

BEFORE THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

**PETITION TO CANCEL REGISTRATION OF PNR1427
INSECTICIDE
(BRAND NAME SERESTO)**

EPA REGISTRATION NO. 11556-155 (REGISTERED MAR. 16, 2012)

Summary by Full Reg. #

Full Product Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439

Summary by 11 Character Reg. #

11 Char Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD	DE
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439	0

Exposure Severity Code	Description
DA	Domestic Animal - Fatality
DB	Domestic Animal - Major
DC	Domestic Animal - Moderate
DCDE	Domestic Animal - Moderate, Minor and Unknown
DD	Domestic Animal - Minor
DE	Domestic Animal - Unspecified
HD	Human - Minor
HE	Human - Unspecified
ONT	Other Nontarget

Reproduction from Aggregate Incident Summary Report for Seresto (June 16, 2020)

**SUBMITTED BY: CENTER FOR BIOLOGICAL DIVERSITY
APRIL 8, 2021**



Via Electronic and Certified Mail

April 8, 2021

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Re: Petition to Cancel Registration of PNR1427 (Brand Name Seresto) under the Federal Insecticide, Fungicide, and Rodenticide Act; Reg. No. 11556-155

Dear Administrator Regan, Acting Assistant Administrator Freedhoff, and Acting Director Messina,

Pursuant to the right to petition the government provided in the First Amendment to the U.S. Constitution¹ and the Administrative Procedure Act,² the Center for Biological Diversity—on behalf of itself and its 1.7 million members and supporters and their beloved companion

¹ See U.S. Const. Amend. I; see also *United Mine Workers v. Ill. State Bar Ass'n*, 389 U.S. 217, 222 (1967) (explaining that the right to “petition for a redress of grievances [is] among the most precious of the liberties safeguarded by the Bill of Rights”).

² See 5 U.S.C. § 553(e).

animals—hereby petitions the U.S. Environmental Protection Agency (EPA) to cancel its registration of insecticide product PNR1427, more commonly known by its brand name Seresto; Registration No. 11556-155. This product, which is registered under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use on adult dogs and puppies and on adult cats and kittens for the purpose of flea and tick treatment, poses a severe risk to the animals on which it is used and to human health. According to a recent aggregate incident summary report, since this product was introduced in 2012, EPA has received over 75,000 adverse incident reports, including at least 1,698 reports linking the use of this product to pet deaths and at least 700 involving human harm.³ Because these harms amount to significant unreasonable adverse effects under FIFRA, cancellation of this product is not only warranted but essential for protecting public health, consumers, imperiled wildlife, and companion animals. In the interim pending complete cancellation of the product, EPA should take additional steps to suspend Seresto’s registration.

I. PETITIONER

The Center for Biological Diversity (Center) is a non-profit environmental organization dedicated to the protection of native species and their habitats through science, policy, and environmental law. The Center has more than 1.7 million members and online activists dedicated to the protection and restoration of endangered species and wild places. For over 30 years, the Center has worked to protect imperiled plants and wildlife, open space, air and water quality, and overall quality of life. The Center’s Environmental Health Program and Pesticides Reduction Campaign aim to improve pesticide regulation in order to reduce the harms of pesticides to the environment, human populations, and threatened and endangered species.

II. ACTION REQUESTED

Because of the dangers posed by Seresto to threatened and endangered species, companion animals, and people, the Center hereby petitions EPA to:

- (1) Cancel registration number 11556-155 pursuant to FIFRA § 136d(b); and
- (2) Suspend Seresto’s registration pending completion of cancellation proceedings pursuant to FIFRA § 136d(c)(1).

III. LEGAL AND FACTUAL BASIS FOR PETITION

a. Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA, 7 U.S.C. § 136 *et seq.*, provides the framework for the federal regulation of pesticide distribution, sale, and use. The law is intended to prohibit the use of pesticides that cause unreasonable adverse effects on the environment.⁴ The Administrator of the EPA is responsible for carrying out the mandates of the Act. Pursuant to this obligation, the Administrator may limit the use of certain pesticides to prevent unreasonable adverse effects.⁵

³ See Exhibit A.

⁴ 7 U.S.C. § 136a(a).

⁵ *Id.* §§ 136a(c)(5)-(6).

FIFRA defines a “pesticide” as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest[.]”⁶ When a pesticide is sold or distributed, it is generally referred to as a “pesticide product.” FIFRA generally prohibits the sale or distribution of a pesticide product unless it has first been “registered” under FIFRA Section 3 by EPA.⁷

EPA “issues a license, referred to as a ‘registration,’ for each specific pesticide product allowed to be marketed; the registration approves sale of a product with a specific formulation, in a specific type of package, and with specific labeling limiting application to specific uses.”⁸ In order for the EPA to evaluate an application for pesticide registration, an application must “describ[e] how the pesticide will be used, the claims made of its benefits, the ingredients, and a description of all tests and studies done and the results thereof, concerning the product’s health, safety, and environmental effects.”⁹

FIFRA Section 3(c)(5), “Approval of Registration,” provides that EPA can register a pesticide only if the agency determines that:

- (A) its composition is such as to warrant the proposed claims for it;
- (B) its labeling and other material required to be submitted comply with the requirements of this subchapter;
- (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.¹⁰

The term “unreasonable adverse effects on the environment” is further defined as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”¹¹ When EPA applies this risk-benefit balancing test, it may only register a pesticide if it finds that the risks associated with the use of a pesticide are justified by the benefits of such use.¹² In order to remain registered, a pesticide must continue to meet this risk-benefit standard, which EPA may reassess at any time.¹³

⁶ *Id.* § 136(u).

⁷ *Id.* § 136a(a).

⁸ 69 Fed. Reg. 47,732, 47,733 (Aug. 5, 2004).

⁹ *Pollinator Stewardship Council v. EPA*, 806 F.3d 520, 523 (9th Cir. 2015).

¹⁰ 7 U.S.C. § 136a(c)(5).

¹¹ *Id.* § 136(bb); *see also id.* §§ 136a(a), 136a(c)(5)(c).

¹² *Washington Toxics Coal. v. Env'tl. Prot. Agency*, 413 F.3d 1024, 1032 (9th Cir. 2005) (explaining that FIFRA uses a “cost-benefit analysis to ensure that there is no unreasonable risk created for people or the environment from a pesticide.”).

¹³ *Id.* at 1033 (The “EPA retains discretion to alter the registration of pesticides for reasons that include environmental concerns.” (citing 7 U.S.C. §§ 136d(c)(1)-(2), 136(l)); *see also Nat. Res. Defense Council v. Johnson*, 422 F. Supp. 2d 105, 109 (D.D.C. 2006) (“The EPA uses numerous types of review processes to periodically reevaluate a registered pesticide’s risks and benefits.” (citing *Beyond Pesticides/Nat'l Coal. Against the Misuse of Pesticides v. Whitman*, 294 F. Supp. 2d 1, 3 (D.D.C. 2003))).

After an applicant submits sufficient data for pesticide registration, EPA may grant “unconditional registration” under § 136a(c)(5). “Unconditional registration necessarily requires sufficient data to evaluate the environmental risks.”¹⁴ If an applicant has not submitted sufficient data to support unconditional registration, EPA may conditionally register the pesticide under certain limited circumstances.¹⁵

A pesticide product remains registered until EPA or the registrant cancels it pursuant to FIFRA Section 6.¹⁶ Under Section 6, if it appears to EPA that a registered pesticide has “unreasonable adverse effects on the environment” when “used in accordance with widespread and commonly recognized practice,” then EPA may undertake cancellation proceedings.¹⁷ Any interested person may petition EPA to cancel a registered pesticide product.¹⁸ EPA is required by the Administrative Procedure Act to resolve the petition “within a reasonable time.”¹⁹

b. Seresto Product Registration

EPA registered insecticide product PNR1427, more commonly known by its brand name Seresto, for use on March 16, 2012. The product was unconditionally registered in accordance with FIFRA Section 3(c)(5) for use on adult cats and kittens above 10 weeks of age, as well as adult dogs and puppies above 7 weeks of age.²⁰ The product, which is dispensed in the form of a pet collar fastened around the neck, is intended to repel and kill ticks for 8 months, including deer ticks, blacklegged ticks, American dog ticks, brown dog ticks, Lone Star ticks, fleas, flea larvae, and lice.²¹ The registration number for this product is 11556-155.

c. Seresto Active Ingredients

Seresto is made up of a plastic band impregnated with insecticides that are released over time to coat the animal’s fur.²² It contains as active ingredients the neonicotinoid imidacloprid (10%) and the pyrethroid flumethrin (4.5%).²³ Understanding each of these ingredients, alone and in combination, is important for understanding the toxicity and risks that their use in Seresto presents to dogs, cats, humans, and exposed threatened and endangered species.

¹⁴ *Pollinator Stewardship Council*, 806 F.3d at 523; *see also* 7 U.S.C. § 136a(c)(5) (listing the findings required for unconditional registration).

¹⁵ *See* 7 U.S.C. § 136a(c)(7).

¹⁶ *Id.* § 136d.

¹⁷ *Id.* § 136d(b).

¹⁸ 40 C.F.R. § 154.10; *Washington Toxics Coal. v. EPA*, 413 F.3d at 1033.

¹⁹ 5 U.S.C § 555(b).

²⁰ EPA, Notice of Pesticide Registration, Reg. No. 11556-155 (2012), https://www3.epa.gov/pesticides/chem_search/ppls/011556-00155-20120316.pdf.

²¹ *Id.*

²² *See* EPA, Weighing Risks to Children from Dogs Wearing Seresto Collars (2016), https://www.epa.gov/sites/production/files/2017-01/documents/weighing_risks_to_children_from_dogs_wearing_seresto-tm_collars.pdf.

²³ *Id.*

i. Imidacloprid

Imidacloprid is a neonicotinoid pesticide. Neonicotinoids are understood to produce neuronal toxicities in insects via a common mechanism of action, that being the disruption of acetylcholine/nAChR signaling. According to EPA, “[i]midacloprid [is] in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) along with clothianidin, thiamethoxam and dinotefuran. Its mode of action on target insects involves out-competing the neurotransmitter, acetylcholine for available binding sites on the nAChRs. At low concentrations, neonicotinoids cause excessive nervous stimulation and at high concentrations, insect paralysis and death will occur.”²⁴

Neonicotinoids like imidacloprid are most well-known for the harms they cause to pollinator species, including threatened and endangered pollinators like the Poweshiek skipperling (endangered), Dakota skipper (threatened), and rusty patched bumble bee (endangered).²⁵ These species are often exposed to neonicotinoids through a broad array of non-intended exposure pathways, including through agricultural and household uses of the pesticide. Laboratory studies have demonstrated that the neonicotinoid imidacloprid is, for example, “highly toxic to bumble bees.”²⁶ Even sub-lethal exposure in bumble bees results in “reduced food consumption, reproduction, worker survival rates, and foraging activity.”²⁷ Neonicotinoids are also toxic to solitary native bees such as blue orchard and alfalfa leafcutter bees, with direct effects including increased mortality rate with direct contact,²⁸ as well as other native pollinators.²⁹

Studies also confirm that small doses of imidacloprid can negatively affected the ability of songbirds to navigate.³⁰ This is especially concerning for birds that may eat an imidacloprid-treated seed or other coated product, since consumption can cause direct mortality as well as sub-

²⁴ EPA, Preliminary Terrestrial Risk Assessment to Support the Registration Review of Imidacloprid, at 11-12 (2017), <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1256>.

²⁵ 79 Fed. Reg. 63,672, 63,737 (Oct. 24, 2014); Szymanski, J., et al., *Rusty Patched Bumble Bee (Bombus affinis) Species Status Assessment* (2016), <https://ecos.fws.gov/ServCat/DownloadFile/120109>.

²⁶ Jennifer Hopwood, et al., The Xerces Soc’y for Invertebrate Conservation, *Are Neonicotinoids Killing Bees?*, at vi (2012), http://cues.cfans.umn.edu/old/pollinators/pdf-pesticides/Are-Neonicotinoids-Killing-Bees_Xerces-Society.pdf; see also Barraud, A., et al., *The Impact of Pollen Quality on the Sensitivity of Bumblebees to Pesticides*, 105 *Acta Oecologica* 103552 (2020); Whitehorn, P. R., et al., *Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production*, 336 *Science* 351–352 (2012); Feltham, H., Park, K., Goulson, D., *Field Realistic Doses of Pesticide Imidacloprid Reduce Bumblebee Pollen Foraging Efficiency*, 23 *Ecotoxicology* 317–323 (2014).

²⁷ Jennifer Hopwood, et al., The Xerces Soc’y for Invertebrate Conservation, *Are Neonicotinoids Killing Bees?*, at vi (2012), http://cues.cfans.umn.edu/old/pollinators/pdf-pesticides/Are-Neonicotinoids-Killing-Bees_Xerces-Society.pdf.

²⁸ *Id.* at 15.

²⁹ Christoph Sandrock et.al., *Sublethal Neonicotinoid Insecticide Exposure Reduces Solitary Bee Reproductive Success*, 16 *Agricultural & Forest Entomology* 119 (2014), https://beyondpesticides.org/assets/media/documents/pollinators/documents/Sandrocketal2013_Sublethalneonicexposurereducessolitarybeereproductivesuccess_AgricForEnt.pdf.

