

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

**LAURA REVOLINSKY, on behalf of
herself and all others similarly
situated,**

Plaintiff

vs.

**ELANCO ANIMAL HEALTH
INCORPORATED and BAYER
HEALTHCARE LLC,**

Defendant

CIVIL ACTION NO.:

**CLASS ACTION COMPLAINT,
JURY DEMAND AND DESIGNATION OF
TRIAL COUNSEL**

Plaintiff Laura Revolinsky, on behalf of herself and all others similarly situated, for their Complaint against the Defendants, Elanco Animal Health Incorporated (“Elanco”) and Bayer HealthCare LLC (“Bayer”), state as follows:

BACKGROUND

1. This class action arises from the defective design of Seresto flea and tick collars for dogs and cats (“Seresto Collar(s)”). Plaintiffs bring this action for actual damages, equitable relief, including restitution, injunctive relief, and disgorgement of profits, and all other relief available on behalf of themselves and all similarly-situated individuals and entities (the “Class” or “Class Members”) who own or have owned Seresto Collars manufactured by Bayer Corporation (“Bayer”) and Elanco (“Elanco”) containing defects that cause injury or death to pets.

2. Seresto Collars, developed by Bayer and now sold by Elanco, work by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.

3. However, since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm. A copy of an article from USA Today dated March 2, 2021 detailing the defect of the Seresto Collar is attached hereto as **Exhibit A**.

4. An article published in USA Today on March 2, 2021 regarding the adverse events related to Seresto, reported that “Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer” stated that the EPA, the agency in charge of regulating products that contain pesticides, “has known about these incidents for years but has not informed the public of the potential risks associated with this product.” Id.

5. “The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation,” she said. “But I think this is a significant problem that needs to be addressed sooner rather than later,” McCormack said. Id.

6. According to the Midwest Center for Investigative Reporting, who conducted an extensive investigation of this issue, the two pesticides contained in Seresto Collars are imidacloprid and flumethrin. A copy of the Midwest Center for Investigative Reporting dated March 2, 2021 is attached hereto as **Exhibit B**.

7. “Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the

European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.” Id.

8. “Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.” Id. Experts have opined that the combination of Imidacloprid and Flumethrin is what is causing the harm to the pets (the “Defect”). Such harm includes but is not limited to the pets experiencing seizures, vomiting, heart arrhythmia, fatigue and even death. Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation said he is not “sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product... You don’t even see these kinds of numbers with many agricultural chemicals... For whatever reason, this combination is just really nasty.” Id.

9. Defendants knew about the Defect in the Seresto Collars as early as 2013. From 2013 through 2019, almost 1,000 human incidents of rash, redness of skin, skin lesions, hives, headaches, numbness, tingling and seizures related to the use of the Seresto Collars on pets were reported to the EPA. Ninety two of the events occurred in 2013. A copy of an EPA memo dated September 17, 2019 detailing a review of human incidents in Seresto collars is attached hereto as **Exhibit C**.

10. In October 2016, the EPA responded to concerns about adverse effects of the collars. The EPA issued a public response bulletin indicating that “since the initial registration [of Seresto in March 2012] EPA has received reports of undesirable effects to domestic animals using Seresto collars. EPA is evaluating those reports as part of the current registration review of flumethrin.” A copy of the EPA Bulletin is attached hereto as **Exhibit D**.

11. Complaints across the web on sites such as Amazon, have been piling up over the years beginning in 2013:

1.0 out of 5 stars Caused gross skin reaction on neck; bleeding and hair loss

Reviewed in the United States on October 30, 2013

Verified Purchase

I purchased two of these after a recommendation from my neighbor who has the same breed (chihuahua). One for my chi and one for my yorkie. The chihuahua was ready for his flea/tick prevention when these arrived, so I put his collar on first. In two days, his neck started to show signs of irritation- redness and a little bleeding appeared on the front of his neck. Two days later, an entire patch of fur in the same area was gone, and the bleeding began to look a lot worse. I looked up the instructions on Bayer's website and on 1800petmeds, and both mention that some irritation can be common, and that it will work itself out in a few weeks. I'm not really comfortable with just leaving the collar on while his neck is dripping blood and tufts of fur are disappearing, so I removed it tonight and am returning it to Amazon. Back to K9 Advantix ii monthly drops. Have used them for a few years with no adverse reactions.

1.0 out of 5 stars Made our dog VERY sick after 1 week

Reviewed in the United States on November 19, 2014

Verified Purchase

We used this collar on our French Bulldog the other week. All was fine for about 5 days and then he got very very sick. He threw up about 15 times and was dry heaving. We figured out it must be the collar and upon removal and yogurt and nursing him back to health he was ok in a few days. The throwing up stopped about 10 hours after collar removal. I know some dogs will tolerate this collar well but for our little guy it was awful. Please pay very close attention to how your dog is feeling. Personally I'll never use this product again nor would ever suggest it. We will use the natural ones next time.. and search him very well for ticks every day.

1.0 out of 5 stars Made both of our pets very sick

Reviewed in the United States on October 5, 2016

Verified Purchase

I wrote a previous review regarding our cat and forgot to follow up with the same collar on our small dog. Pretty much the same effect on both animals. Within two weeks, no more fleas, with the tradeoff being a dog that is constantly vomiting. Huge waste of money on a product "highly recommended" by both our vet and groomer. If you want no fleas and possibly a dead pet, this is the product for you!

1.0 out of 5 stars My dog had a seizure from this product.

Reviewed in the United States on January 21, 2017

Verified Purchase

I have been using this collar on my one year old Toy Australian Shepherd since he was old enough to wear it. Nearing the end of his first collar @ about 8 months it appeared he might have had a flea or two on his body. I thought maybe because the collar had gotten worn too much/was too old - so I immediately purchased a new one and put it on him. About one month into his second collar my dog had a seizure. He was lethargic, stopped breathing, went limp, his tongue went grey.... He is currently recovering. It is apparent there has been something toxic that has effected his brain. With all of this said, I will definitely NOT be purchasing this product again. I should have read more reviews - but trusted the name & professional recommendations I received. I would NOT recommend purchasing this product - too many toxic chemicals.

1.0 out of 5 stars Be careful of putting on older pets

Reviewed in the United States on May 9, 2018

Verified Purchase

Wish I had paid more attention to the reviews, our little schnauzer went into seizures one day. Never had any problems like this before, she started pacing back and forth at first and we couldn't figure what was wrong with her. The first seizure hit lasting a full minute. she started snapping at the family and doing things out of character. An hour and a half later the second one hit lasting 45 sec. after that we pulled off the collar. It took about 5 hours later then she started coming around and acting like her old self. we honestly thought at first we were losing our pet that day . I would be careful of putting this collar on an older pet.

1.0 out of 5 stars Beware of Seizures

Reviewed in the United States on November 4, 2018

Verified Purchase

Good news.... no fleas..... Bad news.... seizures. I bought this collar May 31, 2018 for my 15 lb Bichon. In September I started noticing her moods change. She would sit frozen and gaze into space and could not move. Then my groomer told me she had an "episode" at the groomers.... like she had "checked out" and not coherent. Then in late September she was playfully walking up the driveway when all of a sudden she froze and collapsed. Kept trying to stand up and could not. I grabbed her in my arms to take her inside the house. I sat her down and she walked off as if nothing happened. I called my vet and they dismissed anything I tried to tell them. She has had 3 more seizures that I know of to date. She also started to pee in bed. I know that the seizures that I have witnessed coincide with the bed peeing. I believe that after her seizures she cannot control her bladder. Going to have to find another way to keep the fleas at bay..... Can no longer put this on my dog.

1.0 out of 5 stars made my dog very sick

Reviewed in the United States on December 8, 2018

Verified Purchase

Used this product on my miniature golden doodle. The next few days she developed head wobbling, unsteadiness, loss of appetite and not drinking water. Very unlike her. I had tried this product before and spend lots of \$\$\$ on vet bills due to her having the same issue and almost dying. Did not put 2 & 2 together until it happened the second time. I do not recommend this product

1.0 out of 5 stars CAN MAKES DOGS VERY VERY ILL!

Reviewed in the United States on April 24, 2020

Verified Purchase

My 2 dogs got sick from these collars within 48 hours. 3 YO Shih Tzu recovered in three days. 14 YO maltese pooped straight blood for 30 hours and throwing up. Still sick, not eating, will drink water on 4th day since started. I took collar off maltese and bathed well. I had previously used the collars and they are good but will never ever ever put another flea collar on my dogs. Will updated if maltese recovers. I googled and many people had same problem and had to put their dogs down. Bayer is aware of problem but keep selling at exorbitant rates for the collars.

See https://www.amazon.com/Bayer-Animal-Health-Seresto-Collar/dp/B00B8CG58U/ref=cm_cr_arp_d_product_top?ie=UTF8#customerReviews

(last visited, April 20, 2021)

12. Despite Defendants' knowledge of the defective collars causing injuries and death to dogs and cats using the collars, the packaging for Seresto collars contains no disclaimer warning that the risks of toxicity may be so great that they could possibly be responsible for thousands of pet deaths.

13. Indeed, Congress is extremely concerned about the safety of the Seresto Collars. The Subcommittee on Economic and Consumer Policy of the United States House of Representatives recently requested that Elanco Animal Health Inc. "immediately institute a temporary recall of all Seresto flea and tick collars, following reports that the collars may have killed thousands of pets and may have caused injuries to many more pets as well as humans." A copy of the March 17, 2021 letter from Representative Raja Krishnamoorthi to Jeff Simmons, President and CEO of Elanco is attached hereto as **Exhibit E**.

14. Defendants knew, or were reckless in not knowing, as early as 2013, that the Seresto Collars contained a defect that could cause severe injury or death to pets. Defendants had sole and exclusive possession of this knowledge.

15. Notwithstanding this knowledge, Defendants uniformly concealed this material information in its marketing, advertising, and sale of the Seresto Collars, which Defendants knew to be defective, both at the time of sale and on an ongoing basis.

16. At all times, Defendants uniformly concealed from Plaintiffs and all consumers of Seresto Collars the Defect and failed to remove Seresto Collars from the marketplace or take adequate remedial action. Instead, Bayer and Elanco sold Seresto Collars even though it knew, or was reckless in not knowing, that they were defectively designed and would ultimately result in severe injuries and death to dogs and cats using them.

17. Furthermore, despite Defendant's knowledge of the Defect, they have promoted, and Elanco continues to promote as of the date of this Complaint, its safety and efficacy. Indeed, on its website the only warning disclosed is that "occasionally, scratching may be observed in dogs who are not used to wearing collars during the first few days after fitting. Clients should ensure the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site; this usually clears within one or two weeks without the need for collar removal." See <https://www.elancodvm.com/our-products/seresto/seresto-dogs>. The website provides the same warning for the Seresto for Cats Collar. See <https://www.elancodvm.com/our-products/seresto/seresto-cats>

18. In fact, the labels for all versions of the product (Cats, Small Dogs, Large Dogs) do not warn of any serious injuries or death. Similar to the website warnings, the extent of the warnings on the product labels relate to possible skin irritations and slight hair loss at the

application site which “usually recover in 1or 2 weeks.” Copies of the product labels are attached hereto as **Exhibit F**.

19. As a consequence of Defendants’ false and misleading statements and active and ongoing concealment of the Defect, Plaintiffs and the Class Members purchased Soresto Collars and have incurred damages.

20. Moreover, in addition to affirmatively misleading the Class Members, Defendants routinely declined to provide Class Members refunds for the amount they paid to purchase the Soresto Collar and for any out of pocket damages related to treating their pets for injuries caused by the Soresto Collar.

21. Plaintiffs assert claims on behalf of themselves and the Subclass Members under the New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1, *et seq.*) and Violations of the Truth-in-Consumer Contract, Warranty and Notice Act (“TCCWNA”). Plaintiffs also assert claims on behalf of themselves and the Class for fraudulent concealment/nondisclosure, breach of implied and express warranties, Violation of Magnuson-Moss Act (15 U.S.C. §2301 *et seq.*), negligent misrepresentation, and unjust enrichment.

22. The Class and Subclass Members could not themselves reasonably discovered the design errors, faulty materials or ingredients and manufacturing defects in the Soresto Collar before purchasing the Soresto Collar.

23. Had Defendants disclosed the Defect, the Class and Subclass Members would not have bought the Soresto Collars.

24. Plaintiffs seek actual damages, injunctive relief, restitution and/or disgorgement of profits, statutory damages, attorneys’ fees, costs, and all other relief available to the Class.

PARTIES

Defendants

25. Bayer is a Delaware corporation with its principal place of business in Whippany, New Jersey involved in developing and manufacturing healthcare and medical products including developing and manufacturing products for its Animal and Health Division prior to selling its Animal and Health Division to Elanco in 2020.

26. Prior to selling its Animal and Health Division to Elanco for \$6.89 Billion in cash and stock on August 3, 2020, Bayer was a global leader in animal health products reporting approximately \$1.8 billion in sales in each of 2018 and 2019.

27. Defendant Elanco Animal Health Incorporated is an Indiana corporation, with its principal place of business in Greenfield, Indiana.

28. Elanco is the leading seller of pet collars, which generated over \$300 million of revenue in 2019.

Plaintiff

29. Laura Revolinsky is a citizen of the State of New Jersey. She purchased a King Charles Cavalier Spaniel in December 2012 – named Lord Bentley (“Bentley”). She then purchased another King Charles Cavalier Spaniel in March 2013 – named King Alfred (“Alfred”).

