UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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MAY 17 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Blockade Cat and Dog Oral NOEL and LEL Levels and Rat Inhalation Toxicity

TO: Mr. George LaRocca, PM 15
Registration Division (TS-767C)

FROM: Byron T. Backus, Toxicologist
Toxicology Branch (TS-769C)

THROUGH: Marcia van Gemert, Ph.D.
Section Head, Review Section III
Toxicology Branch (TS-769C)

and

Theodore M. Farber, Ph.D., D.A.B.T.
Branch Chief
Toxicology Branch (TS-769C)

EPA Reg. Nos. 2596-114, 2596-115

Tox. Chem. 77A, 346

Background:

At a meeting in the Director's office on May 10, 1988, it was stated that the Toxicology Branch would have reviews completed on the 3 remaining toxicity studies from the Blockade data-call in by May 13, 1988.

Comments and Recommendations:

1. Both the cat and dog oral NOEL and LEL studies are acceptable. In both species, the NOEL is 125 mg/kg, and the LEL (usually emesis and/or salivation within 1-2 hours of dosage, with no further reactions during the 14-day observation period) is 250 mg/kg. These symptoms were usually those of ingestion of an "inert" (rapidly evaporating) in the Blockade formulation. However, in the case of one 4-year old female cat vomiting did not occur until 6 hours after dosage, and this cat did not eat (although she drank some milk) the next day, with recovery by day 2.

2. For both the cat and dog NOEL and LEL studies, the registrant has claimed a considerable amount of confidentiality. This includes - but is not limited to - the laboratory at which the study was done, as well as the names of the laboratory personnel involved. For this reason it is recommended that a legal interpretation of this submission's claims of confidentiality be made before copies of these reviews (particularly attached data evaluation reports I and II), as well as the one-liner summaries, are made generally available.

3. The rat inhalation acute toxicity study has been classified as core supplementary data (not considered as acceptable to support the continued registration of these products). There is a question as to whether or not the animals received an exposure to a concentration that was equivalent to 5 mg/L of the product. While there are gravimetric data indicating that there was something like 5 mg/L of particulate matter in the chamber, the actual DEET concentration ranged from 5.48 to 10.6 mg/m^3, and the fenvalerate range was from 0.05 to 0.24 mg/m^3. These data are consistent with one another in that Blockade contains about 100x as much DEET as fenvalerate. However, since the formulation is about 10% DEET, the DEET concentration should have been about 10% of 5 mg/L, or about 0.5 mg/L. Since 1 m^3 = 1000 liters then this would have been 500 mg/m^3. The actual reported concentrations (table VII) of 5.48-10.6 mg/m^3 are about 1-2% of this level. Unless it can be demonstrated that the rats actually received an exposure to DEET of 0.5 mg/L, and to fenvalerate of about 0.05 mg/L, the study is classified as core supplementary data.

Reviewed by: Byron T. Backus Byron T. Backus 05/13/88
Section 3, Tox. Branch (TS-769C)
Secondary Reviewer: Marcia van Gemert, Ph.D.
Section 3, Tox. Branch (TS-769C) M. van Gemert 5/13/88

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DATA EVALUATION REPORT I

STUDY TYPE: Domestic animal safety - cat

TOX. CHEM. NO.: 346, 77A

ACCESSION NUMBER:

MRID NO.: 405734-01

TEST MATERIAL: Blockade

CONFIDENTIAL BUSINESS INFORMATION

SYNONYMS: Deet + Pydrin

STUDY NUMBER(S): Hartz Test No. 1006

SPONSOR: Hartz Mountain Corporation

TESTING FACILITY: [redacted]

NOTE: The report has been submitted in two forms, one of which is labeled "confidential." In the non-confidential report the registrant has deleted the name of the laboratory at which this study was conducted, as well as the names and signatures of the laboratory personnel involved.

