Is the Seresto flea and tick collar safe? How does it compare with similar products on the market, in terms of safety for pets and humans?

Response
In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA only registers a pesticide when it determines that it will not cause unreasonable adverse effects on humans or the environment, while taking into account the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA, EPA is charged with balancing the risks posed by the use of a pesticide against its benefits. EPA must determine if the benefits in light of its use outweigh the risks in order for the EPA to register a pesticide.

EPA evaluates pesticide products intended for treatment of pets based on the directions for use on the product label, which must be followed under federal law. Evaluations for pet products like shampoos, collars and spot-ons also rely upon data on (1) companion animal safety, (2) efficacy of the pesticide, and (3) safety for humans who may be exposed as a result of product use. These assessments help ensure that people and pets are protected when pet pesticide treatments are used as directed. EPA registered the Seresto collars only after determining that they met the FIFRA standard for registration, that the label instructions were protective of children and adults who came into contact with the treated pet, and that the collars were effective against fleas and ticks.

EPA completed its re-evaluation decision for flumethrin, one of the two active ingredients in the Seresto collars, in 2020. EPA did not identify any unreasonable adverse effects to human health or the environment for flumethrin in its re-evaluation. Imidicloprid's re-evaluation is expected to be completed later in 2021, and at this point EPA has also not identified any unreasonable adverse effects to human health or the environment from imidacloprid's use in the Seresto collars. EPA has received and evaluated numerous pet incidents on both flumethrin and imidacloprid; however, a comparative assessment of pet incidents across registered pet products based on usage data is not available.

Therefore, at this time, EPA cannot conclude whether Seresto collars, based on the number sold, have more or fewer severe pet incidents than its market alternatives. Both flumethrin and imidacloprid re-evaluations are part of EPA's registration review program conducted pursuant to FIFRA section 3(g). During registration review, the Agency looks at each active ingredient to ensure that it continues to meet the legal standard for registration under FIFRA. During registration review, the agency looks at each active ingredient to ensure that it continues to meet the legal standard for registration under FIFRA.

Records released by the EPA show the incident data system maintained by its pesticide office contains some 75,000 recorded incidents involving Seresto products. Has the EPA documented a similar number of incidents regarding other flea and tick collars on the market?

Response
Comparing incidents across products is not a simple task. Other variables (e.g., sales) must be taken into consideration before such a comparison can be made. At the present time, EPA is still gathering information. The agency queried the ~~IDS~~Incident Data System (IDS) database for pet products ~~in IDS~~ with incidents of pet death or injury and human death or injury, including flea and tick collars and flea and tick spot-on treatments.

Please understand that EPA does not yet know which products may (or may not be) be riskier to pets because we don't know how much of each product is purchased/used in the marketplace.

EPA receives information from a variety of sources about incidents where adverse effects appear to have been caused by pesticides. EPA's High-Priority Incidents Screening Process (HPISP) – also managed within OPP – is intended to ensure that potential high-priority incidents are identified, screened, and disseminated in a timely manner. Once a potential high-priority incident is identified, it is reviewed by OPP's Incident Screening Team (IST) and placed in categories ranging from Tier 1 – Tier 3, signifying the level of concern and priority for further attention and review.

Has the EPA investigated incidents involving Seresto collars? Has it established that Seresto collars caused adverse effects in pets or humans?

Response
EPA is in the early stages of investigating pet incidents involving Seresto collars. Investigations like this can take a substantial amount of time. EPA is currently requesting detailed information about the pet incidents as well as other information about the registered pesticide product involved.

With regard to human health, EPA's risk assessment indicates there are no systemic human health risks from use of Seresto collars. Human health incidents have been reported that indicate there is a low likelihood that someone will experience an adverse effect from using the Seresto collar. In recent years, from January 1, 2016, to August 27, 2019, there were 252 human health incidents reported to the Main Incident Data System that involved the Seresto collar. Of these 252 incidents, 19 were classified as major severity and 233 were classified as moderate severity. In our Aggregate Incident Data System (part of the of the larger IDS), there were 374 human health incidents reported involving the Seresto collar. These incidents were classified as minor severity.

Of the 19 major severity incidents that were further reviewed, the symptoms most often reported were dermal (n=8) and neurological (n=7). However, a patient could exhibit multiple symptoms. Dermal symptoms reported include rash, redness, skin lesions, hives, and pruritus. Neurological symptoms reported include headaches, numbness, tingling and one person reported seizures.
The total number of human health incidents reported to IDS for Seresto, from 2013 to 2018, appears to be increasing over time. However, the production of flumethrin has also increased substantially since the first product containing flumethrin was registered in 2012. For additional information on Seresto human health incidents, see the [HYPERLINK "https://www.regulations.gov/document/EPA-HQ-OPP-2016-0031-0036" \t "_blank"]. EPA will continue to monitor the human health incident data and if a concern is triggered, additional analysis will be conducted.

Has the EPA done enough to inform the public about any potential risk associated with Seresto products?

Response
Before taking action against a registered pesticide product, EPA first investigates whether there is a cause-and-effect relationship between the pesticide and the alleged adverse reactions. FIFRA requires registrants to report factual information about unreasonable adverse effects but does not require registrants to investigate reported incidents.

Accordingly, EPA is looking into the incident data and evaluating the information and existing label. Our goal is to understand the situation and determine if label or regulatory changes are necessary.

EPA understands this is a critical issue. The agency's immediate advice to pet owners is to talk with their veterinarian before using any pet insecticide to find out what the vet recommends, read the label, and follow instructions on safe use of the product, be alert for any unexpected reaction, and report adverse reactions with as much detail as possible.

Background

EPA collects and evaluates the data from the IDS and identifies potential patterns with respect to the extent and severity of the health effects due to pesticides exposure. While IDS reports are broad in scope and can in some cases contain detailed information, the system does not consistently capture details about incident events, such as exposure circumstances or medical outcome.

Some incidents are well investigated and reported in such a way as to establish a strong link between the adverse effect and the exposure. On the other hand, many other reports do not include enough facts to clearly demonstrate causation. Many of the reports are anecdotal, with no indication of whether the user followed label use instructions or used a product appropriate for the pet type and size. Generally, however, there is no process for verifying the information in reports.

Five levels of severity rankings for incidents are specified in 40 CFR § 159.184(c)(5), ranging from death to symptoms being unknown, unspecified, or alleged to be of a delayed or chronic nature that may appear in the future. Symptom information is sometimes included in the narrative portion of the incident, but generally only for the higher-severity rankings for humans.

This information is usually not validated or confirmed by a healthcare professional and represents anecdotal reports or allegations only, unless otherwise stated in the report. IDS reports can sometimes also include narrative information on exposure scenario and hazard information, but generally only for the more severe human incidents.

EPA does not routinely investigate or follow up on incidents, but may do so on a case-by-case basis and/or monitor the situation. Data submitters, likewise, are not required to follow up or investigate incidents under section 6(a)(2); their obligation is limited to reporting these incidents to the Agency. Incident information is generally used as part of the agency's pesticide re-evaluation process, conducted once every 15 years, and provides post-marketing feedback following initial registration of the product. During registration review, EPA evaluates information from all kinds of sources, including adverse effect data reported to IDS.