³⁰ Margaret Eng, et al., *Imidacloprid and Chlorpyrifos Insecticides Impair Migratory Ability in a Seed-Eating Songbird*, 7 *Scientific Reports* 15176, DOI:10.1038/s41598-017-15446-x (2017).

lethal effects, with a leading concern being harm to reproduction.³¹ According to a 2017 EPA Preliminary Terrestrial Risk Assessment of imidacloprid, a large bird (> 1kg) would only need to eat *one* imidacloprid-treated potato seed to nearly exceed the risk of concern for acute harm and possible death.³²

While most frequently associated with agricultural crop uses, imidacloprid is also the most common neonicotinoid used in household products, including flea and tick treatments such as Seresto. According to public records obtained from EPA by the Natural Resources Defense Council (NRDC), over the past decade there have been at least 1,630 recorded imidacloprid poisoning incidents in humans that are attributable to these uses.³³ The reported symptoms include skin rash, muscle tremor, difficulty breathing, vomiting, wheezing, lock jaw, memory loss, and renal failure.³⁴

This follows closely with EPA's own findings about the health risks of imidacloprid to mammals—the class of vertebrates that includes humans, cats, and dogs. “The nervous system is the primary target organ of imidacloprid.”³⁵ In early human health risk assessments of imidacloprid, EPA scientists noted a number of toxic effects in oral studies of rats and mice (surrogates for humans) from dietary exposure to imidacloprid.³⁶ These effects included decreased movement and body weights, tremors, thyroid effects, retinal atrophy, and brain effects.³⁷

Hitting even closer to concerns related to the use of imidacloprid as an active ingredient in Seresto, in a 2017 risk assessment EPA noted that dogs were more sensitive to imidacloprid than the standard test animals (*e.g.*, rats and mice), even at doses seven times lower than the level of

³¹ See Ertl, H. et al., *Potential Impact of Neonicotinoid Use on Northern bobwhite (Colinus virginianus) in Texas: A Historical Analysis*, PLoS ONE 13:e0191100 (2018), <https://doi.org/10.1371/journal.pone.0191100>; Millott et al., *Field Evidence of Bird Poisonings by Imidacloprid-Treated Seeds: A Review of Incidents Reported by the French SAGIR Network from 1995 to 2014*, Environ Sci Pollut Res, DOI 10.1007/s11356-016-8272y (2016); Lopez-Antia et al., *Risk Assessment of Pesticide Seed Treatment for Farmland Birds Using Refined Field Data*, 136 Environmental Research 97 (2015).

³² EPA, Preliminary Terrestrial Risk Assessment to Support the Registration Review of Imidacloprid, (2017), <https://www.regulations.gov/document/EPA-HQ-OPP-2008-0844-1256>.

³³ EPA, FOIAOnline, Request No. EPA-HQ-2019-004044 (2019), <https://foiaonline.gov/foiaonline/action/public/submissionDetails?trackingNumber=EPA-HQ-2019-004044&type=request>; see also NRDC, *Neonicotinoid Pesticides: Potential Risks to Brain and Sperm* (Jan. 6, 2021), [https://www.nrdc.org/experts/jennifer-sass/neonic-pesticides-potential-risks-brain-and-sperm#:~:text=Imidacloprid%20is%20the%20most%20common,by%20EPA%20\(see%20here\)](https://www.nrdc.org/experts/jennifer-sass/neonic-pesticides-potential-risks-brain-and-sperm#:~:text=Imidacloprid%20is%20the%20most%20common,by%20EPA%20(see%20here)).

³⁴ *Id.*

³⁵ EPA, Preliminary Health Effects Division Risk Assessment for Imidacloprid, at 13 (2003), https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-129099_4-Mar-03_111.pdf.

³⁶ *Id.*

³⁷ *Id.*

toxicity for mice and rats.³⁸ The neurotoxic effects consisted of severe tremors and trembling at mid- to high-doses.³⁹ Acute oral toxicity studies in dogs were not further discussed.

The studies reviewed by EPA in generating these human health assessments were based on industry-generated studies and did not include the many published, peer-reviewed studies that have shown toxic effects in mammals from exposure to imidacloprid. The state of California, however, also conducted a human health risk assessment for imidacloprid that took a deeper look at the science around harms to health related to imidacloprid exposure through dietary and drinking water routes. That assessment, conducted by the California Environmental Protection Agency, emphasized that acute oral exposure of rats and mice to imidacloprid produced clinical signs that are similar to nicotine intoxication, including tremors, decreased coordination and mobility, spasms, respiratory difficulties, and lethargy.⁴⁰ Even further, in longer term toxicity studies (subchronic and chronic), rats exposed to imidacloprid experienced body weight reductions.⁴¹ In the subchronic studies, the liver was the principal target organ with necrosis or toxic injury occurring in the liver.⁴² Additional effects noted in these studies included degeneration of the testes, atrophy of the thyroid gland and bone marrow, and effects on the thymus.⁴³ In the chronic toxicity studies, reduction in body weight was a common toxic effect along with thyroid lesions in rats.⁴⁴

In the two dog oral studies reviewed by California toxicologists, toxic effects from exposure to imidacloprid were observed in the liver, testes, thyroid, bone marrow, and thymus.⁴⁵ Severe tremors were also reported in these studies.⁴⁶ No cat-specific studies were analyzed.

For humans, the California assessment also specifically identified pregnant women or women of childbearing age as a high-risk group, finding that: “[e]vidence from the developmental neurotoxicity study in rats, suggested that imidacloprid may affect the neural development. The estimated NOEL for decreases in dimensions of brain structures was 5.5 mg/kg/day. This ENEL might be pertinent to acute exposures of women of childbearing age to protect for fetal exposure. Based on the ENEL of 5.5 mg/kg/day, the acute dietary MOEs for females 13-49 yrs. would be 366 at the 95th and 239 at 99th percentiles, which exceed the general health protective benchmark MOE of 100.”⁴⁷ Further, and more generally, the assessment identified that:

Several human neuropathologies have been linked to genetic alterations of nAChRs genes or autoimmune disruption of the receptor proteins, including congenital

³⁸ EPA, Imidacloprid: Human Health Draft Risk Assessment for Registration Review, at 11-12 (2017), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0844-1235>.

³⁹ *Id.* at 14.

⁴⁰ Cal. EPA, Imidacloprid: Risk Characterization Document; Dietary and Drinking Water Exposure, at ix (2006), <https://www.cdpr.ca.gov/docs/risk/rcd/imidacloprid.pdf>.

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.* at 61.

⁴⁶ *Id.*

⁴⁷ *Id.* at xii.

myasthenia, autosomal dominant frontal lobe nocturnal epilepsy and possibly a schizophrenic syndrome. These receptors are also involved at various degrees in several neuropathologies such as Parkinson and Alzheimer's diseases, and Gilles de la Tourette's syndrome. Autoimmune responses to specific neuronal nAChR subunits have been found in the skin disease pemphigus, in which cells of the epidermis lose adherence.⁴⁸

Furthermore, a systematic review of peer-reviewed literature on human health effects of neonicotinoids reported a link between neonicotinoid exposures and malformations of the developing heart and brain, as well as a cluster of symptoms including memory loss and finger tremors.⁴⁹ For example, the review discussed a study by National Institute of Health-funded researchers from University of North Carolina at Chapel Hill and University of California, Davis that associated frequent exposure to imidacloprid applied as flea and tick treatments for pets (Advantage by Bayer) during pregnancy with a 2-fold elevated risk of autism spectrum disorder in prenatally-exposed children.⁵⁰

ii. *Flumethrin*

The other active ingredient found in Seresto pet collars, at 4.5%, is flumethrin. Flumethrin is a pyrethroid insecticide, which is in a class of pesticides that—like neonicotinoids—target insects' peripheral and central nervous systems.⁵¹ These chemicals are some of the most widely used pesticides in the United States, both in agricultural and residential settings.⁵² Dependency on pyrethroids has increased over the past twenty years, propelled by interest in replacing organophosphate insecticides.⁵³ Today, pyrethroids and pyrethrins are so heavily used that their environmental concentrations exceed regulatory thresholds.⁵⁴

Until recently, pyrethroids were believed to have limited toxicity in humans; this belief was based on the assumption that they are rapidly metabolized by the human body. But current studies and scientific investigations cast serious doubt on that assumption. For example, one recent pharmacokinetic study on the pyrethroid deltamethrin indicates that its peak concentration in the human brain is two times higher than that in rats.⁵⁵ Additionally, mammalian studies showed that repeated exposure to low levels of a pyrethroid insecticide caused learning

⁴⁸ *Id.* at 3-4 (citations omitted).

⁴⁹ Cimino, et al., *Effects of Neonicotinoid Pesticide Exposure on Human Health: A Systematic Review*, 125(2) Environmental Health Perspectives 155 (2017), <https://ehp.niehs.nih.gov/doi/full/10.1289/EHP515>.

⁵⁰ *Id.* at 160 (citing Keil, et al., *Autism Spectrum Disorder, Flea and Tick Medication, and Adjustments for Exposure Misclassification: the CHARGE (CHildhood Autism Risks from Genetics and Environment) Control Study*, 13 Environ. Health 3 (2014), <https://pubmed.ncbi.nlm.nih.gov/24456651/>).

⁵¹ T.G.E. Davies et al., *DDT, Pyrethrins, Pyrethroids and Insect Sodium Channels*, 59 LIFE 151, 155 (2007).

⁵² Muhammad M. Hossain, et al., *Hippocampal ER Stress and Learning Deficits Following Repeated Pyrethroid Exposure*, 143 Toxicological Sciences 220, 220 (2015).

⁵³ Holly A Rogers, et al., *Bifenthrin Causes Trophic Cascade and Altered Insect Emergence in Mesocosms: Implications for Small Streams*, 50 Env'tl. Sci. & Tech. 11,974, 11,974 (2016).

⁵⁴ *Id.*

⁵⁵ Stephen J. Godin, et al., *Physiologically Based Pharmacokinetic Modeling of Deltamethrin: Development of a Rat and Human Diffusion-Limited Model*, 115 Toxicological Sciences 330, 338 (2010).

deficiencies and physiological effects associated with neurodegeneration, Alzheimer's, and Parkinson's diseases, among others.⁵⁶ Even further, one study revealed higher incidences of autism spectrum disorders and developmental delay amongst children whose mothers were living within 1.5 kilometers of sites of pyrethroid applications during the third trimester of pregnancy.⁵⁷

EPA's 2012 human health risk assessment of flumethrin for use in cat and dog collars indicates that it has toxic effects similar to many other pyrethroids.⁵⁸ These effects include pawing, burrowing, writhing, salivation, coarse tremors, decreased body weights, and impaired motor activity.⁵⁹ While a later 2018 human health risk assessment for flumethrin did not find risks of concern, it showed that the relevant toxicity studies were conducted on rats and mice rather than dogs or cats (the animals that the manufacturer of flumethrin was seeking approval for its use on), making it difficult to determine the actual toxic effects of flumethrin on dogs and cats.⁶⁰

Further, according to a 2019 risk assessment of flumethrin, EPA identified that between 2013 and 2018 there were at least 907 incidents reported for humans.⁶¹ The assessment further determined that there were 19 severe incidents, with the most often reported symptoms being dermal (8 total) and neurological (7 total).⁶² Of the 8 people that experienced dermal incidents, the symptoms reported included rashes, skin lesions, and hives; of the 7 people that experienced neurological incidents, the symptoms reported included numbness, headaches, and seizures.⁶³

A sampling of the incidents listed in that 2019 risk assessment include:

- A 12-year-old boy who slept in a bed with a dog wearing a collar started having seizures and vomiting. He had to be hospitalized.⁶⁴
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.⁶⁵
- A 43-year-old man put collars on eight dogs and slept in the same bed as four of the dogs. A week later, he developed ear drainage and nasal and throat irritation and was told by a

⁵⁶ Muhammad M. Hossain, et al., *Hippocampal ER Stress and Learning Deficits Following Repeated Pyrethroid Exposure*, 143 *Toxicological Sciences* 220, 220 (2015).

⁵⁷Janie F. Shelton, et al. *Neurodevelopmental Disorders and Prenatal Residential Proximity to Agricultural Pesticides: The CHARGE Study*, 122 *Children's Health* 1103, 1107 (2014).

⁵⁸ See generally EPA, *Flumethrin: Human Health Risk Assessment for the Section 3 Registration Action for Cat and Dog Collars* (2016), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0031-0005>.

⁵⁹ *Id.* at 5.

⁶⁰ EPA, *Flumethrin: Draft Human Health Risk Assessment for Registration Review* (2018), <https://www.regulations.gov/document?D=EPA-HQ-OPP-2016-0031-0027>.

⁶¹ EPA, *Flumethrin: Tier I Update Review of Humane Incidents and Epidemiology for Proposed Interim Decision*, at 3-4 (2019), <https://www.regulations.gov/document/EPA-HQ-OPP-2016-0031-0031>.

⁶² *Id.* at 4.

⁶³ *Id.*

⁶⁴ *Id.* at 8-9.

⁶⁵ *Id.* at 8.

doctor that he had a hole in his ear drum. He removed the dog collars and the symptoms went away. He later reapplied the collars and the symptoms returned.⁶⁶

Not only do pyrethroids present serious risks to the health of humans, dogs, and cats, but they also present risks to wildlife resources and ecosystems. A study by U.S. Geological Survey scientists found that commonly used pyrethroids have the potential to “alter aquatic and terrestrial ecosystem function at the regional scale.”⁶⁷ More specifically, the study concluded that pyrethroid contamination in freshwater streams resulted in “less abundant and less diverse macroinvertebrate communities.”⁶⁸ Additionally, the study revealed that pyrethroid contamination in aquatic ecosystems “propagate across life stages and generations of invertebrates, trophic levels in aquatic food webs, and ecosystem boundaries to riparian food webs.”⁶⁹ Indeed, in its recent aquatic risk assessment for 20 pyrethroids and pyrethrins, EPA did an analysis on many of the home uses of this pesticide class and found significant risks to aquatic invertebrates from just the indoor uses alone.⁷⁰

iii. The Synergistic Action of Imidacloprid and Flumethrin

Since imidacloprid and flumethrin do not exist in isolation in the Seresto product, their synergistic effects must also be taken into consideration. “Synergy” is the mixing of pesticide ingredients with other pesticides and chemicals before application (or after), and the ways in which the individual ingredients can interact in the mixture in a way that enhances their toxic effects. These synergies, which are generally not assessed by EPA when it approves a pesticide product and specifically were not assessed in its approval of Seresto,⁷¹ can turn what would normally be considered a safe level of exposure to people, wildlife, and the environment into one that causes considerable harm.⁷² However, even published studies by the original manufacturer of Seresto, Bayer, have shown that the combination of imidacloprid and flumethrin produces synergistic action in dogs and cats that may make these two chemicals more powerful and more toxic together than each individual pesticide alone.⁷³

⁶⁶ *Id.*

⁶⁷ Holly A Rogers, et al., *Bifenthrin Causes Trophic Cascade and Altered Insect Emergence in Mesocosms: Implications for Small Streams*, 50 *Envtl. Sci. & Tech.* 11,974, 11,974 (2016).

