Danitol; CASRN 39515-41-8

Human health assessment information on a chemical substance is included in the IRIS database only after a comprehensive review of toxicity data, as outlined in the IRIS assessment development process. Sections I (Health Hazard Assessments for Noncarcinogenic Effects) and II (Carcinogenicity Assessment for Lifetime Exposure) present the conclusions that were reached during the assessment development process. Supporting information and explanations of the methods used to derive the values given in IRIS are provided in the guidance documents located on the IRIS website.

STATUS OF DATA FOR Danitol

File First On-Line 01/31/1987

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<th>Category (section)</th>
<th>Assessment Available?</th>
<th>Last Revised</th>
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I. Chronic Health Hazard Assessments for Noncarcinogenic Effects

I.A. Reference Dose for Chronic Oral Exposure (RfD)

Substance Name — Danitol  
CASRN — 39515-41-8  
Primary Synonym — Fenpropathrin  
Last Revised — 10/01/1994

The oral Reference Dose (RfD) is based on the assumption that thresholds exist for certain toxic effects such as cellular necrosis. It is expressed in units of mg/kg-day. In general, the RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Please refer to the Background Document for an
elaboration of these concepts. RfDs can also be derived for the noncancerous health effects of substances that are also carcinogens. Therefore, it is essential to refer to other sources of information concerning the carcinogenicity of this substance. If the U.S. EPA has evaluated this substance for potential human carcinogenicity, a summary of that evaluation will be contained in Section II of this file.

I.A.1. Oral RfD Summary

<table>
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<th>MF</th>
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<td>Tremors</td>
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<td>1-Year Dog Feeding Study</td>
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*Conversion Factors and Assumptions — 1 ppm = 0.025 mg/kg-day (assumed dog food consumption)

I.A.2. Principal and Supporting Studies (Oral RfD)


Groups of beagle dogs (4/sex/dose) were fed diets containing 0, 100, 250 or 750 ppm (0, 2.5, 6.25 or 18.75 mg/kg-day) danitol for 1 year. Animals were individually housed in cages and given free access to water and food. All animals were terminated after week 52 and a necropsy was performed both on these and on the one animal that died while the study was in progress.

Only one dog, a male from the 750 ppm dose group, did not survive the study. This animal was found dead during week 32 and it was reported that prior to death, this dog was languid, thin and exhibited clinical signs of ataxia, tremor, polypnea and excessive salivation. Numerous gross and histopathological findings were reported for this animal.

Incidences of ataxia (346/4 and 127/4 for males and females, respectively) and languid behavior (100/4 and 47/4 for males and females respectively) were observed at 750 ppm. Incidences of
tremor also were observed in the 250 ppm (160/4 and 97/4 for males and females, respectively) and 750 ppm (1086/4 and 771/4 for males and females, respectively) groups. These effects were judged to be treatment-related. Although the single episode of convulsion in one high-dose female was not described, it seems likely that the incident was also treatment-related. The single incidence of tremor in one low-dose female however, was not considered to be toxicologically significant. Treatment-related increases (compared with control) in alopecia in mid- and high-dose males were noted; however, it could not be determined from the data presented whether the cause of the alopecia involved a direct or indirect systemic effect of the test material, and/or whether it involved a local effect due to contamination of the dog's external body surface with treated food, or whether some other mechanism was operative.

No other significant effects were noted. Therefore based on tremors, the LEL for systemic toxicity is 250 ppm (6.25 mg/kg-day). The NOEL for systemic toxicity is 100 ppm (2.5 mg/kg-day).

**I.A.3. Uncertainty and Modifying Factors (Oral RfD)**

**UF** — The uncertainty factor of 100 reflects 10 for intraspecies-variability and 10 for interspecies extrapolation.

**MF** — None

**I.A.4. Additional Studies/Comments (Oral RfD)**

1) 1-Year Feeding - dog: Principal study -- see previous description; Core grade minimum (Sumitomo Chemical Co., Ltd., 1984).

