

MENFORSAN 3 ACTIVE INGREDIENT ANTI- INSECT COLLAR: MARGOSE/NEEM 2,5% GERANIOL 1% AND LAVANDIN OIL 1%

EFFICACY AND SAFETY DOSSIER

DOG AND CAT PROTECTION

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MENFORSAN ANTI-INSECT COLLAR

1- GENERAL CHARACTERISTICS

DOG COLLAR	Composition: Margose/Neem 2,5%, Geraniol 1% y Lavandin oil 1%
CAT COLLAR	Composition: Margose/Neem 2,5%, Geraniol 1% y Lavandin oil 1%
Application Method	Diffusion through the collar.
Indications	Fleas, ticks, mosquitoes.
Efficacy duration:	3 months
Odor	Citric

2- FLEAS, TICKS AND MOSQUITOES

Fleas, ticks and mosquitoes are parasites that cause the transmission of many of the most frequent and common diseases in dogs and cats.

ARTHROPOD	INFESTATION / RELATED DISEASE	MAIN PATHOGENIC AGENTS TRANSMITTED (CORRESPONDING DISEASES)
Fleas	Flea infestation / flea allergy dermatitis (FAD)	Dipylidium caninum (dipylidiosis) Bartonella hensalae (bartonellosis)
Ticks (Rhipicephalus sanguineus, Ixodes spp, Dermacentor spp, Hyalomma spp, Haemaphysalis spp and others)	Tick infestation: Anaplasmosis. Babesiosis. ... Ehrlichiosis. ... Lyme's disease. ...	Babesia canis, babesia Gibson, babesia [Theileria] anae (piroplasmosis, babesiosis) Hepatozoon spp (hepatozoonosis) Ehrlichia canis, E. spp, Anaplasma phagocytophilum, Anaplasma platys (ehrlichiosis, anaplasmosis) Rickettsia spp (rickettsiosis) Borrelia burgdorferi s.l (enfermedad de Lyme=borreliosis) Flavivirus (ej: encefalitis transmitida por garrapatas, mal de Louping) Acanthocheilonema [Dipetalonema] dracunculoides
Mosquitoes	Leishmaniosis, filariosis	Leishmania infantum (leishmaniasis) Dirofilaria immitis, gusano del corazón (filariosis)

3- COMPOSITION

ANTI-INSECT COLLARS FOR DOGS and CATS contain a unique combination of 3 substances; 2.5% active Margose/Neem, 1% Geraniol and 1% Lavandin Oil and are designed as an antiparasitic supplement for these pets, with the aim of providing repellent protection against fleas, ticks and mosquitoes, thus preventing these parasites from causing them serious damage to health through its bites and the diseases they transmit.

These collars are the result of a research project carried out for 21 months, with the aim of achieving a more effective collar based on a perfect combination and the synergy of 3 repellent assets, minimizing the risk of allergies and sensitizations in pets when used continuously.

MARGOSE (Neem Extract):

More than half a century ago, US researchers raised the benefits that the Neem Tree could provide, and since then it has been used in commercial preparations as an insect repellent, both for humans and animals. The extract contains compounds that mimic the hormones of insects, interfering with their life cycle and causing a rapid death of them, in addition to breaking the life cycle of insects, preventing them from multiplying. For this reason, apart from having repellent properties, Margosa is also characterized by having insecticidal properties, since it acts on the growth of insects, preventing them from developing, thus causing their death.

Margose(Neem) also has a prominent role from a cosmetic point of view due to its ability to hydrate and condition the animal's skin, which can be resented by the action of external elements. Quickly relieves dryness of the skin since it is absorbed in the most superficial layers of it, restoring the water balance.

GERANIOL

Geraniol is a monoterpene, the main component of most essential oils in roses, and it is also present in other types of flowers, plants and fruits such as geraniums, lemons, oranges, etc. It is a basic element of all kinds of perfumes and cosmetics.

It is a powerful repellent and insecticide of natural origin, biodegradable that due to its diffusion capacity, its aroma is gradually released and distributed throughout the body of the animal, preventing fleas, ticks and mosquitoes from approaching it. In addition, it is incorporated into many products for its antiparasitic capacity, since it is capable of affecting the parasite's cuticle, causing dehydration and therefore suffocation. It is not dangerous for animals or people. Only those animals allergic to perfumes can manifest small hypersensitivity reactions that can be easily corrected with the suspension of the treatment.

LAVENDER ESSENTIAL OIL (LAVANDULA HYBRIDA OIL)

It is obtained from the Lavandula Hybrida plant. It is an essential oil of natural origin with great antiparasitic potency that acts in a similar way to how geraniol works, through a gradual continuous release that creates a protective barrier around the animal that prevents and repels insects..

4- ANTI-INSECT COLLAR MODE OF ACTION

The active ingredients (MARGOSE/NEEM, GERANIOL and LAVANDIN OIL), are protected inside the polymer matrix of the ANTI INSECT COLLAR until the product is put on. Once the collar is placed on the animal, being in contact with the skin of the animal, the appropriate dose of these active ingredients begins to be released, which are diffused through the fat layer of the skin and hair thanks to the oil of almonds it contains, protecting it against fleas, ticks and mosquitoes.

5- HOW TO USE

ANTI-INSECT COLLAR FOR DOGS: Remove the collar from its packaging. To unroll the collar, pull the tab down as shown in the diagram. Attach the collar to the animal's neck. Cut off the excess part. Replace the necklace after 3 months of use.

ANTI-INSECT NECKLACE FOR CATS: Remove the collar from its packaging. To unroll the collar, pull the tab down as shown in the diagram. Attach the collar to the animal's neck. Cut off the excess part. Replace the necklace after 3 months of use.

Collar use outline



6- EFFICACY TESTS:

ANTI-INSECT COLLAR FOR DOGS.

