



GLYCO FLEX[®]

SAFETY STUDY

No adverse physiological, allergenic or immunologic effects in dogs receiving up to six times the initial level and twelve times the maintenance level of Glyco FLEX[®] supplementation in an 8 week feeding study.

HYPOTHESIS

Feeding up to six times the initial and twelve times the maintenance recommended levels of Glyco FLEX[®] products 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 GF 300 containing *Perna canaliculus* (1,800 mg per day) (Phase 1) or GFT a combination of *Perna canaliculus*, methylsulfonylmethane, glucosamine HCl, manganese, vitamin C (Phase 2), or Glyco FLEX[®] 3 of which, *Perna canaliculus* is the major constituent combined with methylsulfonylmethane, N,N-dimethylglycine, glucosamine HCl, manganese, vitamin C, and a synergistic combination of antioxidants including grape seed extract, vitamin E, selenium, and glutathione (Phase 3).

ANIMALS

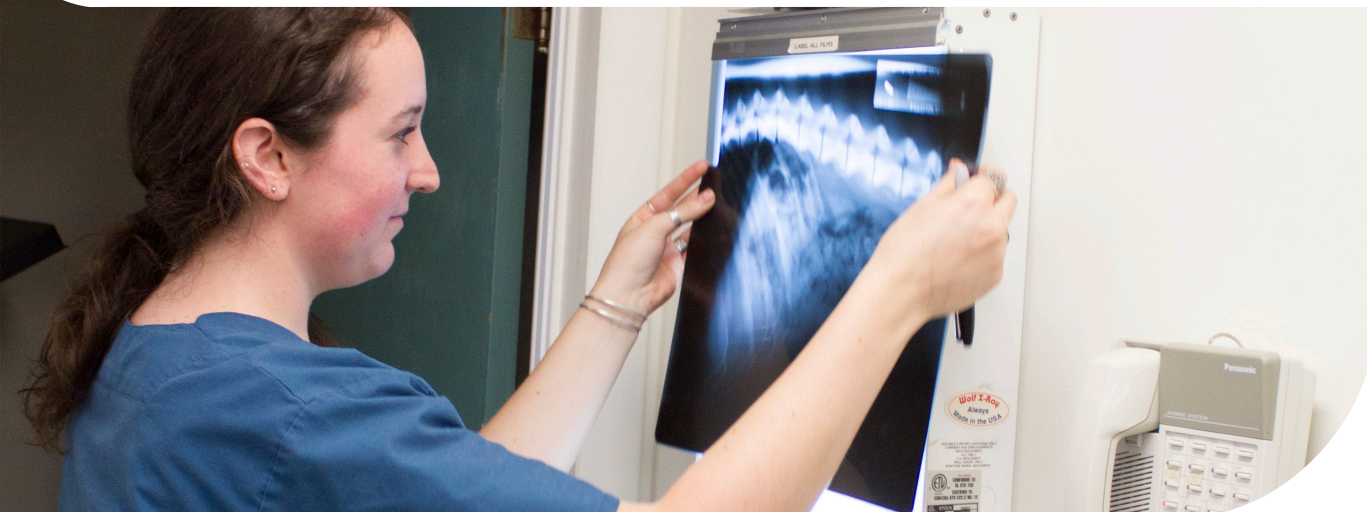
For the first two phases of the study, 17 purebred beagles with a history of acceptance of the control diet

were used. After a physical exam to make sure they were clinically normal, dogs were randomly divided into control (5) and test groups (12). For phase 3 of the study fourteen purebred beagles were randomly divided into control (4) and test groups (10). In phase 3 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 contains three phases. The first involved healthy beagles given GF 300 at twice the initial level and four times the maintenance level; and the second phase feeding three times the initial level and six times the maintenance level of GFT; and the third phase feeding Glyco FLEX[®] 3 at six times the initial level and twelve times the maintenance level. Each phase 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 experiment. Dogs were evaluated weekly up to one week post-treatment. Tests included physical exam, immunoglobulin levels,

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intra-dermal 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

Each of the 8-week feeding trials (Phase 1, 2, and 3) 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 intra-dermal skin test indicated no reactivity to shellfish after the ingestion of GF 300, GFT or Glyco FLEX® 3. Buccal mucosal bleeding test was within the normal clotting times of two to four minutes for all the phases. Urinalysis for the control and test groups in all phases 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 ant weight changes in the beagles in any phase.