30. About four years ago, Ms. Revolinsky began regularly purchasing Seresto Collars for both her dogs as part of their health regimen to help prevent the dogs from being infested and or harmed by fleas and ticks.

31. She began purchasing the Seresto Collars through Amazon because of the convenience of the collar preventing ticks for 8 months at a time as opposed to giving her dogs

medication orally on a monthly basis to prevent fleas and ticks. Moreover, with the collars costing approximately sixty dollars (\$60.00) each, they were much more cost effective than the oral medication.

32. At the time of purchase, Ms. Revolinsky reviewed the packaging and description of the Seresto Collar which stated that the Seresto Collar was a safe and effective way of preventing fleas and ticks for her dogs.

33. Ms. Revolinsky placed the Seresto Collars on both dogs every year for 8 months per year during the Spring, Summer and Fall months.

34. In April 2020, shortly after placing the Seresto Collar on her dog Bentley, Bentley developed a cough. She took Bentley to the veterinarian as a result. After an examination, the veterinarian determined that Bentley had a heart murmur and an enlarged heart. The veterinarian prescribed medication for Bentley's heart condition.

35. In July, after wearing the Seresto Collar for approximately 3 months now, Ms. Revolinsky brought Bentley back to the veterinarian because of the continued cough the dog was experiencing. The veterinarian upon examination again observed an enlarged heart and heart murmur. Medication was again prescribed.

36. On July 12, 2020, Ms. Revolinsky found Bentley unresponsive. He was wearing the Seresto Collar. Bentley had passed away.

37. Ms. Revolinsky never made the connection between the death of her dog and the Seresto Collar until seeing the article published in USA Today on March 2, 2021. She immediately stopped using the Seresto Collar on Alfred.

38. The Product harmed Ms. Revolinsky's dog Bentley to the point that it caused Bentley to pass away from heart disease. Indeed, many users of the Seresto Collar have reported incidents of their dogs or cats suffering heart arrhythmia.

39. Had Defendants disclosed the existence of the serious safety risks associated with Seresto Collars, Plaintiff would have never purchased the Seresto Collars. Plaintiff did not receive the benefit of her bargain. Plaintiff has spent over \$500 on Seresto Collars for her dogs.

40. As a result of Defendants' misrepresentations and omissions related to the manufacture and marketing of the defective Seresto Collars, the Plaintiffs have suffered various damages, including, but not limited to ascertainable loss consisting of the costs the Plaintiff paid to purchase the defective collars as well as expenses associated with medical care for her dog related to injuries sustained as a result of her dog wearing the Seresto Collar.

JURISDICTION AND VENUE

41. This Court has original subject matter jurisdiction under the Class Action Fairness Act, 28 U.S.C. §§ 1332(d) and (6) because (i) the number of Class Members is 100 or more; (ii) the Class Members' damages, the aggregate amount in controversy exclusive of interest and costs, exceeds \$5,000,000; and (iii) minimal diversity exists because at least one of the Class Plaintiffs and one Defendant are citizens of different states.

42. This Court also has original subject matter jurisdiction over the Class Plaintiffs' federal statutory claim under the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq.*

43. This Court has supplemental and pendent jurisdiction over the Class Plaintiffs' state law claims under 28 U.S.C. § 1367.

44. Personal Jurisdiction is proper in this Court because of Bayer's many and important contacts with the State of New Jersey. Bayer is headquartered in New Jersey and has a

registered agent authorized to accept service of process in the State of New Jersey. This Court's exercise of jurisdiction over Bayer offends neither notions of fair play and substantial justice, nor any other due process principles. Bayer reasonably could expect to be summoned before the courts of the State of New Jersey.

45. Moreover, Elanco has many and important contacts with the State of New Jersey. Elanco has a registered agent authorized to accept service of process in the State of New Jersey. A substantial portion of the wrongdoing which is alleged arose from Elanco's sales in New Jersey. This Court's exercise of jurisdiction over Elanco offends neither notions of fair play and substantial justice, nor any other due process principles. Elanco reasonably could expect to be summoned before the courts of the State of New Jersey.

46. Venue is proper in this Court under 28 U.S.C. § 1391(b)(1). For purposes of venue under 28 U.S.C. § 1391(b), Defendants, both corporations, are deemed to reside in any judicial district, including this one, in which they are subject to personal jurisdiction at the time this action is commenced, according to 28 U.S.C. § 1391(c). Defendants are subject to personal jurisdiction in this judicial district because they regularly do business in, have places of operation in, generate substantial revenue and profits in New Jersey and can be found in this judicial district. Indeed, Bayer is headquartered in New Jersey. Venue is also proper in this judicial district under 28 U.S.C. § 1391(c), because a substantial part of the events or omissions giving rising to the Class Plaintiffs' claims took place in this judicial district.

TOLLING OF STATUTES OF LIMITATION

47. Defendants' active and knowing concealment of the problem with the Seresto Collar results in the tolling of any applicable statute(s) of limitation.

48. Plaintiffs and Class and Subclass Members could not have reasonably discovered the true reasons for the Seresto Collar's Defect until just before this Complaint was filed.

49. Defendants had and still have a continuing duty to inform Class and Subclass Members of the truth that the Seresto Collar's dangerous effects resulting from Defendants' design, manufacturing, materials and workmanship defects and failings described above, that the Defect results in serious injury and even death to those pets that wear the Seresto Collar.

50. Defendants' active concealment of, and breach of its duty to disclose the truth about the Defect tolls any applicable statute(s) of limitations.

CLASS ACTION ALLEGATIONS

51. The Plaintiffs bring this action under Fed. R. Civ. P. 23(a), (b)(2) and (b)(3) and seek certification of a Class and Subclass initially defined as follows:

Class (the "Nationwide Class")

All persons who, at any time on or after the day six (6) years prior to the day the original Complaint was filed, purchased a Seresto Collar that has caused injury or death to their pet or is susceptible to causing injury or death to their pet due to the Defect.

52. Alternatively, Plaintiff proposes the following state specific subclasses:

Subclass (the "New Jersey Class")

All persons in New Jersey who, at any time on or after the day six (6) years prior to the day the original Complaint was filed, purchased a Seresto Collar that has caused injury or death to their pet or is susceptible to causing injury or death to their pet due to the Defect.

53. Excluded from the Class and Subclasses are: Defendants and all of their affiliated companies, directors, officers, and employees;, respectively; and the Judge(s) assigned to this case.

54. All Plaintiffs are members of the Class and at least one Subclass.

55. The Plaintiffs reserve the right to modify or expand the Class and Subclasses if discovery and/or further investigation shows that the definitions should be modified.

56. Questions of law and fact exist common to the members of the Class and Subclasses and predominate over any questions that affect only individuals.

57. Principal and predominant common questions of law and fact include, for example:

- a. Were the Seresto Collars defectively designed?
- b. Did Defendants breach express warranties to the Class and Subclass Members?
- c. Did Defendants breach implied warranties to the Class and Subclass Members?
- d. Did Defendants breach the Magnuson-Moss Act in connection with its sales of the Seresto Collars?
- e. Did Defendants breach the New Jersey Consumer Fraud Act because of Defendants' design, manufacture, distribution, promotion, marketing and/or sales of the Seresto Collars constituted deception, fraud, false pretense, false promise, misrepresentation, unfair practice or the concealment, suppression, or omission of any material fact with the intent that the Class and Subclass Members rely upon such concealment, suppression or omission, in connection with the sale or advertisement of the Seresto Collars.
- f. To the extent other State laws prohibiting consumer deception are applicable, did Defendants violate the respective laws of those States?
- g. Would Defendants' retention of payment for the Seresto Collars constitute the knowing receipt, acceptance and retention of a benefit from the Class and

Subclass Members in circumstances in which such receipt, acceptance and retention of that benefit is unjust?

- h. As a result of Defendants' actions and failures to act, are the Class and Subclass Members entitled to compensatory, restitutionary, statutory or other damages against Defendants?

58. Plaintiffs' claims are typical of the claims of all of the members of the Class and Subclass because they are based on the same facts.

59. Plaintiffs' claims are typical of the claims of all of the members of the Class and Subclass because they are based on the same legal theories.

60. Plaintiffs' claims are typical of the claims of all of the members of the Class and Subclass because the respective claims are based on the same remedial theories and requests for redress as those of all the Class and Subclass Members.

61. Each Class is so numerous that joining all of the Class and Subclass Members as plaintiffs in this action is impracticable. Upon information and belief, to be supported as required by Rule 11(b)(3), since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm. *See Exhibit A.* Based on a conservative failure rate of just ten percent (10%), and assuming that each Class Member bought only one Seresto Collar during the Class Period, the class would consist of thousands of consumers.

62. The Plaintiffs are not adverse to those of the Class and Subclasses.

63. The Plaintiffs have no interests that conflict with the interests of the Class and Subclasses.

64. The Plaintiffs are similarly situated with, and have suffered similar injuries, losses and other damages as the Class and Subclass members.

65. The Plaintiffs will fairly and adequately protect the interests of all the Class and Subclass members in further investigating, developing and litigating this action, and in all related administrative and other matters concerning this action.

66. The Plaintiffs have retained counsel experienced in complex and class action litigation, in matters involving consumer products, commercial and contractual claims, and common law and statutory claims.

67. Neither the Plaintiffs, nor their retained counsel, have any interest that might lead them not to vigorously pursue this action.

68. A Class Action is superior to other potentially available methods for resolving the Plaintiffs' claims, because:

- a. The individual Class and Subclass Members' damages are almost certainly too small to justify the expense and effort of individual lawsuits brought by counsel working for an hourly fee. Defendants' misconduct would go unaddressed and unremedied absent class action treatment. Aggregating these fundamentally similar claims, however, makes this action financially feasible.
- b. Even if the individual Class and Subclass Members were wealthy enough to afford to bring such individual cases, the judicial system would be ill served and its scarce resources badly misspent by a myriad of small and fundamentally identical cases involving the same basic allegations, the same discovery and the same proofs, clogging dockets across the country.

- c. Individual litigation is not just supremely impractical and tremendously inefficient, but also poses the risk of inconsistent or contradictory judgments.
- d. Concentration of the action concerning the defective Seresto Collars in this Court will: save judicial resources by, among other things, obviating the need for coordination of motion practice and discovery across numerous courts and jurisdictions; conserve the parties' resources by permitting the well-focused litigation of the many common issues through representative plaintiffs; produce enormous economies of scale by developing the many common issues through just a few representative plaintiffs; and result in consistent judicial findings, promoting respect for the judiciary and judicial system, through comprehensive supervision and administration of the case by a single court well versed in the issues.
- e. Justice will not be served, but will fail, in the absence of a class action of the Plaintiffs' claims. Among other things, many if not all Plaintiffs lack the resources to properly litigate their claims. Expert witnesses are necessary, the cost of which would alone be prohibitive for many if not all Plaintiffs.
- f. The difficulties inherent in and likely to arise in managing this Class Action are neither novel nor substantial. Common issues predominate over individual issues, are readily identifiable, as described above, and will be efficiently developed through litigation of representative Class Members' cases.

CLAIMS FOR RELIEF

**FIRST CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Breach of Express Warranty**

69. Each of the above allegations are incorporated herein.

70. Defendants made numerous express warranties to the Class Plaintiffs about the safety and effectiveness of the Seresto Collars. In fact, through its website and on its product label, Defendants state that the Seresto Collar kills and repels fleas and ticks with minimal if any safety risks. The only safety risk to pets Defendants represent on their website and labels is that occasionally, scratching may be observed in dogs who are not used to wearing collars during the first few days after fitting. Clients should ensure the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site; this usually clears within one or two weeks without the need for collar removal.

See Exhibit E.

71. Plaintiffs notified Defendants of the defects within the warranty period and Defendants received notification about and were on notice of the defects well before Plaintiffs began this litigation.

72. Defendants breached their express warranties, as set forth above, by expressly advertising that the Seresto Collar kills and repels fleas and ticks with minimal if any safety risks as described above when in fact they cause severe injury and death to pets using them.

73. Defendant has received sufficient and timely notice of the breaches of warranty alleged herein. Despite this notice and Defendants' knowledge, Defendants have refused to honor their express warranty, even though they knew of the inherent defect in the Seresto Collars.

74. Plaintiffs have given Defendants a reasonable opportunity to cure their failures with respect to its warranties, and Defendants failed to do so.

75. Defendants' breach of its express warranties caused damages to the Class Plaintiffs and the Class and Subclasses.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class and Subclasses request that the Court issue an Order and grant Judgment to the Class Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class and Subclasses and on behalf of the absent Class and Subclass Members;
- C. Appointing Poulos LoPiccolo PC and Nagel Rice LLP as Class Counsel for all purposes in this action;
- D. Granting the Plaintiffs contractual, restitutionary and statutory damages in full recompense for their damages including and not limited to damages relating to the following:
 - 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
 - 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations;
- E. Granting the Plaintiffs and Class and Subclass Members such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and

F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

SECOND CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Breach of Implied Warranty

76. Each of the above allegations are incorporated herein.

77. The Seresto Collars are "goods" under the Uniform Commercial Code ("UCC").

78. Bayer is a "merchant" under the UCC.

79. Elanco is a "merchant" under the UCC.

80. Defendants made numerous implied warranties to the Class Plaintiffs about the merchantable quality of the Seresto Collars.