6.1- In Vivo efficacy tests: Description of the evaluation method

i) Antiparasitic efficacy against fleas

To test the efficacy of the product, healthy volunteer dogs divided into a single category, that is, animals with the absence of visible fleas, were used. The prevalence of fleas in Spain is taken into account, which is high compared to other European countries in conditions of humidity and high temperature. In response to this, the study is carried out between the months of June-August 2017 in selected dogs from 3 months to 10 years of age and that live in humid areas of northern Spain, which are the most prone to possible infestation with this type of parasites.

20 dogs were selected, apparently without visible fleas: 4 Foxterrier, 4 German Shepherd, 3 Basset Hound, 3 French Cocker, 3 Newfoundland, 2 Dachshund and 1 Greyhound.

Instructions are given so that, during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process.

The presence or absence of fleas in the animal is assessed monthly.

ii) Antiparasitic efficacy against ticks

To test the efficacy of the product, healthy volunteer dogs between 3 months and 10 years old were used. The study is carried out between the months of June-August 2017 in selected dogs from the dry continental zone.

The test is carried out with 35 dogs without ticks present on their head, ears and neck: 6 crossbreeds, 5 German Shepherds, 4 Foxterrier, 4 Greyhounds, 3 French Cocker, 3 Basset Hound, 3 Newfoundland, 2 dachshund, 2 Golden Retriever, 1 Beagle 1 Pitbull terrier and 1 Husky.

Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment, with the only precaution to remove it during the washing process.

The presence or absence of ticks on the animal's head is assessed monthly.

6.1.1- Results.

Dogs that have been wearing the anti-insect collar for 3 months remain protected against flea and tick bites during this time. In the case of efficacy against ticks, we have observed that 1 dog out of the 25 studied, presented ticks fixed in the ear area. After analyzing this specific case, although the owners were warned to remove the collar during the washing process, the owner of this dog confessed that he had bathed the dog with a shampoo without removing the collar, so that the collar slightly lost its properties.

In this case, after removing the ticks from the animal, it was followed-up, and it was found that when changing the collar at 3 months and following the marked method of use, it did not show ticks again within the period of durability of this collar.

6.2- In Vitro Efficacy Tests: Description of the evaluation method.

i) Antiparasitic efficacy against mosquitoes.

10 mosquitoes of Culex genus are used for the test, which were stored in a glass bottle at room temperature of 25°C.

Mosquitoes were introduced one by one into the Y-shaped olfactometer. One arm contained a filter paper with the collar sample under study, the other arm contained nothing and served as a control.

The behavior of mosquitoes is observed upon reaching the decision area of the olfactometer. They have two possibilities of advancement, the path that leads to the area with the collar or the path of the control sample. Mosquitoes that stay on the road in the decision area are considered not to be repelled. The test is repeated weekly for the three months the study lasts.

6.2.1- Results.

The efficacy study carried out under in-vitro conditions, the repellent effect of the product against mosquitoes is very optimal during the 12 weeks of the study. During the first two months, weekly it was found that the number of mosquitoes repelled was greater than 95%, and during the third and last month that percentage decreased somewhat but always remained above 90%

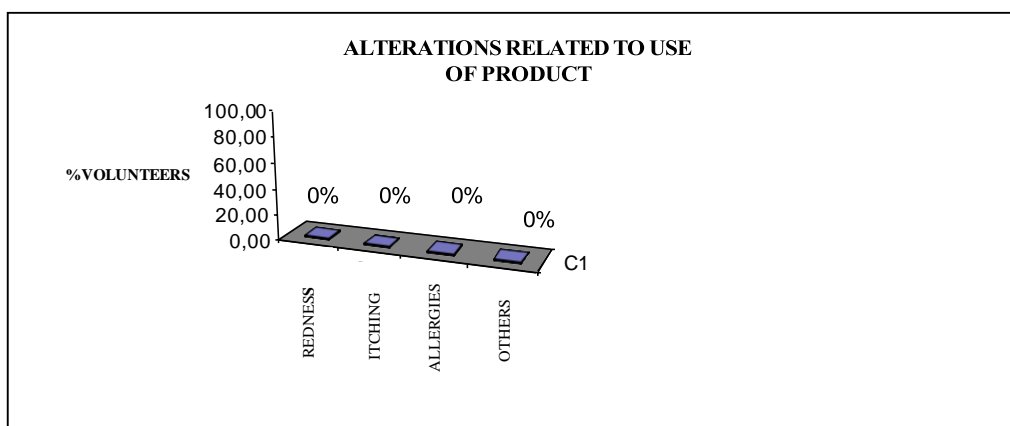
6.3- Subjective evaluation. Questionnaire after using the product.

The owners of the dogs that completed the study completed a questionnaire answering questions regarding the subjective efficacy of the product, general impressions, organoleptic

characteristics (color, smell, appearance ...) as well as the tolerance of the product and its possible future use.

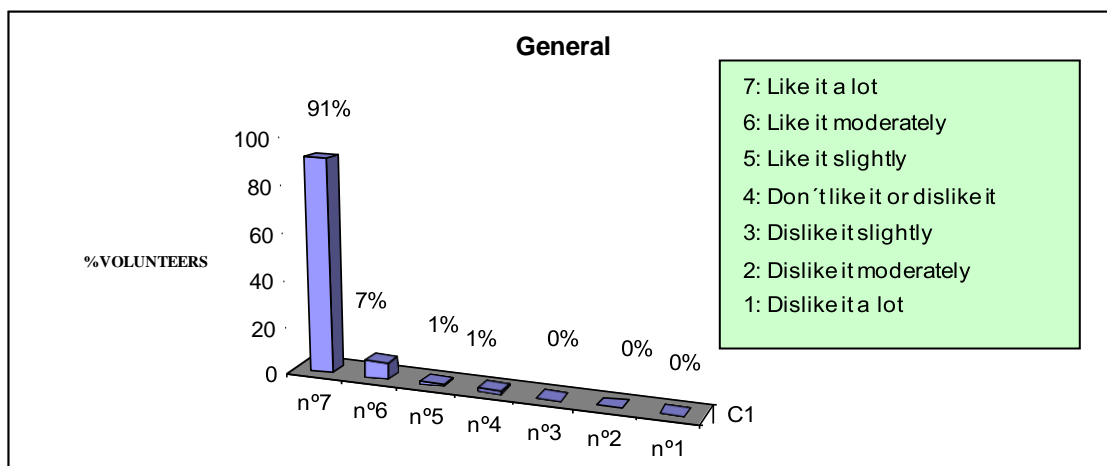
- **Tolerance evaluation. Alterations associated with the use of the product.**