⁶⁸ *Id.* at 11,979.

⁶⁹ *Id.* at 11,980.

⁷⁰ EPA, Preliminary Comparative Environmental Fate and Ecological Risk Assessment for the Registration Review of Eight Synthetic Pyrethroids and the Pyrethrins, (2016), <https://www.regulations.gov/document/EPA-HQ-OPP-2010-0384-0045>.

⁷¹ EPA, Weighing Risks to Children from Dogs Wearing Seresto Collars (2016), https://www.epa.gov/sites/production/files/2017-01/documents/weighing_risks_to_children_from_dogs_wearing_seresto-tm_collars.pdf (“The risk of the combination of the two active ingredients, flumethrin and imidacloprid, was not assessed . . .”).

⁷² Nathan Donley, Center for Biological Diversity, *Toxic Concoctions: How the EPA Ignores The Dangers of Pesticide Cocktails*, 1 (2016),

https://www.biologicaldiversity.org/campaigns/pesticides_reduction/pdfs/Toxic_concoctions.pdf.

⁷³ Stanneck, et al., *The Synergistic Action of Imidacloprid and Flumethrin and Their Release Kinetics From Collars Applied for Ectoparasite Control in Dogs and Cats*, 5 *Parasites & Vectors* 73 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3361670/>.

Even further, as it relates to these two pesticides, recent research published by the journal *Science* has determined that neonicotinoids and pyrethroids have driven an increase in the toxicity of pesticides to aquatic invertebrates and pollinators, even as effects have generally fallen for vertebrates.⁷⁴ As summarized by the researchers who conducted the study, "[o]ur results challenge the claims of a decrease in the environmental impacts of pesticide use."⁷⁵

IV. STATEMENT OF LEGAL GROUNDS

FIFRA provides the legal framework for federal regulation of pesticide use, sale, and distribution. The law is intended to prohibit the use of pesticides that cause unreasonable adverse effects on the environment. EPA, the recipient of this petition, is responsible for carrying out the mandates of the Act. As identified through Exhibits A-C and *supra* in Section III (b) – (c), evidence exists that past and present uses of Seresto have caused unreasonable adverse impacts upon the environment and present an imminent hazard. The harms caused by Seresto use are not outweighed by the benefits of continued use. Therefore, pursuant to its obligations under FIFRA, EPA must cancel registration number 11556-155 pursuant to Section 136d(b) in order to prevent any additional unreasonable adverse effects on the environment, and, pending completion of cancellation proceedings, must suspend Seresto’s registration pursuant to Section 136d(c)(1).

a. Seresto Must be Cancelled for Causing an “Unreasonable Risk” to Man and the Environment in Violation of FIFRA

Cancellation of a pesticide product’s registration is warranted where the pesticide, “when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment,” including “any unreasonable risk to man or the environment.”⁷⁶ Here, the registration of Seresto must be cancelled because its continued use as a flea and tick collar for dogs and cats—which is the use for which it has been approved, and is therefore appropriately identified as use “in accordance with widespread and commonly recognized practice”—is causing unreasonable adverse effects on members of the public, imperiled species, and companion animals.

According to a recent aggregate incident summary report, since Seresto was introduced in 2012, EPA has received over 75,000 adverse incident reports on this product, including at least 1,698 reports linking the use of this product to pet deaths and nearly 700 involving harm humans.⁷⁷ In addition, use of the collar has caused rashes, seizures, motor dysfunction, fatigue, diarrhea, vomiting, and excessive drooling in animals.⁷⁸ According to Karen McCormack, a former

⁷⁴ Schulz, *Applied Pesticide Toxicity Shifts Toward Plants and Invertebrates, Even in GM Crops*, 372 *Science* 81-84 (2021), <https://science.sciencemag.org/content/372/6537/81>.

⁷⁵ Marc Heller, *Farm Chemicals Turning More Toxic for Wildlife*, E&E News (Apr. 1, 2021), <https://www.eenews.net/eenewspm/stories/1063729071/feed>.

⁷⁶ 7 U.S.C. § 136d(b); *see also id.* § 136(bb) (providing that “[t]he term ‘unreasonable adverse effects on the environment’ means (1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide . . .”).

⁷⁷ *See Exhibit A.*

⁷⁸ Jimmy Tallal, *Seresto Flea Collar Linked to 1,700 Pet Deaths*, *The Malibu Times* (Mar. 26, 2021), http://www.malibutimes.com/news/article_36818990-8db8-11eb-9bf9-cf20318319cf.html; *see also*

pesticide researcher, policy analyst, environmental fate scientist, and communications specialist for EPA, Seresto collars “have the most incidents of any pesticide product she’s ever seen.”⁷⁹

For comparison, in 2009 NRDC petitioned EPA to cancel all pet uses for the pesticide tetrachlorvinphos (TCVP) due to the risks it posed to the health of children and because EPA relied on a faulty health assessment in approving its use in flea collars and powders.⁸⁰ In 2020, in response to a legal challenge brought by NRDC against EPA’s for its delay in responding to the 2009 petition, the Ninth Circuit Court of Appeals issued a decision highlighting the gravity of these risks and finding that “[r]epeatedly, the EPA has kicked the can down the road and betrayed its prior assurances of timely action, even as it has acknowledged that the pesticide poses widespread, serious risks to the neurodevelopmental health of children.”⁸¹ Yet, even in that case the number of incidents related to the use of TCVP (approximately 4,600, including 363 deaths, between 1992 and 2008) paled in comparison to those being reported for Seresto (75,000, including almost 1,700 deaths).⁸²

Further, in the case of TCVP, one of the primary concerns expressed in that petition was that:

These products are designed to leave chemical residues on a pet's fur. Children playing with their cat or dog get these residues on their hands, where the chemical can be absorbed through the skin or ingested when they put their hands in their mouths—and young kids, especially toddlers, put their hands in their mouths a lot. When we redid the calculations, we found that these vulnerable children could be exposed at levels that put their developing brains at risk.⁸³

The exact same exposure pathway (and suite of concerns) exists with regards to pesticide exposure for children and other humans that come into contact with a companion animal wearing a Seresto collar. In fact, when used “in accordance with widespread and commonly recognized practice,” Seresto “gradually releas[es] a consistent low-dose of its active ingredients . . . once the collar comes in contact with your pet’s skin or coat. The active ingredients diffuse into the lipid (fatty/oily) layer of your pet’s skin and fur and cover your pet within 24 hours.”⁸⁴ Once in place, the collar then “remains effective for eight months at a time,” meaning that the potential for a child or other person to be exposed to its active ingredients (for example, through petting,

Exhibit B (National Pesticide Information Center Reports to EPA); Exhibit C (MedWatch Veterinary Incident Reports).

⁷⁹ Jonathan Hettinger, *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning*, USA Today (Mar. 2, 2021),

<https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>.

⁸⁰ NRDC, Petition to Cancel All Tetrachlorvinphos (TCVP) Pet Uses (Apr. 23, 2009), <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0308-0002>.

⁸¹ *NRDC v. United States EPA (In re NRDC)*, 956 F.3d 1134, 1136 (9th Cir. 2020).

⁸² EPA, Tetrachlorvinphos: Animal Incident Summary (Feb. 3, 2009),

https://www.documentcloud.org/documents/20491417-epa-hq-opp-2008-0316-0018_pet-poisoning.

⁸³ NRDC, *No More Poisons on Pets: The EPA Must Act* (May 29, 2019),

<https://www.nrdc.org/experts/miriam-rotkin-ellman/no-more-poisons-pets-epa-must-act>.

⁸⁴ Advantage Petcare, *How Do Seresto Flea Collars Work?* (Feb. 2021),

<https://www.advantagepetcare.com.au/au/parasites/fleas/how-do-seresto-flea-collars-work/>.

kissing, snuggling, sleeping, or other contact—affections common between people, and especially children, and their companion animals) is also sustained over a long period of time, lasting up to eight months.⁸⁵ And there can be no question that these impacts on human health are significant here since approximately 700 of the adverse incident reports for Seresto involved harm to humans.⁸⁶

For the animals themselves, this also means that exposure to the active ingredients in Seresto is chronic since the collar is designed for the consumer to “buy it, put it on and then forget about it for months.”⁸⁷ For example, while the product label indicates that the collar is for external use only, that direction does not account for the fact that dogs and cats frequently clean themselves (by, for example, licking their fur), and can ingest the collar’s pesticides in so doing. As identified *supra* in Section III (c), such exposure can lead to a variety of unreasonable and harmful effects in the animals, the significance of which is underscored by the product’s stunning 75,000 adverse incident reports and staggering almost 1,700 pet deaths.

In addition, to the extent animals wearing the Seresto collar are washed or otherwise sluff the collar’s active ingredients into the surrounding environment—for example through rolling or other activities, those active ingredients can come into contact with wildlife, including federally protected threatened and endangered species, and further place those already imperiled species at a greater risk of extinction. For example, as identified *supra* in Section III (c), uses of imidacloprid are directly implicated in declines of rusty patched bumble bee populations, a species that is listed as endangered under the federal Endangered Species Act.⁸⁸

Finally, the harms caused by Seresto use are not outweighed by the benefits of continued use because numerous proven effective methods exist for treating fleas and ticks on companion animals that do not put the animal’s health, or the health of exposed humans and wildlife, at risk. These alternatives include oral flea-prevention treatments, frequent grooming, and use of non-toxic flea and tick shampoos.⁸⁹

In sum, considerable evidence exists that past and present uses of the pesticide product Seresto are causing unreasonable adverse impacts on the environment, including “unreasonable risk[s] to man,” companion animals, and threatened and endangered species. Because these harms are significant and ongoing, cancellation of this product is not only warranted by EPA but essential for protecting public health, consumers, imperiled wildlife, and companion animals.

⁸⁵ *Id.*

⁸⁶ *See* Exhibit A.

⁸⁷ *Id.*

⁸⁸ *See, e.g.,* Szymanski, J. *et al.* *Rusty Patched Bumble Bee (Bombus affinis) Species Status Assessment* (2016), <https://ecos.fws.gov/ServCat/DownloadFile/120109>.

⁸⁹ *See, e.g.,* NRDC, *Nontoxic Ways to Protect Your Pet* (Jan. 22, 2016), <https://www.nrdc.org/stories/nontoxic-ways-protect-your-pet>.

b. Immediate Suspension of Seresto’s Registration Pending Cancellation is Warranted

Suspension of a pesticide’s registration is warranted under FIFRA § 136d(c)(1) when such action is necessary to prevent an imminent hazard⁹⁰ during the time required for cancellation.⁹¹ The term "imminent hazard" is defined as "a situation which exists when the continued use of a pesticide during the time required for [a] cancellation proceeding would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered or threatened."⁹² Here, as documented *supra* in Sections III(b) – (c) and IV(a), both of these situations exist (ongoing and imminent unreasonable adverse effects on the environment *and* unreasonable hazard to the survival of the endangered rusty patched bumble bee, as well as other imperiled pollinators).⁹³

Quick action from EPA to remove this product from the market is also a matter of substantial public concern. The significant harms associated with the use of this product have sparked a public outcry,⁹⁴ retailers considering whether they should discontinue sale of the product,⁹⁵ and a federal Congressional request to the manufacturer of Seresto to voluntarily recall the collars (the

⁹⁰ 7 U.S.C. § 136(l) (“The term ‘imminent hazard’ means a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding would be likely to result in unreasonable adverse effects on the environment . . .”).

⁹¹ *Id.* § 136d(c)(1) (“If the Administrator determines that action is necessary to prevent an imminent hazard during the time required for cancellation . . . the Administrator may, by order, suspend the registration of the pesticide immediately.”).

⁹² *Id.* § 136(l).

⁹³ See also *Envtl. Defense Fund, Inc. v. EPA*, 510 F. 2d 1292, 1297 (D.C. Cir. 1975) (upholding an EPA suspension and cancellation order for aldrin and dieldrin and stating: “We have cautioned that the term ‘imminent hazard’ is not limited to a concept of crisis. ‘It is enough if there is a substantial likelihood that serious harm will be experienced during the year or two required in any realized projection of the administrative process.’” (citing *Envtl. Defense Fund, Inc. v. EPA*, 465 F.2d 528, 540 (D.C. Cir. 1972)); EPA, E.I. du Pont de Nemours and Company Imprelis Order (Aug. 11, 2011), <https://www.epa.gov/enforcement/e-i-du-pont-de-nemours-and-company-imprelis-order> (EPA order under FIFRA to E.I. DuPont de Nemours (DuPont) directing the company to immediately cease the distribution, sale, use or removal of Imprelis herbicide products under its ownership, control, or custody because “[t]he directions for use and/or warning or caution statements on DuPont’s Imprelis labeling are inadequate to protect non-target species.”).

⁹⁴ Jonathan Hettinger, *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning*, USA Today (Mar. 2, 2021), <https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>; CBS New York, *Questions Raised About Safety of Popular Seresto Flea Collar* (Mar. 24, 2021), <https://newyork.cbslocal.com/2021/03/24/seresto-pet-collar-safety-concerns/>.

⁹⁵ Jonathan Hettinger, *Amazon is Reviewing Best-Selling Seresto Flea Collar After Report of Illnesses, Deaths*, USA Today (Mar. 5, 2021), <https://www.usatoday.com/story/news/investigations/2021/03/05/amazon-reviewing-seresto-flea-collar-amid-reports-illnesses-deaths/4586990001/>.

manufacturer declined to do so).⁹⁶ In furtherance of the public interest and the objectives of FIFRA, the registration for Seresto should, therefore, be suspended pending cancellation proceedings to prevent an imminent hazard to human health and companion animals, and to protect threatened and endangered species.

