



OTC PRODUCTS

Facts about Lead Content in Pet Supplements

You may be aware of misleading claims circulating on the Internet about the lead content of Pet-Tabs®. These inaccurate claims are substantially short of facts and intended to scare consumers. Virbac Corporation (Virbac), marketer of Pet-Tabs®, wants to assure our customers that Pet-Tabs® continue to be a safe and beneficial product for their pets.

The claims of increased lead don't hold up to scrutiny. Most of these web postings refer to the results from a testing facility, ConsumerLabs.com (CSL). Further, Dr. Robert Jay Russell is distributing this misleading information and using it on his website. The lead content in Pet-Tabs® (as reported by CSL in 2009) is more than 500 times below the chronic toxic dose for dogs as determined by the National Animal Poison Control Center. However, while CSL admits that safe lead limits for dogs are not defined by the Food and Drug Administration (FDA), CSL goes on to compare the lead levels in pet supplements to FDA and California warning label requirements for safe lead levels for humans. Virbac conducted its own study, highlighted below, that shows such a comparison has no scientific basis.

Virbac strongly refutes the information provided by CSL and Dr. Russell's assumptions about the danger of the lead content in Pet-Tabs®. Dr. Russell's assessment that Pet-Tabs taken as recommended would cause lead poisoning in dogs is inaccurate and is not based on facts or scientific findings.

Just the fact that the claim is being made is of great concern to us at Virbac Corporation. We are committed to the health and well being of your pets. We assure pet owners that consumption of Pet-Tabs® by your pets will not contribute to any significant levels of lead in the body. Pet-Tabs® are manufactured to the rigorous specifications of the industry's governing bodies, including the United States Pharmacopoeia (USP), and in accordance with legal requirements and good manufacturing practices.

Here are the facts:

History of Lead: It is difficult to completely eliminate the background level of lead in any product and particularly in products containing calcium. Lead is in the environment, in the air we breathe, in the food we eat and the water we drink. It has increased significantly from prehistoric times to the present because of human activity and has resulted in increased levels of lead exposure in even the remotest regions of the world.^{1,2}

Lead Testing in Pet Supplements: Testing a single lot of a single product, as done by CSL, can produce misleading results. Virbac hired an independent firm to conduct lead testing of commercially available multivitamin supplements for pets to determine the levels of lead present. For comparison purposes, a limited number of human vitamin supplements were also tested. A total of eight brands

were submitted for testing, including the brand CSL reported as LEAD FREE (in 2007 & 2009), the brand Dr. Russell states he personally uses, the human brand suggested by Dr. Russell's veterinarian, and Pet-Tabs®. A total of 49 lots were analyzed and ALL the lots tested were found to contain some amount of lead. It is noteworthy to report that even within each brand tested the amount of lead varied from lot to lot. These results show that it is highly unlikely to find any pet supplements that do not contain lead and testing a single lot of a single product can be very misleading.

Virbac would like to emphasize that:

- ◆ **ALL OF THE VITAMIN BRANDS TESTED ARE COMPLETELY SAFE FOR DOGS**, based on the expert evaluation of the independent lab.
- ◆ Even the single highest lot of the 49 tested for lead (which was not a Virbac product) **is still OVER 300 TIMES BELOW THE TOXIC CHRONIC DOSE** as reported by The National Animal Poison Control Center.
- ◆ Even if CSL's test results are taken as representative, a dog weighing 25 lbs would have to ingest 562 Pet-Tabs® per day for an undetermined period of time to reach the published chronic toxic dose of 145 µg/lb. The recommended dose of Pet-Tabs® for a 25 lb dog is 1 tablet per day.
- ◆ Pet-Tabs® have the National Animal Supplement Council Seal (NASC) and Virbac conforms to the requirements of the NASC and reporting of adverse events.
- ◆ Pet-Tabs® have been used and trusted by veterinarians and pet owners for **OVER 50 YEARS**.

Virbac's intention in conducting these tests was to demonstrate that some level of lead exists in most, if not all, supplements and is nearly impossible to completely eliminate. It is Virbac's belief that, as a market leader, Pet-Tabs® was singled out by a CSL and Dr. Russell. Virbac would like to further clarify that their assessments did not accurately reflect the results that were reported or the potential dangers of lead to dogs. Since the primary goal of our report is to clarify the facts surrounding lead in pet supplements and since our findings determined all products tested were safe, we have decided not to release the brand names of the competitive products tested.

Lead Poisoning in Dogs: The lowest known published chronic toxic dose of lead in dogs is 145 µg (µg = microgram, 1000 µg = 1 milligram)/lb of body weight.³ However, not all lead that is ingested is absorbed from the stomach and intestines. Various factors including high calcium and iron diets will significantly reduce lead absorption and subsequent accumulation of lead in the body. The recommended dose of Pet-Tabs® for a 25 lb dog is 1 tablet per day. The µg/lb exposure from ingesting a Pet-Tab® tablet containing 6.45 µg of lead, the lead concentration in the single lot of Pet-Tabs® reportedly tested by CSL, would be 0.258 µg/lb. Therefore, a dog weighing 25 lbs would have to ingest 562 Pet-Tabs® per day for an undetermined period of time to reach the published chronic toxic dose of 145 µg/lb. For dogs weighing over 25 lbs, the µg/lb exposure would be even lower than 0.258 µg/lb.

To determine what level of lead poses a hazard to human health, the FDA has established safe/tolerable exposure levels for age and sex groups, termed provisional total tolerable intake (PTTI) levels.⁴ These levels were established by evaluating the blood lead levels associated with toxic effects in humans based upon specific end points. There are no PTTI levels established for dogs, nor do the California warning label requirements cited by CSL apply to dogs.

Absorption, release, and excretion of lead in humans is influenced by several things including age, gender, health status, nutritional status, existing body burden of lead, and the duration of the exposure over a lifetime which are quite different in humans versus animals. Estimated risk in humans is often extrapolated from animal data by applying a safety factor of 1000 (accounting for uncertainties in extrapolating the animal data to humans) to the No Observed Effect Level (NOEL) in animals (NOEL/1000). The California action level for humans was derived in this manner. Applying the same level to dogs overestimates the risk of lead exposure in dogs and is not a scientific approach. Furthermore, in the case of animals, data often exists for doses that produce these toxic effects such as the published chronic toxic dose of lead discussed above.

Pet-Tabs is a registered trademark of Pfizer Inc.

References

1. Casteel SW, Cowart RP, Weis CP. Bioavailability of Lead to Juvenile Swine Dosed with Soil From the Smuggler Mountain NPL Site of Aspen, Colorado. *Fundam Appl Toxicol* 36, 177-187, 1997.
2. Ruby MV, Schoof R, Brattin W, Goldade M, Post G, Harnois M, Mosby DE, Casteel SW. Advances in evaluating the oral bioavailability of inorganics in soil for use in human health risk assessment. *Environmental Science and Technology*. 33:3697-3705, 1999.
3. Demayo A, Taylor MC, Taylor KW, Hodson V. Toxic effects of lead and lead compounds on human health, aquatic life, wildlife plants, and livestock. *CRC Crit Rev Environ Contr* 12:257–305, 1982.
4. Mindak WR, Cheng J, Canas BJ, Bolger PM. Lead in Women's and Children's Vitamins. *J Agric Food Chem* 56, 6892-6896, 2008.