

US EPA ARCHIVE DOCUMENT

(12-6-01)

U. S. ENVIRONMENTAL PROTECTION AGENCY
Washington, D.C. 20460



OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

**ALIPHATIC SOLVENTS (Mineral Oil): Data Reviews of Avian Dietary and Oral
Toxicity, MRID No. 453908-01 and 453908-02.**

DP BARCODE: D275034

DATE: November 29, 2001

CHEMICAL: Aliphatic Solvents (Mineral Oil)
PC Code 063502/ Company: Petro-Canada Lubricants.

SUBJECT: Data Evaluation Records (DERs)

FROM: Stephen Carey, Biologist *Stephen Carey 11/29/01*
Environmental Risk Branch III/EFED

THRU: Thomas Steeger, Acting Branch 3 Chief *Thomas M Steeger 12/6/01*
Environmental Risk Branch III/EFED

TO: Susan Lewis: Product Manager
Deanna Scher: PM Team Reviewer
Reregistration Division

SUMMARY

Petro-Canada Lubricants has submitted an avian subacute dietary and an acute oral toxicity data with Northern bobwhite using N65DW, a mineral oil (MRID No. 453908-01 and 453908-02). Environmental Fate and Effects Division has determined that the studies fulfill Subdivision E guideline data requirements. Based on an acute oral LD₅₀ greater than 2,250 mg/kg and a subacute dietary LC₅₀ greater than 5,518 mg/kg of diet, N65DW is classified as practically nontoxic to upland gamebirds. The studies are classified as **Core**.

Attached are EFED's data evaluation records (DERs) of the avian subacute dietary and acute oral toxicity tests with Northern bobwhite using N65DW (mineral oil).

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Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

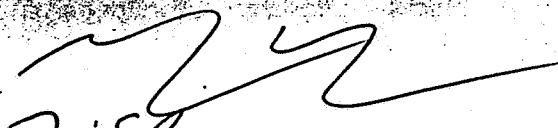
PMRA Submission Number {.....}

EPA MRID Number 45390801


Data Requirement: PMRA DATA CODE {.....}
EPA DP Barcode D275034
OECD Data Point Mortality, signs of toxicity and abnormal behavior
EPA MRID 45390801
EPA Guideline 71-1 (a)

Test material: N65DW Purity: 100% a.i.
Common name: Mineral Oil
Chemical name: IUPAC Not reported
CAS name Not reported
CAS No. 72623-86-0
Synonyms Not reported


Primary Reviewer: Gregory Hess
Staff Scientist, Dynamac Corporation

Signature: 
Date: 8/6/01

QC Reviewer: Teri Myers, Ph.D.
Staff Scientist, Dynamac Corporation

Signature: 
Date: 8/6/01

Primary Reviewer: Stephen Carey
Biologist; ERB3, EFED, USEPA
{EPA}

Signature: 
Date: 10/28/01

Reference/Submission No. {.....}

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
EPA PC Code 063502

Date Evaluation Completed: November 28, 2001

CITATION: Gallagher, S.P., J. Grimes and J.B. Beavers. 2001. N65DW: An Acute Oral LD₅₀ Toxicity Study With the Northern Bobwhite. An unpublished study performed by Wildlife International, Ltd. 8598 Commerce Drive, Easton, MD 21601 and sponsored by Petro-Canada Lubricants, 2489 North Sheridan Way, Mississauga, Ontario Canada. Laboratory project number 480-103. Study initiated on June 6, 2000 and completed on February 9, 2001.

Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

EXECUTIVE SUMMARY:

The acute oral toxicity of Mineral Oil to 18 week old Northern Bobwhite quail was assessed over 14 days. Mineral Oil was administered to the birds by intubation into the crop at 0.0, 292, 486, 810, 1350 and 2250 mg/kg bw. The 14 day-acute oral LD₅₀ was >2250 mg/kg bw. The 14 day NOEL of Mineral Oil to the Northern Bobwhite quail, based on mortality was >2250 mg/kg bw. According to the US EPA classification, Mineral Oil would be classified as practically nontoxic to Northern Bobwhite quail on an acute oral basis.