V. CONCLUSION

For the forgoing reasons, Petitioner the Center for Biological Diversity requests that, pursuant to its obligations under FIFRA, EPA cancel registration number 11556-155 (Seresto) pursuant to Section 136d(b) to prevent additional unreasonable adverse effects on the environment, and, pending completion of cancellation proceedings, suspend Seresto's registration pursuant to Section 136d(c)(1). As the government agency that has assumed the responsibility of lawfully managing pesticide product registrations in a way that does not harm the environment and human health, EPA can and must do better. The Center urges EPA to act on this petition without delay.

Sincerely,



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Enclosures

⁹⁶ Jonathan Hettinger, *House Subcommittee Seeks Voluntary Recall of Seresto Flea and Tick Collars*, Midwest Center for Investigative Reporting (Mar. 18, 2021), <https://investigatamidwest.org/2021/03/18/house-subcommittee-seeks-voluntarily-recall-of-seresto-flea-and-tick-collars/>.

EXHIBIT A

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Reg No. Selected :	011556-00155		
Product Name:	All		
Exposure Severity Code :	All		Reporting Date Range: 01/01/2012 To 06/16/2020

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
024671-00008	011556-00155	SERESTO CAT	Impregnated Materials	10	0	0	0	0	0	0	10	0	0	0	0	0	0	0	0	0	0	0	0	0	0
024968-00005	011556-00155	SERESTO LARGE DOG	Impregnated Materials	56	0	0	2	0	0	23	31	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025109-00007	011556-00155	SERESTO	Impregnated Materials	141	2	0	6	0	0	32	101	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025472-00010	011556-00155	SERESTO	Impregnated Materials	944	25	0	19	9	0	222	669	0	0	0	0	0	0	0	0	0	0	0	0	0	0
025767-00009	011556-00155	SERESTO	Impregnated Materials	1,661	13	0	37	90	0	447	1,074	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026184-00005	011556-00155	SERESTO	Impregnated Materials	1,076	15	0	23	101	0	269	668	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026494-00002	011556-00155	SERESTO	Impregnated Materials	602	4	0	17	80	0	161	350	0	0	0	0	0	0	0	0	0	0	0	0	0	0
026745-00008	011556-00155	SERESTO	Impregnated Materials	1,896	25	0	29	90	0	433	1,319	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027067-00012	011556-00155	SERESTO	Impregnated Materials	2,028	30	0	31	159	0	505	1,303	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027348-00007	011556-00155	SERESTO	Impregnated Materials	1,301	19	0	28	98	0	315	841	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027609-00005	011556-00155	SERESTO	Impregnated Materials	775	8	0	20	80	0	197	471	0	0	0	0	0	0	0	0	0	0	0	0	0	0
027876-00012	011556-00155	SERESTO	Impregnated Materials	3,265	39	0	52	133	0	747	2,296	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028098-00010	011556-00155	SERESTO	Impregnated Materials	3,507	24	0	70	273	0	770	2,370	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028336-00008	011556-00155	SERESTO	Impregnated Materials	2,221	15	0	49	229	0	507	1,421	0	0	0	0	0	0	0	0	0	0	0	0	0	0
028777-00004	011556-00155	SERESTO	Impregnated Materials	1,456	20	0	37	125	0	324	950	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029069-00009	011556-00155	SERESTO	Impregnated Materials	4,076	33	0	69	148	0	858	2,970	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029169-00002	011556-00155	SERESTO LARGE DOG	Impregnated Materials	1	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029308-00008	011556-00155	SERESTO	Impregnated Materials	4,417	26	0	86	309	0	981	3,015	0	0	0	0	0	0	0	0	0	0	0	0	0	0

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
029600-00007	011556-00155	SERESTO	Impregnated Materials	2,488	15	0	54	239	0	600	1,580	0	0	0	0	0	0	0	0	0	0	0	0	0	0
029843-00005	011556-00155	SERESTO	Impregnated Materials	1,697	15	0	54	159	1,118	351	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
030205-00008	011556-00155	SERESTO	Impregnated Materials	4,101	34	0	92	208	3,767	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
030491-00009	011556-00155	SERESTO	Impregnated Materials	4,564	24	0	87	350	4,103	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
030703-00006	011556-00155	SERESTO	Impregnated Materials	3,011	21	0	86	299	2,605	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
030964-00006	011556-00155	SERESTO	Impregnated Materials	1,490	18	0	63	157	1,252	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
031245-00008	011556-00155	SERESTO	Impregnated Materials	4,381	35	0	125	226	3,995	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
031516-00012	011556-00155	SERESTO	Impregnated Materials	5,247	40	0	148	102	4,958	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
031728-00008	011556-00155	SERESTO	Impregnated Materials	3,019	24	0	81	21	2,893	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032053-00003	011556-00155	SERESTO	Impregnated Materials	1,669	25	0	70	13	1,561	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032333-00010	011556-00155	SERESTO	Impregnated Materials	4,651	44	0	151	30	4,426	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00008	011556-00155	SERESTO	Impregnated Materials	31	2	0	2	0	27	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00009	011556-00155	SERESTO	Impregnated Materials	1,157	7	0	14	2	1,134	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00010	011556-00155	SERESTO	Impregnated Materials	168	4	0	8	2	154	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00011	011556-00155	SERESTO	Impregnated Materials	2,511	10	0	24	14	2,463	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00012	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032632-00013	011556-00155	SERESTO	Impregnated Materials	1,476	6	0	4	5	1,461	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032924-00004	011556-00155	SERESTO	Impregnated Materials	14	2	0	0	0	12	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032924-00005	011556-00155	SERESTO	Impregnated Materials	668	5	0	12	3	648	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032924-00006	011556-00155	SERESTO	Impregnated Materials	117	5	0	4	0	108	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032924-00007	011556-00155	SERESTO	Impregnated Materials	1,231	11	0	9	3	1,208	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

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Report Date & Time : 06/16/2020 2:46:00 PM GMT

Package and Seq. #	Full Product Reg. #	Product Name	Form.	Total Inc.	H D	H E	D A	D B	D C D E	D C	D D	D E	W B	P B	O N T	G B	G C	D W B	D W C	G W B	G W C	S W B	S W C	P D B	P D C
032924-00008	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
032924-00009	011556-00155	SERESTO	Impregnated Materials	693	6	1	12	2	672	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00006	011556-00155	SERESTO	Impregnated Materials	11	1	0	1	0	9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00007	011556-00155	SERESTO	Impregnated Materials	502	2	0	6	1	493	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00008	011556-00155	SERESTO	Impregnated Materials	80	1	0	4	1	74	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00009	011556-00155	SERESTO	Impregnated Materials	602	6	0	9	3	584	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00010	011556-00155	SERESTO	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00011	011556-00155	SERESTO	Impregnated Materials	361	5	0	3	3	350	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
033132-00012	011556-00155	SERESTO CAT	Impregnated Materials	3	0	0	0	0	3	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Summary by Full Reg.

Full Product Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD	DE	WB	PB	ONT	GB	GC	DWB	DWC	GWB	GWC	SWB	SWC	PDB	PDC	
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Summary by 11 Character Reg.

11 Char Reg. #	Total Inc.	HD	HE	DA	DB	DCDE	DC	DD	DE	WB	PB	ONT	GB	GC	DWB	DWC	GWB	GWC	SWB	SWC	PDB	PDC
011556-00155	75,385	666	1	1,698	3,767	40,087	7,743	21,439	0	0	0	0	0	0	0	0	0	0	0	0	0	0

Exposure Severity Code	Description
DA	Domestic Animal - Fatality
DB	Domestic Animal - Major
DC	Domestic Animal - Moderate
DCDE	Domestic Animal - Moderate, Minor and Unknown
DD	Domestic Animal - Minor
DE	Domestic Animal - Unspecified
DWB	Drinking Water - Moderate

US EPA Office of Pesticide Programs Incident Data System

Total Rows Returned : 48

Aggregate Incident Summary Report by Product

Report Date & Time : 06/16/2020 2:46:00 PM GMT

Exposure Severity Code	Description
DWC	Drinking Water - Minor
GB	Groundwater - Moderate (with possibly mixed types of water)
GC	Groundwater - Minor (with possibly mixed types of water)
GWB	Groundwater - Moderate
GWC	Groundwater - Minor
HD	Human - Minor
HE	Human - Unspecified
ONT	Other Nontarget
PB	Plant Damage - Minor
PDB	Property Damage - Moderate
PDC	Property Damage - Minor
PL	Plant Lawn
SWB	Surface Water - Moderate
SWC	Surface Water - Minor
WB	Wildlife - Minor

EXHIBIT B



2016 REFERRAL TO EPA

LOG: 3159

Veterinary Pesticide Adverse Effects Reporting
<http://npic.orst.edu/vet>

An additional mode of reporting adverse effects is by contacting the manufacturer. Under FIFRA 6(a)(2), manufacturers are required to submit adverse effects information about their products to the U.S. EPA. From your email, it sounds like the manufacturer may have been Bayer - Bayer appears to have a phone number specifically for their Bayer Animal Health division. If you haven't contacted them directly, you may consider calling them to report this issue. Their number, as well as additional manufacturer contact information can be accessed from the following link (alphabetical order):
<http://npic.orst.edu/ingred/manuf.htm>

Again, please contact us at 800-858-7378, Monday - Friday from 8:00am to 12:00pm PT. We look forward to answering any questions you have, and documenting your situation further.

Possible product information (per NPIRS database): active ingredient flumethrin and imidacloprid.

Inquirer sent follow up email with photos of cat's hair loss; no further incident details provided. Provided information to EPA, Executive Committee and Project Coordinator.







2016 REFERRAL TO EPA

LOG: 10548

Date: November 9, 2016

City, State: WINSTED, CT

Narrative: Caller wanted to report 2 of her 5 dogs had a reaction to a Seresto Collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported six days ago (11/3/2016) she used a collar on each dog. Caller reported having 3 small dogs on which she used Seresto Small Dog and 2 bigger dogs on which she used Seresto Large Dog. Caller reported 5 days after the application her 2 bigger dogs had a reaction to the collar. Caller reported one dog (2 year old, English Bulldog, male, neutered, 55 pounds) had a seizure 5 days after application (11/8), has a bleeding sore near the top of its head right where the collar was, and its eyes are bright red and irritated. Caller reported her other big dog (14 year old, 55 pounds, female, spayed, American Bulldog) started shaking all over and urinated all over itself, 3 to 4 hours after the first dog had a seizure. Caller reported one of the smaller dogs (Mini Dachshund, 7.5 year old, male, neutered, 20 pounds) keeps scratching by the collar. Caller reported the other 2 dogs (both 7 years old, 7 pounds, female, Maltipoo) are fine and caller reported there were no symptoms. Caller reported she used the collars because they were recommended by the veterinarian. Caller reported the veterinarian told her to use the large collar, for dogs over 18 pounds, for the big dogs and the small collar, for dogs under 18 pounds for the others. Caller reported after her two dogs had a reaction she removed all the collars from her pets. Caller reported she also wanted to complain about the label having conflicted information, because it claims it is better than monthly use products but at the same time it says people cannot sleep with the pet if it is wearing a collar and to not let children touch a pet wearing a collar, "which implies the product is toxic". Discussed NPIC services, including role as a pesticide health and safety information resource and discussed not having legal or regulatory authority. Discussed that NPIC incident reports are made available to the U.S. EPA. Discussed that an additional mode of reporting adverse effects is by contacting the manufacturer. Discussed that under FIFRA 6(a)(2), manufacturers are required to submit adverse effects information about their products to the U.S. EPA. Provided contact information for manufacturer. Discussed ways to minimize exposure, including option of asking for next steps or asking about potential benefit of bathing the dogs. Resources used: Inchem and ATSDR, Toxicological Profile for Pyrethrins and Pyrethroids - 2. Relevance to Public Health.



2017 REFERRAL TO EPA

LOG: 8944

Date: October 2, 2017

City, State: St. Louis, MO

Narrative: Caller (age 63) seeking information on how long her reaction to a Seresto Flea Collar (active ingredients flumethrin, imidacloprid) may last, and wants to report her reaction. Caller reported that she applied a collar to her two cats and small dog 9 days ago, and by the next evening her lips and tongue were swollen, her eyes were beginning to swell, she had tingling and burning inside her mouth and on her lips, and she had blisters form inside her mouth. Caller reported she picks up and carries her dog frequently throughout the day, and each time she picks it up she kisses it on the head. Caller reported that it took several days before she realized that the collar was the only thing that had changed in the house, and she removed the collars four days after she had put them on.

Caller reported she called the manufacturer (Bayer Healthcare) on the day she removed the collars, was told that in rare cases people do have these reactions, was advised to use vitamin E on her skin, and to shampoo the animals. Caller reported she washed all of the animals that day. Caller reported that the next day (four days ago) she went to the urgent care, was given a steroid shot and a 5-day supply of steroids, and was told to not use the vitamin E oil. Caller reported that the swelling has gone down, but the tingling and burning on her lips and mouth are still present, and it has influenced her ability to eat and has a hard time eating anything with salt because it burns. Caller reported there were no symptoms for any of her animals from the collars. Caller reported she has since returned the collars and their packaging back to the store where she bought them.

Discussed NPIC services, including the inability to provide medical treatment advice. Discussed risk equation concepts, including toxicity and routes of exposure. Discussed the toxicity of the active ingredients, and reported symptoms from exposure to them (NPIC Fact Sheet, "Inchem UKPID Monograph Flumethrin", & "NY DEQ Human Health Assessment Flumethrin - 2012"). Discussed providing the Recognition and Management of Pesticide Poisonings to her medical provider as a resource for toxicology information on active ingredients, and provided NPIC website.



