

Final Report

Study Title	AKD-3088: 13 Week Oral (Gavage Administration) Toxicity Study in the Dog with a 4 Week Treatment-free Period
Data Requirement	EPA Health Effects Test Guidelines OPPTS 870.3150, August 1998 OECD 409 Guideline for Testing of Chemicals, August 1999 JMAFF Guidelines on the Compiling of Test Results on Toxicity, December 1998
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Covance Study Number	619/81
Covance Report Number	619/81-D6154
Report Issued	April 2002
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TEST SYSTEM

Species, strain and supplier

The actual number of purpose-bred beagle dogs were obtained from Marshall Farms USA, in order to provide 24 healthy animals of each sex.

Specification

The animals were 4 to 5 months old and in the weight range of 4.95 to 8.25 kg on arrival, this is slightly out of the range 4 to 8 kg specified in the protocol although this was considered not to affect the outcome or integrity of the study. They were between 5 to 6 months old at the start of dosing.

Environment

The animals were housed in exclusive rooms, air-conditioned to provide a minimum of 10 air changes/hour. Routinely, the temperature and relative humidity ranges were 16 to 22°C and 40 to 80% respectively. However on several occasions, the temperature and humidity were below and above the indicated ranges, the highest temperature recording was 24°C and the lowest was 15°C, the highest humidity recording was 82% and the lowest was 26%. The deviations were not considered to have affected the health and/or outcome of the study. Fluorescent lighting was controlled automatically to give a cycle of 12 hours light (0700 to 1900) and 12 hours dark.

Each animal was allocated to a pen with a floor area of 2.25 m². Routinely, animals of the same sex and group were housed in groups of two or three by removal of the barrier dividing the pens. Animals remained separated each day during the feeding period.

Environmental enrichment

A number of methods are used at Covance to enrich the environment and welfare of animals, such as the provision of "toys" (balls, inert nylon chews etc), raised platforms and exercise/socialisation periods. Exercise and socialisation are tailored around the daily study schedule to ensure the objectives and scientific integrity of the study are maintained whilst providing meaningful enrichment for the animals. Actual methods are defined in Standard Operating Procedures and details were recorded in the daily study log.