2) 2-Year Feeding - rat: Core grade guideline (Sumitomo Chemical Co., Ltd., 1986)

Groups of CD rats (50/sex/group with an additional 15/sex/group for interim sacrifices) were administered technical danitol in the diet at dose levels of 0, 50, 150, 450 or 600 ppm (Male: 0, 1.93, 5.71, 17.06 and 22.8 mg/kg-day; Female: 0, 2.43, 7.23, 19.45 and 23.98 mg/kg-day) for 2 years. Danitol was dispersed in corn oil and formulated into the diet. Control animals were dosed with a volume of corn oil in the diet that was equivalent to the volume given to the dosed rats. Animals were group housed 5 to a cage with food and water available ad libitum.

Mortality during the first 26 weeks was greatest in females receiving 450 and 600 ppm (main study: 8/50 and 23/50; satellite: 3/15 and 8/15). All the surviving 600 ppm females were terminated at the 1-year mark. Mortality was also increased during the first 52 weeks in males
receiving 600 ppm (main study: 24/50; satellite: 2/15). During the remainder of the study, mortality was not dose-related.

The only dose-related clinical sign was body tremors, which were seen in the 600 ppm males (<6% affected between weeks 1 and 10), the 450 ppm females (<5% affected between weeks 1 and 14) and 600 ppm females (<65% affected between weeks 1 and 52). Body weight gain, food consumption, and water consumption were similar for all main groups. The food conversion ratio was increased for the 600 ppm females because of impaired efficiency, but was similar for all other groups. No compound-related ophthalmologic lesions or dose-related clinical pathology anomalies were observed.

Organ weight anomalies observed in the satellite groups included an increase in absolute and relative kidney weights in the 600 ppm males and an increase in absolute and relative adrenal weights in the females. In the main study, the 600 ppm males had nearly a doubling in the absolute and relative pituitary weights, and significant increases in absolute and relative kidney and adrenal weights; and the 600 ppm females had decreased absolute and relative ovary weights.

Based on increased mortality and body tremors, the LEL for systemic toxicity in females is 450 ppm (19.45 mg/kg-day). The NOEL for systemic toxicity in females is 150 ppm (7.23 mg/kg-day). Based on increased mortality, body tremors and increased pituitary, kidney, and adrenal weights, the LEL for systemic toxicity in males is 600 ppm (22.8 mg/kg-day). The NOEL for systemic toxicity in males is 450 ppm (17.06 mg/kg-day).

3) 3-Generation Reproduction - rat: Core grade minimum (Sumitomo Chemical America, Inc., 1986)

Groups of 28 male and 28 female SPF (CrL:COBS CD (SD) BR strain) rats were randomly assigned to four groups and served as the F0 generation. Animals were fed diets containing 0, 40, 120 or 360 ppm (Male: 0, 3, 8.9 or 26.9 mg/kg-day; Female: 0, 3.4 10.1, or 32 mg/kg-day) danitol over three generations.

One low-dose and 3 mid-dose males died during the study. One control, 3 low- dose, 2 mid-dose and 18 high-dose females died during the study. The deaths in the mid- and high-dose females could be attributed to the test material; death typically was preceded by body tremors. Clinical signs observed in the high-dose dams of all generations included body tremors with spasmodic muscle twitches and increased sensitivity. No clinical signs were reported for males (it is not clear whether the males were observed). Based on the effects observed at the mid- and high-dose, the LEL for systemic toxicity is 120 ppm (Male: 8.9 mg/kg-day; Female: 10.1 mg/kg-day). The NOEL for systemic toxicity is 40 ppm (Male: 3 mg/kg-day; Female: 3.4 mg/kg-day).
Litter data for F1a pups was similar for all dosed and control groups. The high-dose F1b pups had significantly (p<0.05) decreased mean weight on lactation days 8, 12 and 21. The high-dose F2a pups had increased loss (compared with controls) at lactation days 1, 4, 8, 12 and 21, but little overall effect was noted in the mean litter size on lactation day 21. The high-dose F2b pups had increased loss (compared with controls) at lactation days 4 and 21. No compound-related effects on the sex ratios was observed. At 120 ppm, body tremors were observed in three F2b pups, two of which subsequently died.