2016 REFERRAL TO EPA

LOG: 7313

Date: August 1, 2016

City, State: Johnson City, NY

Narrative: Caller wishing to report a reaction her dog (100 lb, 8 year old, intact male German shepherd) had to a dog collar, EPA registration number 11556-155 (active ingredients imidacloprid, flumethrin). Caller reported that she applied the collar to the dog on 06/29/2016, that he lives in an outdoor kennel, and that she noticed the next morning that the dog was shaking his head more than normal, but her husband had an accident that kept her from paying much attention to the dog for quite awhile. Caller reported that on 07/12/2016 she was visiting the dog in his outside kennel, touched his head and ears and noticed that they were very hot and felt like they were "on fire". Caller reported that she called her veterinarian, and was told to check the dog's neck to see if he had sores, and if he did to remove the collar and bathe him. Caller reported that the dog did have noticeable oozing sores on his neck, she washed him with Dawn dish soap, and the veterinarian prescribed antibiotics and steroids to help with the inflammation without a clinic visit.

Caller reported that she took the dog into the veterinarian on 07/19/2016 because his symptoms seemed to continue, and the vet shaved the dog around his neck and down to his shoulder blades because the sores covered that entire area. Caller reported that the dog had an ear infection also, and was prescribed another antibiotic, and another cream ointment. Caller reported that she has been using a medicated shampoo on the dog, and has had to move him indoors while he has open wounds on his skin. Caller reported that she that she has been incredibly disappointed with the response of the manufacturer (Bayer Healthcare) to her situation. Caller reported she is planning on doing everything she can to try to stop other consumers from going through a similar experience.

Discussed NPIC services. Discussed the registration of products through both federal and state agencies, and provided contact information for the State Lead Pesticide Agency as a resource for reporting concerning pesticides. Resources used: Registration Decision for Flumethrin for Use in Cat and Dog Collars - 2012, NPIC Fact Sheet, & Hazardous Substances Data Bank (HSDB).

EXHIBIT C

I 028710

MEDWATCH
The FDA Safety Information and Adverse Event Reporting Program

FDA USE ONLY	
Triage unit sequence #	
FDA Rec. Date	641268

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2015.

A. PATIENT INFORMATION

1. Patient Identifier 20684-1	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Days(s) or Date of Birth (e.g., 08 Feb 1925) 23-12-2010	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male Altered	4. Weight 113.6 <input checked="" type="checkbox"/> lb <input type="checkbox"/> kg
5.a. Ethnicity (Check single best answer) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino		5.b. Race (Check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander	

B. ADVERSE EVENT, PRODUCT PROBLEM

1. Check all that apply
 Adverse Event Product Problem (e.g., defects/malfunctions)
 Product Use Error Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (Check all that apply)
 Death Include date (dd-mmm-yyyy)
 Life-threatening Disability or Permanent Damage
 Hospitalization - initial or prolonged Congenital Anomaly/Birth Defects
 Other Serious (Important Medical Events)
 Required Intervention to Prevent Permanent Impairment/Damage (Devices)

3. Date of Event (dd-mmm-yyyy) 11-02-2016	4. Date of this Report (dd-mmm-yyyy) 17-02-2016
--	--

5. Describe Event, Problem or Product Use Error
Seresto collar for large dogs applied to pet, developed depression and mild muscle tremors in pelvic limbs overnight.

6. Relevant Tests/Laboratory Data, Including Dates
CBC - leukocytosis (18.67 K/wb), neutrophilia (15 K/wb), monocytosis (1.96 K/wb); PCV/TS: 50%/8.1g/dl
Serum chemistry - normal values

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)
Collar was part of a treatment for flea allergic dermatitis - pet also started on prednisone + cephalexin P.O.

C. PRODUCT AVAILABILITY

2. Product Available for Evaluation? (Do not send product to FDA)
 Yes No Returned to Manufacturer on (dd-mmm-yyyy)

D. SUSPECT PRODUCTS

1. Name, Manufacturer/Compounder, Strength (from product label)	
#1 - Name and Strength Seresto flea collar for large dogs	#1 - NDC # or Unique ID AHN10637
#1 - Manufacturer/Compounder Bayer	#1 - Lot # AHN1098T
#2 - Name and Strength fort	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

3. Dose or Amount	Frequency	Route
#1 45g	Continuous	Topical
#2		

4. Dates of Use (From/To for each) (If unknown, give duration, or best estimate) (dd-mmm-yyyy) #1 11/02/2016	9. Event Abated After Use Stopped or Dose Reduced? #1 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply
#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply

5. Diagnosis or Reason for Use (indication) #1 Flea allergy	10. Event Reappeared After Reintroduction? #1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> Doesn't apply
#2 House flea infestation	

6. Is the Product Compounded? #1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	7. Is the Product Over-the-Counter? #1 <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No
---	---	---	---

8. Expiration Date (dd-mmm-yyyy)
#1 _____ #2 _____

E. SUSPECT MEDICAL DEVICE

1. Brand Name	
2. Common Device Name CTU	2b. Procode
3. Manufacturer Name, City and State MAR - 2 2016	
4. Model #	Lot #
Catalog #	Expiration Date (dd-mmm-yyyy)
Serial #	Unique Identifier (UDI) #

6. If Implanted, Give Date (dd-mmm-yyyy)	7. If Explanted, Give Date (dd-mmm-yyyy)
--	--

8. Is this a single-use device that was reprocessed and reused on a patient? Yes No

9. If Yes to Item 8, Enter Name and Address of Reprocessor

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

Product names and therapy dates (Exclude treatment of event)
Prednisone 20mg BID
Cephalexin 500mg 2 caps BID

G. REPORTER (See confidentiality section on back)

1. Name and Address	
Last Name: HARRISON	First Name: ELLEN
Address: CALVERT ANIMAL HOSPITAL	
City: OWINGS	State/Province/Region: MD
Country:	ZIP/Postal Code:
Phone #:	Email:

2. Health Professional? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	3. Occupation Veterinarian	4. Also Reported to: <input checked="" type="checkbox"/> Manufacturer/Compounder <input type="checkbox"/> User Facility <input type="checkbox"/> Distributor/Importer
5. If you do NOT want your identity disclosed to the manufacturer, please mark this box: <input type="checkbox"/>		

PLEASE TYPE OR USE BLACK INK

**VETERINARY ADVERSE DRUG REACTION, LACK OF
EFFECTIVENESS, OR PRODUCT DEFECT REPORT**
(For VOLUNTARY Reporting)

003

NOTE: This report is authorized by 21 U.S.C 352 (a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling.

Individual Case Safety Report Number (FDA Assigned Number)	Submission Type <input checked="" type="checkbox"/> Initial <input type="checkbox"/> Follow-up
Report Type <input checked="" type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem <input type="checkbox"/> Both Adverse Event and Product Problem	
Date of this Report (mm/dd/yyyy) (18) Month <input type="text" value="07"/> Day <input type="text" value="18"/> Year <input type="text" value="2016"/>	Date of Initial Report (If this report is a follow-up) (mm/dd/yyyy) Month <input type="text"/> Day <input type="text"/> Year <input type="text"/>

Sender Information

First Name Katie	Last Name Mayberger	
Street Address 14 School St		
City Ronkonkoma	State or Province NY	Postal/ZIP Code 11779
Country USA	Telephone Number 631-487-9994	Telephone Number (Other)
Fax Number	Email Address nursekatie16@gmail.com	
Sender Category <input type="checkbox"/> Veterinarian <input checked="" type="checkbox"/> Animal Owner <input type="checkbox"/> Physician <input type="checkbox"/> Patient <input checked="" type="checkbox"/> Other Health Care Professional <input type="checkbox"/> Other <input type="checkbox"/> Unknown		

Sender Previously Reported to the Manufacturer? Yes No
If Yes, provide the Manufacturer's Case Number: 1866314

No Identity Disclosure If you do NOT want your identity disclosed to the manufacturer, mark this box.

Preferred Method of Contact Telephone Email either

Health Care Professional Information (If different from Sender Information)

First Name Atlantic Coast Veterinary	Last Name Specialists	RECEIVED AUG 09 2016
Street Address 3250 Veterans Highway		
City Bohemia	State or Province NY	Postal/ZIP Code 11716
Country USA	Telephone Number 631-285-7780	Telephone Number (Other)
Fax Number (631)285-7781	Email Address	

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Owner Information (If different from Sender Information)

First Name		Last Name	
Street Address			
City	State or Province	Postal/ZIP Code	
Country	Telephone Number	Telephone Number (Other)	
Fax Number	Email Address		

Suspected Product Information

Name of Suspected Product
Seresto collar - small dog

Diagnosis and/or Reason for Use of the Product
Flea & tick prevention

Dosage Form (Chewable, liquid, tablet, topical, injection, etc.)
collar

Date of First Exposure (mm/dd/yyyy) Month <u>07</u> Day <u>08</u> Year <u>2016</u>	Date of Last Exposure (mm/dd/yyyy) Month <u>07</u> Day <u>16</u> Year <u>2016</u>
---	--

Duration of Product Use
~ 9 days

Product Use Information for Suspected Product

Dose Administered
1 collar - size small

Interval of Administration (Frequency)
worn continuously

Route of Administration
collar/topical

Product Administered By
 Veterinarian/Veterinary Staff Owner Other

Lot Number <u>KPOAEZO</u>	Expiration Date (mm/dd/yyyy) <u>unknown at present</u> Month <input type="checkbox"/> Day <input type="checkbox"/> Year <input type="checkbox"/>
------------------------------	---

Name of Manufacturer of Suspected Product
Bayer

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Adverse Event Information

Veterinarian's Level of Suspicion that Product Caused the Adverse Event

- High
- Medium
- Low
- Unknown

Treatment of Adverse Event (Describe briefly) *CBC, Chemistry, IV Fluids, Valium drip continuous IV, Keppra started, monitoring*

Did Adverse Event Abate After Stopping the Product?

- Yes
- No
- Not Applicable

Did Adverse Event Reappear After Reintroduction of the Product?

- Yes
- No
- Not Applicable

Outcome

- Recovered
- Died
- Other

Species and Related Information

- | | | | | |
|---|---|---------------------------------|------------------------------------|-------------------------------------|
| <input type="checkbox"/> Budgerigar | <input type="checkbox"/> Cat | <input type="checkbox"/> Cattle | <input type="checkbox"/> Cockatiel | <input type="checkbox"/> Cockatoo |
| <input checked="" type="checkbox"/> Dog | <input type="checkbox"/> Ferret | <input type="checkbox"/> Fish | <input type="checkbox"/> Goat | <input type="checkbox"/> Guinea Pig |
| <input type="checkbox"/> Horse | <input type="checkbox"/> Human | <input type="checkbox"/> Parrot | <input type="checkbox"/> Pig | <input type="checkbox"/> Rabbit |
| <input type="checkbox"/> Sheep | <input type="checkbox"/> Other (Specify): _____ | | | |

Breed

Havanese

Gender

- Male
- Female
- Male Neutered
- Female Neutered

Age: *9 years*

Weight: *15 lbs*

Overall Health Status When Suspected Product Given

- Excellent
- Good
- Fair
- Poor
- Critical

Number of Animals Treated:

Number of Animals Affected:

Adverse Event Occurrence

Date of Onset of Adverse Event (mm/dd/yyyy)

Month *07* Day *16* Year *2016*

Length of Time Between First Exposure to Suspected Product(s) and Onset of Adverse Event

~ 9 days

Length of Time Between Last Administration of Suspected Product(s) and Onset of Adverse Event

product continuously doses after administrati

When the Adverse Event Occurred, Treatment with Suspected Product

- Had already been completed
- Was discontinued
- Was discontinued and replaced with another product
- Was discontinued and reintroduced later
- Was continued at an altered dose
- Other (Specify): _____

Document Information

Attached Document Name (Filename if Electronic)

Attached Document Description

Attached Document Name (Filename if Electronic)

Attached Document Description

Attached Document Name (Filename if Electronic)

Attached Document Description

15

Concurrent Clinical Problem(s)

Were There Concurrent Clinical Problems?

Yes

No

Do not know

None

List Concurrent Clinical Problem(s).

N/A

Concurrent Product Information (Excluding Treatment of Current Event)

Please provide name(s), dose(s), interval(s), date(s) of treatment(s), and other relevant information to describe other products that the patient was taking at the time of the event. Either copy this section as needed (you may fill out this section in other copies of this form) or provide comments in the long narrative section that follows this one.

Were Concurrent Products Given?

Yes

No

Do not know

None

List Names of Concurrent Products Administered.

/

Date of First Exposure (mm/dd/yyyy)

Month Day Year

Date of Last Exposure (mm/dd/yyyy)

Month Day Year

Duration of Product Use

Adverse Event/Product Problem (Long Narrative)

Describe the Adverse Event/Product Problem.

Previously healthy dog with no medical history, brought for annual physical 2 weeks prior with normal exam & blood work, stool specimen. Seresto collar recommended by vet at physical visit for flea/tick prevention. Dog was groomed Thursday 7/7/16 & coat was cut short. Seresto collar applied Friday 7/8/16 per instructions. 7/12/16 - 7/13/16, appetite slightly ↓, dog acted very nervous, anxious, hyperresponsive. 7/14/16 - 7/15/16 dog was lethargic, not herself, slept all day in an unusual location. 7/16/16, Saturday, woke up as usual, had not gotten up, noticed the dog trying to clear/clean teeth on @ side of mouth with her tongue, scant white foamy secretions noticed on lower jaw, movement became more rapid, repetitive. than the "gum chewing" movements stopped & entire body started trembling. I called for my mother, picked the dog up & the convulsions became stronger & more severe, vet called, dog became rigid, apneic, eyes rolled in the back of her head. She then began gasping, trying to move air unsuccessfully. She then started breathing, her body relaxed, she initially couldn't stand or

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Adverse Event/Product Problem (Long Narrative, Continued)

If more space is needed, continue description below of the Adverse Event/Product Problem.

support herself. The collar was removed & she was brought to the vet immediately. She was back to normal upon arrival to the vet, still slightly over anxious, labs drawn with normal results & we returned home being advised just to monitor her as she never had this or any issue before. About 10:30pm the same night (7/16/16, Saturday) she presented with another seizure - "gum chewing" → full body convulsions & then it broke. This episode lasted ~15-30 seconds. The first & largest seizure lasted ~2-3min in entirety and started at about 10:30am of that morning (7/16/16). After looking online I read about washing her neck off with dawn detergent + water, as there are many similar stories of neurological issues after starting Seresto, specifically in smaller breeds. Dog's neckline was cleaned off ~11:30pm that night. At 12:30^{AM} now Sunday morning a 3rd seizure occurred, "gum chewing," → confusion disoriented/scarred → convulsions → fell over on side → gasping for air. After regaining consciousness she was weak, confused, howling, running around the house, appearing lost. This last episode lasted 1-2min. She was rushed to Vet ER & admitted until Sunday (7/17/16) night. Upon arrival she was oriented & again, back to herself. Her admission was uneventful, ϕ seizure activity, vital signs stable, chemistries/CBC normal. She was started on a Valium continuous IV drip, maintenance IV fluids and oral Keppra. She was brought home Sunday (7/17/16) @ ~8:30pm & has returned to her normal self, eating/drinking/playing & has had no more seizure activity.