After using the product, the owners who completed the study pointed out those alterations related to the product, if any. As can be seen in the graph, in none of the dogs that finished the study were alterations associated with the product observed



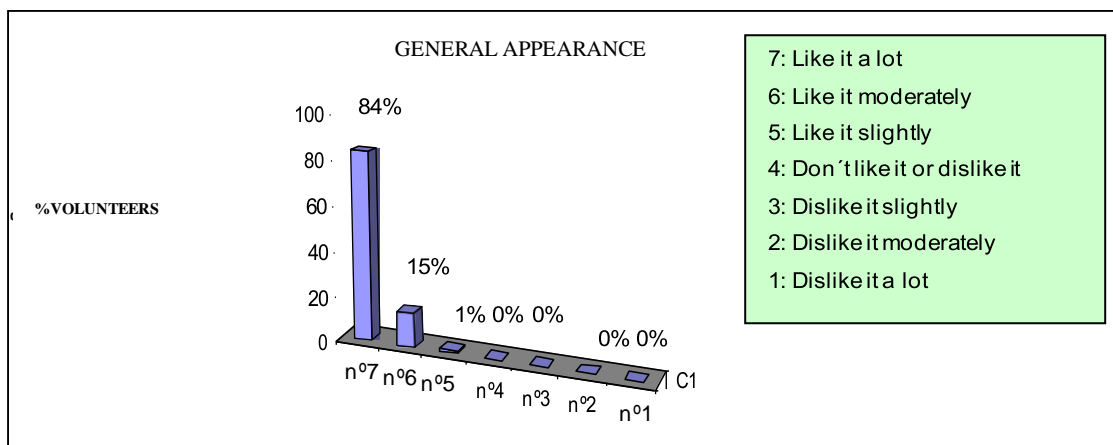
- **General opinion related to the product.**

Regarding the general opinion about the product, which includes the question if it helps prevent infestation, 91% of dog owners liked it a lot, 7% liked it moderately, 1% liked it slightly and 1% neither liked nor disliked.



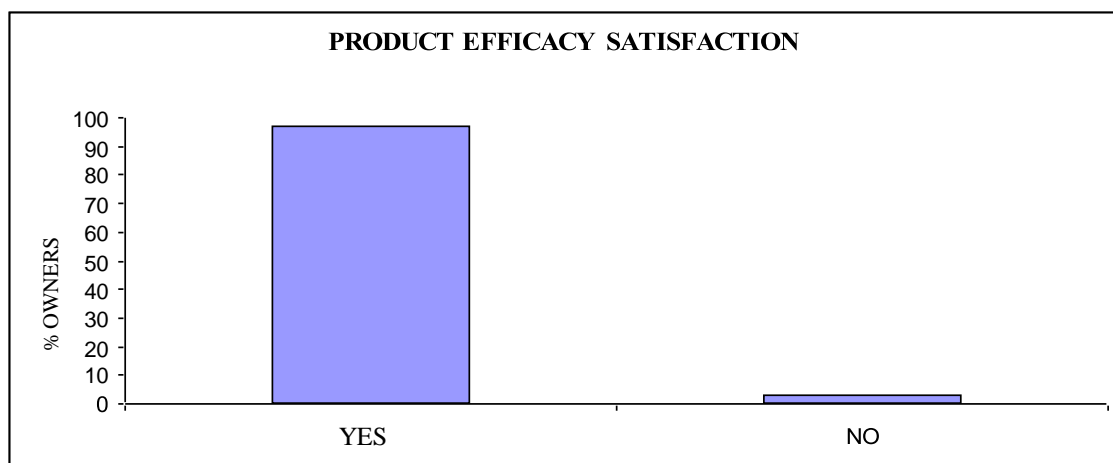
- **General product appearance.**

This section includes: smell, color, texture, ease of use, attractiveness of the package and its ease of use. 84% of dog owners liked it very much, 15% liked it moderately and 1% liked it slightly.



▪ **Product effectivity**

In this section, the owners are asked if they are satisfied with the result of repellency of the collars on fleas, ticks, mites and mosquitoes.

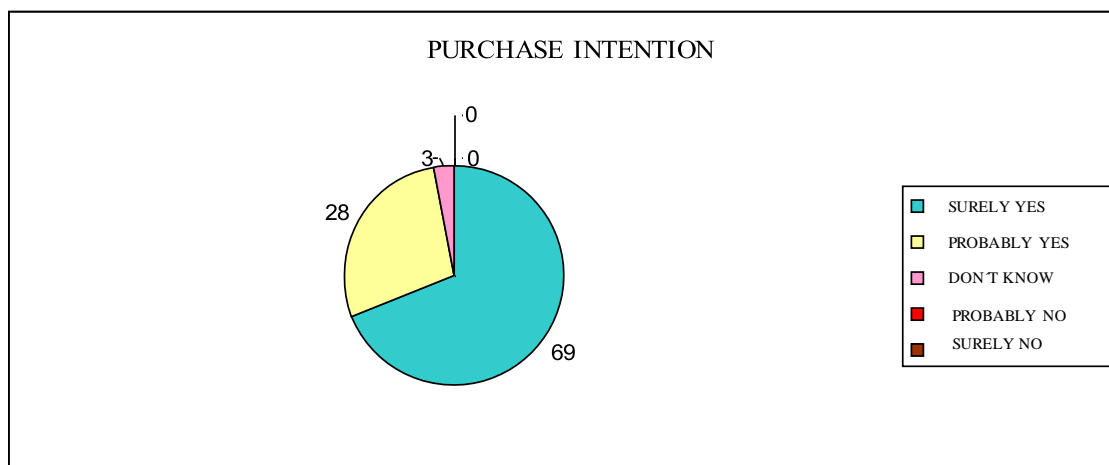


6.4- Conclusions

Evaluating the global results of the in vivo and in vitro efficacy tests, as well as the subjective tests carried out on the owners of the animals, it can be concluded that the product ANTI-INSECTS COLLAR FOR DOGS with 3 active ingredients; Margosa, geraniol and lavandin, presents an excellent repellent efficacy ratio for protection against fleas, ticks and mosquitoes following the recommended treatment guidelines

In addition, the owners have been very satisfied with the quality of the product and the protection it provides.

