

VSL 110

CANINE SAFETY STUDY ON GLYCO-FLEX® III: PHYSIOLOGICAL, ALLERGENIC OR IMMUNOLOGIC EFFECTS IN DOGS RECEIVING ORAL GLYCO-FLEX® III FOR 8 WEEKS.

HYPOTHESIS

Feeding up to six times the initial and twelve times the maintenance recommended levels of Glyco-Flex® III over an eight week period will have no effect on any measurable parameters that would indicate changes in physiological, allergenic or immunological traits.

OBJECTIVE

To determine the physiological changes, allergenic and immunological response of dogs fed Glyco-Flex® III of which, Perna canaliculus (green-lipped mussel) is a major constituent combined with methylsulfonylmethane, N,N-dimethylglycine, glucosamine HCl, manganese, vitamin C, and a combination of antioxidants including grape seed extract, vitamin E, selenium, and glutathione.

ANIMALS

14 purebred beagles with a history of acceptance of the control diet were used. After a physical exam to make sure they were clinically normal, dogs were randomly divided into control (4) and test groups (10). One dog, Linus, was removed from the trial due to inguinal hernia and an abscess that required surgery, bringing the test group number down to nine animals.

PROCEDURE

This safety study ran for 56 days (8 weeks) on test diet and 7 days post-test diet. Dogs were given a physical exam and had basic tests done before starting the study. Test dogs were fed 1.5 Glyco-Flex® III tablets twice daily for a total of 3 tablets per day. Dogs were evaluated weekly up to one week post-treatment. Procedures and tests included physical exams, immunoglobulin and liver enzyme evaluations, intradermal skin test, complete blood count (CBC), buccal mucosal bleeding test, urinalysis, and complete chemistry panels, as well as recording the weekly consumption and weight of the beagles.

RESULTS

The 8-week feeding study with Glyco-Flex® III found no statistical differences in the physical exam or test parameters evaluated pre or post-trial. The overall condition of the individual dogs remained unchanged. The intradermal skin test indicated no reactivity to shellfish after the ingestion of Glyco-Flex® III. Buccal mucosal bleeding test was within the normal clotting times of two to four minutes. Urinalysis for the control and test groups were normal with no outstanding values. The blood chemistry panel results were found to be within normal ranges as prescribed by the Texas Veterinary Medical Diagnostic Laboratory (TVMDL) for all groups. The complete blood count (CBC) showed no outstanding difference between control and test dogs. There were no notable changes observed for the dietary consumption or any weight changes in the beagles.

CONCLUSION

Administration of up to six times the initial and twelve times the maintenance recommended levels of Glyco-Flex® III caused no measurable physiological, immunological or allergenic changes in the test animals as compared to the control dogs.

CLINICAL RELEVANCE

Glyco-Flex® III is recommended by veterinarians to support the structure of healthy cartilage tissue and of joint and connective tissue function. This safety study demonstrates that Glyco-Flex® III at six times the recommended initial level and twelve times the recommended maintenance level caused no physiological or biological changes in healthy dogs when administered over an eight week period.

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ABSTRACT

In this safety study, 14 healthy purebred beagles were randomly selected and divided between the test group (10) and the control group (4). The study was conducted for 56 days (8 weeks) on Glyco-Flex® III and 7 days post evaluation. Beagles were fed a standard diet at maintenance for the control, while the treatment groups received the standard diet plus six times the recommended initial level and twelve times the recommended maintenance level of Glyco-Flex® III at three tablets per day. There was no difference in the physical exam pre- and post-trial and the overall condition of the individual dogs was unchanged in the study. The intradermal skin test indicated no reactivity to shellfish after treatment. The results of the urinalysis, buccal mucosal bleeding test, liver enzyme and blood chemistry panel, immunoglobulin levels, and complete blood count were all within the normal ranges and were found to be consistent between groups. There were no notable changes observed in dietary consumption or weight of the dogs in any phase. Results from this study show that Glyco-Flex® III has no adverse physiological, immunological or allergenic effects in healthy beagles when administered six times the recommended initial level and twelve times the recommended maintenance levels for eight weeks.

FORMULA TESTED

Glyco-Flex® III

Tablets given per day for dogs under 30 lbs: 3

Active Ingredients Per Tablet:

Glucosamine Hydrochloride	1000 mg
Methylsulfonylmethane	1000 mg
Perna canaliculus	600 mg
Dimethylglycine Hydrochloride	100 mg
Vitamin E	50 IU
Calcium Ascorbate (vitamin C)	30 mg
Manganese (aminio acid chelate)	10 mg
Grape Seed Extract	5 mg
Glutathione	2 mg
Selenium	0.002 mg

Hill, W. "Canine Safety Study on Glyco-Flex® III: Physiological, allergenic, immunologic effects in dogs receiving oral Glyco-Flex® III for 8 weeks" completed 4-01-04. Conducted by Nutrition Service Associates at Merrick Nutrition Center Hereford, Texas. W. Hill, DVM: Veterinarian Consultant, Hill Veterinary Clinic, Dimmitt, TX.