Based on the Agency's scientific review of incident data, EPA is denying a [2021 petition](#) from the Center for Biological Diversity (CBD) that requests the cancellation of Seresto collars and the suspension of Seresto collars pending cancellation. EPA received and reviewed more than 5,400 comments on the petition. Read [EPA's full response to the petition and public comments](#).

### **EPA and FDA Continue to Discuss Pet Product Jurisdiction**

EPA and FDA jointly released a whitepaper in February 2023 that outlines an updated approach to clarify regulatory oversight of certain animal products to better align with each agency's expertise. One aspect of that proposed modernized approach includes a process for transferring oversight of flea and tick pet products, such as Seresto collars, from EPA to FDA.

The agencies started discussing a modernized approach to product oversight years before the current review of Seresto collars. However, EPA's review of Seresto pet-related incident reports has highlighted that, as compared to FDA, EPA has less expertise and resources (staff, infrastructure, and funding) to evaluate animal safety and conduct ongoing monitoring of marketed products. Read the [whitepaper](#) to learn more.

### **Safety Tips for Using Pet Collars**

EPA encourages pet owners to discuss with their veterinarian when flea and tick control is needed for their pets and which type of control product they should use. Pet owners should read the entire label before using the recommended product and follow all directions carefully, as well as monitor the pet after treatment.

EPA understands and shares the public's concerns about reported incidents with Seresto pet collars. Pets are part of the family in many American households and the

Agency is committed to following the science and the law as we work on this issue and pursue our mission. [Learn more](#) about how to use these products safely.

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