Regarding the intention to buy the product after the test, this was the final result:



ANTI-INSECT COLLAR FOR CATS.

6.5- In Vivo efficacy tests: Description of the evaluation method.

i) Antiparasitic efficacy against fleas

To test the efficacy of the product, healthy volunteer cats were used. The prevalence of fleas in Spain is taken into account, which is higher in conditions of humidity and high temperature. Based on this, the study is carried out between the months of June-August 2017 in selected cats from 1 to 8 years of age, from humid and warm areas that have access to the outside of landscaped areas or that may have frequent contacts with other animals likely to be infested (dogs).

Twenty cats were selected, apparently without visible fleas: 13 crossbreeds, 4 Siamese twins, 2 Persians, and 1 Angora.

Instructions are given so that, during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process (in case cats bathe).

The presence or absence of fleas in the animal in the area of the head and neck is assessed monthly.

ii) Antiparasitic efficacy against ticks

To test the efficacy of the product, healthy voluntary cats between 1 and 8 years of age were used. The study is carried out between the months of June-August 2017 in selected cats from the dry continental zone.

The test is carried out with 35 cats of the following breeds without ticks present on their head, ears and neck: 20 crossbreeds, 6 Siamese, 5 Persians, 2 Exotics, 1 Angora and 1 Maine Coon. Mention that all of these cats had access to the outside of their habitat.

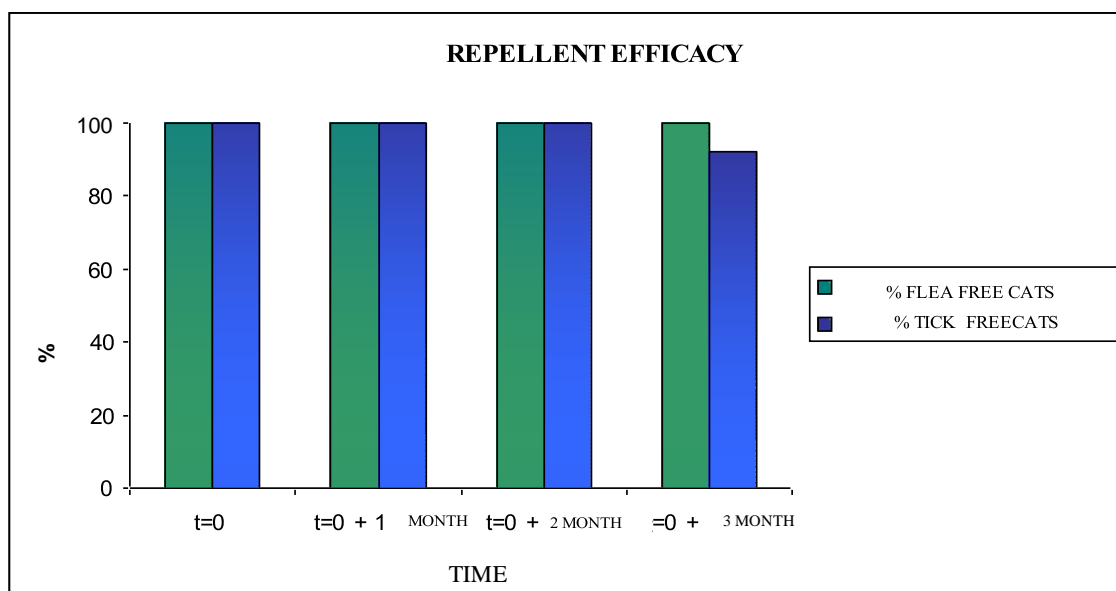
Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process (in case cats bathe).

The presence or absence of ticks in the animal is assessed monthly.

6.5.1- Results.

Cats that have been wearing the insect collar for 3 months remain protected from flea and tick bites during this time. In the case of efficacy against ticks (effective in 92% of treated cats), we have observed that certain cats that lived in rural areas, after three months of using the collar, 2 of the 25 cats studied, it had ticks attached to the ears.

In these two cases, cats with ticks, after removing them, had another collar placed for the next 3 months. At the end of this time, they were reviewed again and it was observed that by then they no longer had visible ticks.



6.6- In Vitro Efficacy Tests: Description of the evaluation method.

i) Antiparasitic efficacy against mosquitoes.

10 mosquitoes of the genus *Culex* are used for the test, which were stored in a glass bottle at room temperature of 25°C.

Mosquitoes were introduced one by one into the Y-shaped olfactometer. One arm contained a filter paper with the collar sample under study, the other arm contained nothing and served as a control.

The behavior of mosquitoes is observed upon reaching the decision area of the olfactometer. They have two possibilities of advancement, the path that leads to the area with the collar or the path of the control sample. Mosquitoes that stay on the road in the decision area are considered not to be repelled. The test is repeated weekly for the three months the study lasts.

6.6.1- Results.