Based on decreased mean F1b pup weight and increased F2b loss, the LEL for reproductive toxicity is 360 ppm (Male: 26.9 mg/kg-day; Female: 32 mg/kg-day). The NOEL for reproductive toxicity is 120 ppm (Male: 8.9 mg/kg-day; Female: 10.1 mg/kg-day). Based on body tremors and increase mortality, the LEL for fetotoxicity is 120 ppm (Male: 8.9 mg/kg-day; Female: 10.1 mg/kg-day). The NOEL for fetotoxicity is 40 ppm (Male: 3 mg/kg-day; Female: 3.4 mg/kg-day).

4) Developmental toxicity - rat: Core grade guideline (Valent USA Corp., 1990)

Pregnant CDF(F-344)/CrlBR rats (30/dose) were dosed with danitol by gavage on gestation days 6-15 at dose levels of 0 (corn oil control), 0.4, 1.5, 2, 3, 6 or 10 mg/kg-day.

In the high-dose group, six dams died between gestation days 7 and 14, and one was sacrificed moribund on day 8 because of convulsions and prostration. Clinical signs observed in the majority of high-dose dams included ataxia, sensitivity to external stimuli, spastic jumping and tremors. These signs were most severe 2 hours after dosing, and during the first days of dosing, although sensitivity to external stimuli persisted throughout the dosing period. Prostration, convulsions, hunched posture and squinted eyes were each seen in one high-dose dam. Chromodacryorrhea and lacrimation, which occurred sporadically in all other groups, became dose-related in the high-dose group.

Although food consumption and body weight gain were decreased between days 6 and 8 in the mid- and high-dose groups, the effect was short lived and was probably due to neurotoxicity rather than metabolic or palatability factors. Therefore, based on the effects observed at the highest dose tested, the LEL for maternal toxicity is 10 mg/kg-day. The NOEL for maternal toxicity is 6 mg/kg-day.

None of the fetuses had any external variations or malformations. The incidences of soft tissue variations and malformations were few and not dose-related. Incomplete and assymetrical ossification variations were slightly more frequent in the dosed groups than in controls, but no dose-relationship was established. No skeletal malformations were observed. Therefore, the NOEL for developmental toxicity is equal to or greater than 10 mg/kg-day.
5) Developmental toxicity - rabbit: Core grade guideline (Sumitomo Chemical America, Inc., 1985a)

This study was performed in three parts, a pilot study to establish dose levels, a preliminary study and a developmental toxicity study.

In the pilot study, 4 groups of 2 nonpregnant female New Zealand White rabbits were given seven daily administrations of danitol by gastric intubation at dose levels of 0, 20, 30, 45 or 67.5 mg/kg-day. Dosing began on days 0, 3, 5 and 7, respectively. The rabbits were observed and weighed daily, then sacrificed after 7 days of treatment. Dose-related clinical signs included nasal or eye exudate, anorexia, grooming, flicking of the forepaws, tremors or shaky movement and unsteadiness. One rabbit each at the 30 and 67.5 mg/kg-day doses had yellow stained perianal fur, and a 45 mg/kg-day rabbit had an enlarged liver with subcapsular pale areas. Body weight gain was not significantly altered.

In the preliminary study, 5 groups of 6 nonpregnant female New Zealand White rabbits were given 13 daily administrations of danitol by oral gavage at dose levels of 0, 15, 22, 33 or 50 mg/kg-day. Dosing began on day 0. Dose-related clinical signs noted included grooming, anorexia, flicking of the forepaws, scratching and chewing of the cage, tremors and shaky movements, and unsteadiness. Neither body weight nor food consumption were significantly altered.