81. Defendants impliedly warranted, among other things, that the Seresto Collars were of good and merchantable quality, and safely and effectively repel fleas and ticks from cats and dogs without serious injuries or death to the pets.

82. Through the conduct alleged herein, Defendants breached the implied warranty of fitness for a particular purpose. The defectively designed Seresto Collars were not fit for the particular purpose for which they were purchased by Class and Subclass Members to perform. The Class and Subclass Members purchased the Seresto Collars for a particular purpose of safely and effectively repel fleas and ticks from cats and dogs without serious injuries or death to the pets. Defendants knew that the Class and Subclass Members were purchasing the Seresto Collars for this purpose and marketed the Seresto Collars for this particular purpose.

83. Plaintiffs and Class and Subclass Members relied on Defendant's misrepresentations and omission by purchasing the Seresto Collars.

84. Defendant knew or had reason to know that Plaintiffs and Class and Subclass Members were influenced to purchase the Seresto Collars through Defendant's expertise, skill, judgment and knowledge in furnishing the products for their intended use.

85. The Seresto Collars were not of merchantable quality and were not fit for their particular intended use because the design and/or manufacturing defects alleged herein render them incapable of being safely worn by their dogs or cats without the risk of serious injury or death.

86. Defendant's actions, as complained of herein, breached their implied warranty that the Seresto Collars were of merchantable quality as fit for such use, in violation of the Uniform Commercial Code (UCC § 2-314 and § 2-315) and the common law of this State, as well as the common law and statutory laws of the other states.

87. Plaintiffs and the Class and Subclass Members have incurred damage as described herein as a direct and proximate result of the failure of Defendant to honor its implied warranty. In particular, Plaintiffs and the Class and Subclass Members would not have purchased the Seresto Collars had they known the truth about their defects; nor would they have suffered the damages associated with these defects.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class and Subclass request that the Court issue an Order and grant Judgment to the Class and Subclass Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class and Subclasses and on behalf of the absent Class and Subclass Members;

C. Appointing Poulos LoPiccolo PC and Nagel Rice LLP as Class Counsel for all purposes in this action;

D. Granting the Plaintiffs contractual, restitutionary and statutory damages in full recompense for their damages including and not limited to damages relating to the following:

- 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
- 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations.

E. Granting the Plaintiffs and Class and Subclass Members such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and

F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

**THIRD CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Violation of Magnuson-Moss Act (15 U.S.C. §2301 et seq.)**

88. Each of the above allegations are incorporated herein.

89. The Class Plaintiffs and the Class and Subclass Members are "consumers" within the meaning the of the Magnuson-Moss Warranty Act, 15 U.S.C. § 2301 *et seq* ("Magnuson Moss Act").

90. Bayer is a “supplier” and “warrantor” within the meaning of the Magnuson-Moss Act.

91. Elanco is a “supplier” and “warrantor” within the meaning of the Magnuson-Moss Act

92. The Seresto Collars are “consumer products” within the meaning of the Magnuson-Moss Act.

93. Under the Magnuson-Moss Act, Defendants were obligated to disclose to consumers the known defects of the Seresto Collars, in particular, the Defect.

94. Under the Magnuson-Moss Act, Defendants were obligated to repair or replace the Seresto Collars.

95. Despite reasonable opportunity to honor its disclosure and remedy obligations, Defendants violated these obligations under the Magnuson-Moss Act, causing injury to the Class Plaintiffs and Class and Subclass Members.

96. The amount in controversy with respect to the Class Plaintiffs’ individual claims meets or exceeds the sum or value of \$25. There are more than 100 individuals in the Class and Subclasses. In addition, the amount in controversy meets or exceeds the sum or value of \$50,000 (exclusive of interest and costs) computed on the basis of all claims to be determined in this suit.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class and Subclass request that the Court issue an Order and grant Judgment to the Class and Subclass Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class and Subclass and on behalf of the absent Class and Subclass Members;

C. Appointing Poulos LoPiccolo PC and Nagel Rice LLP as Class Counsel for all purposes in this action;

D. Granting the Plaintiffs contractual, restitutionary and statutory damages in full recompense for their damages including and not limited to damages relating to the following:

- 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
- 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations.

E. Granting the Plaintiffs and Class and Subclass Members such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and

F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

FOURTH CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Injunctive and Equitable Relief

97. Each of the above allegations are incorporated herein.

98. Injunctive and equitable relief is appropriate and proper to remedy Defendants' past misconduct and prevent such misconduct from continuing to occur.

99. Appropriate and proper injunctive and equitable relief includes a Judicial Order compelling Defendants to pay for a notice process in which Defendants notify the Class and Subclass Members about the Seresto Collars Defect, and recall all Seresto Collars from the market.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs and the Class and Subclass request that the Court issue an Order and grant Judgment to the Class and Subclass Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class and Subclass and on behalf of the absent Class and Subclass Members;
- C. Appointing Poulos LoPiccolo PC and Nagel Rice, LLP as Class Counsel for all purposes in this action;
- D. Granting the Plaintiff appropriate injunctive and equitable relief;
- E. Granting the Plaintiff and Class and Subclass Members such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and
- F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

FIFTH CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Unjust Enrichment

100. Each of the above allegations are incorporated herein.

101. Defendants have been unjustly enriched and received an economic benefit by the sale of the Seresto Collars herein to Plaintiffs and the Class and Subclass Members.

102. Plaintiffs seek to recover for Defendants' unjust enrichment.

103. Plaintiffs and the Class and Subclass Members conferred a benefit on Defendants, but Defendants failed to disclose its knowledge that Plaintiffs did not receive what they paid for and misled Plaintiffs and the Class and Subclass Members regarding the risks associated with the Soresto Collars while profiting from this deception.

104. The circumstances are such that it would be inequitable, unconscionable, and unjust to permit Defendants to retain the benefit of these profits that it has unfairly obtained from Plaintiffs and the Class and Subclass Members.

105. Plaintiffs and the Class and Subclass Members, having been injured by Defendants' conduct, are entitled to restitution or disgorgement of profits as a result of the unjust enrichment of Defendants to their detriment.

SIXTH CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Common Law Fraud

106. Each of the above allegations are incorporated herein.

107. The above described conduct and actions constitute common law fraud by way of misrepresentations, concealment and omissions of material facts made by Defendants in inducing Plaintiffs and the Class and Subclass to purchase Seresto Collars with the Defect.

108. Defendant, upon information and belief, made the above-described misrepresentations, concealment and omissions of material facts to all Class and Subclass Members concerning the Defect. Indeed, the only risks of the Seresto Collars that Defendants disclosed is that occasionally, scratching may be observed in dogs who are not used to wearing

collars during the first few days after fitting. Clients should ensure the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site; this usually clears within one or two weeks without the need for collar removal.” However, the Seresto Collars actually contained a defect that caused thousands of serious injuries and deaths to pets. Indeed, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm *See Exhibit A.*

109. Defendants intended that the Plaintiffs and the other members of the Class and Subclass rely upon the above-described uniform misrepresentations, concealment and omissions.

110. Defendant’s misrepresentations, concealments and omissions concerning the Defect, were material to Plaintiffs’ and other Class Members’ and Subclass Members’ decisions to purchase the Seresto Collars. In fact, the representations and omissions regarding the Defect were so fundamental to Plaintiffs’ and Class Members’ and Subclass Members’ decision making process that they would not have purchased the Seresto Collars had they known that the Seresto Collars could cause serious injuries and deaths to dogs and cats.

111. Plaintiffs and other Class and Subclass Members justifiably relied upon Defendant’s misrepresentations, concealment and omissions to their damage and detriment.

112. Plaintiffs and the Class and Subclass suffered the damage described in this complaint as a proximate result thereof.

113. Defendants’ conduct was willful, wanton, and reckless. Based on the intentionally dishonest nature of Defendants’ conduct, which was directed at the Class and

Subclass, Defendants should also be held liable to the Class and Subclass for punitive damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs request that the Court issue an Order and grant Judgment to the Class Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class Plaintiffs on behalf of the absent Class and Subclass Members;
- C. Appointing Poulos LoPiccolo PC and Nagel Rice, LLP as Class Counsel for all purposes in this action;
- D. Granting the Class Plaintiffs contractual, restitutionary and statutory, common law and punitive damages in full recompense for their damages including and not limited to damages relating to the following:
 - 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
 - 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations.
- E. Granting the Class Plaintiffs such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and
- F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard

costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

**SEVENTH CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Violation of New Jersey Consumer Fraud Act (N.J.S.A. 56:8-1, et seq.)**

114. Each of the above allegations are incorporated herein.

115. Numerous controlling state and federal cases recite and explain the broadly remedial aims of the New Jersey Consumer Fraud Act. (hereinafter "NJFCA").

116. The Seresto Collars are "merchandise" within the NJCFA.

117. The Plaintiffs and Class and Subclass Members are consumers within the protective ambit of the NJCFA, who bought Seresto Collars for their domestic pets.

118. Protecting the Plaintiffs and Class and Subclass Members from and against "any unconscionable commercial practice, deception, fraud, false pretense, or misrepresentation, or the knowing concealment, suppression or omission of any material fact with the intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any merchandise,"¹ the NJCFA applies to Defendants' sales of the Seresto Collars to the Plaintiffs and Class and Subclass Members.

119. During the Class Period, Defendants advertised that the only risks associated with the Seresto Collars is that "occasionally, scratching may be observed in dogs who are not used to wearing collars during the first few days after fitting. Clients should ensure the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site; this usually clears within one or two weeks without the need for collar removal." However, the Seresto Collars actually contained a defect that caused

¹ *N.J.S.A.* 56:8-2.

thousands of serious injuries and deaths to pets. Indeed, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm. See

Exhibit A.

120. Defendants' distribution, promotion, marketing and sales of the Seresto Collars, without disclosing that the Seresto Collars actually contained a defect that causes serious injuries and deaths to pets, was an unconscionable commercial practice, deception, fraud, false pretense, misrepresentation, or otherwise constituted the knowing, concealment, suppression or omission of material fact with the intent that others including the Class and Subclass Members would rely upon Defendants' knowing, concealment, suppression or omission of information that the Seresto Collars contained the Defect, in connection with Defendants' sales and the Class and Subclass Members' purchases of the Seresto Collars.

121. Class Plaintiffs suffered ascertainable losses, measurable in dollar values, as a result of Defendants' unconscionable, deceptive, false and misleading behavior described in this Complaint. These ascertainable losses include, among others, costs associated with the purchase of the Seresto Collars and costs associated with treating injuries and in some circumstances death of Plaintiff's and Class Members' dogs and cats..

122. A causal nexus exists between Defendants' unconscionable, deceptive, false and misleading actions described above and the Plaintiffs' ascertainable losses. Without Defendants' defective design, substandard workmanship of the Seresto Collars and related parts and ingredients and defective materials, the Plaintiffs would not have suffered their ascertainable losses.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs requests that the Court issue an Order and grant Judgment to the Class Plaintiffs as follows:

- A. Certifying this action as a Class Action;
- B. Naming the Plaintiffs as the representatives of the Named Class Plaintiffs on behalf of the absent Class and Subclass Members;
- C. Appointing Poulos LoPiccolo PC and Nagel Rice, LLP as Class Counsel for all purposes in this action;
- D. Granting the Class Plaintiffs contractual, restitutionary and statutory, common law and punitive damages in full recompense for their damages including and not limited to damages relating to the following:
 - 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
 - 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations.
- E. Granting the Class Plaintiffs such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and
- F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity.

**EIGHTH CAUSE OF ACTION (On Behalf of Plaintiffs, Class and Subclass Members)
Violations of the Truth-in-Consumer Contract, Warranty and Notice Act**

123. Each of the above allegations are incorporated herein.

124. Plaintiffs and those similarly situated are “consumers” within the meaning of TCCWNA, as set forth at N.J.S.A. 56:12-15.

125. Defendants are sellers within the meaning of TCCWNA, as set forth at N.J.S.A. 56:12-15 and -17.

126. TCCWNA, at N.J.S.A. 56:12-15, provides in relevant part that “no seller, creditor, lender or bailee may offer or enter into any written consumer contract or give or display any notice which includes any provision that violates a clearly established right of the consumer or responsibility of the seller, lessor, creditor, lender or bailee as established by State or Federal law at the time the offer is made or the consumer contract is signed or the warranty, notice or sign is given or displayed.”

127. By violating the CFA, and a clearly established legal right of a consumer and/or responsibility of the seller to not engage in any misrepresentations, deception, or unconscionable commercial conduct in connection with consumer sales as detailed in this Complaint, Defendant thereby violated the Truth-in-Consumer Contract, Warranty and Notice Act, N.J.S.A. 56:12-14 *et seq.*

128. As the result of Defendants’ violations of TCCWNA, Plaintiffs and the Class and Subclass Members are entitled to statutory damages of not less than \$100 each as provided by N.J.S.A. 56:12-17.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiffs request that the Court issue an Order and grant Judgment to the Class Plaintiffs as follows:

A. Certifying this action as a Class Action;

B. Naming the Plaintiffs as the representatives of the Named Class and Subclass Plaintiffs on behalf of the absent Class and Subclass Members;

C. Appointing Poulos LoPiccolo PC and Nagel Rice, LLP as Class Counsel for all purposes in this action;

D. Granting the Class Plaintiffs contractual, restitutionary and statutory, common law and punitive damages in full recompense for their damages including and not limited to damages relating to the following:

- 1) All recoverable compensatory and other damages sustained by Plaintiff and the Class and Subclasses;
- 2) Restitution and disgorgement of all amounts obtained by Defendants as a result of its misconduct, together with interest thereon from the date of payment to the victims of such violations

E. Granting the Class Plaintiffs such other and further relief, including, without limitation, injunctive and equitable relief, as the Court deems just in all the circumstances; and

F. Granting Class Counsel an award of their attorneys' fees and costs of suit, reflective of the work done in prosecuting this action, the time spent, the effort and hard costs invested, and results obtained, in light of the Court's judgment informed by awards in other similar cases of comparable difficulty and complexity

JURY DEMAND

Plaintiffs demand a jury trial on all issues so triable.