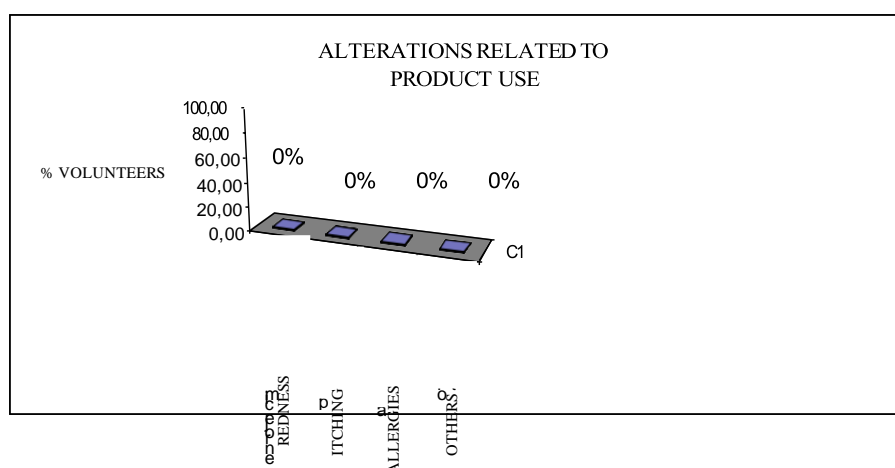
In the efficacy study carried out under in-vitro conditions, the repellent effect of the product against mosquitoes is optimal during the 12 weeks of the study. During the first two months, weekly it was found that the number of mosquitoes repelled was greater than 95%, and during the third and last month that percentage decreased somewhat but always remained above 90%

6.7- Subjective evaluation. Questionnaire after using the product.

The owners of the cats who completed the study filled out a questionnaire answering questions regarding the subjective efficacy of the product, general impressions, organoleptic characteristics (color, smell, appearance ...), as well as the tolerance of the product and its possible future use.

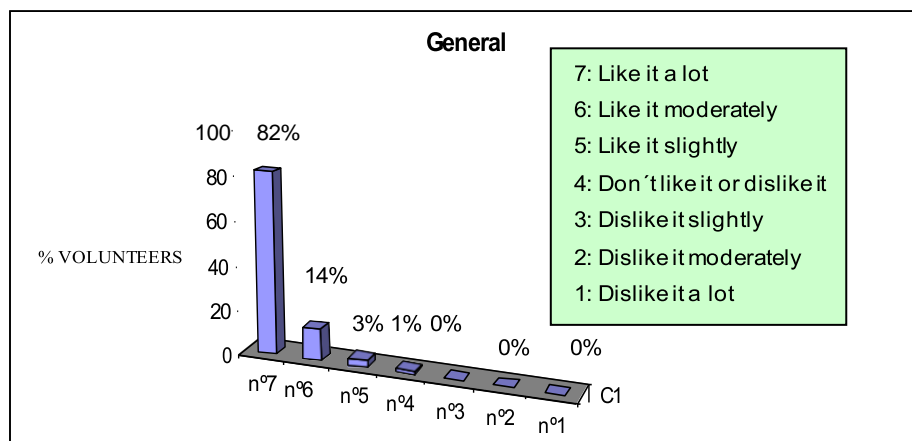
- **Tolerance evaluation. Alterations associated with the use of the product.**

After the use of the product in the cats that finished the study, they were given the option of pointing out those alterations related to the collar, if any. As can be seen in the graph, none of the owners who completed the study indicated alterations associated with the product.



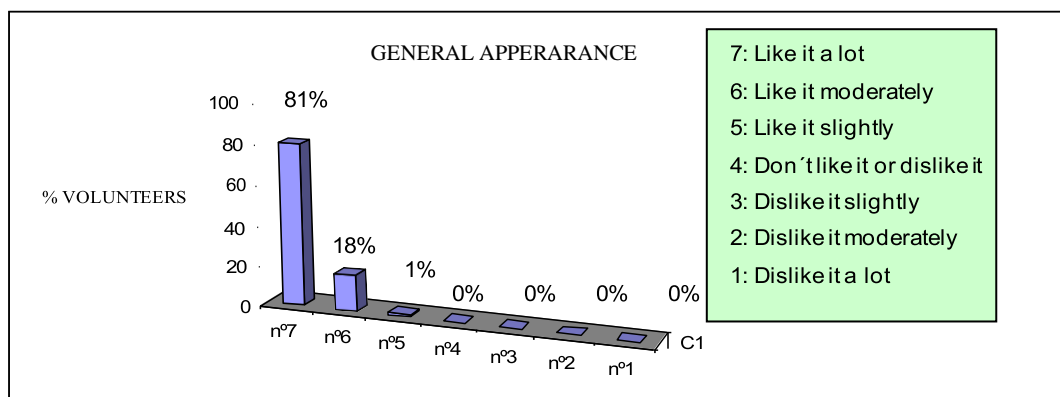
- **General opinion of the product.**

Regarding the general opinion on the product, which includes the question whether it helps prevent infestation, 82% of cat owners liked it a lot, 14% liked it moderately, 3% liked it slightly and the 1% neither liked nor disliked it.



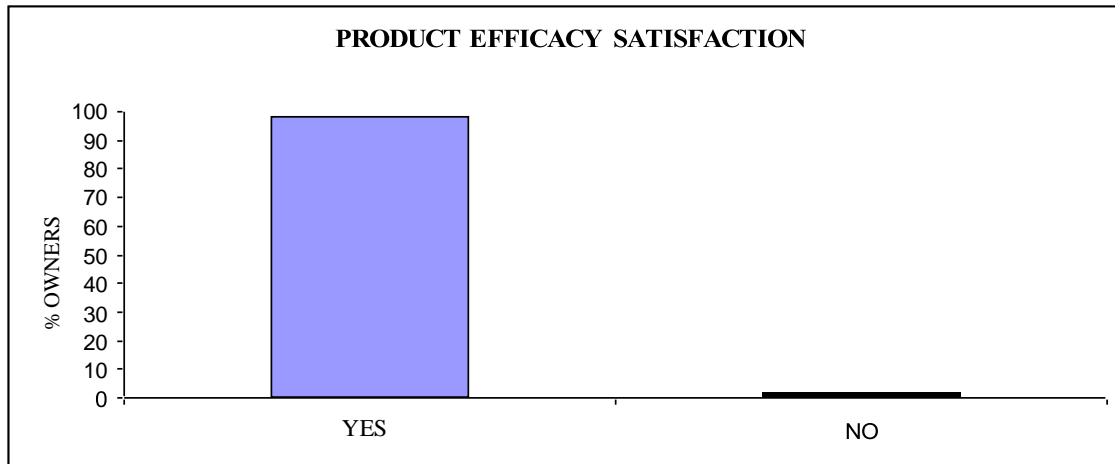
- **General appearance of the product.**

This section includes; smell, color, texture, ease of use and attractiveness of the package and its comfort. 81% of owners liked it very much, 18% liked it moderately and 1% liked it slightly.