In the developmental toxicity study, 4 groups of nonpregnant female New Zealand White rabbits were mated with males of proven fertility. The groups initially consisted of 18, 17, 19 and 17 rabbits, respectively. They were given 13 daily administrations of danitol by oral gavage on gestation days 7 through 19 at dose levels of 0, 4, 12 and 36 mg/kg-day. Dose-related clinical signs included grooming, anorexia, flicking of the forepaws, flicking of the hind feet, shaky movements and trembling, stamping of hind feet and lethargy were observed in the mid- and high-dose groups. Neither body weight gain nor food consumption were significantly altered. There was one death and several dams were sacrificed moribund, but no deaths were attributed to treatment. No dose-related effects were noted on the incidence or types of malformations and anomalies observed.

Based on the effects observed in the mid- and high-dose groups, the NOEL and LEL for maternal toxicity are 4 and 12 mg/kg-day, respectively. The NOEL for developmental toxicity is equal to or greater than 36 mg/kg-day.

Other Data Reviewed:

6) 2-Year Feeding - mouse: Core grade guideline (Sumitomo Chemical America, Inc., 1985b)
Groups of CD-1 mice (52/sex/dose) were administered danitol in the diet at dose levels of 0, 40, 150 or 600 ppm (Male: 0, 3.9, 13.7 and 56 mg/kg-day; Female: 0, 4.2, 16.2, and 65.2 mg/kg-day) for 2 years. An additional 40 animals/sex/dose were used for interim sacrifices at 26, 52 and 78 weeks.

As expected, mortality was highest during the final quarter of the study, but the incidence was similar in all dosed and control groups. The only clinical sign reported was marginally increased hyperactivity in high-dose females prior to week 78. This event was considered to be of minor significance. No other indications of toxicity were observed at any dose tested. Therefore, the NOEL for systemic toxicity is equal to or greater than 600 ppm (Male: 56 mg/kg-day; Female: 65.2 mg/kg-day).

7) 2-Year Feeding - rat: Core grade supplementary (Sumitomo Chemical America, Inc., 1979a)

Groups of COBS rats were administered danitol in the diet at dose levels of 0, 1, 5, 25, 125 or 500 ppm (0, 0.05, 0.25, 1.25, 6.25 and 25 mg/kg-day) for 2 years. The control group consisted of 72 males and 72 females. Each group receiving the test material consisted of 36 males and 36 females. Interim sacrifices of 6/sex/dose were scheduled at 6 and 12 months.

Sporadic decreases in body weight, which were not always statistically significant, were reported in high-dose females. Occasionally the mid-dose group (125 ppm) was also decreased. Final body weight of high-dose females was 91% of controls and the mid-dose group was 92%.

The gross pathological examination revealed that the lungs of high-dose females had a higher rate of "subplural white foci/plaques" (42% affected) when compared with controls (only 16% affected). The other groups had 17% or less affected. Males displayed higher incidences of "medial muscle hypertrophy" in the test groups than in the controls. Females were not affected. Starting at the 5 ppm dose level (in males) there were 3 to 4 times as many incidences of this lesion (5/70, 3/33, 9/32, 7/35, 6/34 and 10/34 for control, 1, 5, 25, 125 and 500 ppm dose groups, respectively). The Sumitomo Chemical America, Inc. pathology staff believed the medial muscle hypertrophy in the lung to be artifactual or a misdiagnosis and stressed that it was not found in a repeat study (Sumitomo Chemical Co., Ltd., 1986). The U.S. EPA pathologist stated that while this interpretation could not be confirmed without seeing the actual slides, there was no reason for concern since the lesion was not found in the repeat study.

Since the medial muscle hypertrophy is not considered a compound-related effect, the LEL for systemic toxicity is 500 ppm (25 mg/kg-day) based on a slight weight loss in females. The NOEL for systemic toxicity is 125 ppm (6.25 mg/kg-day).
8) 3-Generation Reproduction - rat: Core grade minimum (Sumitomo Chemical America, Inc., 1979b)

Groups of COBS rats (30/sex/dose) were administered danitol in the diet at dose levels of 0, 5, 25, or 250 ppm (0, 0.25, 1.25, 12.5 mg/kg-day) over three generations. The original parental generation produced F1a and F1b generations. The F1b groups were culled to produce F2a and F2b generations. Similarly, the F2b group was culled to produce the F3a and F3b generations.