TRIAL COUNSEL DESIGNATION

Plaintiffs designate as trial counsel: Bruce H. Nagel of Nagel Rice LLP and Joseph LoPiccolo of Poulos LoPiccolo PC.

Dated: April 21, 2021

POULOS LOPICCOLO PC

/s/ Joseph LoPiccolo

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EXHIBIT

A



INVESTIGATIONS

Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

Johnathan Hettinger Midwest Center for Investigative Reporting

Published 6:00 a.m. ET Mar. 2, 2021 | Updated 6:40 a.m. ET Mar. 3, 2021

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, U.S. Environmental Protection Agency documents show.

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.

But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that

watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, including nearly 1,000 involving human harm.

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

“The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation,” she said. “But I think this is a significant problem that needs to be addressed sooner rather than later.”

The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have “been found eligible for continued registration” based on best available science, including incident data.

“No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk,” the spokesperson said. “The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment.”

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn't the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. That pet collar continues to be sold under the brand name Hartz Ultraguard, Hartz InControl and Longlife.

NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents.

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2019, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the the nonprofit Center for Responsive Politics, which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”

The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto's pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn't sure what

makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its safety issues, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman’s research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children’s health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It’s not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

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.

A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.

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 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.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

“As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure,” the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars, including a letter to an animal doctor column in the St. Louis Post-Dispatch in 2013, a radio news story in New York in 2016 and extensive comments on pet forums.

Without the federal government stepping in, individuals are left in the dark. That’s something Ron Packard, of Brockton, Massachusetts, is hoping to address.

In the days after the death of his two dogs in June 2019, Packard did what any person looking for answers does: He went to the internet

Two of Packard's four dogs had recently had seizures on the same day, before becoming lethargic and vomiting and finally, refusing to eat. He brought them to the veterinarian, who couldn't find a problem.

Within weeks, the two previously healthy cavachons, 10-year-old Danny and 5-year-old Dominic, were both dead.

The only thing Packard could figure out was both dogs had started wearing Seresto flea and tick collars a month before.

"Thirty-three and 54 days later, they're both dead," Packard said.

Packard created a Facebook page, asking people who had similar issues to share their stories.

Today, the page fills up with pictures and stories like Packard's.

A dog starts wearing a collar. Within weeks, a dog will have a seizure, sometimes it will later die. Other stories aren't quite as extreme. Loss of hair around the neck. Lethargy.

Packard encourages everyone to report their story to the EPA.

"I don't want others to go through what we went through," he said. "Every time I read the stories, it brings me back to my dogs. But if I can save a few pets, I can deal with it."

This story is a collaboration between USA TODAY and the Midwest Center for Investigative Reporting. The center is an independent, nonprofit newsroom covering agribusiness, Big Ag and related issues. USA TODAY is funding a fellowship at the center for expanded coverage of agribusiness and its impact on communities.

EXHIBIT

B



Popular flea collar linked to almost 1,700 pet deaths. The EPA has issued no warning.

By Johnathan Hettinger, Midwest Center for Investigative Reporting March 2, 2021

This story was co-published with [USA TODAY](#)

(<https://www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/>) and is embargoed for republication until March 12, 2021.

Rhonda Bomwell had never used a flea and tick collar before. Pierre, her 9-year-old Papillon service dog, was mostly an indoor animal.

Still, her veterinarian recommended she purchase one, so Bomwell went to the pet store near her home in Somerset, New Jersey, and selected Bayer's Seresto collar.

A day later, on June 2, 2020, Pierre had a seizure, collapsing while Bomwell was making dinner. Lying on his back, the dog stopped breathing and his eyes rolled back.

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Bomwell tried giving him CPR. Then she called the police. An officer helped her lift the dog into her car, and she rushed him to the hospital. Pierre died before he could receive medical treatment. Bomwell didn't think to take off Pierre's collar.

"I just didn't put it together," she said.

Bomwell isn't alone. Seresto, one of the most popular flea and tick collars in the country, has been linked to hundreds of pet deaths, tens of thousands of injured animals and hundreds of harmed humans, [U.S. Environmental Protection Agency documents show](#).

<https://beta.documentcloud.org/documents/20473296-aggregate-incident-summary-report-for-epa-reg-no-11556-155-1-1-2012-10-6-16-2020>

Yet the EPA has done nothing to inform the public of the risks.

Seresto, developed by Bayer and now sold by Elanco, works by releasing small amounts of pesticide onto the animal for months at a time. The pesticide is supposed to kill fleas, ticks and other pests but be safe for cats and dogs.

But thousands of pets are being harmed, according to federal documents obtained through a public records request from the Center for Biological Diversity, a nonprofit organization that watchdogs the EPA as part of its work to protect endangered species. The center provided the documents to the Midwest Center for Investigative Reporting.

Since Seresto flea and tick collars were introduced in 2012, the EPA has received incident reports of at least 1,698 related pet deaths. Overall, through June 2020, the agency has received more than 75,000 incident reports related to the collars, [including nearly 1,000 involving human harm](#). (<https://beta.documentcloud.org/documents/20473297-epa-hq-opp-2016-0031-0031>)

The EPA is in charge of regulating products that contain pesticides. The agency has known about these incidents for years but has not informed the public of the potential risks associated with this product, said Karen McCormack, a retired EPA employee who worked as both a scientist and communications officer.

McCormack said the collars have the most incidents of any pesticide pet product she's ever seen.

"The EPA appears to be turning a blind eye to this problem, and after seven years of an increasing number of incidents, they are telling the public that they are continuing to monitor the situation," she said. "But I think this is a significant problem that needs to be addressed sooner rather than later."

The EPA declined to say how Seresto compares to other pet products. But in response to a question about whether the product is safe, an agency spokesperson said in an emailed statement that the two pesticides in Seresto have "been found eligible for continued registration" based on best available science, including incident data.

"No pesticide is completely without harm, but EPA ensures that there are measures on the product label that reduce risk," the spokesperson said. "The product label is the law, and applicators must follow label directions. Some pets, however, like some humans, are more sensitive than others and may experience adverse symptoms after treatment."

Amazon, where Seresto is the top-selling collar, also has received numerous complaints about the product from customers who detailed significant issues. Dozens of people over the years have claimed the collar caused skin rashes in their pet. Others said it led to neurological issues in their pets.

Despite the many warnings, Amazon has not removed the product from its online marketplace. Amazon did not respond to multiple requests for comment for this story.

This isn't the first time that the EPA has failed to properly regulate flea and tick collars containing pesticides, said Miriam Rotkin-Ellman, a senior scientist at the Natural Resources Defense Council.

The NRDC filed a petition against the agency more than a decade ago over its approval of a different pesticide than the one used in Seresto that is linked to cancer and brain development issues in children.

In April 2020, a federal appeals court called the EPA's refusal to respond to NRDC's requests "nothing short of egregious" (<https://cen.acs.org/environment/pesticides/EPA-ban-hazardous-pesticide-pet/08/web/2020/04>) and told agency officials to make a decision on whether to ban the pesticide within 90 days. The EPA decided not to ban the pesticide, called tetrachlorvinphos. NRDC has challenged that decision; that lawsuit is currently pending.

Even so, the number of incidents linked to that pesticide pales in comparison to those linked to Seresto. From 1992 to 2008, the EPA received about 4,600 incident reports regarding pet collars containing tetrachlorvinphos, including 363 deaths, according to EPA documents. (https://beta.documentcloud.org/documents/20491417-epa-hq-opp-2008-0316-0018_pet-poisoning)

Broken down per year, that's 30 times fewer incidents and 10 times fewer deaths than Seresto.

And those are most likely an undercount, said Nathan Donley, a senior scientist at the Center for Biological Diversity and an expert on U.S. pesticide regulation. Donley said the number of reported incidents for Seresto is "just the tip of the iceberg."

In order to report an incident, a person has to make the connection between the collar and the issue with the dog, understand who to contact and how to report it, he said.

"Most of the time, people are not going to make the connection or they're not going to take an hour or so out of the day and figure out how to call and spend time on hold," Donley said.

He said the incident data creates lots of questions about EPA processes.

"My God, if this doesn't trigger a concern, that's a fundamental problem with the process," Donley said. "The fact that EPA has not done anything to alert the public that there might be an issue here, it strikes me as bordering on criminal. The EPA has this system in place to compile information and it's just collecting dust in some database."

A big business

Pet collars are big business. In its 2019 annual report, German agribusiness and pharmaceutical company Bayer reported revenue of more than \$300 million on Seresto alone.

The company sold its animal health division to Elanco Animal Health, a former subsidiary of Eli Lilly and Co., for \$7.6 billion in 2019. The deal was finalized in 2020. As part of the deal, Bayer received \$2.3 billion in Elanco stock, which the company said it would sell over time.

Bayer did not respond to multiple requests for comment.

Since being spun off as its own company in 2010, Elanco has lobbied the EPA quarterly on issues relating to animal health, according to the nonprofit Center for Responsive Politics (<https://www.opensecrets.org/federal-lobbying/clients/reports?cycle=2019&id=D000050450>), which maintains a website tracking political contributions. Over two years, the company has spent \$1.6 million on lobbying, records show.

Keri McGrath, a spokeswoman for Elanco, said in an email the company “takes the safety of our products very seriously and thoroughly investigates potential concerns related to their use.” McGrath pointed out that regulatory authorities have approved the product in more than 80 countries, and the EPA is in the final stages of re-approving both pesticides. There is no timeline on the final decision.

McGrath said that global data shows that 1 in 568 users of Seresto have an incident and “the majority of these incident reports relate to non-serious effects such as application site disorders, e.g. a reddening of the skin or hair loss below the collar.”

“Keep in mind that the existence of an adverse event report does not necessarily mean the product caused the problem,” she said. “Causality between the observed signs and the use of the product is evaluated on a case-by-case basis. That said, every adverse event collected, regardless of causality, is reported to the authorities.”

The EPA did not respond to a request about how Seresto compared to other flea and tick collars in terms of incidents. The Midwest Center has filed a Freedom of Information request for the incident database, but that request has not yet been filled.

The extent of the damage is uncommon, said McCormack, the former EPA staffer.

“I’ve never seen any product that had 75,000 incidents,” McCormack said.

Seresto’s pesticides more toxic together

The EPA approved Seresto collars on March 16, 2012. The collars are designed to work for eight months.

Under the Federal Insecticide, Fungicide and Rodenticide Act, the EPA must determine a pesticide product will not cause “unreasonable effects on the environment.”

This determination requires weighing harms versus benefits, including assessments of risks to human health and the environment.

Seresto contains two pesticides: imidacloprid and flumethrin.

Imidacloprid belongs to the neonicotinoid class of insecticides, which are the most commonly used insecticides on crops in the U.S. Despite neonicotinoids being connected to massive die-offs of non-target insects such as bees and butterflies, the EPA proposed re-approving imidacloprid and other class members last year. The pesticide is banned in the European Union for outdoor use but allowed in pet collars. There is also growing evidence that mammals can be harmed by these pesticides as well.

Flumethrin, EPA documents show, is only an active ingredient in one product: Seresto.

Like with most pesticides, the data supporting the registration of Seresto was conducted by the company that produced it, Bayer. The majority of the studies were looking at each pesticide individually.

However, a 2012 Bayer study found they have a “synergistic effect,” meaning they are more toxic together on fleas. The study found that the “unique pharmacological synergism” works as quickly as six hours to prevent ticks from attaching and feeding, preventing disease transmission.

Additionally, eight companion animal safety studies were conducted by Bayer looking at the effect of Seresto collars on domestic cats and dogs. The EPA used these studies to approve Seresto. The California Department of Pesticide Regulation (<https://beta.documentcloud.org/documents/20473299-california-companion-animal-safety-studies>) took issue with the validity of two of the studies but approved the collars anyway.

Another issue could be a reaction of inactive ingredients, which are unknown and have caused problems in spot-on treatments, said Donley of the Center for Biological Diversity.

Donley, who has a doctorate in cell and developmental biology and is a former cancer researcher, said this “synergistic effect” likely extends to pets. He said he wasn’t sure what makes the two pesticides so likely to cause harm, but it is clear something is wrong with the product.

“You don’t even see these kinds of numbers with many agricultural chemicals,” Donley said.

“For whatever reason, this combination is just really nasty.”

History of unsafe pet treatments

There are currently 18 flea and tick collars on the market: three that are approved for both dogs and cats (including Seresto), 10 approved for dogs and five for cats, according to the National Pesticide Information Center.

In addition to allowing tetrachlorvinphos in pet collars despite evidence of its unsafety, the EPA also had approved the use of another pesticide linked to cancer and brain development problems – propoxur, which was sold under many brand names, including Bio Spot, Scratex Color, Zodiac, Sergeant’s Dual Action and Sentry Dual Action.