- **Product effectiveness**

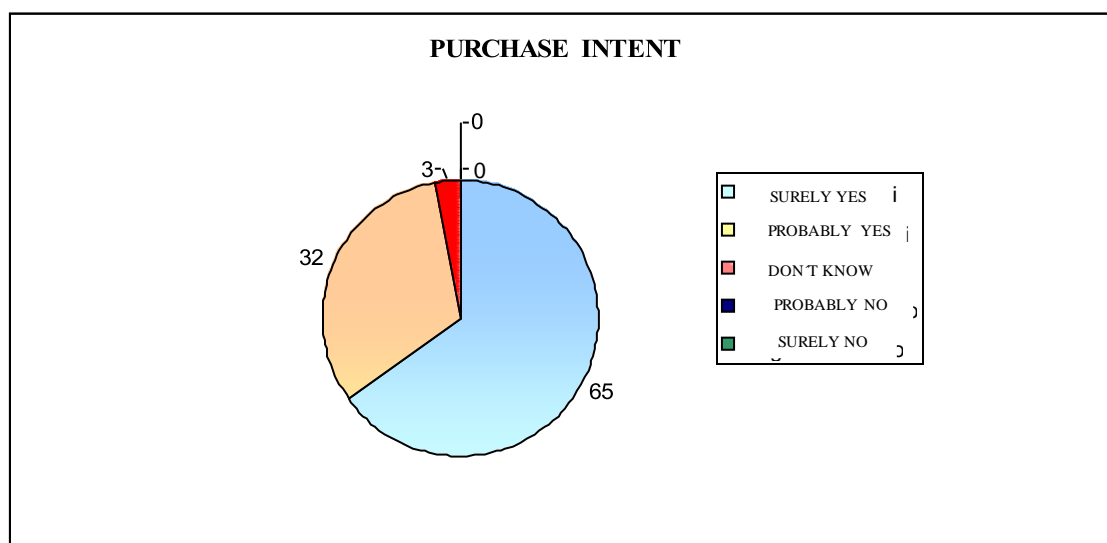
In this section, the owners are asked if they are satisfied with the result of repellency of the collars on fleas, ticks, mites and mosquitoes.



6.8- Conclusions

Evaluating the global results of the efficacy field tests and the subjective tests carried out on the owners of the animals, it can be concluded that the product ANTI-INSECT COLLAR FOR CATS with 3 active ingredients; Margose/Neem, Geraniol and Lavandin, presents an excellent repellent efficacy ratio against fleas, ticks and mosquitoes following the recommended treatment guidelines. In addition, the owners have been very satisfied with the quality of the product and the protection it presents.

Regarding the intention to buy the product, this was the final result.:



7. COMPARATIVE CLINICAL STUDY BETWEEN COLLAR OF MARGOSE/NEEM 2.5%, GERANIOL 1% AND LAVANDINO 1% AND COLLAR OF MARGOSE/NEEM 2.5%

The present study aims to compare the repellent activity against fleas, ticks and mosquitoes, between the collar containing 2.5% margosa/neem and the new 3-active potentiated formula containing 2.5% margosa, 1% Geraniol and 1% Lavandin.

ANTI-INSECT COLLAR FOR DOGS

7.1- In Vivo efficacy tests: Description of the evaluation method

i) Antiparasitic efficacy against fleas

To test the efficacy of the product, healthy volunteer dogs divided into a single category were used, that is, animals with no visible fleas of the genus *Ctenocephalides canis/felis*. The prevalence of fleas in Spain is taken into account, which is high in conditions of humidity and high temperature. In response to this, the study is carried out between the months of June- August 2016 in selected dogs from 3 months to 10 years of age and that live in humid areas of northern Spain, which are the most prone to possible infestation with this type of parasites.

10 dogs were selected, apparently without visible fleas: 3 Foxterrier, 3 German Shepherd, 2 French Cocker, 1 Newfoundland and 1 Greyhound.

Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process.

The presence or absence of fleas in the animal is assessed monthly.

ii) Antiparasitic efficacy against ticks

To test the efficacy of the product, healthy volunteer dogs between 3 months and 10 years old were used. The study is carried out between the months of June-August 2016 in selected dogs from the dry continental zone of Spain.