TITLE OF REPORT: Domestic Animal Safety: Oral Effect Level: Determination of an Oral No-Effect Level in Cats

AUTHOR(S): [redacted]

REPORT ISSUED: March 24, 1988

CLASSIFICATION: Acceptable

CONCLUSIONS:

1. The primary symptom (emesis within an hour of dosage) observed with Blockade at 250 mg/kg was the same as that observed after dosage with 250 mg/kg of 30% isopropanol. Three of 4 cats with symptoms after Blockade dosage simply vomited at least once within an hour after dosage, with recovery by 4 hours. However, it is noteworthy that the one other Blockade-dosed cat with symptoms (a 4-year old female) did not vomit until 6 hours after treatment and then did not eat (although it drank milk) until day 2. These delayed symptoms may have been due to either the deet or fenvalerate. It is interesting that this cat subsequently showed no adverse reaction to oral dosage with 250 mg/kg of 30% isopropanol alone. This suggests the possibility that some cats may show adverse effects after ingestion of as little as 350 mg/kg of the product (value is obtained by multiplying the 250 mg/kg dosage level by 1.4X, to account for loss of volatiles when the product was sprayed into a beaker).

2. The study is acceptable as demonstrating a single-dose NOEL of 125 mg/kg for the concentrate (equivalent to about 175 mg/kg of the product as formulated), and a LEL of 250 mg/kg for the concentrate (equivalent to about 350 mg/kg of the product).

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3. Quality assurance: there is a Good Laboratory Practice Statement on p. 3 of the report labeled confidential, as well as a signed Quality Assurance Unit Statement signed and dated on 2/15/88 and 3/25/88 on p. 23 of the report labeled confidential.

C. METHODS AND RESULTS:

1. Observations: From p. 28: "Animals shall be monitored once per hour after dosing for the first 8 hours for any signs of adverse effects. Thereafter, the animals should be observed daily 5 days a week for a minimum of 14 days."

Results: The following summary is reported on p. 8 as occurring at dose levels of 250 mg/kg:

Sample #	Product	Reaction Rate	Type Effect
8340	Blockade	4/12	Emesis
8403	30% isopropanol	2/12	Emesis
8400	Commercial Product	8/12	1 Emesis, 8 increased bowel movement frequencies

No effects occurred in cats receiving 125 mg/kg of Blockade.

The following cats showed effects after dosage with 250 mg/kg Blockade and/or 30% isopropanol (the same cats were dosed with 250 mg/kg Blockade and, 2-4 weeks later, with 250 mg/kg 30% isopropanol):

Cat No.	Sex	250 mg/kg Blockade	250 mg/kg 30% isopropanol
32	M	"Salivation & blood on lips from the procedure. Emesis 50 and 55 minutes. Appeared nauseated at 1 hour. NFR.*	Emesis at 14 minutes. NFR.*
65	M	Emesis at 15 minutes. NFR.*	None
69	M	Gagged as stomach tube was removed. Appeared nauseated for 10 minutes. Did not appear to be treatment related. NFR.*	None
55	F	Emesis at 20 minutes. NFR.*	None
76	F	Ate lightly at 4 hours after treatment. Emesis at 6 and 7 hours after treatment. Appeared nauseated at 8 hours. Appeared nauseated and would not eat next day. Drank milk. Good appetite on day 2. NFR.*	None
72		None	Emesis at 26 minutes. NFR.*

*NFR = no further reactions.

A. MATERIALS:

1. Test compound: Test sample #8340, obtained from a pallet of product manufactured 13 March 1987, production lot No. MR10727. Analysis showed an average of 10.16% Deet and 0.095% Fenvalerate (label declaration: 10.0% Deet; 0.110% Fenvalerate). The material that was administered to test animals was the condensate from product that was sprayed into a beaker. Analysis of this condensate indicated there was approximately 14% Deet and about 0.135% Fenvalerate.

2. "Control" test compounds: sample #8403 was an isopropanol solution, with 30% (nominal value) isopropanol in water. Sample #8400 was a commercial spray (Double Duty Flea and Tick Repellent - EPA 21165-1-2517, Lot #5726, containing 0.3% pyrethrins; 2.4% piperonyl butoxide, technical; 33% butoxypolypropylene glycol; 1.5% petroleum distillate; and 62.8% inert ingredients).

3. Test animals: A total of 35 adult cats, both females and males, ages 1-5 years, weights ranging from 4 to 13 lbs at the time of dosage, a few with some Persian ancestry. The source of these cats is not reported.