There were no sublethal or compound related toxicity effects.

This toxicity study is scientifically sound, and satisfies the guideline requirement for an acute oral toxicity study on Northern bobwhite quail because no toxicity was elicited at the highest concentration tested. This study is classified as Core.

Results Synopsis

Test Organism Size/Age (mean Weight): 18-weeks old (195 g)
LD₅₀: >2250 mg/kg b.w. 95% C.I.: NA
NOEL: >2250 mg/kg b.w. Probit Slope: NA
Endpoint(s) Affected: None

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I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: Subdivision E, §71-1(a). The following deviations are noted:

- 1) The photoperiod (8:16) was slightly different than that recommended by US EPA (10:14).
- 2) The stability of the test substance was not indicated and OECD requirements were not reported.
- 3) The authors failed to indicate whether or not the test material was regurgitated after dosing.
- 4) Test concentrations (mean-measured) were not verified at end of test experiment.

COMPLIANCE: Signed and dated GLP, Quality Assurance and No Data Confidentiality statements were provided.

A. MATERIALS:

1. Test Material N65DW (Mineral Oil)

Description: Clear liquid

Lot No./Batch No. : 971488

Purity: 100%

Stability of Compound

Under Test Conditions: The stability of the test material was not reported. OECD requirements were not reported.

(OECD requires water solubility, stability in water and light, pKa, Pow, vapor pressure of test compound)

Storage Conditions of

Test Chemicals: Held under ambient conditions in locked storage.

2. Test organism:

Species (common and scientific names): Northern Bobwhite quail (*Colinus virginianus*)

Age at study initiation: Approximately 18 weeks

Weight at study initiation: (mean and range): mean=195 g; range=172-225g

Source: Pine Creek Game farm, Montrose, IA 52639

(EPA recommends that either bobwhite quail or mallard duck be used. Birds should be at least 16 weeks old at test initiation and should be uniform in size and weight as well as phenotypically indistinguishable from wild birds).

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: Not reported

b) Definitive Study

Table 1. Experimental Parameters

Parameter	Details	Remarks
		Criteria
Acclimation period: conditions (same as test or not): feeding: health (any mortality observed):	3 weeks Same as test. fed a game bird ration formulated to Wildlife Int. Ltd's. Specifications; birds were fasted approx. 20 hours prior to dosing. All animals were reported to be in good health at test initiation.	<i>EPA recommends that birds be pre-conditioned to the test facilities for at least 15 days.</i> <i>OECD recommends that birds be pre-conditioned to the test facilities for at least 7 days.</i>
Pen size and construction materials	Floor spaced measured 78 x 51 cm. Floors were sloped so that ceiling height ranged from approx. 20 to 25 cm. External walls, ceilings and floors were constructed of galvanized wire while side walls were constructed of galvanized sheeting.	<i>EPA requires: pens must conform to good husbandry practices and should not create crowding stress.</i> <i>OECD lists no criteria for pen construction other than stating that pens should be suitable for the captive rearing of that species.</i>
Test duration	14 days	<i>EPA requires a day for dosing and at least 14 days observation.</i>
Dose preparation [Indicate method of confirmation of dose]	Test material was dispersed in corn oil. The concentration of the test substance in the diluent was adjusted to provide constant volume to body weight dosages for all treatment birds. Confirmation of dose was not reported.	
Mode of dose administration	Orally intubated into the crop or proventriculus of each bird using a stainless steel 14 gauge cannula	<i>Gavage or gelatin capsule.</i>

Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

Parameter	Details	Remarks
		Criteria
Dose levels nominal: measured:	0.0, 292, 486, 810, 1350 and 2250 mg/kg b.w. Not reported	<i>EPA requires a minimum of 5 treatment levels unless LD₅₀ is demonstrated to be greater than 2000 mg ai/kg</i>
Solvent/vehicle, if used type: amount/bw:	Corn oil 4 mg/kg b.w.	<i>EPA recommends that the test material be administered without a vehicle if possible. Maximum vehicle should not exceed 0.1 to 1.0% of body weight.</i>
Number of birds per groups/treatment for negative control: for solvent/vehicle control: for treated:	NA 5 male and 5 female 5 male and 5 female	EPA recommends 10 birds per treatment group and 10 birds for each control and vehicle group.
No. of feed withholding days before dosing	approx. 20 hours	<i>EPA recommends that food should be withheld for at least 15 hours prior to dosing.</i>
Test conditions Temperature: Relative humidity: Photoperiod:	mean = 23.9°C mean = 71% 8 hr light / 16 hr dark	<i>EPA recommends that a 10 hr light/14 hr dark photo-period.</i>
Reference chemical, if used name: concentrations tested:	NA	

Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

2. Observations:

Table 2: Observations

Criteria	Details	Remarks
		Criteria
Parameters measured (mortality/individual body weight at test initiation and termination/ mean feed consumption/ others)	Mortality, body weight at test initiation and days 3, 7 and 14, average feed consumption by pen. Birds were also observed for abnormal behavior and signs of toxicity.	<i>EPA recommends: Body weight measured at test initiation, on Day 14 and at end of the test if the test is extended beyond 14 days. Calculation of mortality. Mortality must NOT be more than 10% in controls. Feed consumption may be measured as average daily food consumption.</i>
Indicate if the test material was regurgitated	Not reported	<i>Regurgitation is an indication that the does was rejected. The test may have to be repeated if the problem persists.</i>
Groups on which necropsies were performed	All dead birds and surviving birds were necropsied at test termination.	<i>EPA recommends that gross necropsies be performed with inspections of the GI tract, liver, kidneys, heart, and spleen.</i>
Observation intervals	at least once daily	
were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

There were no treatment related mortalities.

Table 3: Effect of Mineral Oil on mortality of Northern bobwhite quail.

Treatment (mg a.i./kg bw)	No. of birds	Cumulative mortality				
		day 1	day 2	day 3	day 4	day 14
Solvent/vehicle control	10	0	0	0	0	0
292	10	0	0	0	0	0
486	10	0	0	0	0	1*
810	10	0	0	0	0	0
1350	10	0	0	0	0	0
2250	10	0	0	0	0	0

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Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

Treatment (mg a.i./kg bw)	No. of birds	Cumulative mortality				
		day 1	day 2	day 3	day 4	day 14
NOEL	>2250 mg/kg b.w., the highest dosage tested					
LD ₅₀	>2250 mg/kg b.w., the highest dosage tested.					
Reference chemical	mortality	NA				
	LD ₅₀	NA				
	NOAEL	NA				

* Mortality not considered to be treatment related by the study authors.

B: SUBLETHAL TOXICITY ENDPOINTS:

There were no treatment related sublethal effects reported. On day 9, a female in the 486 mg/kg b.w. group was noted as lethargic and ruffled. Due to her deteriorating condition the bird was euthanized. Necropsy revealed this bird to be emaciated with a loss of muscle mass and a prominent keel. The ceca was distended with caseous necrotic material, and localized peritonitis was evident. Similar clinical effects were not observed in any other treatment group. Therefore the cause of death was not considered treatment related. One male in the 486 mg/kg b.w. group was noted with a drooping wing, this was attributed to injury and considered not to be treatment related. Gross necropsy results indicated that one bird in the 292 mg/kg b.w. treatment group and one bird in the 1350 mg/kg b.w. dosage level were noted with areas of hyperemia in the intestinal tract. In addition, one bird at the 810 mg/kg b.w. dosage level was noted with distended ceca containing caseous necrotic tissue. None of the above findings were considered treatment related. The necropsy results for all other birds were not remarkable.