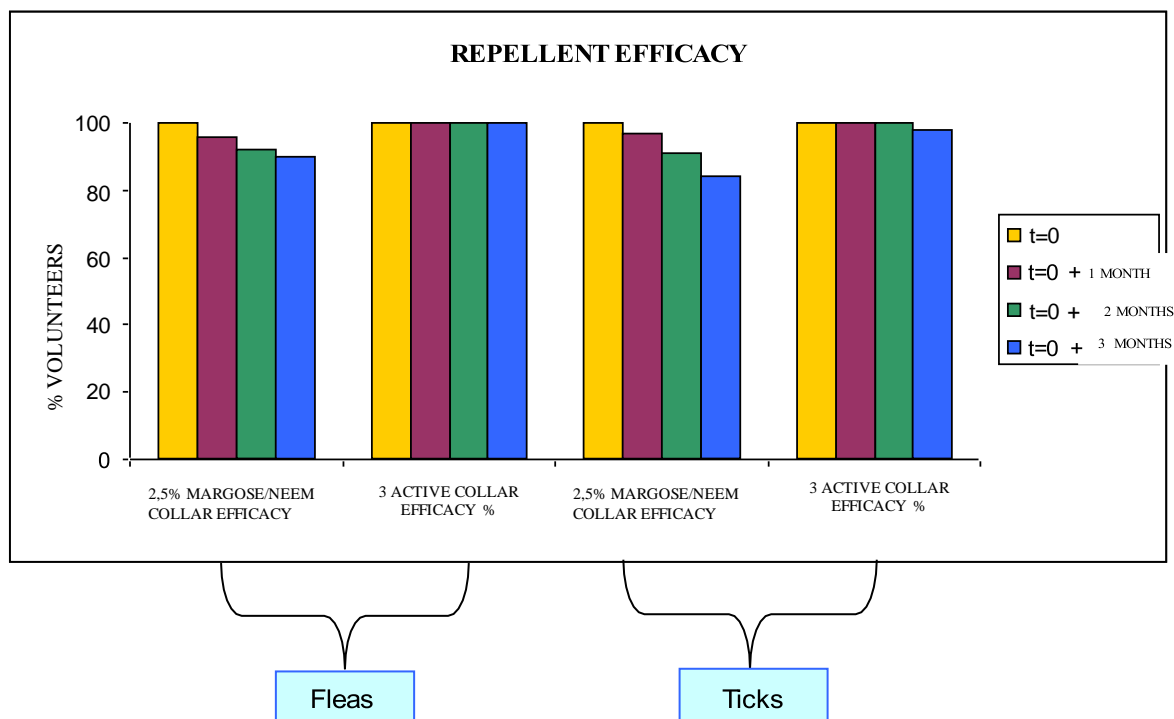
The test is performed with 10 dogs of the following breeds without ticks present on their head, ears and neck: 3 Foxterrier, 3 German Shepherd, 2 French Cocker, 1 Newfoundland and 1 Greyhound.

Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process.

The presence or absence of fleas in the animal is assessed monthly.

7.1.1- Results.

In the following graph, we can see the comparative effectiveness of the collar against fleas and ticks on the collar with 2.5% margosa, along with 2.5% margosa, 1% geraniol and 1% Lavandin.



The repellent efficacy against fleas and ticks, as we can see in the 3 active collar, remains stable throughout its 3-month shelf life, when in the 2.5% Margosa collar, although the efficacy is also good, over time it tends to decrease, detecting some presence of fleas and ticks in 18% of volunteer dogs over time.

7.2- In Vitro Efficacy Tests: Description of the evaluation method.

i) Antiparasitic efficacy against mosquitoes

10 mosquitoes of Culex genus are used for the test, which were stored in a glass bottle at room temperature of 25°C.

Mosquitoes were introduced one by one into the Y-shaped olfactometer. One arm contained a filter paper with the collar sample under study, the other arm contained nothing and served as a control.

The behavior of mosquitoes is observed upon reaching the decision area of the olfactometer. They have two possibilities of advancement, the path that leads to the area with the collar or the path of the control sample. Mosquitoes that stay on the road in the decision area are considered not to be repelled. The test is repeated weekly for the three months the study lasts.

7.2.1- Results.

In the efficacy study carried out under in-vitro conditions, it is observed that although the repellent effect of both products against mosquitoes is optimal during the 12 weeks of the study, in the case of the 2.5% margosa collar the second month it is verified that the percentage of repelled mosquitoes falls to levels below 90% and the third month reaches repellency levels close to 70%. While in the case of the collar with the three assets, the percentage of mosquitoes repelled is greater than 90% during the entire duration of the study.

7.3- Conclusion

Evaluating the global results of the field tests of efficacy of both anti-insect collars, it can be concluded that the reinforced product ANTI-INSECT COLLAR FOR DOGS with 3 active ingredients, has a greater repellent capacity over time against fleas, ticks and mosquitoes. The necklace 2.5% margosa. In addition, it is reflected as the synergy of the 3 assets that the collar contains, does not represent any increase in risk for these pets, being a good anti-insect product.

Finally, it should be noted that the perfume that incorporates in its formula the 3 active collar, is hypoallergenic to minimize possible allergies and irritations that these animals may suffer.

ANTI-INSECT COLLAR FOR CATS

7.4- In Vitro Efficacy Tests: Description of the evaluation method

i) Antiparasitic efficacy against fleas.

To test the efficacy of the product, healthy volunteer cats were used. The prevalence of fleas in Spain is taken into account, which is higher in conditions of humidity and high temperature. In response to this, the study is carried out between the months of June-August 2016 in selected cats from 1 to 8 years of age in humid and warm areas that have access to the exterior of landscaped areas or that may have frequent contacts with other animals that may be infested (dogs).

10 cats were selected, apparently without visible fleas: 6 crossbreeds, 2 Siamese and 2 Persians.

Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process (in case cats bathe). The presence or absence of fleas in the animal is assessed monthly.

iii) Antiparasitic efficacy against ticks

To test the efficacy of the product, healthy voluntary cats between 1 and 8 years of age were used. The study is carried out between the months of June-August 2016 in selected cats from the dry continental zone.

10 cats were selected, apparently without ticks present on their head, ears and neck: 6 mongrels, 2 Siamese and 2 Persians.