Rotkin-Ellman’s research showed residues were high enough to pose a risk to children and adults who play with pets that were wearing the collars.

In April 2016, pesticide companies voluntarily agreed to stop using propoxur to help protect children’s health. The brand names that used propoxur have switched to other active ingredients.

In addition, in 2010, the EPA increased label requirements and limited some inert ingredients (<https://www.epa.gov/pets/epa-evaluation-pet-spot-products-analysis-and-plans-reducing-harmful-effects>) in spot-on treatments, which are applied to a specific area of a pet. This happened after incident data showed the treatments were causing hundreds of pet deaths, as well as issues such as irritation, rashes and hair loss, gastrointestinal problems and seizures.

Collars have caused seizures, rashes in humans

It’s not just pets that are being harmed, EPA documents show.

Between 2013 and 2018, 907 incidents were reported with humans, according to a September 2019 EPA assessment of human health risk.

The assessment determined that there were 19 severe incidents. Of those, eight people had dermal symptoms, such as a rash or hives, and seven had neurological symptoms, which included numbness and headaches.

Incidents listed by the EPA included:

- 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.
- A 67-year-old woman who slept in a bed with a dog wearing a collar reported having heart arrhythmia and fatigue.

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 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.

An October 2016 EPA bulletin responded to citizen concerns about children being exposed to Seresto, saying it had found exposure to the collars to be negligible.

“As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure,” the bulletin said.

“It’s really not just happening to animals. It’s happening to people who pet them as well,” Donley said. “I have two young kids who are all over our dog all the time. I can imagine how highly exposed people would be to residues.”



Rhonda Bomwell of Somerset holds a photograph as she talks about her 9-year-old Papillon, Pierre, who passed away on June 1st due to side effects from wearing a popular flea and tick collar for pets, at Colonial Park in Somerset, NJ Monday, March 1, 2021.

‘It’s just been a nightmare’

To Bomwell, the worst part was the lack of warning. Pierre had never been sick or had a seizure. He was just 9, so she thought he had half a decade left. Her last dog had died at 18. Plus, she felt like she was responsible. She was the one who put the collar on.

“It was so bizarre,” Bomwell said. “It’s just been a nightmare.”

Even if the EPA had not received tens of thousands of complaints, a cursory search of the web would find dozens of posts from pet owners warning others to be careful with the collars.

A letter to an animal doctor column in the St. Louis Post-Dispatch in 2013. A radio news story in New York in 2016. Comments on pet forums. More than 1,000 people marked a review linking the collar to adverse incidents as “helpful” on Amazon, where the collar is labeled as a bestseller.

Without the federal government stepping in, individuals are left in the dark. [Privacy & Cookies Policy](#)

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MEMBER OF



EXHIBIT

C



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM

Date: September 17, 2019

SUBJECT: **Flumethrin:** Tier I Update Review of Human Incidents and Epidemiology for Proposed Interim Decision

PC Code: 036007
Decision No.: 555349
Petition No.: NA
Risk Assessment Type: NA
TXR No.: NA
MRID No.: NA

DP Barcode: D454235
Registration No.: NA
Regulatory Action: NA
Case No.: NA
CAS No.: 69770-45-2
40 CFR: NA

Ver. Apr. 08

FROM: Shanna Recore, Industrial Hygienist
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

Shanna Recore

THROUGH: David J. Miller, Acting Branch Chief
Toxicology and Epidemiology Branch
Health Effects Division (7509P)

David J. Miller

TO: Julie Van Alstine, Branch Chief
Risk Assessment Branch VI
Health Effects Division (7509P)
and
Rachel Fletcher, Chemical Review Manager
Risk Management & Implementation Branch 5
Pesticide Re-evaluation Division (7508P)

Summary and Conclusions

Flumethrin incidents were previously reviewed in 2016 (S. Recore and E. Evans, D435503, 9/7/2016). At that time, the Agency stated that it would continue to monitor the incident data due to the fact that the only flumethrin end use product (Seresto Collar, Registration No. 11556-155) was a relatively new product that was registered on March 16, 2012..

In the current IDS analysis from January 1, 2016 to August 27, 2019, 252 flumethrin human incidents were reported to Main IDS; there were 374 flumethrin human incidents reported to

Aggregate IDS. A query of SENSOR-Pesticides 1998-2015 identified three cases involving flumethrin. A query of NPIC from 2016 to August 14, 2019, identified three flumethrin cases.

The Agricultural Health Study (AHS) is a federally-funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. Flumethrin is not included in the AHS, and therefore this study does not provide information for this report.

The Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

Detailed Review

I. ACTION REQUESTED

Flumethrin is being considered under the FQPA-mandated Registration Review program established to review, on a 15-year cycle, pesticides for which a Re-registration Eligibility Decision has been made. Pesticide Re-Evaluation Division's, RMIB 5 has requested that TEB conduct a Tier I Update review summary of recent incident data from IDS, SENSOR, and NPIC. One component of the Agency's Registration Review Program is consideration of human incident data. In conjunction with a human health risk assessment based on other data sources, such human incident data can assist the Agency in better defining and characterizing the risk of pesticides/pesticide products.

It is important to remember that reports of adverse health effects allegedly due to a specific pesticide exposure (*i.e.*, an "incident") are largely self-reported and therefore, generally speaking, neither exposure to a pesticide or reported symptom (or the connection between the two) is validated or otherwise confirmed. Typically, causation cannot be determined based on incident data, and such data should be interpreted with caution. Nonetheless, incident information can be an important source of feedback to the Agency: incidents of severe outcome, or a suggested pattern or trend among less severe incidents, can signal the Agency to further investigate a particular chemical or product. Epidemiology studies can also be useful and relate the risk of disease, *e.g.*, cancer, and exposure to an agent such as a pesticide product in the general population or specific sub-groups like pesticide applicators.

II. BACKGROUND

Flumethrin is a synthetic pyrethroid insecticide. Flumethrin has one end use product (Seresto Collar, Registration No. 11556-155) which was registered by the Agency on March 16, 2012. This product, which also contains imidacloprid, is an eight-month collar used on dogs and cats for flea and tick control.

For this evaluation, both OPP Incident Data System (IDS), the Centers for Disease Control and Prevention/National Institute for Occupational Safety and Health (CDC/NIOSH) Sentinel Event

Notification System for Occupational Risk-Pesticides (SENSOR) and National Pesticide Information Center (NPIC) databases were consulted for pesticide incident data on the active ingredient flumethrin (PC Code:036007). The purpose of the database search is to identify potential patterns in the frequency and severity of the health effects attributed to flumethrin exposure.

III. RESULTS/DISCUSSION

a. IDS (Incident Data System)

OPP's IDS includes reports of alleged human health incidents from various sources, including mandatory Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) Section 6(a)(2) reports from registrants, other federal and state health and environmental agencies, and individual consumers. Since 1992, OPP has compiled these reports in IDS. IDS contains reports from across the U.S. and most incidents have all relevant product information recorded. Reports submitted to the IDS represent anecdotal reports or allegations only, unless otherwise stated in the report.

IDS records incidents in one of two modules: Main IDS and Aggregate IDS:

- Main IDS generally contains incidents resulting in higher severity outcomes and provides more detail with regard to case specifics.¹ This system stores incident data for death, major and moderate incidents, and it includes information about the location, date and nature of the incident. Main IDS incidents involving only one pesticide are considered to provide more certain information about the potential effects of exposure from the pesticide.
- Aggregate IDS contains incidents resulting in less severe human incidents (minor, unknown, or no effects outcomes). These are reported by registrants only as counts in what are aggregate summaries.

For the Main IDS for the three years from January 1, 2016 to August 27, 2019, there were 252 incidents reported that involved the active ingredient flumethrin. Nineteen of these incidents were classified as major severity. Narrative information for these 19 incidents and is found in Appendix A. Two hundred and thirty-three incidents were classified as moderate severity.

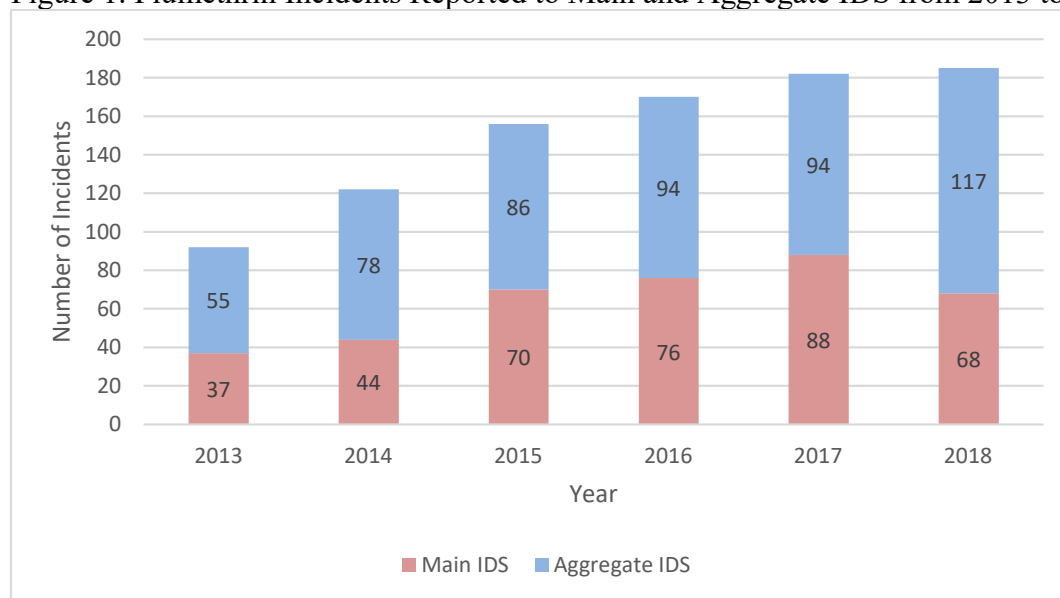
For the Aggregate IDS for the three years from January 1, 2016 to August 27, 2019, there were 374 incidents reported involving flumethrin. These incidents were classified as minor severity.

All the incidents reported to IDS involved Registration No. 11556-155 (Seresto Collar) which contains 4.5% flumethrin and 10% imidacloprid. Seresto Collar is used in dogs and cats to control fleas and ticks.

The total number of flumethrin incidents reported to Main and Aggregate IDS, from 2013 to 2018, appears to be increasing over time (Figure 1).

¹ Occasionally, low severity incidents are self-reported by the consumer directly to Main IDS.

Figure 1. Flumethrin Incidents Reported to Main and Aggregate IDS from 2013 to 2018



Of the 19 major severity incidents that were further reviewed, the symptoms most often reported were dermal (n=8) and neurological (n=7). Note that a patient could exhibit multiple symptoms. Dermal symptoms reported include rash, redness, skin lesions, hives, and pruritus. Neurological symptoms reported include headaches, numbness, tingling and one person reported seizures.

b. SENSOR-Pesticides

The Center for Disease Control's National Institute for Occupational Safety and Health (CDC/NIOSH) manages a pesticide surveillance program and database entitled the Sentinel Event Notification System for Occupational Risk (SENSOR)-Pesticides.² All cases must report at least two adverse health effects. Evidence for each case is evaluated for its causal relationship between exposure and illness based on the NIOSH case classification index.³ Using standardized protocol and case definitions, SENSOR-Pesticides state coordinators, operating out of the state's department of health, receive state pesticide incident reports from local sources, then follow up with case sources to get incident scenario to obtain medical records and verify exposure scenario information.⁴ This database includes pesticide illness case reports from multiple states from 1998-2015.⁵

A query of SENSOR-Pesticides from 2013-2015 identified three cases involving flumethrin. The three incidents were classified as low severity and are described in Appendix B.

² SENSOR-Pesticides webpage: <http://www.cdc.gov/niosh/topics/pesticides/overview.html>.

³ <https://www.cdc.gov/niosh/topics/pesticides/pdfs/casedef.pdf>

⁴ <https://www.cdc.gov/niosh/topics/pesticides/pdfs/pest-sevindexv6.pdf>

⁵ Currently participating states are: California, Florida, Illinois, Louisiana, Michigan, Nebraska, New Mexico, North Carolina, Oregon, Texas and Washington. The participating states for a given year vary depending on state and federal funding for pesticide surveillance.

c. National Pesticide Information Center (NPIC)

The National Pesticide Information Center or NPIC is a cooperative effort between Oregon State University and EPA which is funded by EPA to serve as a source of objective, science-based pesticide information and respond to inquiries from the public and to incidents. NPIC functions nationally through a toll-free telephone number in addition to the internet (www.npic.orst.edu) and email. Similar to Poison Control Centers, NPIC's primary purpose is not to collect incident data, but rather to provide information to inquirers on a wide range of pesticide topics, and direct callers for pesticide incident investigation and emergency treatment. Nevertheless, NPIC does collect information about incidents (approximately 4000 incidents per year) from inquirers and records that information in a database. NPIC is a source of national incident information but generally receives fewer reports than IDS. Regardless, if a high frequency is observed in IDS, NPIC provides an additional source of information to see whether there is evidence of consistency across national data sets or possibly duplication and additional information about the same incident(s).