Table 4: Sublethal effect of Mineral Oil on Northern Bobwhite quail.

Treatment (mg a.i./kg bw)	Observation						
	body weight			food consumption			other endpoint
	day 0	day 7	day 14	day 0-3	day 4-7	day 8-14	% affected
Solvent/vehicle control	195 ¹	203	206	18	20	24	0
	193 ²	201	202	16	20	21	
292	190	199	203	18	21	21	0
	199	208	212	16	20	20	
486	196	202	206	17	24	23	0
	198	195	216	23	25	28	
810	194	201	205	12	23	22	0
	185	193	198	19	25	19	
1350	199	205	209	17	21	17	0
	194	200	205	15	18	15	
2250	198	208	212	21	23	18	0
	204	212	216	17	21	17	

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Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

Treatment (mg a.i./kg bw)	Observation						
	body weight			food consumption			other endpoint
	day 0	day 7	day 14	day 0-3	day 4-7	day 8-14	% affected
NOEL	>2250 mg/kg b.w.						
EC ₅₀	>2250 mg/kg b.w.						
Reference chemical	effect	NA					
	NOAEL	NA					
	LD ₅₀	NA					

Mean male weight (g)

Mean female weight (g)

C. REPORTED STATISTICS:

Statistical Method: Statistical analyses and the LD50 calculation were not performed due to a lack of mortality and sublethal effects.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Observation analysis.

LD₅₀: >2250 mg/kg b.w. 95% C.I.: NA

NOAEL: >2250 mg/kg b.w.

Probit Slope: NA 95% C.I.: NA

E. STUDY DEFICIENCIES:

No toxicity was elicited in this experiment. All other reported deviations were considered minor and did not affect the acceptability or the validity of the study.

F. REVIEWER'S COMMENTS:

The reviewer's conclusions were identical to those reported by the study authors, except for the LD50s determined by nominal concentrations instead of mean-measured concentrations.

Data Evaluation Report on the Acute Oral Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite (*Colinus virginianus*)

PMRA Submission Number {.....}

EPA MRID Number 45390801

G. CONCLUSIONS: The study is scientifically sound and satisfies US EPA guidelines, it is classified as Core.

LD₅₀ >2250 mg/kg b.w
Probit slope NA
NOAEL ≥2250 mg/kg b.w.
Sublethal effects: None

III. REFERENCES:

U.S. Environmental Protection Agency. 1996. Series 850-Ecological Effects Test Guidelines (draft), OPPTS Number 850.2100: *Avian Acute Oral Toxicity Test*.

U.S. Environmental Protection Agency. 1982. *Pesticide Assessment Guidelines, FIFRA Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms*, subsection 71-1, Environmental Protection Agency, Office of Pesticide Programs. Washington, D.C.

National Research Council. 1996. *Guide for the care and use of laboratory animals*. Washington, D.C. National Academy Press. 125 pp.

Stephan, C.E. 1978. U.S. EPA, Environmental Research Laboratory, Duluth Minnesota, Personal Communication.

Finney, D.J. 1971. *Statistical Methods in Biological Assay*. Second edition. Griffin Press, London.

Thompson, W.R. 1947. *Bacteriological Reviews*. Vol II, No. 2 (June): 115-145.

Stephan, C.E. 1977. Methods for calculating an LC₅₀. *Aquatic Toxicology and Hazard Evaluations*. Pages 65-84
In American Society for Testing and Materials, Pub. No. STP634.

Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite


PMRA Submission Number {.....}

EPA MRID Number 45390802


Data Requirement:	PMRA DATA CODE	{.....}
	EPA DP Barcode	D275034
	OECD Data Point	Mortality
	EPA MRID	45390802
	EPA Guideline	§ 71-2

Test material: N65DW **Purity:** 100% a.i.
Common name: Mineral Oil
Chemical name: IUPAC: Not reported
CAS name: Not reported
CAS No.: 72623-86-03
Synonyms: Not reported


Primary Reviewer: Gregory Hess
Staff Scientist, Dynamac Corporation

Signature: 
Date: 8/6/01

QC Reviewer: Teri Myers, Ph.D.
Staff Scientist, Dynamac Corporation

Signature: 
Date: 8/6/01

Primary Reviewer: Stephen Carey
Biologist; ERB3, EFED, USEPA
{EPA}

Signature: 
Date: 10/28/01

Reference/Submission No. {.....}

Company Code {.....} [For PMRA]
Active Code {.....} [For PMRA]
EPA PC Code 063502

Date Evaluation Completed: November 28, 2001

CITATION: Gallagher, S.P., J. Grimes and J.B. Beavers. 2001. N65DW: A Dietary LC50 Study with the Northern Bobwhite. An unpublished study performed by Wildlife International, Ltd. 8598 Commerce Drive, Easton, MD 21601 and sponsored by Petro-Canada Lubricants, 2489 North Sheridan Way, Mississauga, Ontario Canada. Laboratory project number 480-102 initiated on May 2, 2000 and completed on February 9, 2001.

Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

EPA MRID Number 45390802

EXECUTIVE SUMMARY:

The acute dietary toxicity of Mineral Oil to 10 day old Northern Bobwhite (*Colinus virginianus*) was assessed over 8 days. Nominal dietary concentrations were 0, 562, 1000, 1780, 3160 and 5620 ppm. Measured dietary concentrations were 0.0, 576.4, 984, 1639.5, 3111 and 5518.3 ppm. The 8-day acute dietary LC₅₀ was >5518.3 ppm. The 8 day NOEC of Mineral Oil based on mortality and sublethal effects, was >5518.3 ppm. According to the US EPA classification, N65DW would be classified as practically nontoxic to Northern Bobwhite on an acute subacute dietary basis.

This toxicity study is scientifically sound and satisfies the guideline requirement for an acute dietary toxicity study on Northern bobwhite quail because no toxicity was elicited at the highest concentration tested. This study is classified as Core.

Results Synopsis

Test Organism Size/Age(mean Weight): 10 days (20 g)

LC₅₀: >5518.3 ppm 95% C.I.: NA

NOEC: >5518.3 ppm

Sublethal effects: None

I. MATERIALS AND METHODS

GUIDELINE FOLLOWED: U.S. EPA Series 850-Ecological Effects Test Guidelines OPPTS Number 850.2200; section 71-2. OECD Guideline 205, Guideline for testing of Chemicals, Avian Dietary Toxicity test. ASTM Standard E857-87.

Deviations included:

1. Necropsies were not performed/reported after test termination.
2. The stability of the test substance was not indicated and OECD requirements were not reported.

COMPLIANCE: Signed and dated GLP, Quality Assurance and Data Confidentiality statements were provided.

A. MATERIALS:

1. Test Material N65DW (Mineral Oil)

Description: Clear liquid

Lot No./Batch No. : 971488

Purity: 100%

Stability of Compound: Not reported, OECD requirements not reported.
(OECD requires water solubility, stability in water and light, pKa, Pow, vapor pressure of test compound)

Storage Conditions of

Test Chemicals: The test substance was stored under ambient conditions.

2. Test organism:

Species (common and scientific names): Northern bobwhite (*Colinus virginianus*)
(EPA recommends that either bobwhite quail or mallard duck be used.)

Age at study initiation: 10 days old
(EPA requires: 10-14 days old)

Weight at study initiation: (mean and range): mean=20g; range=18-23 g

Source: Wildlife International, Ltd Production Flock, Easton, MD.