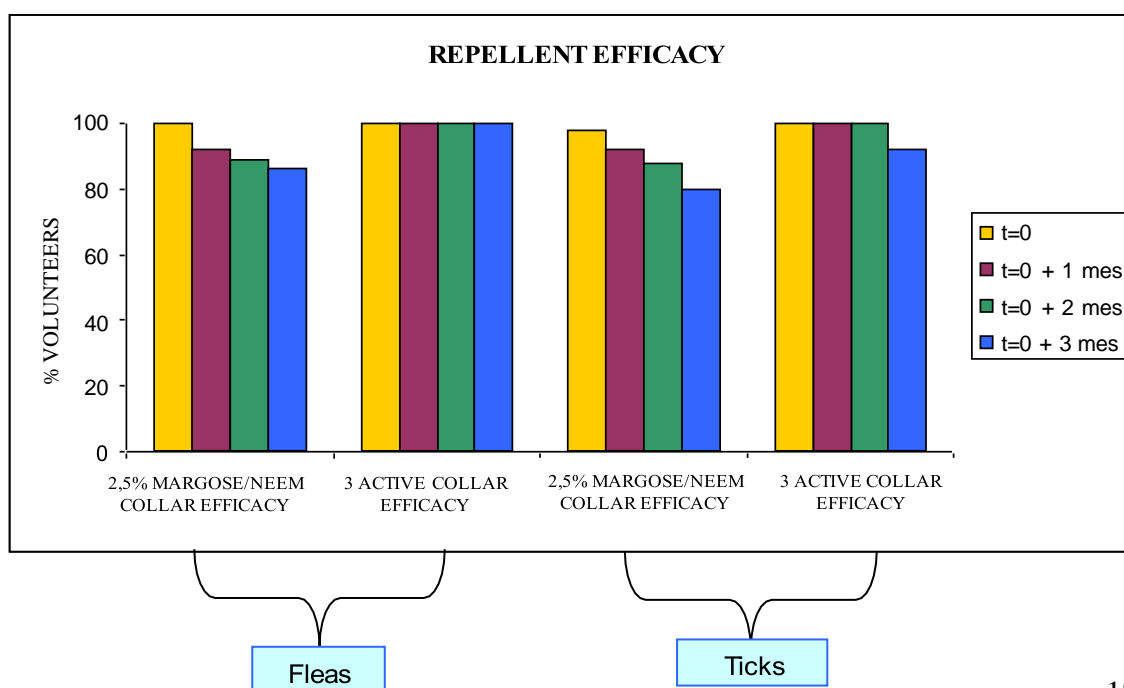
Instructions are given so that during the 3 months of summer, they put on the anti-insect collar to start the preventive treatment and to remove it during the washing process (in case cats bathe).

The presence or absence of fleas in the animal is assessed monthly

7.4.1- Results.

The repellent efficacy against fleas and ticks, as we can see in the collar with 3 active ingredients, remains stable throughout the 3-month lifespan of the test, when in the collar of 2.5% Margosa, although the efficacy is also good, with time it tends to decrease, detecting some presence of fleas and ticks in 20% of volunteer cats over time.

In the following graph, we can see the comparison of the repellent efficacy against fleas and ticks of the collar of 2.5% margosa together with that of the 3 active ingredients (2.5% margosa, 1% geraniol and 1% Lavandin).



7.5- In Vitro Efficacy Tests: Description of the evaluation method.

i) Antiparasitic efficacy against mosquitoes.

10 mosquitoes of Culex genus are used for the test, which were stored in a glass bottle at room temperature of 25°C.

Mosquitoes were introduced one by one into the Y-shaped olfactometer. One arm contained a filter paper with the collar sample under study, the other arm contained nothing and served as a control.

The behavior of mosquitoes is observed upon reaching the decision area of the olfactometer. They have two possibilities of advancement, the path that leads to the area with the collar or the path of the control sample. Mosquitoes that stay on the road in the decision area are considered not to be repelled. The test is repeated weekly during the three months that the study lasts.

7.5.1- Results.

In the efficacy study carried out under in-vitro conditions, it is observed that although the repellent effect of both products against mosquitoes is optimal during the 12 weeks of the study, in the case of the 2.5% margosa collar the second month it is verified that the percentage of repelled mosquitoes falls to levels below 90% and the third month reaches repellency levels close to 70%. While in the case of the collar with the three assets, the percentage of mosquitoes repelled is greater than 90% during the entire duration of the study.

7.6- Conclusion

Evaluating the global results of the efficacy field tests of both collars, it can be concluded that the ANTI-INSECT NECKLACE FOR CATS with 3 assets, has a greater repellent capacity over time against fleas, ticks and mosquitoes than the collar at 2, 5% margosa. In addition, it is reflected as the synergy of the 3 assets that the collar contains, does not represent any increase in risk for these pets, being a good anti-insect product.

Finally, it should be noted that the perfume that incorporates in its formula the collar with the 3 assets, is hypoallergenic to minimize possible allergies and irritations that these animals may suffer.

8. GENERAL CONCLUSION

The studies carried out are internal studies of Bilper Laboratories that have been carried out thanks to the collaboration of both volunteers and their pets, as well as the University of the Basque Country, which have cooperated in their development.

After completing all the field tests carried out, it has been concluded that the collar with the 3 active ingredients (2.5% margosa, 1% geraniol and 1% lavandin) protects in a much more effective and more complete way from all infestations of fleas, ticks and mosquitoes, thanks to the synergy that exists between the 3 active substances.

Likewise, it has been shown through this study that the collar with 3 assets perfectly covers the need to protect pets from insect bites,

using for this 3 active substances of natural origin, meeting expectations and leaving all owners of the animals with which they have worked very satisfied, since apart from the protection it provides, it has not provided any type of alteration or effect secondary effect in them.

It is very important to emphasize the efficacy shown in field studies, that the collar with 3 active ingredients, protects the head and ears area very effectively. This area is frequently colonized by different ectoparasites and they are also the target of mosquito bites because the area of the ears and nose are not covered with hair.

The owners, who tested both collars with their pets, commented that they preferred and felt more secure when their pet was wearing the 3 active collar compared to the one that only contained Margosa.

For all these reasons, we can conclude that, thanks to the combination and synergy created by mixing these 3 active ingredients selected by Bilper Laboratories, the formula offers very good effectiveness, as both the repellent action and the spectrum are enhanced. of action of the same. In this way, it provides great protection to pets, taking care of bites and discomfort that fleas, ticks and mosquitoes can cause.