B. STUDY DESIGN:

1. Animal assignment:

From p. 27: "Animals placed on test will be randomly assigned to dose groups. However, effort will be made to make the group weight distributions and length and type of coat as equivalent as possible." Some of the assignments were apparently based on animal availability.

		Dosed with:
Group 1	6M, 6F	125 mg/kg Blockade concentrate 10 cats dosed on 2-16-88 2 cats dosed on 2-22-88
Group 2	6M, 6F	250 mg/kg Blockade concentrate 11 cats dosed on 2-10-88 1 cat dosed on 2-22-88 and subsequently with 250 mg/kg 30% isopropanol solution 12 cats dosed on 3-10-88
Group 3	3M, 9F	250 mg/kg Double Duty Flea and Tick Repellent - EPA Reg. No. 21165-1-2517. 12 cats dosed 3-7-88

2. Test material dosing: From p. 28: "The cats will be fasted for approximately 13 hours prior to dosing. Feeding will resume 4 hours after treatment." The test material was administered as a single dose by gavage.

None of the other cats in this group showed any symptoms to oral dosage with either 250 mg/kg Blockade or 250 mg/kg 30% isopropanol in water.

Of the 12 cats dosed with 250 mg/kg of sample #8400, 1 vomited at 45 minutes, while 8/12 (including the one which vomited) had 2-3 bowel movements within the next 3 1/2 hours.

2. Animal weights:

Individual animals were weighed on the day of dosage, and at 7 and 14 days afterwards.

Results:

Weight variations for any individual cat were no more than 1 lb during the 14-day observation period after dosing.

D. DISCUSSION:

The primary symptom (emesis within an hour of dosage) observed in this cat study with Blockade at 250 mg/kg was the same as that observed with 250 mg/kg of 30% isopropanol. Three of 4 cats showing symptoms after dosage with Blockade simply vomited at least once within an hour after dosage, and had recovered by 4 hours. However, it is noteworthy that the one other cat with symptoms (a 4-year old female) did not vomit until 6 hours after treatment and then did not eat (although it drank milk) the following day, not fully recovering until day 2. These delayed symptoms may have been due to either or both of the actives (Deet and fenvalerate) in this formulation, rather than to the to the isopropanol. It is particularly interesting that this cat subsequently showed no adverse reaction to oral dosage with 30% isopropanol alone. This suggests the possibility that some cats may show adverse effects following ingestion of as little as 350 mg/kg of the product (this value is obtained by multiplying the 250 mg/kg dosage level by 1.4X, which takes into account the loss of volatiles which took place when the product was sprayed into a beaker).

Overall, the study is acceptable as demonstrating a single-dose NOEL of 125 mg/kg for the concentrate (equivalent to about 175 mg/kg of the product as formulated), and a LEL of 250 mg/kg for the concentrate (equivalent to about 350 mg/kg of the formulated product).

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DATA EVALUATION REPORT II

STUDY TYPE: Domestic animal safety - dog TOX. CHEM. NO.: 346, 77A

ACCESSION NUMBER: 405735-01 MRID NO.:

TEST MATERIAL: Blockade

SYNONYMS: Deet + Pydrin

STUDY NUMBER(S): Hartz Test No. 1005

SPONSOR: Hartz Mountain Corporation

TESTING FACILITY: [redacted]

NOTE: The report has been submitted in two forms, one of which is labeled "confidential." In the non-confidential report the registrant has deleted the name of the laboratory at which this study was conducted, as well as the names and signatures of the laboratory personnel involved.

TITLE OF REPORT: Domestic Animal Safety: Oral Effect Level: Determination of an Oral No-Effect Level in Dogs

AUTHOR(S): [redacted] CONFIDENTIAL BUSINESS INFORMATION

REPORT ISSUED: March 23, 1988

CLASSIFICATION: Acceptable

CONCLUSIONS:

1. The primary symptom (emesis within an hour of dosage) observed in this dog study with Blockade concentrate following dosage at 250 mg/kg was the same as that observed following dosage with 250 mg/kg of 30% isopropanol. No symptoms were observed in dogs following dosage with 125 mg/kg Blockade concentrate.

2. Overall, the study is acceptable as demonstrating a single-dose NOEL of 125 mg/kg for the concentrate (equivalent to about 175 mg/kg of the product as formulated), and a LEL of 250 mg/kg for the concentrate (equivalent to about 350 mg/kg of the formulated product).