CONCLUSION

Administration of up to six times the initial and twelve times the maintenance recommended levels of GF 300 (Phase 1), GFT (Phase 2) or Glyco FLEX® 3 (Phase 3) caused no measurable physiological, immunological or allergenic changes as compared to the control dogs (not given product) in each phase.

CLINICAL RELEVANCE

Glyco FLEX® products are recommended by veterinarians to support maintenance of the structure of healthy cartilage tissue and of joint and connective tissue function. However, very few studies have been done on their general safety in dogs. This three phase safety study demonstrates that GF 300 (Phase 1) containing *Perna canaliculus* at twice the initial and four times the maintenance level, GFT (Phase 2) the combination of *Perna canaliculus*, methylsulfonylmethane, glucosamine HCl, manganese, and vitamin C at three times the initial and six times the maintenance level, Glyco FLEX® 3 (Phase 3) at six times the initial level and twelve times the maintenance level caused no physiological or biological changes in healthy dogs when administered over an eight week period.

ABSTRACT

In each phase of this three phase safety study, purebred beagles were randomly selected and divided between the test group and the control group. Each phase of the study was conducted for 56 days (8 weeks) on each of the Glyco FLEX® products and 7 days post evaluation. Beagles were fed a standard diet at maintenance for the control, while the treatment groups received the standard diet and from two to six times the initial level and from four to twelve times the maintenance level of either GF 300 containing *Perna canaliculus* (Phase 1) or GFT containing the combination of *Perna canaliculus*, methylsulfonylmethane, glucosamine HCl, manganese, vitamin C (Phase 2) or Glyco FLEX® 3 (Phase 3) containing the ingredients tested in Phase 2 with the addition of N,N-dimethylglycine and various antioxidants including vitamin C, vitamin E, glutathione, selenium, and grape seed extract. There was no difference in the physical exam pre- and post-trial and the overall condition of the individual dogs was unchanged in each of the three phases of the study. The intra-dermal skin test indicated no reactivity to shellfish after treatment. The results of the urinalysis, buccal mucosal bleeding test, blood chemistry panel, immunoglobulin levels, and complete blood count were all within the normal ranges and were found to be consistent between groups in each phase. There were no notable changes observed in dietary consumption or weight of the dogs in any phase. Results from this study show GF 300 (Phase 1), GFT (Phase 2), and Glyco FLEX® 3 (Phase 3) have no adverse physiological, immunological or allergenic effects in healthy beagles when administered from two to six times the initial levels and from four to twelve times the maintenance levels for eight weeks.

Formulations Tested

	GF300**	GFT**	Glyco FLEX® 3***
Tablets given per day for 30 lbs dogs:	6	3	3

Active Ingredients Per Tablet (mg):

Methylsulfonylmethane	0	1000	1000
Perna canaliculus	300	600	600
Brewers Yeast	100	514	810
Alfalfa	100	0	0
Glucosamine Hydrochloride	0	500	1000
Manganese (amino acid chelate)	0	10	10
Calcium Ascorbate (Vitamin C)	0	30	30
Dimethylglycine	0	0	100
Grape Seed Extract	0	0	5
Glutathione	0	0	2
Selenium	0	0	0.002
Vitamin E	0	0	50 IU

*Administered at twice the initial and four times the maintenance recommended levels for 8 weeks.

**Administered at three times the initial and six times the maintenance recommended levels for 8 weeks.

***Administered at six times the initial and twelve times the maintenance recommended levels for 8 weeks.

Hill, W. "Physiological, allergenic, immunologic effects in dogs receiving oral Glyco FLEX® supplements for 8 weeks." Phase 1 completed 11-28-01; phase 2 completed 6-12-02; phase 3 completed 4-01-04. Conducted by Nutrition Service Associates at Merrick Nutrition Center. Hereford, Texas W.J. Hill, D.V.M. Veterinarian Consultant, Hill Veterinary Clinic, Dimmitt, TX.