*Product expiration date unknown at present because I had thrown out the items case. However, I have been an RN, 10+ years & know it was not expired. The company I purchased the Seresto collar from is trying to obtain the expiration date for me at present. I will submit follow up documentation if additional information is acquired.

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**VETERINARY ADVERSE DRUG REACTION, LACK OF
EFFECTIVENESS, OR PRODUCT DEFECT REPORT**
(For VOLUNTARY Reporting)

NOTE: This report is authorized by 21 U.S.C 352 (a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling.

Individual Case Safety Report Number (FDA Assigned Number) _____ Submission Type Initial Follow-up

Report Type Adverse Event Product Problem Both Adverse Event and Product Problem

Date of this Report (mm/dd/yyyy) Month Day Year Date of Initial Report (If this report is a follow-up) (mm/dd/yyyy) Month Day Year

Sender Information

First Name Katya Last Name Hernandez

Street Address 1503 Noble Forest Drive

City Norcross State or Province GA Postal/ZIP Code 30092

Country USA Telephone Number 770 865 1317 Telephone Number (Other) _____

Fax Number _____ Email Address Kbella18@gmail.com

Sender Category Veterinarian Animal Owner Physician Patient
 Other Health Care Professional Other Unknown

Sender Previously Reported to the Manufacturer? Yes No

If Yes, provide the Manufacturer's Case Number: _____

No Identity Disclosure If you do NOT want your identity disclosed to the manufacturer, mark this box.

Preferred Method of Contact Telephone Email

Health Care Professional Information (If different from Sender Information)

First Name Dr. Mary Pat Last Name Hill

Street Address 6225 Peachtree Industrial Blvd

City Atlanta State or Province GA Postal/ZIP Code 30306

Country USA Telephone Number 770 455-1011 Telephone Number (Other) _____

Fax Number _____ Email Address _____

18

Owner Information (If different from Sender Information)

First Name		Last Name	
Street Address			
City		State or Province	Postal/ZIP Code
Country	Telephone Number		Telephone Number (Other)
Fax Number	Email Address		

Suspected Product Information

Name of Suspected Product
Activyl - spot on for cats (For cats over 9 lb ONLY)

Diagnosis and/or Reason for Use of the Product
I used Activyl as a flea treatment.

Dosage Form (Chewable, liquid, tablet, topical, injection, etc.)

Liquid

Date of First Exposure (mm/dd/yyyy)

Month **6** Day **26** Year **2016**

Date of Last Exposure (mm/dd/yyyy)

Month **6** Day **26** Year **2016**

Duration of Product Use

used just 1 dose

Product Use Information for Suspected Product

Dose Administered

1 dose

Interval of Administration (Frequency)

once

Route of Administration

Product Administered By

Veterinarian/Veterinary Staff

Owner

Other

Lot Number

50410FO

Expiration Date (mm/dd/yyyy)

Month Day Year

Date not listed on package

Name of Manufacturer of Suspected Product

Merck Animal Health

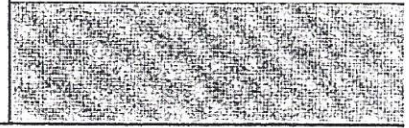
1674694

0157

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

Form Approved: OMB No. 0910-0645
Expiration Date: 4/30/2016
(See mailer page for Burden Statement)

**VETERINARY ADVERSE DRUG REACTION, LACK OF
EFFECTIVENESS, OR PRODUCT DEFECT REPORT**
(For VOLUNTARY Reporting)



NOTE: This report is authorized by 21 U.S.C 352 (a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling

Individual Case Safety Report Number (FDA Assigned Number) _____ Submission Type Initial Follow-up

Report Type Adverse Event Product Problem Both Adverse Event and Product Problem

Date of this Report (mm/dd/yyyy) Month Day Year Date of Initial Report (If this report is a follow-up) (mm/dd/yyyy) Month Day Year

Sender Information

First Name: Kenneth Last Name: Tack

Street Address: 5102 Canyon Oaks Drive

City: Brighton State or Province: MI Postal/ZIP Code: 48114

Country: USA Telephone Number: (810) 227-1386 Telephone Number (Other):

Fax Number: Email Address: kjtack@comcast.net

Sender Category Veterinarian Animal Owner Physician Patient Other Health Care Professional Other Unknown

Sender Previously Reported to the Manufacturer? Yes No

CTU

If Yes, provide the Manufacturer's Case Number: _____

AUG 18 2016

No Identity Disclosure If you do NOT want your identity disclosed to the manufacturer, mark this box.

Preferred Method of Contact Telephone Email

Health Care Professional Information (If different from Sender Information)

First Name: _____ Last Name: _____

Street Address: _____

City: _____ State or Province: _____ Postal/ZIP Code: _____

Country: _____ Telephone Number: _____ Telephone Number (Other): _____

Fax Number: _____ Email Address: _____

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674694

Owner Information (If different from Sender Information)

First Name		Last Name	
Street Address			
City	State or Province	Postal/ZIP Code	
Country	Telephone Number	Telephone Number (Other)	
Fax Number	Email Address		

Suspected Product Information

Name of Suspected Product
Seresto collar (imidacloprid/flumethrin)

Diagnosis and/or Reason for Use of the Product
Prophylaxis of tick and flea infestation

Dosage Form (Chewable, liquid, tablet, topical, injection, etc.)
Topical - dog collar

Date of First Exposure (mm/dd/yyyy) Month <input type="text" value="06"/> Day <input type="text" value="6"/> Year <input type="text" value="2016"/>	Date of Last Exposure (mm/dd/yyyy) Month <input type="text" value="07"/> Day <input type="text" value="21"/> Year <input type="text" value="2016"/>
--	--

Duration of Product Use
Approximately 6 weeks

Product Use Information for Suspected Product

Dose Administered
Dog collar

Interval of Administration (Frequency)
Continuous

Route of Administration
Dog collar

Product Administered By
 Veterinarian/Veterinary Staff
 Owner
 Other

Lot Number Unknown	Expiration Date (mm/dd/yyyy) Month <input type="text"/> Day <input type="text"/> Year <input type="text"/>
-----------------------	---

Name of Manufacturer of Suspected Product
Bayer

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Adverse Event Information

Veterinarian's Level of Suspicion that Product Caused the Adverse Event

- High
- Medium
- Low
- Unknown

Treatment of Adverse Event (Describe briefly)

Removal of collar

Did Adverse Event Abate After Stopping the Product?

- Yes
- No
- Not Applicable

Did Adverse Event Reappear After Reintroduction of the Product?

- Yes
- No
- Not Applicable

Outcome

- Recovered
- Died
- Other

Species and Related Information

- | | | | | |
|---|---|---------------------------------|------------------------------------|-------------------------------------|
| <input type="checkbox"/> Budgerigar | <input type="checkbox"/> Cat | <input type="checkbox"/> Cattle | <input type="checkbox"/> Cockatiel | <input type="checkbox"/> Cockatoo |
| <input checked="" type="checkbox"/> Dog | <input type="checkbox"/> Ferret | <input type="checkbox"/> Fish | <input type="checkbox"/> Goat | <input type="checkbox"/> Guinea Pig |
| <input type="checkbox"/> Horse | <input type="checkbox"/> Human | <input type="checkbox"/> Parrot | <input type="checkbox"/> Pig | <input type="checkbox"/> Rabbit |
| <input type="checkbox"/> Sheep | <input type="checkbox"/> Other (Specify): _____ | | | |

Breed

West Highland Terrier

Gender

- Male
- Male Neutered
- Female
- Female Neutered

Age: 7 years

Weight: 20 lbs

Overall Health Status When Suspected Product Given

- Excellent
- Good
- Fair
- Poor
- Critical

Number of Animals Treated: 1

Number of Animals Affected: 1

Adverse Event Occurrence

Date of Onset of Adverse Event (mm/dd/yyyy)

Month Day Year

Length of Time Between First Exposure to Suspected Product(s) and Onset of Adverse Event
Approximately 6 weeks

Length of Time Between Last Administration of Suspected Product(s) and Onset of Adverse Event
N/A

When the Adverse Event Occurred, Treatment with Suspected Product

- Had already been completed
- Was discontinued
- Was discontinued and replaced with another product
- Was discontinued and reintroduced later
- Was continued at an altered dose
- Other (Specify): _____

Document Information

Attached Document Name (Filename if Electronic)

Attached Document Description

Attached Document Name (Filename if Electronic)

Attached Document Description

Attached Document Name (Filename if Electronic)

Attached Document Description

Handwritten mark resembling a stylized 'H' or '11'.

674694

Concurrent Clinical Problem(s)

Were There Concurrent Clinical Problems?

Yes No Do not know None

List Concurrent Clinical Problem(s).

Concurrent Product Information (Excluding Treatment of Current Event)

Please provide name(s), dose(s), interval(s), date(s) of treatment(s), and other relevant information to describe other products that the patient was taking at the time of the event. Either copy this section as needed (you may fill out this section in other copies of this form) or provide comments in the long narrative section that follows this one.

Were Concurrent Products Given?

Yes No Do not know None

List Names of Concurrent Products Administered:

Date of First Exposure (mm/dd/yyyy)

Month Day Year

Date of Last Exposure (mm/dd/yyyy)

Month Day Year

Duration of Product Use

Adverse Event/Product Problem (Long Narrative)

Describe the Adverse Event/Product Problem.

The patient, a 7-year old male West Highland Terrier, was in excellent health. On about June 6, a Seresto collar was started for prevention of tick/flea infestation. On July 18 he became lethargic and would not eat. There was no known exposure to toxins or sick animals or humans.

Veterinary evaluation on July 21 showed a slight fever. Laboratory testing at that time showed an ALT of 1335 U/L (upper limit of normal (ULN) 125 U/L), Alkaline Phosphatase 1726 U/L (ULN 212), normal creatinine and total bilirubin. CBC showed total WBC $22.6 \times 10^6/\text{mcL}$ with normal neutrophils but lymphocytes were $12.8 \times 10^6/\text{mcL}$ (ULN $5.1 \times 10^6/\text{mcL}$), monocytes $4.0 \times 10^6/\text{mcL}$ (ULN $1.1 \times 10^6/\text{mcL}$), and platelets $87 \times 10^6/\text{mcL}$ (LLN $148 \times 10^6/\text{mcL}$). Hemoglobin was normal. The Seresto collar was removed.

On July 22, an abdominal ultrasound examination showed a normal appearing liver, sludge in the gall bladder, and a small amount of ascitic fluid. A CBC, done at a different laboratory, showed lymphocytosis, $6.4 \times 10^6/\text{mcL}$ (ULN $3.9 \times 10^6/\text{mcL}$); the platelet estimate was $300 - 450 \times 10^6/\text{mcL}$, with clumps; total WBC, neutrophils, monocytes, and hemoglobin were normal. Serology for leptospirosis was consistent with previous vaccination. A diagnosis of cholangiohepatitis was considered.

On July 23, the dog's appetite and energy were much improved. Oral amoxicillin was started. Over the next few days, the patient's condition returned to normal.

The patient's clinical course is consistent with a toxic hepatitis potentially caused by imidacloprid/flumethin.

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1029227

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Veterinary Medicine

Form Approved: OMB No. 0910-0645
Expiration Date: 4/30/2016
(See mailer page for Burden Statement)

**VETERINARY ADVERSE DRUG REACTION, LACK OF
EFFECTIVENESS, OR PRODUCT DEFECT REPORT**
(For VOLUNTARY Reporting)

NOTE: This report is authorized by 21 U.S.C 352 (a) and (f). While you are not required to report, your cooperation is needed to assure comprehensive and timely assessment of product labeling.

Individual Case Safety Report Number (FDA Assigned Number) _____ Submission Type Initial Follow-up

Report Type Adverse Event Product Problem Both Adverse Event and Product Problem

Date of this Report (mm/dd/yyyy) Month Day Year Date of Initial Report (If this report is a follow-up) (mm/dd/yyyy) Month Day Year

Sender Information

First Name: Jane Last Name: Lucy

Street Address: 14508 Broadway Road

City: Onancock State or Province: VA Postal/ZIP Code: 23417

Country: United States Telephone Number: 757-787-2705 Telephone Number (Other): 757-768-7828

Fax Number: _____ Email Address: 0

Sender Category Veterinarian Animal Owner Physician Patient Other Health Care Professional Other Unknown

Sender Previously Reported to the Manufacturer? Yes No

If Yes, provide the Manufacturer's Case Number: _____

No Identity Disclosure If you do NOT want your identity disclosed to the manufacturer, mark this box.

Preferred Method of Contact Telephone Email

Health Care Professional Information (If different from Sender Information)

First Name: Drew Last Name: Humphries

Street Address: Eastern Shore Animal Hospital, 34424 Lankford Highway

City: Painter State or Province: VA Postal/ZIP Code: 23420

Country: United States Telephone Number: 757-442-3150 Telephone Number (Other): _____

Fax Number: _____ Email Address: _____

Owner Information (If different from Sender Information)

First Name		Last Name	
Street Address			
City		State or Province	Postal/ZIP Code
Country		Telephone Number	Telephone Number (Other)
Fax Number		Email Address	

Suspected Product Information

Name of Suspected Product
Seresto Flea Collar

Diagnosis and/or Reason for Use of the Product
Was prescribed by Veterinarian to help control fleas.