A. MATERIALS:

1. Test compound: Test sample #8340, obtained from a pallet of product manufactured 13 March 1987, production lot No. MR10727. Analysis showed an average of 10.16% Deet and 0.095% Fenvalerate (label declaration: 10.0% Deet; 0.110% Fenvalerate). The material that was administered to test animals was the condensate from product that was sprayed into a beaker. Analysis of this condensate indicated there was approximately 14% Deet and about 0.135% Fenvalerate.

2. "Control" test compounds: sample #8403 was an isopropanol solution, with 30% (nominal value) isopropanol in water. Sample #8400 was a commercial spray (Double Duty Flea and Tick Repellent - EPA 21165-1-2517, Lot #5726, containing 0.3% pyrethrins; 2.4% piperonyl butoxide, technical; 33% butoxypolypropylene glycol; 1.5% petroleum distillate; and 62.8% inert ingredients).

3. Test animals: A total of 42 dogs, equal numbers of males and females, ages 1-10 years, weights ranging from 13 to 51 lbs at the time of dosage. According to the protocol, the dogs were an established colony obtained from the local animal shelter over an extended period.

B. STUDY DESIGN:

1. Animal assignment:

From p. 31: "Animals placed on test will be randomly assigned to dose groups. However, effort will be made to make the group weight distributions and length and type of coat as equivalent as possible." In an initial range-finding study with Blockade (4 dogs dosed at 750 mg/kg; 2 at 500 mg/kg, 2 at 250 mg/kg and 2 at 125 mg/kg) emesis was noted at 250 mg/kg and above. The following gives the range-finding results (from p. 20):

Blockade Dosage	Number of Dogs	Incidence of Symptoms*
750 mg/kg	4 (2M, 2F)	4/4
500 mg/kg	2 (1M, 1F)	1/2
250 mg/kg	2 (1M, 1F)	1/2
125 mg/kg	2 (1M, 1F)	0/2

*Symptoms = emesis and/or salivation. Symptoms lasted no more than 2 hours, after which there were "no further reactions."

An additional ten dogs (5M, 5F) were then dosed at 250 mg/kg, and another group of 5M, 5F was dosed at 125 mg/kg. Another group of 6M, 6F was dosed with 250 mg/kg of sample #8400 (the commercially-available pyrethrin-containing product). The 12 dogs that had been previously dosed with 250 mg/kg Blockade condensate were orally dosed with 250 mg/kg of 30% (nominal) isopropanol.

Group 1	6M, 6F	125 mg/kg Blockade concentrate *2 dogs dosed on 1-20-88 10 dogs dosed on 1-21-88
Group 2	6M, 6F	250 mg/kg Blockade concentrate *2 dogs dosed on 1-20-88 10 dogs dosed on 1-27-88 and subsequently with 250 mg/kg 30% isopropanol solution 12 dogs dosed on 3-09-88
Group 3	6M, 6F	250 mg/kg Double Duty Flea and Tick Repellent - EPA Reg. No. 21165-1-2517. 4 dogs dosed 2-29-88 8 dogs dosed 3-01-88

*From the range-finding study.

2. Test material dosing:

The test material was administered as a single dose by gavage. According to the protocol (p. 32): "The dogs will be fasted for approximately 13 hours prior to dosing. Feeding will resume 4 hours after treatment.

3. Quality assurance: there is a Good Laboratory Practice Statement on p. 3 of the report labeled confidential, as well as a Quality Assurance Unit Statement signed and dated on 1/22/88 and 3/25/88 on p. 25 of the same report. Signed and dated sponsor inspection statements are on pages 26, 27 and 28 of this report.

C. METHODS AND RESULTS:

1. Observations: From p. 32: "Animals should be monitored once per hour after dosing for the first 8 hours for any signs of adverse effects. Thereafter, the animals should be observed daily 5 days a week for a minimum of 14 days."

Results: The following summary is reported on p. 8 as occurring at dose levels of 250 mg/kg:

Sample #	Product	Reaction Rate	Type Effect
8340	Blockade	4/12	Emesis and/or salivation
8403	30% isopropanol	3/12	Emesis and/or salivation
8400	Commercial Product	3/12	Emesis and/or salivation

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All of the symptoms occurred within an hour after treatment.