B. STUDY DESIGN:

1. Experimental Conditions

a) Range-finding Study: Not reported

b) Definitive Study:

Table 1 . Experimental Parameters

Parameter	Details	Remarks <i>Criteria</i>
Acclimation period: conditions (same as test or not): feeding: health (any mortality observed):	-10 days -Same as test -Birds fed <i>ad libitum</i> during acclimation and exposure periods. Birds were observed for mortality, abnormal behavior and physical injury daily during acclimation period	
Pen size and construction materials	72 x 90 x 23 cm; external walls, ceilings and floors were constructed of galvanized steel wire and sheeting.	----- EPA requires: about 35 x 100 x 24 cm
Test duration	5 days of exposure and 3 days of post exposure observation	----- EPA requires: 5 days with treated feed and at least 3 days observation with "clean" feed.
Test concentrations nominal: measured:	0 (control), 562, 1000, 1780, 3160 and 5620 ppm 0.0 (control), 576.4, 984, 1639.5, 3111 and 5518.3 ppm.	The reviewer calculated the mean measured concentrations as the average of dietary samples from days 0 and 5 (p. 29). ----- Four minimum, 5 or 6 strongly recommended, in a geometric scale, unless $LC_{50} > 5000$ ppm.

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Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

EPA MRID Number 45390802

Parameter	Details	Remarks <i>Criteria</i>
Solvent/vehicle, if used type: amount:	Corn oil 2%	<i>EPA requires: Distilled water, corn oil, propylene glycol, 1% carboxymethylcellulose, or gum arabic. Solvent: not more than 2%.</i>
Diet preparation and feeding	Test material was mixed with feed; feed was analytically verified for proper dosing regime via FTIR	<i>EPA requires: Control group tested with diet containing the maximum amount of vehicle used in treated diets?</i>
Feed withholding period	0 Days	
Stability and homogeneity of test material in the diet determined (Yes/No)	Yes	Frozen and ambient stability were determined for all test concentrations. Homogeneity was determined for the lowest and highest treatment levels only.
Number of birds per replicate/groups for negative control: for vehicle control: for treated:	30 10 NA	<i>EPA requires: 10 (strongly recommended)</i>
Number of replicates/group (if used) for negative control: for vehicle control: for treated:	6 2 NA	

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Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

EPA MRID Number 45390802

Parameter	Details	Remarks
		Criteria
Test conditions temperature: relative humidity(%): photoperiod:	brooding compartment mean = 38°C, mean room temp. 26.9°C ± 1.4°C 39% ± 6% 16 hr light/ 8 hr dark	The brooder temperature was slightly higher than recommended. ----- <i>Brooder temperature:</i> about 35°C (95°F) <i>Room temperature:</i> 22-27°C (71-81°F) <i>Relative humidity:</i> 30-80% <i>Photoperiod:</i> Minimum of 14 h of light.
Reference chemical, if used	NA	

2. Observation:

Table 2: Observations

Criteria	Details	Remarks
		Criteria
Parameters measured (mortality/body weight/ mean feed consumption/ others)	Mortality, body weight, and food consumption by pen.	
Indicate the stability and homogeneity of test chemical in the diet	Stability averaged 114, 105, 110, 104 and 107% of the Day 0 after being held at room temperature for 5 days in the 562, 1000, 1780, 3160 and 5620 ppm test concentrations, respectively.	
Indicate if the test material was regurgitated	Not reported	

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Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

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Treatments on which necropsies were performed	Not performed	
Observation intervals	Observations were made at least once daily for mortality, toxicological responses. Body weights were measured on day 0, 5, and 8. Food consumption was measured daily throughout the exposure period (days 1-5) and once during the post-exposure period (days 6-8).	
Were raw data included?	Yes	

II. RESULTS AND DISCUSSION:

A. MORTALITY:

No treatment-related mortality was observed in any group.

One bird in the control group suffered a leg injury on day 0, this condition continued throughout the test duration.

Two control birds were also noted as toe picked and lame on day 7 of the test.

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Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

EPA MRID Number 45390802

Table 3: Effect of N65DW (Mineral Oil) on mortality of Northern bobwhite quail.