No obvious reactions to the test material were noted in the mature rats. Some inconsistencies in body weight were noted in pups. For example, all dosed pups had increases in body weight for the F1a generation (as much as 11%). The F1b generation also was slightly higher in some cases (4%, females only). The F2a and F2b generations did not display increases or decreases in pup weight that were statistically significant. The F3a generation high-dose males (-11%) and females (-10%) showed decreases in pup weight. For the F3a generation mid-dose level the males (-5%) and females (-7%) also were lower. No other effects on the pups were considered to be of toxicological concern.

Based on changes in pup weight, the NOEL and LEL for this study are 25 and 250 ppm (1.25 and 12.5 mg/kg-day), respectively.

9) 3-Month Feeding - dog: Core grade minimum (Sumitomo Chemical America, Inc., 1980)

Groups of purebred beagle dogs (6/sex/dose) were administered danitol in the diet at dose levels of 0, 250, 500 and 750 ppm (0, 6.25, 12.5 and 18.75 mg/kg-day) for 13 weeks. The high-dose group received 1000 ppm (25 mg/kg-day) for weeks 1-3 and the lower level of 750 ppm for weeks 4-13.

A single dog receiving 1000 ppm was sacrificed in a moribund state during the third week of the study. This dog showed severe tremors and other signs of toxicity. Its death was determined to be treatment-related. Thus, the high-dose was reduced to 750 ppm. Several types of signs of reaction to the test material were noted. These included soft and mucoid stools, and/or diarrhea (Male: 24, 34, 40 and 34; Female: 16, 66, 25 and 36 for the controls, low-, mid- and high-dose groups, respectively), emesis (Male: 2, 10, 25 and 19; Female: 5, 9, 10 and 25 for the controls, low-, mid- and high-dose groups, respectively), tremors, ataxia, and sometimes lethargy, panting, and salivation. With respect to tremors, the total incidences reported for males were 0, 2, 5 and 94 and for females were 0, 2, 3 and 149 for the controls, low-, mid- and high-dose groups, respectively. For both the males and females only a single dog was affected at the low-dose and this was in the first 2 or 3 weeks of the study.
High-dose animals did not gain weight as well as the controls and other dosed groups. For males, the high-dose group was an average of 6% higher at study initiation but was an average 9% or less lower than the controls at the end of the study. For females, the weight of the high-dose group was 96% of controls at study initiation, but was 90% at the end of 90 days. Thus, the high-dose group was mildly affected with respect to weight gain. Mid-dose group females also were slightly affected; they were 97% of the controls at study initiation, but were 92% at the end of the study.

The mean hematocrit, hemoglobin, and erythrocyte count of both high-dose males and females were depressed. The magnitude of these depressions was 9% (females, hematocrit), 11% (male, hemoglobin), and 13% (females, RBC count).

No other significant effects were noted. Based on the gastrointestinal effects noted at all dose levels tested, the LEL for systemic toxicity is 250 ppm (6.25 mg/kg-day). A NOEL for systemic toxicity was not established.

10) 3-Month Feeding - rat: Core grade minimum (Sumitomo Chemical America, Inc., 1976)

Groups of Charles River rats (12/sex/dose) were administered danitol in the diet at dose levels of 0, 3, 30, 300 and 600 ppm (0, 0.15, 1.5, 15 and 30 mg/kg-day) for 3 months. The high-dose group receiving 600 ppm was included after the plans for the experiment were made and animals in this group were not randomized in the same way as the other groups.

Females receiving 600 ppm had reduced body weight. Clinical signs were noted in animals receiving 600 ppm, but in this group the tremors noted occurred at week 5 and were reported to have disappeared by week 11. The packed cell volume was depressed by 2-5% in males and females at 300 ppm but no difference was noted at 600 ppm (at best only 2%). At 600 ppm some "minor" reductions were observed in Hb (3% both sexes) and mean cell volume (2% both sexes) in the prothrombin time in males (2%) and a small decrease was noted in kaolin- cephalin clotting time (14%) in females at 600 ppm. Also at 600 ppm noted an increase in plasma alkaline phosphatase was noted in both males and females (33% for males and 42% females). Also noted at 600 ppm, the serum K+ level in males was elevated (10%) and the Cl- level in females was decreased (2%). Increases in kidney weight (males, +7.2%) and in brain weight (female, +6.9%) were observed at 600 ppm.