From January 1, 2016 to August 14, 2019, three human incidents involving flumethrin were reported to NPIC. One incidents was classified as inconsistent with flumethrin exposure and one incident was asymptomatic. These incidents were not further reviewed. The third incident was classified as minor severity. This incident involved a 74-year-old male that was exposed to the collar when a dog that was staying with him got into his bed. The following night he broke out in hives and was itching uncontrollably. He went to the ER and was treated with prednisone. He went home for 24-48 hours, had the same reaction, and went to the ER a second time. After the collar was removed from the dog he had no further symptoms. His wife (age unknown) was also sleeping in the bed and she had no symptoms.

d. Agricultural Health Study (AHS)

The AHS is a federally-funded study that evaluates associations between pesticide exposures and cancer and other health outcomes and represents a collaborative effort between the US National Cancer Institute (NCI), National Institute of Environmental Health Sciences (NIEHS), CDC's National Institute of Occupational Safety and Health (NIOSH), and the US EPA. The AHS participant cohort includes more than 89,000 licensed commercial and private pesticide applicators and their spouses from Iowa and North Carolina. Enrollment occurred from 1993 – 1997, and data collection is ongoing. The AHS maintains a list of publications resulting from AHS studies⁶. If there are AHS findings in the published literature relevant to a pesticide undergoing registration review, the Agency will ensure these findings are considered in the problem formulation/scoping phase of the registration review process and, if appropriate, fully reviewed in the risk assessment phase of the process. Flumethrin is not included in the AHS, and therefore this study does not provide information for this report.

⁶ Agricultural Health Study: Publications <https://aghealth.nih.gov/news/publications.html>

IV. CONCLUSION

Flumethrin is the active ingredient in only one end use product (Seresto Collar, Registration No. 11556-155) that was registered on March 16, 2012. This product is a pet collar used on dogs and cats to control fleas and ticks. It contains the active ingredients flumethrin and imidacloprid.

IDS, SENSOR-Pesticides, and NPIC databases were queried for flumethrin incidents. There were 252 flumethrin incidents reported to Main IDS and 374 flumethrin incidents reported to Aggregate IDS from January 1, 2016 to August 27, 2019. Nineteen of these incidents were classified a major severity, 233 incidents were classified as moderate severity and 374 were classified as minor severity. There were three low severity flumethrin incidents reported to SENSOR-Pesticide (2013-2015) and three incidents were reported to NPIC (2016-2019).

The total number of flumethrin incidents reported to IDS, from 2013 to 2018, appears to be increasing over time.

The Agency will continue to monitor the incident data and if a concern is triggered, additional analysis will be conducted.

Appendix A.

Major Severity Flumethrin Incidents Reported to Main IDS from 1/1/16 to 8/27/19				
Incident Package Report	Incident Date	Location	Product Name	Incident Description
029467 - 00005	6/27/2016	SYRACUSE, NE	SERESTO LARGE DOG	An adult male was exposed to a Seresto Large Dog Collar after the collar was applied to his dog. No direct product exposure was known. Immediately after petting the dog, he developed an erythematous rash on his arms. The rash resolved a week after the collar was removed from the dog.
029467 - 00007	2/1/2016	GA	SERESTO CAT	An adult female was exposed to a Seresto Cat collar when she applied it to her cat. At an unknown date (during the same month) post exposure, she experienced numbness and pain in her arms and legs. She was diagnosed with an unspecified inflammatory neurological disease.
029467 - 00009	8/1/2016	ARKADELPHIA, AR	SERESTO LARGE DOG	A 50-year-old female was exposed to a Seresto Large Dog collar when it was placed around the neck of her dog. On an unknown date post administration, her neck tingled and turned red after she hugged her dog. The symptoms resolved after she washed her neck. The cycle of symptoms and resolution continued every time she hugged the dog.
029516 - 00002	5/1/2016		SERESTO SMALL DOG	A 74-year-old female was exposed to a Seresto Small Dog collar when she placed around her dog's neck. Six months after application of the collar, she was examined by a physician who determined she had an unspecified interstitial lung disease.
029685 - 00005	6/27/2016		SERESTO LARGE DOG	An adult female was exposed to one Seresto Large dog collar after the collar was applied to her dog and she pet the dog. No direct product exposure with the collar was known. Immediately after petting the dog, she developed an erythematous rash on her arms. Three months later, the collar was removed. Approximately a week later, her rash resolved.
029959 - 00008	10/1/2016	PEPPERELL, MA	SERESTO LARGE DOG	A 73-year-old female was exposed to a Seresto Large Dog collar on her hands when she placed it on her dog. Six month later, she experienced skin lesions inside of her nose. Three months later, she removed the collar from the dog and the clinical sign continued but improved.
030085 - 00006	10/1/2016	BEAVER FALLS, PA	SERESTO LARGE DOG	A 37-year-old male was exposed to an unknown amount of 1 Seresto Large Dog caller when he mouthed his dog that had the collar applied on the same day. No known direct exposure to the collar. Immediately post exposure, he experienced intermittent numbing sensation on his tongue. He continued to mouth his dog and the sign continued intermittently. He removed the collar from the dog and recovered.
030303 - 00020	5/27/2017	TUNKHANNOCK, PA	SERESTO	A 58-year-old woman was exposed to 1 Seresto Cat collar and 1 Seresto large dog collar when her boyfriend applied them to the pets. Approximately one month later, she experienced ocular pain, ocular redness, blurred vision and eyelid edema. She was examined by an ocular physician who determined there was an eye infection.

030314 - 00004	5/1/2017	CHESTER, IL	SERESTO SMALL DOG	A 43-year-old male was exposed to 8 collars on his hands when he applied them to the dogs in his home. He was also exposed to the collars when four of the dogs slept in his bed each night. Approximately one-week post exposure, he developed nasal congestion, a bleeding skin lesion on his ear, ear drainage, a nasal irritation, and a throat irritation. He was examined by a physician who determined that he had a hole in the ear drum and started medication. He also removed the 8 dog collars from his dogs. The ear drainage resolved. He replaced the 8 dog collars and approximately 10 days later, his ear drainage returned.
030475 - 00002	1/1/2016	EASTLAKE, OH	SERESTO DOG (UNSPECIFIED)	An 83-year-old male was exposed to multiple Seresto Dog collars that were worn by his neighbor's dogs when he played with and pet them. An unspecified date post exposure, he developed a pruritic rash on his hands, arms, back and legs.
030589 - 00001	4/30/2017	FLEETWOOD, PA	SERESTO LARGE DOG	An adult female was exposed to two Seresto Large Dog collars when she nuzzled her dogs face to face. She developed a rash on her chin and lower eye lids. Three months later, she replaced her dogs' collars with new Seresto collars and approximately four hours later, the clinical signs worsened.
030942 - 00006	12/25/2017	IA	SERESTO (UNSPECIFIED)	A 34-year-old male was secondarily exposed to the collar when he was in the home of his parent's dog who was wearing the collar around its neck. Approximately four hours post exposure, he experienced generalized pruritus and hives on both arms. When he left the dog's residence, the clinical signs improved but continued.
031139 - 00010	6/1/2016	LILLIAN, AL	SERESTO (UNSPECIFIED)	An 84-year-old female was exposed to multiple collars when she applied them to her dog and 9 cats without wearing gloves. Sometime after exposure, she experienced a tingling sensation in her entire body, the sensation of the right side of the body being asleep and difficulty using the right arm and right hand.
031139 - 00012	5/1/2017	PLYMOUTH, MA	SERESTO DOG (UNSPECIFIED)	A 78-year-old male with asthma and allergies was exposed to a Seresto dog collar when his dog would rest against his neck. He had a tick removed from his neck and experienced a lesion and localized pruritus. The next month he experienced a lesion under his arm and localized pruritus. He was tested for Lyme disease and other tick-borne illnesses and the results were negative.
031139 - 00014	10/1/2017	ALVERTON, PA	SERESTO DOG (UNSPECIFIED)	An 80-year-old female to one dog collar. She developed a digestive tract disorder.
031139 - 00015	5/2/2018	BARNEVELD, WI	SERESTO LARGE DOG	A 67-year-old woman was exposed to 1 Seresto Large Dog collar when she would pet the dog and slept in the same bed as the dog after the collar was applied. Two days later, she experienced fatigue and heart flutter (arrhythmia).
032334 - 00009	2/15/2019	OLIVER SPRINGS, TN	SERESTO DOG (UNSPECIFIED)	On 14-Feb-2019, a 12-year-old, 130-pound boy in unknown condition, with the concomitant medical conditions of a digestive tract disorder NOS and elevated blood pressure. that was taking 15 mg of Lisinopril by mouth daily since an unknown date in 2019, was secondarily exposed to an unknown amount of a Seresto Dog (unspecified) collar that was worn by the dog in the home since approximately 14-Feb-2019, and the dog slept in the bed with the boy. It was unknown if direct contact with the collar occurred. On approximately, 15-Feb-2019, the boy experienced intermittent grand mal seizures, 1 episode of emesis that resolved approximately 5 minutes post onset and mental impairment. A toxicology blood screening

				<p>panel and other unspecified blood panel were performed and were both within normal limits. The boy continued to have intermittent seizures and was examined by a pediatrician on emergency. Magnetic Resonance Imaging testing was performed of the brain with the results within normal limits. Approximately 12 hours post onset, the boy recovered. It was unknown if treatments were performed. The boy remained hospitalized for observation. On 19-Feb-2019, the boy was released from the hospital. On 26-Jun-2019, the boy had a follow up exam performed with a pediatric neurologist. An electroencephalogram was performed and showed normal brain activity .</p>
030787 - 00003	5/1/2017	TUCKERTON, NJ	SERESTO LARGE DOG	<p>In approximately May 2017, an adult female was exposed to a Seresto Large Dog collar when she placed it on her dog. Sometime after that in May 2017, the she exhibited an unspecified eye disorder. She was examined by 5 different physicians and an allergy specialist. It was determined that she had an allergy. No known treatments were provided and the clinical signs continued. In Dec 2017, the individual removed the collar from the dog. The clinical signs continued.</p>
030787 - 00006	6/1/2017	HARRISBURG, PA	SERESTO DOG (UNSPECIFIED)	<p>A 68 year old female with concomitant medical conditions of arthritis, osteoarthritis of the hand, carpal tunnel syndrome, a chronic renal disorder NOS, bile duct disorder NOS, gastric esophageal reflux disease (gastric irritation), heartburn, hypothyroidism, hypertension, osteoporosis (bone and joint disorder NOS), atrial fibrillation, pancreatic lesion (pancreas disorder), stenosing tenosynovitis/trigger finger (tendon injury), vitamin D deficiency, Fuchs corneal dystrophy (eye disorder NOS), corneal ulcer (corneal disorder NOS), diplopia esotropia (diplopia), posterior capsule opacification (eye disorder NOS), peripheral vascular disorder, anterior basement membrane dystrophy (eye disorder NOS) and abducens (6th) nerve palsy (cranial nerve disorder), was exposed to 1 Seresto Large Dog collar while the dog slept with her each night.</p> <p>Sometime post exposure she experienced double vision. She was examined by multiple physicians (neurologist, primary care physician, prism eye doctor and a general eye doctor) and had multiple tests performed (MRI, fluorescein, various ocular tests, CT scan and bloodwork). No abnormalities were found.</p> <p>In June 2017, the individual experienced headaches and one eye was unable to move (eye disorder NOS). She was examined by a physician, hospitalized for 3 days, and administered an unspecified dose of intravenous fluids. It was determined by physicians that the woman had an unspecified nerve palsy (cranial nerve disorder).</p> <p>Sometime after that she removed the collar from the dog. Sometime later she replaced the collar on her dog and her clinical signs worsened.</p>

Appendix B.

Flumethrin Incidents Reported SENSOR-Pesticide from 2013-2015			
Year	State	Severity	Incident Description
2013	North Carolina	Low	An adult woman was exposed to the collar when it was applied to her dog. She experienced a rash.
Not Available	New York	Low	The case was exposed to the collar when she 1) slept with dogs while the dogs were wearing their collar, 2) exposed to collar while trying to restrain dogs, and 3) placed collar on her bare skin (stomach). She experienced rhinitis, urticaria, pruritus, erythema, eye irritation, conjunctivitis, nasal irritation and nasal discharge, and ocular irritation
2013	New York	Low	A veterinarian applied the collar to the case's dog. The collar accidentally broke open on the case's hands. She experienced nausea, blurred vision, and heart palpitations

EXHIBIT

D



U.S. Environmental Protection Agency
Pacific Southwest / Region 9



Serving Arizona, California, Hawaii, Nevada, the Pacific Islands and 148 Tribes

Land Division
Pesticides Office • October 2016

75 Hawthorne Street, San Francisco, CA 94105
866-EPA-WEST • www.epa.gov/region9

Weighing Risks to Children from Dogs Wearing Seresto™ Collars

At the Vector-Borne Diseases (VBD) Workshop hosted by Region 9 on August 8, 2016, the Centers for Disease Control and Prevention (CDC) presented information about its work with American Indian communities in Arizona to control Rocky Mountain spotted fever (RMSF) after an outbreak of the vector-borne disease. The CDC developed and implemented a reservation-wide dog-collaring program to combat spread of the disease by dogs.^{1,2} The collars used in the program were a new product sold under the brand name Seresto™. Workshop participants expressed concern about any adverse effects of the collars, particularly to children who interact with collared dogs. It is important for communities to weigh the risks of both RMSF and any proposed tick-control approach and then decide what is best for the community.