No effects ascribable to the Blockade occurred in dogs receiving a dose of 125 mg/kg of Blockade, although one dog is reported (p. 21) as gagging and spitting up foam within 5 minutes after dosing. This "appeared to be caused by passing stomach tube."

2. Animal weights:

Individual animals were weighed on the day of dosage, and at 7 and 14 days afterwards.

Results:

From p. 15: "The animals gained an average of 1.5 lbs during the test and no dog lost more than one pound."

D. DISCUSSION:

The primary symptom (emesis within an nour of dosage) observed in this dog study with Blockade at 250 mg/kg was the same as that observed with 250 mg/kg of 30% isopropanol.

Overall, the study is acceptable as demonstrating a single-dose NOEL of 125 mg/kg for the concentrate (equivalent to about 175 mg/kg of the product as formulated), and a LEL of 250 mg/kg for the concentrate (equivalent to about 350 mg/kg of the formulated product).

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DATA EVALUATION REPORT III

STUDY TYPE: Acute inhalation - rat

TOX. CHEM. NO.: 346, 77A

ACCESSION NUMBER: 405712-01

MRID NO.:

TEST MATERIAL: Blockade

SYNONYMS: Deet + Pydrin

STUDY NUMBER(S): Hartz Test No. 1004

SPONSOR: Hartz Mountain Corporation

TESTING FACILITY: Leberco Testing, Inc.
Roselle Park, NJ 07204

TITLE OF REPORT: Acute Inhalation Toxicity in Rats

AUTHOR(S): Levy, E.

REPORT ISSUED: March 9, 1988

CLASSIFICATION: Core Supplementary Data

CONCLUSION:

There is a question as to whether the test animals received an exposure that was equivalent to 5 mg/L of the product. According to table VII (p. 30) DEET concentration ranged from 5.48 to 10.6 mg/m^3 in the chamber, and the fenvalerate concentration was from 0.05 to 0.24 mg/m^3. These data are consistent with one another in that Blockade contains about 100 times as much DEET as fenvalerate. However, since about 10% of the formulation consists of DEET, the DEET concentration should have been about 10% of 5 mg/L which is equal to 0.5 mg/L, which in turn (since 1 m^3 = 1000 liters) would be equal to 500 mg/m^3. The actual reported values (table VII) are about 1-2% of this. Unless it can be demonstrated that the rats actually received an exposure to DEET of 0.5 mg/L, and to fenvalerate of about 0.05 mg/L, the study is classified as core supplementary data.

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A. MATERIALS:

1. Test compound: Test sample #8340, obtained from a pallet of product manufactured 13 March 1987, production lot No. MR10727. An analysis showed that the material contained the label declaration of 10.0% Deet and 0.10% Fenvalerate.

2. Test animals: 8-week old Sprague-Dawley rats of both sexes. At the time of exposure males weighed 250-294 grams; females 201-207 grams.

B. STUDY DESIGN:

1. Animal assignment:

From p. 9: "Animals placed on test were randomly assigned to dose groups. Only rats with body weight within ± 20% of the mean body weight of rats of the same age, strain and sex were used."

2. Exposure to the test material:

Five male and 5 female rats were placed in the exposure chamber ("a 200-liter, non-porous, airtight, square with glass viewing window."). From p. 11: "Operating parameters and test conditions were established prior to the exposure or use of test animals." "The test material was manually introduced into the chamber as a 1-second burst every 60 seconds. Only 175 grams of test material was evacuated from each 200 grams aerosol can. The aerosol can was weighed after every ten bursts." The exposure was for 4 hours, with subsequent 14-day observation.

From p. 14: "Immediately after exposure the animals were rinsed with warm water to remove any residual test material from their body to avoid toxicity by oral route."

3. Quality assurance: there is a Good Laboratory Practice Statement on p. 3 of the report, as well as a Quality Assurance Unit Statement signed and dated on 3/4/88.