Dosage Form (Chewable, liquid, tablet, topical, injection, etc.)
Flea Collar

Date of First Exposure (mm/dd/yyyy)		Date of Last Exposure (mm/dd/yyyy)	
Month <input type="text" value="10"/>	Day <input type="text" value="10"/>	Year <input type="text" value="2015"/>	Month <input type="text" value="10"/>
			Day <input type="text" value="15"/>
			Year <input type="text" value="2015"/>

Duration of Product Use
5 days

Product Use Information for Suspected Product

Dose Administered
N/A Flea Collar

Interval of Administration (Frequency)

Route of Administration

Product Administered By
 Veterinarian/Veterinary Staff Owner Other

Lot Number		Expiration Date (mm/dd/yyyy)	
		Month <input type="text"/>	Day <input type="text"/>
			Year <input type="text"/>

Name of Manufacturer of Suspected Product
Bayer HealthCare LLC

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Adverse Event Information

Veterinarian's Level of Suspicion that Product Caused the Adverse Event:

- High Medium Low Unknown

Treatment of Adverse Event (*Describe briefly*)

Patient presented with diarrhea, vomiting and drooling. Patient was treated for diarrhea and vomiting.

Did Adverse Event Abate After Stopping the Product?

- Yes No Not Applicable

Did Adverse Event Reappear After Reintroduction of the Product?

- Yes No Not Applicable

Outcome

- Recovered Died Other

Species and Related Information

- Budgerigar Cat Cattle Cockatiel Cockatoo
 Dog Ferret Fish Goat Guinea Pig
 Horse Human Parrot Pig Rabbit
 Sheep Other (*Specify*): _____

Breed
Persian

Gender

- Male Female
 Male Neutered Female Neutered

Age: 1 year 6 months

Weight: 10 lbs 8 oz

Overall Health Status When Suspected Product Given

- Excellent Good Fair Poor Critical

Number of Animals Treated:

Number of Animals Affected:

Adverse Event Occurrence

Date of Onset of Adverse Event (*mm/dd/yyyy*)

Month Day Year

Length of Time Between First Exposure to Suspected Product(s) and Onset of Adverse Event
3 days

Length of Time Between Last Administration of Suspected Product(s) and Onset of Adverse Event
N/A

When the Adverse Event Occurred, Treatment with Suspected Product

- Had already been completed Was discontinued Was discontinued and replaced with another product
 Was discontinued and reintroduced later Was continued at an altered dose
 Other (*Specify*): Patient was treated for nausea and vomiting, the next day, the collar was removed as nothing was working.

Document Information

Attached Document Name (*Filename if Electronic*)

Letter of complaint / concerns with details to Bayer HealthCare LLC

Attached Document Description

Attached Document Name (*Filename if Electronic*)

Attached Document Description

Attached Document Name (*Filename if Electronic*)

Attached Document Description

3

Concurrent Clinical Problem(s)

Were There Concurrent Clinical Problems?

Yes No Do not know None

List Concurrent Clinical Problem(s).

Patient had soft stools, treated for RoundWorms with ProFender.

Concurrent Product Information (Excluding Treatment of Current Event)

Please provide name(s), dose(s), interval(s), date(s) of treatment(s), and other relevant information to describe other products that the patient was taking at the time of the event. Either copy this section as needed (you may fill out this section in other copies of this form) or provide comments in the long narrative section that follows this one.

Were Concurrent Products Given?

Yes No Do not know None

List Names of Concurrent Products Administered.

ProFender
Cerenia
Albon
SubQ Fluids
Vitamin B12 Injection

Date of First Exposure (mm/dd/yyyy)

Month Day Year

Date of Last Exposure (mm/dd/yyyy)

Month Day Year

Duration of Product Use

Adverse Event/Product Problem (Long Narrative)

Describe the Adverse Event/Product Problem.

As per the advice of our Veterinarian, I placed the flea collar on my cat on Saturday, October 10. On Tuesday, October 13, I noticed a small amount of diarrhea, and on Wednesday, October 14, I discovered where he had vomited during the night. I tried to syringe a little water for him, but he foamed/drooled excessively. I immediately took him to our vet, and told him that Nuggett showed all the signs of being poisoned, but I could not explain why, as there was nothing he could have gotten into. Our Vet assured me that the collar was safe, and left it on. The next day, Nuggett was still no better, and I insisted we remove the collar. During this time, Nuggett was also administered ProFender (also manufactured by Bayer HealthCare LLC). The Veterinarian agreed that Nuggett was having an adverse reaction/ poisonous reaction to the product (s). The following morning, Nuggett threw up blood, crashed and passed. Prior to all of this, he had been a thriving, healthy, growing one year old. It should be noted that on Wednesday, October 14, the choice to leave Nuggett at the vet was mine so that the Vet could obtain a stool sample. All blood work came back showing a perfectly healthy cat. Please see attached letter for explicit details of the events and treatments.

File a Report

Patricia J. Johnson
710 Beech St.
Rome, New York 13440

Received 0700

701 101 20 11 11



US Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
Attention: Safety Complaint
Phone: 1-800-638-2772
E-mail: info@cpsc.gov
www.saferproducts.gov

This form provides a way for you to collect the information you will need to submit when you are ready to submit this form online. We encourage you to use the online form to formally submit a report. However, if you can't fill in the online form, you may choose to print this form and mail a signed copy to the address on the right. Do not send in the form and fill it out online, only submit it once.

If you are unsure about how to fill in a multiple-selection field in this form skip it. Please make sure that you provide full detail in the description of the hazardous incident or safety concern.

* Indicates required field

* I am a / ~~I am affiliated with:~~

- Consumer
- Local Government Agency
- State Government Agency
- Federal Government Agency
- Public Safety Entity
- Health Care Professional
- Medical Examiner and Coroner
- Child Service Provider

RECEIVED
DEC 02 2016
BY: *Mc*

Tell Us What Happened

* I am reporting:

- A hazardous incident: An actual incident or injury involving an unsafe consumer product.
- A safety concern: The potential for an unsafe consumer product to cause an incident or injury.

* Please describe the hazardous incident or safety concern:

Serious Within 3wks after putting the Bayer Seresto Flea Collar on my dog, she experienced (2) seizures, lethargy, diarrhea; poisoning in blood; loss of mobility & final death. Company has agreed my dog experienced all side effects & are willing to pay for collar & some vet bills. I am requesting reimbursement of all vet bills & collar refund. I no longer have my 3yr old puppy & the reimbursement is a very, very small amount to pay for the poisoning of my dog. (See Attached for full information)

Important: Include details such as how the product was being used, what happened to prompt your report and any injuries that were sustained. Do not provide personally identifiable information in this box.

Disclaimer: The Commission does not guarantee the accuracy, completeness or adequacy of the contents of the Consumer Product Safety Information Database, particularly with respect to the accuracy, completeness or adequacy of information submitted by persons outside of the CPSC.

Tell Us What Happened (continued)

*Incident Date: (mm/dd/yyyy)

Is this an Estimated Date? Yes No

Location:

- Home / Apartment / Condominium
- Mobile / Manufactured Home
- Place of Recreation or Sports
- Street or Highway
- School
- Industrial
- Farm / Ranch
- Other Public Property / Office
- Unknown

Incident Address:

Apt / Office / Suite:

City:

State:

Postal Code:

Country:

This is my home address

People Involved and Their Injuries

This section only applies if you are reporting a hazardous incident, not a safety concern.

For each victim involved you will need to provide the following information. We have provided space for one victim, when you fill in the online report you can enter the information for many victims.

Number of Victims Involved The term "victim" covers any individual killed, injured or exposed to a possible product-related hazard and does not imply that the product caused an incident.

- * Injury Information (select one):
- Incident, No Injury
 - Injury, No First Aid or Medical Attention Received
 - Injury, First Aid Received
 - Injury, Medical Attention Received
 - Injury, Emergency Department Treatment Received
 - Injury, Hospital Admission
 - Death

Patricia J. Johnson
710 Beech St.
Rome, New York 13440

Location of Injury (if applicable):

- | | | |
|--|--|--|
| <input type="checkbox"/> 25 - 50 % of body | <input type="checkbox"/> Foot | <input checked="" type="checkbox"/> Neck |
| <input type="checkbox"/> All parts of body (more than 50% of body) | <input type="checkbox"/> Hand | <input type="checkbox"/> Pubic Region |
| <input type="checkbox"/> Ankle | <input type="checkbox"/> Head | <input type="checkbox"/> Shoulder (including clavicle, collarbone) |
| <input type="checkbox"/> Arm | <input type="checkbox"/> Head | <input type="checkbox"/> Toe |
| <input type="checkbox"/> Ear | <input checked="" type="checkbox"/> Internal (use with Aspiration and Ingestion) | <input type="checkbox"/> Torso |
| <input type="checkbox"/> Elbow | <input type="checkbox"/> Knee | <input type="checkbox"/> Wrist |
| <input type="checkbox"/> Eyeball | <input type="checkbox"/> Leg | <input type="checkbox"/> Not Recorded |
| <input type="checkbox"/> Face (including eyelid, eye area, and nose) | <input type="checkbox"/> Mouth | |
| <input type="checkbox"/> Finger | | |

Type of Injury (select up to two):

- | | | |
|--|---|--|
| <input type="checkbox"/> Amputation | <input type="checkbox"/> Dislocation | <input type="checkbox"/> Object Swallowed |
| <input type="checkbox"/> Bleeding | <input type="checkbox"/> Drowning | <input checked="" type="checkbox"/> Poisoning |
| <input type="checkbox"/> Break, Fracture | <input type="checkbox"/> Electric Shock | <input type="checkbox"/> Puncture |
| <input type="checkbox"/> Bruising, Scratches | <input type="checkbox"/> Foreign Object Stuck In or On the Body | |
| <input checked="" type="checkbox"/> Burn | <input checked="" type="checkbox"/> Internal Organ Injury | <input type="checkbox"/> Severe Bruising |
| <input type="checkbox"/> Concussion | <input type="checkbox"/> Lack of Oxygen | <input type="checkbox"/> Skin Tear, Skin Flap, Nail Detachment |
| <input type="checkbox"/> Cut | <input checked="" type="checkbox"/> Nerve Damage | <input type="checkbox"/> Strain, Sprain |
| <input type="checkbox"/> Dental injury | <input type="checkbox"/> Object Inhaled | <input type="checkbox"/> Other/Not Stated |
| <input type="checkbox"/> Dermatitis, Conjunctivitis, Skin or Eye Irritation/Rash | | |

Your relationship to this victim:

- | | |
|------------------------------------|---|
| <input type="checkbox"/> Self | <input type="checkbox"/> Other relative |
| <input type="checkbox"/> My child | <input type="checkbox"/> My friend /neighbor / co-worker |
| <input type="checkbox"/> My parent | <input type="checkbox"/> My client, patient, student etc. (professional relationship) |
| <input type="checkbox"/> My spouse | <input type="checkbox"/> No relationship |

Victim's Gender: Male Female

Pet - Dog

Victim's age at the time of the incident:

For children under age 3, provide the age in years and months Years Months

Victim is of Hispanic/Latino origin Yes No

- Victim's Race: White Other
- Black/African American
- Asian
- American Indian/Alaska Native
- Native Hawaiian/Pacific Islander
- Unknown

Specify Other Race:

Victim's First Name: E-mail:

Victim's Last Name: Phone:

- The victim's address is the same as the incident address.
 Use the address below.

Victim's Address: Apt / Office / Suite:

City: State: Postal Code:

Country:

Tell Us About the Product

In order to investigate your report, CPSC needs to know about the product. Product identification found on labels or manuals is especially important. We ask that you fill in as much information as you can about the product.

*Product Category (select one):

- | | | |
|---|--|---|
| <input type="checkbox"/> Clothing & Accessories | <input type="checkbox"/> Hobby | <input type="checkbox"/> Sports & Recreation |
| <input type="checkbox"/> Containers & Packaging | <input type="checkbox"/> Home Maintenance & Structures | <input type="checkbox"/> Toys, Kids, & Baby |
| <input type="checkbox"/> Drywall | <input type="checkbox"/> Kitchen | <input type="checkbox"/> Yard & Garden |
| <input type="checkbox"/> Electronics | <input type="checkbox"/> Personal Care | <input checked="" type="checkbox"/> None of these |
| <input type="checkbox"/> Fuel, Lighters & Fireworks | <input type="checkbox"/> Products at Public Facilities | |
| <input type="checkbox"/> Furniture, Furnishings & Decorations | | |

*Product Description:

Important: Please write a description of the product, including the product name and any other information that will help us identify the product and purpose for which it is used.

Bayer Seresto Flea & Tick Collar for Small Dogs. Company has acknowledged dog had adverse side effects from the poison. I am willing to pay \$321.83 of the \$1596.79 Vet Bills plus \$65.24 for the collar. I have refused this payment as well as the original amount of \$130.17.

Brand Name: Seresto Flea & Tick Collar for small Dogs.

Model Name or Number: Serial Number: Lot # AHNS029T

Manufacturer/Private Labeler Name: Bayer Healthcare, LLC Animal Health Division

Date Manufactured (mm/dd/yyyy):

Manufactured Date Code: V-01/2015 (84586560)

Manufacturer or Private Labeler Address: (if known) PO Box 390

Purchased From (Store Name or Internet site): Tractor Supply Retailer Location (State): New York

Purchase Date: (mm/dd/yyyy) 08-07-2016 Is this an Estimated Date? Yes No

More Important Questions About the Product

- I still have the product. Yes No N/A
(Please try to keep the product for at least 30 days after submitting the report for CPSC's use.)
- The product was damaged before the incident. Yes No N/A
- The product was repaired before the incident. Yes No N/A
- The product was modified before the incident. Yes No N/A
- Have you contacted the manufacturer? Yes No N/A
- If not, do you plan to contact them? Yes No N/A

NOTE: The online form contains a section where you may upload pictures or similar documentation from your computer. You are encouraged to submit pictures of the product, its packaging, bar code or other identifying information.

