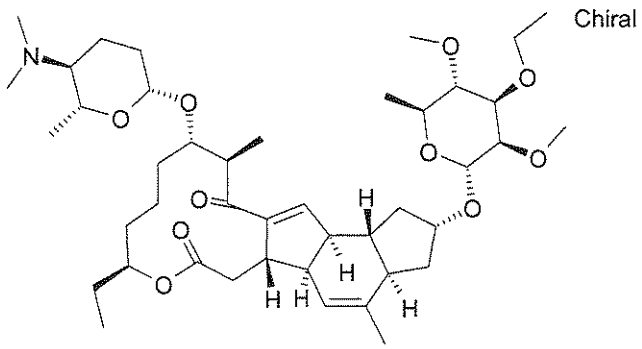

Formula II

(Podhorez *et al.*, US 2008/0108800A1). Spinetoram is described as providing long-lasting control of a broad spectrum of insect pests in a variety of crops (Dow AgroSciences Spinetoram Technical Bulletin, November 2006). It has been reported spinetoram has been registered in New Zealand as an insecticide in the pome fruit market ("Dow AgroSciences Receives First Global Registration for Spinetoram Insecticide," Dow AgroSciences Newsroom, Corporate News, August 10, 2007).

While the use of spinosyns and other insecticides and pesticides have been beneficial, alternative or improved formulations and methods are needed. Desirable formulations and methods would not only provide alternative therapies, but would also overcome at least some limitations of current therapies. Such limitations include toxicity and safety, efficacy (potency and duration), and resistance issues. Also impacting the beneficial use of insecticides and pesticides are administration obstacles, which include mode and recurrence of administration. For example, reducing the frequency of administration while maintaining efficacy is desirable, as dosing animals is often inconvenient and/or difficult. The present invention encompasses ectoparasiticidal methods and formulations for use in animals which provide alternative options for combating ectoparasiticite infestations. Further, they overcome at least some limitations in the use of current insecticides and pesticides, particularly in providing effective long term, safe, systemic control of ectoparasites.

The disclosure~~invention~~ provides methods of controlling ectoparasite infestations of an animal by systemically administering an effective amount of spinetoram or a pharmaceutically acceptable salt thereof to the animal, as well as pharmaceutical formulations for systemically controlling ectoparasite infestations using spinetoram or a pharmaceutically acceptable salt

thereof, and a pharmaceutically acceptable carrier. The disclosure~~invention~~ also provides methods for controlling flea infestations of a dog or cat by orally or parenterally systemically administering an effective amount of spinetoram or a pharmaceutically acceptable salt thereof to said dog or cat, and single or pulse dose formulations for systemically controlling an ectoparasite infestation on a dog or cat using spinetoram or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier in an oral dosage form selected from a tablet, capsule, or liquid at a dose of 10 to 60 mg of spinetoram or a pharmaceutically acceptable salt thereof per kg of body weight of the dog or cat. Another embodiment~~aspect~~ of the methods and formulations using spinetoram is the ability to provide prolonged systemic control of ectoparasite infestations, thus decreasing the recurrence of dosing an animal, such as no more than every one or two weeks, or every month or more.

In one aspect, there is provided the use of spinetoram, or a pharmaceutically acceptable salt thereof, in the manufacture of a medicament for the control of flea infestations on a dog or cat, wherein the spinetoram is to be systemically administered by oral administration.

In another aspect, there is provided a single or pulse dose formulation for systemically controlling ectoparasite infestations on a dog or cat comprising spinetoram or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier, in an oral dosage form selected from a tablet, capsule or liquid, at a dose of 10 to 60 mg of said spinetoram or a pharmaceutically acceptable salt thereof per kg of body weight of said dog or cat.

The host animal may be a mammal or non-mammal, such as a bird (turkeys, chickens) or fish. Where the host animal is a mammal, it may be a human or non-human mammal. Non-human mammals include domestic animals, such as livestock animals and companion animals. Livestock animals include cattle, camellids, pigs, sheep, goats, and horses. Companion animals include dogs, rabbits, cats, and other pets owned and maintained in close association with humans as part of the human-animal bond.

Ectoparasites include insect and acarine pests which commonly infest or infect animals, and include the egg, larval, pupal, nymphal, and adult stages thereof. Such pests include fleas, lice, mosquitoes, mites, ticks, and blood-sucking, biting or nuisance fly species. A particular target is fleas, and more particularly *Ctenocephalides felis.*

"Controlling" refers to either ameliorating or eliminating a current infestation, or preventing an infestation, in an animal host.

"Effective amount" refers to the amount of spinetoram, or a salt thereof, sufficient to control an ectoparasite, and includes causing a measurable reduction in the ectoparasite infestation population. This control may be the result of spinetoram or its conjugate or salt entering the system of the pest when it feeds, or through a repellant or in vivo action due to the systemic presence of spinetoram or its conjugate or salt thereof. Ranges for spinetoram or a salt thereof in the methods and formulations range from 0.01 to 1000 mg/kg, more desirably, 0.1 to 100 mg/kg, and particularly desirable, 10 to 60 mg/kg of body weight of the animal.