Based on the effects observed at the highest dose tested, the LEL for systemic toxicity is 600 ppm (30 mg/kg-day). The NOEL for systemic toxicity is 300 ppm (15 mg/kg-day).

11) 3-Month Feeding - rat: Core grade supplementary (Sumitomo Chemical America, Inc., 1975)
Groups of Carworth Farms E strain rats (12/sex/dose) were administered danitol in the diet at dose levels of 0, 2, 10, 50 or 250 ppm (0, 0.1, 0.5, 2.5 and 12.5 mg/kg-day) for 3 months. No significant effects were noted at any dose tested. Therefore, the NOEL for systemic toxicity is equal to or greater than 250 ppm (12.5 mg/kg-day).

Data Gap(s): None

**I.A.5. Confidence in the Oral RfD**

Study — Medium  
Database — High  
RfD — High

The principal study was a well conducted study that and identified a NOEL and LEL for systemic toxicity. The confidence in the study was determined to be medium due to the fact that food and test material were given ad libitum; also the study authors should have described in detail how the amount of food and test material ingested by each dog was measured. The database has no data gaps and contains a number of additional studies that support the NOEL/LEL established in the principal study. Therefore, the database is given a high confidence rating. High confidence in the RfD follows.

**I.A.6. EPA Documentation and Review of the Oral RfD**

Source Document — This assessment is not presented in any existing U.S. EPA document.

Other EPA Documentation — None

Agency Work Group Review — 06/10/1986, 04/01/1993

Verification Date — 04/01/1993

Screening-Level Literature Review Findings — A screening-level review conducted by an EPA contractor of the more recent toxicology literature pertinent to the RfD for Danitol conducted in September 2002 did not identify any critical new studies. IRIS users who know of important new studies may provide that information to the IRIS Hotline at hotline.iris@epa.gov or (202)566-1676.
I.A.7. EPA Contacts (Oral RfD)

Please contact the IRIS Hotline for all questions concerning this assessment or IRIS, in general, at (202)566-1676 (phone), (202)566-1749 (FAX) or hotline.iris@epa.gov (internet address).

I.B. Reference Concentration for Chronic Inhalation Exposure (RfC)

Substance Name — Danitol
CASRN — 39515-41-8
Primary Synonym — Fenpropathrin

Not available at this time.

II. Carcinogenicity Assessment for Lifetime Exposure

Substance Name — Danitol
CASRN — 39515-41-8
Primary Synonym — Fenpropathrin

This substance/agent has not undergone a complete evaluation and determination under US EPA's IRIS program for evidence of human carcinogenic potential.

III. [reserved]
IV. [reserved]
V. [reserved]

VI. Bibliography

Substance Name — Danitol
CASRN — 39515-41-8
Primary Synonym — Fenpropathrin
VI.A. Oral RfD References


VI.B. Inhalation RfC References

None

VI.C. Carcinogenicity Assessment References

None

VII. Revision History

Substance Name — Danitol
CASRN — 39515-41-8
Primary Synonym — Fenpropathrin

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VIII. Synonyms

Substance Name — Danitol
CASRN — 39515-41-8
Primary Synonym — Fenpropathrin
Last Revised — 01/31/1987

- 39515-41-8
- alpha-CYANO-3-PHENOXYBENZYL 2,2,3,3-TETRAMETHYL-1-CYCLO-PROPANE CARBOXYLATE
- CYCLOPROPANECARBOXYLIC ACID, 2,2,3,3-TETRAMETHYL-,CYANO(3-PHENOXY-PHENYL) METHYL ESTER
- Danitol
- FENPROPANATE
- FENPROPATHRIN
- MEOTHRIN
- RODY
- S 3206
- SD 41706
- WL 41706