Patricia J. Johnson
710 Beech St.
Rome, New York 13440

Your Contact Information

Please provide your contact information below. Your name and contact information will never appear in the Public Database.

*First Name: PATRICIA J *Last Name: JOHNSON

You must be 18 years old to submit a report. If you are not 18, please skip down the form and provide the contact information for your parent or guardian. CPSC will contact this person to verify this report.

- I am 18 years of age or older.
- My contact address is the same as the incident address.
- Use the address below.

*Address: _____ Apt / Office / Suite: _____
*City: _____ *State: _____ *Postal Code: _____
*Country: _____
E-mail: NEW778VENTURE@AOL.COM Phone: 315-337-9846

Please provide a parent or guardian's information below only if you are younger than 18 years old.

First Name: _____ Last Name: _____
Phone: _____ E-mail: _____
Address: _____ Apt / Office / Suite: _____
City: _____ State: _____ Postal Code: _____
Country: _____

Consent & Submit

Please let us know how you would like us to handle your report.

*May we include your report including any documents or photographs that you have attached to your report, but without your name and contact information, in CPSC's Public Database?

- Yes, you may include my report in the Public Database.
- No, do not include my report in the Public Database.

*May we release your name and contact information to the product manufacturer or private labeler?

- Yes, you may release my name and contact information to the product manufacturer or private labeler.
- No, do not release my name and contact information to the product manufacturer or private labeler.

*By signing this form I certify that the information provided in this report is true and accurate to the best of my knowledge, information, and belief.

Patricia J. Johnson
Signature

11-17-16
Date

Jane W Lucy
14508 Broadway Road
Onancock, Virginia 23417

October 21, 2015

Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201

To Whom It May Concern:

On Saturday, October 10, we put a Seresto Cat Collar, manufactured and distributed by your company, on our one year old Flame Point Persian, Nuggett. Nuggett was a virile, healthy, perfect little cat who had thrived in his first year with us. The Seresto Collar was strongly recommended by our Veterinarian. I have never been a fan of using flea collars on cats, however, considering that we live in a very low, damp area, and consequently, even though our cats are never, ever allowed outside, fleas still become a problem. And so, despite my concerns, we trusted our vet and purchased not only one, but four collars for all of our fur-children. Our vet also put him on Metronidazole for soft stools.

The next several days, Nuggett presented no symptoms, but then, on Tuesday, October 13, Nuggett had a small amount of very liquid diarrhea. By Wednesday morning, October 14, he had also thrown up several times and would drool/foam excessively when I would attempt to syringe water in him to make sure he was hydrated before leaving home to take him to our vet. Nuggett presented all the symptoms of having been poisoned; there was no fever, and his health was otherwise perfect according to all tests run. They found evidence of roundworms, so he was treated with Profender. The vet could not find anything that would explain what was happening, and so I asked that he be allowed to stay with them until he had another bowel movement so they could test to see what was going on.

By that night, Nuggett still had not had a bowel movement, so we decided to let him stay overnight. On Thursday morning, October 15, I called our vet and Nuggett had more vomiting and a little more diarrhea. The vet said his heart and lungs were strong, and the blood work had come back great, with absolutely no cause for concern. There simply was no explanation for what was going on. When I went to visit with him that day, he was a little quiet, but did not seem to be in any distress, and was happy as I sat in the floor loving him, even trying to escape his kennel as I stood up to speak with the vet when he came in. The vet stated he had tightened the Seresto Collar as he still saw a few live fleas. As we sat there talking, trying to figure out what, if anything he could have possibly gotten into that would have caused this, we ruled out each and every possibility; we are extremely conscientious pet owners, there wasn't/isn't a single thing in our house that would be dangerous to them, nothing. I asked the vet to remove the collar immediately, it was the only thing that could possibly be causing this type of problem.

Friday morning, October 16, I called to speak with the vet, and the report was unchanged. Nuggett was strong, good heartbeat, lungs strong and clear, but still having diarrhea, this time, bloody. They had tested his stool and found coccidia, and had treated him with Albon, and he had tolerated the medicine and not thrown it up. We discussed my concern that Nuggett wasn't eating or drinking, and the vet stated he would attempt to syringe feed him a little that morning, and administer Sub Q fluids to ensure hydration. He suggested I bring some of his food from home that may be more appealing to him and help coax him to eat. Less than 30 minutes later, the vet called and informed me that Nuggett had vomited, this time bloody vomit, and was crashing. My beautiful, healthy, vibrant little boy could not breathe on his own and his heartbeat was fading.

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Jane W Lucy
14508 Broadway Road
Onancock, Virginia 23417

October 21, 2015

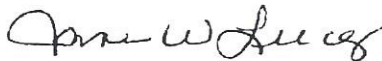
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, HFV-1
Rockville, MD 20855

To Whom It May Concern:

Attached please find FDA Complaint Form 1932a along with a copy of my letter of complaint/concerns which I have sent to Bayer HealthCare LLC. I appreciate any help and attention you may be able to offer.

Thanking you in advance.

Sincerely,



Jane W Lucy
14508 Broadway Road
Onancock, VA 23417
757-787-2705

enc.

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We raced to the veterinary office where our vet and his staff were working fervently over Nuggett to keep him alive until we got there. But it was too late, if they stopped massaging his little heart, it simply would not beat on its own. So we were left to accept the fact his little heart wasn't beating, his little lungs weren't breathing .. we were left to say goodbye to our beautiful, strong, healthy little one year old baby, a baby that should have had fifteen or more years of a pampered, privileged life to enjoy.

I have several areas of concern here. As a short recap, to begin with, prior to Saturday, Nuggett was healthy, growing, active, very, very much a normal healthy cat. Because his stools were a little soft, and because we had begun to see a few fleas, we took him to the vet. Our vet records will show that all of our babies get the very best veterinary care possible, we always err on the side of caution, taking them in just to be safe if a problem or issue presents itself, so their health was always our utmost concern, hence the trip to the vet on Saturday. The vet told us to put the Seresto collar on him, and treated him with Metronidazole for soft stools. A little less than a year ago, Nuggett had taken Metronidazole when we had changed his food and his stools had become soft. There were absolutely no ill effects from the medication, and no cause to believe this affected him adversely at this time either, since he had taken it before without incident. Saturday, Sunday and Monday, Nuggett continued to be a completely healthy, virile cat. Playful, good appetite, eating and drinking normally, no signs whatsoever of anything wrong. Then, Tuesday night, the diarrhea. On Wednesday morning, I awoke to discover that he had vomited, and we called the vet, telling them we were bringing him down. Before leaving I syringed a little water into his mouth, upon which he started drooling and foaming profusely. Please keep in mind that at this point, Nuggett was still active, rushing into whatever room we walked into, outside of the diarrhea and vomiting, there were absolutely no signs of debilitation. Once we arrived at the vet, they treated him with Profender. They tightened his Seresto collar the next morning as they still saw a few live fleas. He was treated with Cerenia for the nausea and vomiting, which had no effect, as he continued to have a few episodes of vomiting. I asked our vet to remove the collar and he did. When I returned home, we had agreed that we would both do some research into possible side effects of the collar, and so I began searching for potential problems. I was not happy at all with the complaints and problems I was finding, many horrific stories of consequences and death to pets that had been subjected to the Seresto collar, and so I immediately called our vet and told him under no circumstances was he to put that collar back on my baby.

Since Nuggett left us on Friday, our family has been grieving in a way we did not know was possible. This beautiful healthy cat was dead, for no reason, no explanation, no justification. When I left him on Thursday evening, I certainly didn't in a million years, expect that I would never see him again. I do not know how to come to grips with this, I cannot wrap my head around the fact that he is gone. Why?

I told our vet when we left on Friday that I would be contacting your company to express my concerns over the role your Seresto collar has played in Nuggetts death. When I sat down to write you yesterday, I wanted to make sure that I had done all of my research before I began, and just imagine my surprise when I learned that the Profender, which was applied to Nuggett on Wednesday night, is also made by your company, and also carries horror stories of reactions from people that have suffered devastating consequences, even pet death, after using your product.

Yes, Nuggett presented with coccidia on Thursday, which in an extreme case, can cause death. However, as I am certain you are aware, a large percentage of cats carry the coccidia parasite in their bodies, where it lies dormant causing no symptoms or problems throughout their entire lives. It presents itself most frequently in young kittens, only rearing its heads in older cats who have a weakened immune system. I would like to remind you that Nuggett was a healthy, strong and growing cat prior to having the collar put on him on Saturday.

I do not know if the Seresto Collar is to blame for his quick decline, or perhaps the Profender application on Wednesday night. Realistically, it could have been a combination of the two, these very potent poisons coursing through his little body to further weaken and debilitate him. I do know that on Wednesday night, the vet was ready to send him home, it was my decision to leave him there so that they could get a stool sample, and I also know that it was only after the application of YOUR products that my precious, amazing little baby began his decline. At no point, let me repeat that, at NO POINT did any of us think for one minute my beautiful baby was on deaths door, prior to his demise Friday morning.

The bottom line is, your product or a combination of your two products caused Nuggett to crash, and subsequently pass. It is completely irresponsible and unethical that your company does not provide a warning

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to pet owners of the possible dangers associated with these products. I don't care if it is only one cat out of all the many you tested; if there is an adverse reaction - ONE adverse reaction, pet owners need to be aware of that potential side effect. It is also heinously irresponsible for you to push these products as safe to use together, particularly on a cat that is having symptoms such as nausea and/or diarrhea; what possible good can come from putting all of these poisons into a tiny cats body when their system is already having another issue?

In your rush to promote these products you have affected so very many lives in such a horrific, tragic way. To begin, a beautiful, healthy, vigorous and spirited baby is gone, taken from us at only one year old, robbed of an amazing, wonderful life. We, his parents, are left reeling, a void that is both devastating and crushing consuming our every waking moment. Although yes, Nuggett was a beautiful purebred "animal" he was never JUST an animal to us, he was a member of our family, he was loved, he was cherished. Your products have stolen precious years with this beloved family member from us, and that is unforgivable. But there is more. Just for a moment, can you also think about our vet? Our vet recommended your products based on YOUR assurances, YOUR promises, YOUR statistics. Can you for just a moment think about how he feels, knowing that this amazing creature is gone because of what HE recommended? Our vet is one of the most loving, compassionate, skilled and competent vets I have ever had the pleasure to work with, I cannot imagine the hell he is dealing with right now, all because he took your words in good faith. How dare you put any of us in this situation, leave us with this crippling grief? HOW DARE YOU?

Rest assured that we not only feel this issue needs to be resolved, but that we will not rest until Nuggett's death can stand for something. HE WILL NOT HAVE DIED IN VAIN ... every ounce of strength I have within me will be devoted to ensuring that you and your company right this wrong, and that this never, ever happens again to an unsuspecting pet parent.

Sincerely,



Jane W Lucy
14508 Broadway Road
Onancock, VA 23417
757-787-2705

Veterinary Hospital:
Eastern Shore Animal Hospital
34424 Lankford Highway
Painter, VA 23420
757-442-3150
Attending Veterinarian: Dr. Drew Humphries

cc: Center for Veterinary Medicine, FDA



Cc: Milbourn, Cathy

Subject: Getting deadline--- WNBC-TV NY- consumer producer asking about Seresto dog collar

Hi Cathy,

Can you help us with a story we are working on?

We were contacted by a viewer about her experiences using a flea and tick dog collar called the Seresto dog collar and she claims that after using it for four months, her dog went blind as a result. I am pasting her original email to us below.

Do you have any complaints on file about it? any investigation?

Anything you can share would be very much appreciated!

Thank you,

Doreen

WNBC-TV consumer producer

212-664-6252

FROM THE PET OWNER:

From: Sarah Ziolkowski [<mailto:s.m.e.ziolkowski@gmail.com>]

Sent: Sunday, June 28, 2015 7:40 AM

To: Consumer Help

Subject: Seresto dog collar

Last August my vet told us about a new dog collar made by Bayer- called Seresto- that was supposed to be safe and prevent fleas and ticks. I was pregnant at the time, and we hated using the drops because we have a cat and the drops are dangerous for cats. So we, like my parents, listened to our vet and got the Seresto collar. The vet fit the collar for my dog (a Cockapoo) and we were told we would need a new one in 8 months.

My dog started acting differently shortly thereafter. She began eating our cat's food (something she had never done in her ten years) and by December was completely blind. We equate this entirely with the Seresto dog collar as she had NO health issues before placement of this collar. -001

My parents had also used the Seresto collar on their miniature schnauzer, and he too experienced severe medical issues, which ultimately led to his death. He admittedly had some issues before using the collar, but after using the collar he experienced different issues which led to my parents expending a fortune on his medical care. He was hospitalized for kidney failure and kept in ICU for several days. He was in and out of the pet hospital for weeks before my parents had to ultimately put him down. -002

Shortly after his death, my parents got two puppies. Despite my urging, my parents put the Seresto collar on the puppies (at their vet's recommendation) only to learn that the collar got caught on a piece of furniture, nearly choking one of them to death! -003

Finally, my best friend also had a negative experience with the use of the Seresto collar on her morkipoo. Her dog wore it only for a few hours and the negative effects were immediately known. The dog began to vomit and wouldn't eat. She became dehydrated and lethargic and also required hospitalization. She, luckily, removed the collar in time and has no long term negative effects from its use.

I have contacted Bayer and they said they would lodge a report with the FDA. However, i

want other consumers to be aware of the dangers of this product. While i realize there could be other causes of all of the incidents I have reported above, the single common factor is the use of the Seresto collar.

I would welcome the opportunity to discuss further.

Sarah M. Ziolkowski

Catherine C. Milbourn
U.S. EPA HQ
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Office of Media Relations
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202-420-8648 (mobile)
Milbourn.cathy@epa.gov

EXHIBIT D

Index to Exhibit D

(Petition to Cancel Registration of PNR1427 (Brand Name Seresto) under the Federal Insecticide, Fungicide, and Rodenticide Act; Reg. No. 11556-155)

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