Child's hand and wrist displaying rash of Rocky Mountain spotted fever.

Rocky Mountain Spotted Fever

The CDC describes RMSF as a serious illness that can be fatal in the first eight days of symptoms, even in previously healthy people, if not treated correctly. The progression of the disease varies greatly. Patients who are treated early may recover quickly on outpatient medication, while those who experience a more severe course may require intravenous antibiotics, prolonged hospitalization or intensive care.³ At the Region 9 VBD workshop, Naomi Drexler of the CDC reported high mortality rates in Arizona for children under 10 years old who contract RMSF.²

Rocky Mountain spotted fever is a tick-borne disease caused by the bacterium *Rickettsia rickettsii*. This organism is transmitted to humans by the bite of infected tick species. In the United States, these include the American dog tick (*Dermacentor variabilis*), Rocky Mountain wood tick (*Dermacentor andersoni*) and brown dog tick (*Rhipicephalus sanguineus*).⁴

Seresto™ Collars

The collars used in the CDC project are registered by the U.S. EPA (Reg. No. 11556-155). They are made of plastic impregnated with insecticides that are released over time and coat the animal's fur. The active ingredients are imidacloprid (10%) and flumethrin (4.5%). Imidacloprid, which affects the central nervous system of fleas, is a member of the neonicotinoid class of insecticides; flumethrin, which repels and kills ticks, is in the pyrethroid class. The collar label includes the following language: DO NOT LET CHILDREN PLAY WITH THIS COLLAR OR REFLECTORS; KEEP OUT OF REACH OF CHILDREN; CHOKING HAZARD—CONTAINS SMALL PARTS.



Rocky Mountain wood tick. Photo by James Gathany.

In its human health risk assessment, EPA determined that the collars may cause slight skin irritation but will not cause skin allergies. EPA also determined that flumethrin exposures to people placing collars on pets, and to adults and children interacting with pets (including incidental ingestion because of children's hand-to-mouth activities), are below levels of concern. The assessment of imidacloprid identified no risks to humans placing the collars on pets or interacting with pets wearing the collars. The risk of the combination of the two active ingredients, flumethrin and imidacloprid, was not assessed because the two chemicals act in completely different ways. As stated in the precautions on the label, do not allow children to play with the collars. In addition, try to keep the pet away from young children for a day after putting on the collar to minimize exposure.

At the time it registered the Seresto™ collar, EPA determined that the collars could be safely used on adult dogs and puppies of seven weeks of age and older, and on adult cats and kittens of 10 weeks of age and older. Studies also demonstrated no decrease in safety or increase in toxicological hazard to animals associated with wearing collars with reflectors. The only adverse effects observed for adult dogs and puppies was slight reddening of the skin and loss of hair, both of which were temporary conditions that occurred in dogs wearing collars impregnated with insecticides as well as in dogs wearing collars with no insecticide. Since the initial registration, EPA has received reports of undesirable effects to domestic animals using Seresto™ collars. EPA is evaluating those reports as part of the current registration review of flumethrin.

This bulletin addresses only Seresto™ brand collars. Other brands of flea and tick collars have also been registered by EPA.

Additional Information and Reporting

Further information about pesticides and pets is available at www.epa.gov/pets.

Report adverse incidents caused by use of pest collars at www.epa.gov/pesticide-incidents/report-pesticide-exposure-incidents-affecting-pets-or-domestic-animals.

For questions about information in this bulletin, contact Patti TenBrook in the U.S. EPA Region 9 Pesticides Office at (415) 947-4223.

1 www.cdc.gov/nceh/ehs/News/Features/2014/rmsf_rodeo.html

2 www.epa.gov/sites/production/files/2016-08/documents/vector-borne_diseases_workshop_presentations_epa_region_9_2016-08-08.pdf, pp 135 ff

3 www.cdc.gov/rmsf/symptoms/index.html

4 www.cdc.gov/rmsf/index.html

EXHIBIT

E

CAROLYN B. MALONEY, NEW YORK
CHAIRWOMAN

ONE HUNDRED SEVENTEENTH CONGRESS

JAMES COMER, KENTUCKY
RANKING MINORITY MEMBER

Congress of the United States
House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051
MINORITY (202) 225-5074

<https://oversight.house.gov>

March 17, 2021

Mr. Jeff Simmons
President and Chief Executive Officer
Elanco Animal Health Inc.
2500 Innovation Way
Greenfield, IN 46140

Dear Mr. Simmons:

The Subcommittee on Economic and Consumer Policy calls on Elanco Animal Health—which recently acquired Bayer Animal Health—to immediately institute a temporary recall of all Seresto flea and tick collars, following reports that the collars may have killed thousands of pets and may have caused injuries to many more pets as well as humans. The Subcommittee also seeks documents and information from Elanco regarding Seresto collars and associated risks.

Recently disclosed documents from the Environmental Protection Agency (EPA) reveal that Seresto flea and tick collars were associated with almost 1,700 pet deaths, over 75,000 incidents involving harm to pets, and nearly 1,000 incidents involving human harm.¹ We believe that the actual number of deaths and injuries is much greater, since the average consumer would not know to report pet harm to EPA, an agency seemingly unrelated to consumer pet products. EPA receives complaints because the active ingredients in Seresto collars are pesticides.

The packaging for Seresto collars contains no disclaimer warning that the risks of toxicity may be so great that they could possibly be responsible for thousands of pet deaths:

¹ *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning.*, USA Today (Mar. 2, 2020) (online at www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/).

Mr. Jeff Simmons

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Mr. Jeff Simmons
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The Seresto collar is the only flea and tick collar that combines a cocktail of two pesticides: imidacloprid and flumethrin. Reportedly, a 2012 Bayer study found that combining the two pesticides makes them more toxic against fleas.²

Apparently, they may be more toxic to pets and humans as well. In addition to being linked to 1,700 pet deaths, a Seresto collar caused one twelve-year-old boy, who slept in bed with a dog wearing the collar, to be hospitalized due to seizures and vomiting.³

To assist the Subcommittee in its oversight of this matter, please provide the following documents and information by March 31, 2021:

1. A written description of all steps, taken and planned, to effectuate a voluntary recall of Seresto flea and tick collars and to issue full consumer refunds;
2. All consumer complaints and administrative or legal actions regarding Seresto flea and tick collars involving harm to pets and/or humans, and all documents and communications related thereto;
3. All communications with the federal government regarding or relating to Seresto flea and tick collars and the effect on pet and/or human health;
4. All internal documents, including communications, meeting minutes, and reports, referring or relating to toxicity or risks of death and injury to pets or humans from Seresto flea and tick collars;
5. All communications between Bayer and Elanco during Elanco's acquisition of Bayer Animal Health regarding toxicity or risks of death and injury to pets or humans from Seresto flea and tick collars and the transfer of liabilities related thereto; and
6. The number of Seresto flea and tick collars sold in the United States, and the total sales volume.

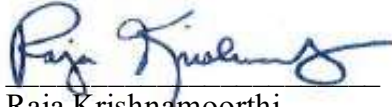
The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

² *Popular Flea Collar Linked to Almost 1,700 Pet Deaths. The EPA Has Issued No Warning.*, USA Today (Mar. 2, 2020) (online at www.usatoday.com/story/news/investigations/2021/03/02/seresto-dog-cat-collars-found-harm-pets-humans-epa-records-show/4574753001/).

³ *Id.*

Mr. Jeff Simmons
Page 4

Sincerely,

A handwritten signature in blue ink, appearing to read "Raja Krishnamoorthi", written over a horizontal line.

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.
2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.
3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.
4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.
5. Documents produced in electronic format should be organized, identified, and indexed electronically.
6. Electronic document productions should be prepared according to the following standards:
 - a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.
 - b. Document numbers in the load file should match document Bates numbers and TIF file names.
 - c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.
 - d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.
8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.
9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.
10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.
11. The pendency of or potential for litigation shall not be a basis to withhold any information.
12. In accordance with 5 U.S.C. § 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.
13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.
14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.
15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.
16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.
17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.
19. All documents shall be Bates-stamped sequentially and produced sequentially.
20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.
21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term “document” means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.
2. The term “communication” means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.
4. The term “including” shall be construed broadly to mean “including, but not limited to.”
5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.
6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.
7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.
8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.
9. The term “individual” means all natural persons and all persons or entities acting on their behalf.

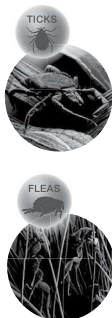
EXHIBIT

F



For 8-month prevention and treatment of ticks and fleas on cats and kittens 10 weeks of age and older.

- Kills and Repels fleas and ticks.
- Repels and kills ticks, including Deer ticks (vector of Lyme disease and anaplasmosis), American dog ticks (vector of Rocky Mountain spotted fever, cytauxzoonosis and ehrlichiosis), Brown dog ticks (vector of ehrlichiosis, anaplasmosis, babesiosis, and Rocky Mountain spotted fever), and Lone Star ticks (vector of cytauxzoonosis and ehrlichiosis).
- Prevents tick infestations within 48 hours after application.
- Quickly kills fleas on cats within 24 hours and continues to prevent infestations for 8 months.
- Treatment with Seresto kills fleas that may vector bartonellosis (*Bartonella henselae*), tapeworm infections (*Dipylidium caninum*), feline infectious anemia (*Mycoplasma spp.*), and rickettsiosis (*Rickettsia felis*).
- Re-infesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months.
- Kills and repels fleas before they lay eggs.
- Seresto aids in control of flea larvae in the cat's surroundings following contact with a Seresto-treated cat.
- Bayer Polymer Matrix ensures that both active ingredients are continuously released in low concentrations.



- Make sure to replace the collar after 8 months for year-round tick and flea pest prevention.
- Light reflectors for added visibility in the evening and at night.

ACTIVE INGREDIENTS:	% by Weight
Flumethrin*.....	4.5 %
Imidacloprid.....	10.0 %
OTHER INGREDIENTS	85.5 %
TOTAL	100.0 %

* Trans Z-1/trans Z-2 ratio: max 66 % trans Z-1 and min 34 % trans Z-2

READ THE ENTIRE LABEL BEFORE USE
DO NOT OPEN UNTIL READY TO USE
DO NOT LET CHILDREN PLAY WITH THIS COLLAR OR REFLECTORS
KEEP OUT OF REACH OF CHILDREN
CHOKING HAZARD – CONTAINS SMALL PARTS

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

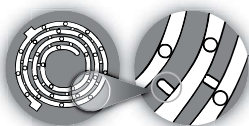
- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS or ANIMALS, call 1-800-422-9874

DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

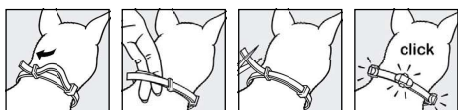
HOW TO APPLY

One collar per animal to be fastened around the neck.
Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.



Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight or leaving it too loose. As a guide, it should be possible to only insert 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Collar length of greater than 1 inch (2 cm) beyond the loop(s) should be cut off unless it is on a growing kitten, where some additional length may be needed for adjustment as the animal grows.

After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.



The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when kittens are rapidly growing.
This collar is designed with a release mechanism. In the unlikely event of a cat being trapped, the cat's own strength is sufficient to widen the collar to allow for quick release.



Replace the collar after 8 months for optimal flea and tick protection.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH).
Seresto kills existing fleas on cats within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in control of flea larvae in the cat's surroundings following contact with a Seresto-treated cat.
Ticks already on the cat prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the cat. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

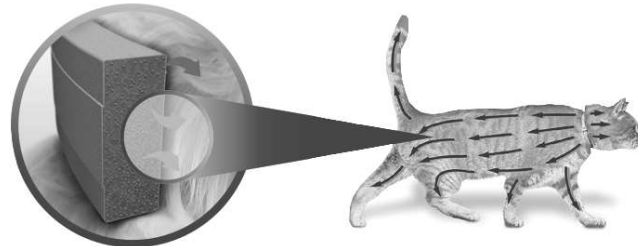
Re-infesting ticks are repelled and/or killed as quickly as 6 hours.
Occasionally scratching may be observed in animals that are not used to wearing collars in the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. For further guidance regarding individual animal sensitivities, see information below.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.
Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar or reflectors, or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. Choking hazard. Contains small parts. Do not place collar or reflectors in mouth. Not intended for use on humans.

For external use on cats only. Do not use on other animals. Do not use on kittens under ten weeks of age. Do not get this product in cat's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. Rarely, mild application site reactions may occur, such as scratching, redness and hair loss, which usually recover within 1 to 2 weeks without the need for collar removal. In some cases, a temporary collar removal and bathing may be recommended until symptoms have disappeared. In very rare cases, application site reactions such as dermatitis, inflammation, eczema or lesions may occur. In these instances, collar removal is recommended. If signs persist, or become more severe, consult a veterinarian immediately.

If your animal is on medication, consult your veterinarian before using this or any other product. If your cat is experiencing an adverse event, contact your veterinarian and call 1-800-422-9874.

The patented continuous release technology ensures that both active ingredients are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active ingredients are present in the cat's haircoat during the entire efficacy period. The active ingredients spread from the site of direct contact over the skin surface.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.
Do not use container for food storage or other purposes.
Pesticide Storage: Store in original unopened container in a cool, dry place that is inaccessible to children.
Container Disposal: Dispose of pouch and expired collar in trash. Outer container may be recycled or disposed of in trash.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc. The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.