Treatment Nominal values mg/kg dw diet (ppm) (mean measured)*	No. of birds	Cumulative mortality								
		day 1	day 2	day 3	day 4	day 5	day 6	day 7	day 8	
Negative control; < 30 (0)	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
Solvent/vehicle control (2% corn oil)	30	0	0	0	0	0	0	0	0	0
562 (576.4)	10	0	0	0	0	0	0	0	0	0
1000 (984)	10	0	0	0	0	0	0	0	0	0
1780 (1639.5)	10	0	0	0	0	0	0	0	0	0
3160 (3111)	10	0	0	0	0	0	0	0	0	0
5620 (5518.3)	10	0	0	0	0	0	0	0	0	0
NOEL	>5518.3 ppm									
LC ₅₀	>5518.3 ppm									
Reference chemical	mortality	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	LC ₅₀	N/A								
	NOAEL	N/A								

* The reviewer calculated the mean measured concentrations using data from days 0 and 5 from the diet analysis report (p. 29).

B. SUB-LETHAL TOXICITY ENDPOINTS:

No signs of toxicity were observed in any of the treatment groups. Birds in all test concentrations were normal in appearance and behavior for the duration of the test.

Table 4: Sublethal effects of N65DW (Mineral Oil) on Northern bobwhite quail.

Treatment Nominal values mg/kg dw diet (ppm) (mean measured)*	Observation					
	body weight			food consumption		other
	day 0	day 5	day 8	day 0-5	day 6-8	% affected
Negative control	N/A	N/A	N/A	N/A	N/A	N/A
Solvent/vehicle control	20	32	40	8	11	0
562 (576.4)	20	32	40	9	8	0

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Data Evaluation Report on the Acute Dietary Toxicity of N65DW (Mineral Oil) to Avian Species Northern Bobwhite

PMRA Submission Number {.....}

EPA MRID Number 45390802

1000 (984)	20	33	41	10	10	0
1780 (1639.5)	20	32	39	9	11	0
3160 (3111)	20	33	41	9	11	0
5620 (5518.3)	20	32	41	8	9	0
NOEL	>5518.3 ppm					
EC ₅₀	>5518.3 ppm					
Reference chemical	effect	N/A	N/A	N/A	N/A	N/A
	NOAEL	N/A				
	LC ₅₀	N/A				

* The reviewer calculated the mean measured concentrations using data from days 0 and 5 from the diet analysis report (p. 29).

C. STATISTICS:

The study authors reported that there were no treatment related mortalities observed in this study. Therefore, it was not possible to calculate an LC50 value using the computer program of C.E. Stephan. The LC50 value was determined to be greater than the highest concentration tested.

D. VERIFICATION OF STATISTICAL RESULTS:

Statistical Method: Observation analysis was performed due to the absence of mortality in the control and treatment levels.

LC₅₀: >5518.3 ppm 95% C.I.: N/A

NOEL: >5518.3 ppm

Probit Slope: N/A 95% C.I.: N/A

Adjusted for active ingredient: (Optional if over 80% ai)

LC₅₀: NA 95% C.I.: N/A

NOEL: NA

E. STUDY DEFICIENCIES:

All other reported deviations were considered minor and did not affect the acceptability or the validity of the study.

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F. REVIEWER'S COMMENTS:

The reviewer calculated measured concentrations as the average of day 0 and 5 measured concentrations from the diet analysis results (p. 29).

The reviewer's conclusions were identical to those reported by the study authors.

G. CONCLUSIONS:

The study is scientifically sound and satisfies US EPA guidelines, it is classified as Core.

LC₅₀: >5518.3 ppm 95% C.I.: N/A

NOEL: >5518.3 ppm

Probit Slope: N/A 95% C.I.: N/A

Sublethal effects: None

Adjusted for active ingredient: (Optional if over 80% ai)

LC₅₀: NA 95% C.I.: N/A

NOEL: NA

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