C. METHODS AND RESULTS:

1. Observations: From p. 37: "All test animals are observed fo signs of toxicity...and mortality during the exposure period, once an hour for four hours following exposure, twice daily 5 days a week for the first week after exposure and once daily thereafter. Test animals are observed for a total of 14 days after exposure."

Results: From p. 14: "All ten animals spent the first hour preening themselves. At one and two hours post exposure the males had a slight decrease in spontaneous motor activity and at three hours all ten animals appeared normal and remained so throughout the 14 day observation period.

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2. Animal weights:

Individual animals were weighed on the day of dosage, and at 7 and 14 days afterwards.

Results:

From data presented on p. 29 one female lost weight in the period from day 0 to day 7. All others gained, although it is noteworthy that weight gains for most females were less during the period from day 0 to day 7 than from day 7 through 14. For males the converse was true. From p. 29:

		Weight change (grams)	
Rat #	Sex	day 0 to 7	day 7 to 14
1	F	16	18
2	F	-7	12
3	F	4	31
4	F	20	23
5	F	11	28
6	M	33	27
7	M	35	22
8	M	50	25
9	M	44	26
10	M	45	24

3. Necropsy:

"A gross necropsy was performed on all test animals 14 days after exposure. The gross necropsy included examination of the adnexa, eyes, thoracic and visceral organs. Emphasis was placed on examination of the respiratory tract. Animals were sacrificed by CO_2 overdose." From p. 11: "At the request of the Hartz Mountain Corporation, tissue samples of the lungs were sent to independent pathologists for review." Slides were prepared and evaluated by two different pathologists.

Results:

According to individual data (p. 114) 4/5 females and 3/5 males had slightly or moderately mottled lungs on necropsy. According to one pathologist who examined slides prepared from these animals (see p. 154): "The changes seen in the lungs and bronchioles of rats...are of trace severity and are commonly seen in experimental rats. They are interpreted as being unrelated to treatment." The other pathologist (see p. 160) made no statement as to whether or not these findings might have been related to treatment. One of the males is reported as having foamy macrophages in the alveoli by one pathologist and as having a granuloma with foamy macrophages in wall of the bronchus by the other.

4. Analysis of test substance concentration:

From p. 11: "Representative air samples were removed from the "breathing zone" of the inhalation chamber via a probe attached to a vacuum system with a flow rate of 5 L/min. The samples were taken 30 minutes into the test...and every half hour thereafter throughout the 4 hour test period... The samples were measured gravimetrically to assure that the average concentration in the breathing zone was 5 mg/L or greater."

Results:

Gravimetric samplings indicated a range of 5.06 to 6.75 mg/L. From table VII (p. 30) the fenvalerate (combined isomers) concentration ranged from 0.05 to 0.24 mg/L; the DEET concentration ranged from 5.48 to 10.60 mg/m^3.

5. Particle size analysis:

From p. 12: "During the generation of the test material three air samples were taken at the breathing zone for particle size analysis by a California Measurements, Inc. 6 stage Cascade Impactor Model PC-5S. Samples were taken at 75 minutes, 190 minutes and 225 minutes into the four hour exposure period."

Results:

Most of the measured particulate matter was in the range of 0.26 to 1.7 microns (see table IV, p. 27). The cumulative amount collected at any one time is given in terms of mg/m^3 (concentration?), and ranges from a total of about 0.3 mg/m^3 at 225 minutes to about 0.6 mg/m^3 at 75 minutes.

D. DISCUSSION:

The major concern of this reviewer is whether, in fact, the test animals received an exposure that was equivalent to 5 mg/L of the product. According to table VII (p. 30) DEET concentration ranged from 5.48 to 10.6 mg/m^3 in the chamber, and the fenvalerate concentration was from 0.05 to 0.24 mg m^3. These data are consistent with one another in that Blockade contains approximately 100 times as much DEET as fenvalerate. However, since about 10% of the formulation consists of DEET, the DEET concentration should have been about 10% of 5 mg/L which is equal to 0.5 mg/L, which in turn (since 1 m^3 = 1000 liters) would be equal to 500 mg/m^3. The actual reported values (table VII) are about 1-2% of this. Unless it can be demonstrated that the rats actually were exposed to a concentration of about 0.5 mg/L DEET, and to about 0.05 mg/L fenvalerate, the study is classified as core supplementary data.