EPA Reg. No. 11556-155
Manufactured For Bayer HealthCare LLC
Animal Health Division
P.O. Box 390
Shawnee Mission, Kansas 66201, USA
Made in Germany

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LV1807





Seresto[®] Small Dog

The collar should be worn continuously for the 8 month protection period. Check periodically and adjust fit if necessary, especially when puppies are rapidly growing.

This collar is designed with a release mechanism. In the unlikely event of a dog being trapped, the dog's own strength is sufficient to widen the collar to allow for quick release.

For 8-month prevention and treatment of ticks, fleas and lice on dogs and puppies 7 weeks of age and older and up to 18 lbs. (8 kg)

- Kills and Repels fleas and ticks.
- Repels and kills ticks for 8 months, including Deer ticks (vector of Lyme disease and anaplasmosis), American dog ticks (vector of Rocky Mountain spotted fever and ehrlichiosis), Brown dog ticks (vector of ehrlichiosis, anaplasmosis, bartonellosis, babesiosis, canine hemoplasmosis and Rocky Mountain spotted fever), and Lone Star ticks (vector of ehrlichiosis).
- Prevents tick infestations within 48 hours after application.
- Re-infesting ticks are repelled and/or killed as quickly as 6 hours.
- Treatment with Seresto kills fleas that may vector tapeworm infections (*Dipylidium caninum*), bartonellosis (*Bartonella vinsonii*, *Bartonella* spp.), and rickettsiosis (*Rickettsia felis*), which are types of canine vector borne diseases.
- Re-infesting fleas are killed within 2 hours with protection against further flea infestation lasting 8 months.
- Kills and repels fleas before they lay eggs.
- Seresto aids in the control of flea larvae in the dog's surroundings following contact with a Seresto-treated dog.
- Kills chewing lice.
- Aids in the treatment and control of Sarcoptic mange on dogs.
- No need to remove collar when your pet goes swimming or gets bathed.
- Bayer Polymer Matrix ensures that both active ingredients are continuously released in low concentrations.



Replace the collar after 8 months for optimal flea and tick protection.

PRODUCT INFORMATION

Kills fleas which may cause flea allergy dermatitis (FAD) or flea bite hypersensitivity (FBH). Seresto kills existing fleas on dogs within 24 hours. Reinfesting fleas are killed within 2 hours with protection against further flea infestation lasting eight (8) months. Pre-existing pupae in the environment may continue to emerge for six (6) weeks or longer depending upon the climatic conditions.

Seresto aids in control of flea larvae in the dog's surroundings following contact with a Seresto-treated dog. Ticks already on the dog prior to treatment may not be killed immediately after collar application and may remain attached and visible. At the time of application remove ticks already on the dog. The prevention of infestations with new ticks starts within 48 hours after application of the collar.

Re-infesting ticks are repelled and/or killed as quickly as 6 hours.

Kills lice on dogs.

Aids in the treatment and control of Sarcoptic mange on dogs.

Seresto is water resistant and remains effective following a shampoo treatment, swimming or after exposure to rain or sunlight. Under normal conditions, effectiveness lasts for 8 months. In order to maintain an eight-month duration, dogs must not be bathed more than once per month. For dogs that swim once a month or more, the control duration is reduced to 5 months for flea control and reduced to 7 months for tick control.

Occasionally scratching may be observed in animals that are not used to wearing collars during the first few days after fitting. Ensure that the collar is not fitted too tightly. Slight hair loss and mild skin reactions due to the mechanical irritation of the collar may occur at the application site which usually recover within 1 or 2 weeks without the need for collar removal. For further guidance regarding individual animal sensitivities, see information below.

In case of loss of collar, a new collar may be applied immediately. Do not attach a leash to the collar as this may cause breakage.

Keep the collar in the bag and in the outer packaging until use. As with any pesticide product, do not allow small children to play with the collar or reflectors, or to put them into their mouths. Avoid contact with eyes, skin or clothing. Wash thoroughly with soap and cold water after fitting the collar. People with sensitivity reactions to the ingredients of the collar should avoid contact with the collar. Choking hazard, Contains small parts. Do not place collar or reflectors in mouth. Not intended for use on humans.

For external use on dogs only. Do not use on other animals. Do not use on puppies under seven weeks of age. Do not get this product in dog's eyes or mouth. As with any product, consult your veterinarian before using this product on debilitated, aged, breeding, pregnant, or nursing animals. Individual sensitivities, while rare, may occur after using ANY pesticide product for pets. Rarely, mild application site reactions may occur, such as scratching, redness and hair loss, which usually recover within 1 to 2 weeks without the need for collar removal. In some cases, a temporary collar removal and bathing may be recommended until symptoms have disappeared. In very rare cases, application site reactions such as dermatitis, inflammation, eczema or lesions may occur. In these instances, collar removal is recommended. If signs persist, or become more severe, consult a veterinarian immediately. If your animal is on medication, consult your veterinarian before using this or any other product. If your dog is experiencing an adverse event, contact your veterinarian and call 1-800-422-9874.

The patented continuous release technology ensures that both active ingredients are slowly and continuously released in low concentrations from the collar towards the animal. This avoids peak concentrations and ensures that concentrations of both active ingredients are present in the dog's haircoat during the entire efficacy period. The active ingredients spread from the site of direct contact over the skin surface.



- Make sure to replace the collar after 8 months for year-round tick and flea prevention.
- Light reflectors for added visibility in the evening and at night.



ACTIVE INGREDIENTS:	% by Weight
Flumethrin*	4.5%
Imidacloprid	10.0%
OTHER INGREDIENTS	85.5%
TOTAL	100.0%

* Trans Z-1/trans Z-2 ratio: max 66 % trans Z-1 and min 34 % trans Z-2

READ THE ENTIRE LABEL BEFORE USE

DO NOT OPEN UNTIL READY TO USE
DO NOT LET CHILDREN PLAY WITH THIS COLLAR OR REFLECTORS
KEEP OUT OF REACH OF CHILDREN
CHOKING HAZARD – CONTAINS SMALL PARTS

HOT LINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

- For CONSUMER QUESTIONS, call 1-800-255-6826.
- For medical emergencies involving HUMANS or ANIMALS, call 1-800-422-9874.

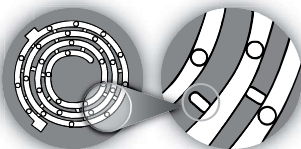
DIRECTIONS FOR USE

It is a violation of Federal Law to use this product in a manner inconsistent with its labeling. Do not contaminate feed or food.

HOW TO APPLY

One collar per animal to be fastened around the neck.

Remove collar from protective bag directly before use. Unroll collar and make sure that there are no remnants from the plastic connectors inside the collar.



Insert end of the collar through the buckle. Adjust the collar around the animal's neck without tightening it too tight or leaving it too loose. As a guide, it should be possible to only insert 2 fingers comfortably between the collar and the neck. Pull excess collar through the loop(s). Collar length of greater than 1 inch (2 cm) beyond the loop(s) should be cut off unless it is on a growing puppy, where some additional length may be needed for adjustment as the animal grows.

After application of the collar, three reflector clips may be fixed permanently to the collar to increase the animal's visibility in the dark. Take the clips out of the bag. The clips should be evenly distributed on the non-overlapping part of the collar. The clips are correctly applied when a clicking sound is heard. For safety reasons once the reflectors are fixed to the collar the clasp closes permanently and cannot be re-opened.



STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Do not use container for food storage or other purposes.

Pesticide Storage: Store in original unopened container in a cool, dry place that is inaccessible to children.

Container Disposal: Dispose of pouch and expired collar in trash. Outer container may be recycled or disposed of in trash.

LIMITED WARRANTY AND LIMITATION OF DAMAGES

Bayer HealthCare LLC, Animal Health Division, warrants that this material conforms to the chemical description on the label. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY, INCLUDING ANY OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR MERCHANTABILITY, and no agent of Bayer is authorized to do so except in writing with a specific reference to this warranty. To the extent consistent with applicable law any damages arising from a breach of this warranty shall be limited to direct damages and shall not include consequential commercial damages such as loss of profits or values, etc. The reflector clips contained herein are only meant to be used in combination with the specific collar and have been tested only for such use and purpose. To the extent consistent with applicable law, Bayer excludes liability for any misuse and use other than in combination with the specific collar as described in the packaging insert.

EPA Reg. No. 11556-155

Manufactured for
Bayer HealthCare LLC, Animal Health Division
P.O. Box 390, Shawnee Mission, Kansas 66201, USA
Made in Germany

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LV1807



JS 44 (Rev. 10/20)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)

<p>I. (a) PLAINTIFFS</p> <p>LAURA REVOLINSKY, on behalf of herself and all others similarly situated</p> <p>(b) County of Residence of First Listed Plaintiff <u>Monmouth</u> <i>(EXCEPT IN U.S. PLAINTIFF CASES)</i></p> <p>(c) Attorneys <i>(Firm Name, Address, and Telephone Number)</i></p> <p>Poulos LoPiccolo, PC; 1305 South Roller Road, Ocean, NJ 07712; (732) 757-0165</p>	<p>DEFENDANTS</p> <p>ELANCO ANIMAL HEALTH INCORPORATED and BAYER HEALTHCARE LLC</p> <p>County of Residence of First Listed Defendant _____ <i>(IN U.S. PLAINTIFF CASES ONLY)</i></p> <p>NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.</p> <p>Attorneys <i>(If Known)</i></p>
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<p>II. BASIS OF JURISDICTION <i>(Place an "X" in One Box Only)</i></p> <p><input type="checkbox"/> 1 U.S. Government Plaintiff</p> <p><input type="checkbox"/> 2 U.S. Government Defendant</p> <p><input checked="" type="checkbox"/> 3 Federal Question <i>(U.S. Government Not a Party)</i></p> <p><input type="checkbox"/> 4 Diversity <i>(Indicate Citizenship of Parties in Item III)</i></p>	<p>III. CITIZENSHIP OF PRINCIPAL PARTIES <i>(Place an "X" in One Box for Plaintiff and One Box for Defendant)</i></p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:33%;"></td> <td style="width:33%; text-align: center;">PTF</td> <td style="width:33%; text-align: center;">DEF</td> <td style="width:33%;"></td> <td style="width:33%; text-align: center;">PTF</td> <td style="width:33%; text-align: center;">DEF</td> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
	PTF	DEF		PTF	DEF																				
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

IV. NATURE OF SUIT *(Place an "X" in One Box Only)* Click here for: [Nature of Suit Code Descriptions.](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	<p>PERSONAL INJURY</p> <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	<p>PERSONAL INJURY</p> <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability <p>PERSONAL PROPERTY</p> <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157
<p>REAL PROPERTY</p> <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	<p>CIVIL RIGHTS</p> <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	<p>LABOR</p> <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act	<p>PROPERTY RIGHTS</p> <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark <input type="checkbox"/> 880 Defend Trade Secrets Act of 2016	<input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit (15 USC 1681 or 1692) <input type="checkbox"/> 485 Telephone Consumer Protection Act <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input checked="" type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
	<p>PRISONER PETITIONS</p> <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty <p>Other:</p> <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement	<p>IMMIGRATION</p> <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<p>SOCIAL SECURITY</p> <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g))	<p>FEDERAL TAX SUITS</p> <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609

V. ORIGIN *(Place an "X" in One Box Only)*

1 Original Proceeding 2 Removed from State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from Another District *(specify)* 6 Multidistrict Litigation - Transfer 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
15 U.S.C. 2301 et seq.

Brief description of cause:
Breach of warranty and consumer fraud action

VII. REQUESTED IN COMPLAINT: CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$ _____ CHECK YES only if demanded in complaint: JURY DEMAND: Yes No

VIII. RELATED CASE(S) IF ANY *(See instructions):* JUDGE _____ DOCKET NUMBER _____

DATE: 04/22/2021 SIGNATURE OF ATTORNEY OF RECORD: Joseph LoPiccolo

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

- I.(a) Plaintiffs-Defendants.** Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.
- (b) County of Residence.** For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)
- (c) Attorneys.** Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".
- II. Jurisdiction.** The basis of jurisdiction is set forth under Rule 8(a), F.R.Cv.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.
 United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.
 United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.
 Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.
 Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; **NOTE: federal question actions take precedence over diversity cases.**)
- III. Residence (citizenship) of Principal Parties.** This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.
- IV. Nature of Suit.** Place an "X" in the appropriate box. If there are multiple nature of suit codes associated with the case, pick the nature of suit code that is most applicable. Click here for: [Nature of Suit Code Descriptions](#).
- V. Origin.** Place an "X" in one of the seven boxes.
 Original Proceedings. (1) Cases which originate in the United States district courts.
 Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441.
 Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.
 Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.
 Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.
 Multidistrict Litigation – Transfer. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407.
 Multidistrict Litigation – Direct File. (8) Check this box when a multidistrict case is filed in the same district as the Master MDL docket.
PLEASE NOTE THAT THERE IS NOT AN ORIGIN CODE 7. Origin Code 7 was used for historical records and is no longer relevant due to changes in statute.
- VI. Cause of Action.** Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity.** Example: U.S. Civil Statute: 47 USC 553 Brief Description: Unauthorized reception of cable service.
- VII. Requested in Complaint.** Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.
 Demand. In this space enter the actual dollar amount being demanded or indicate other demand, such as a preliminary injunction.
 Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.
- VIII. Related Cases.** This section of the JS 44 is used to reference related pending cases, if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.