US EPA ARCHIVE DOCUMENT

Data Evaluation Record

1. Chemical: PT No. 137-M (SYSTEM), Copper Carbonate

2. Formulation: ~~Unknown~~ 55.8 % a.i.

3. Citation: Acute Oral Toxicity Study - Mallard Ducks. Industrial Biotest Laboratory Report No. J-7624. 10/22/69.
MRID# R10COP02

4. Reviewed by: Carol M. Natella
Wildlife Biologist
Ecological Effects Branch, HED

5. Date Reviewed: June 1, 1981

6. Test Type: Avian acute oral

7. Reported Results: The test material is shown to be unpalatable at a level of five percent in the feed and water and emetic at dose levels as low as 1.0 mg/kg. Due to emesis at all levels, determination of a definite minimal lethal dose or LD_{50} value was not possible.

8. Reviewer's Conclusions: The study is scientifically sound and shows that PT No. 137-M can cause mortality in mallard ducks at levels at least as low as 147 mg/kg, and caused emesis at levels ranging from 1.0 -10,000 mg/kg. This study will not support a registration requirement, since inadequate numbers of birds were tested at each dose level.

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Materials/Methods

Test Procedures

The animals employed in the study were 16-week old pen-reared mallards ducks. The animals were observed for a period of 21 days prior to testing. A total of 31 animals were divided into 18 test groups and one control group. Test material was administered on a mg/kg fasted body weight basis either by capsule or oral gavage. Eighteen dose levels ranging from 10,000 to 1.00 mg/kg were tested. All ducks were fasted for 15 hours prior to dosing. Food and water were allowed ad libitum all other times. One animal received the test material mixed as a 5% mixture with its food and water (Test XVIII).

Observations were made daily for 21 days after dosing to ascertain the presence or absence of clinical signs of toxicity attributable to the test material. All animals surviving after the 21-day observation period were weighed and sacrificed. These animals and all animals dying during the observation period were given a gross pathological examination.

Statistical Analysis

No statistical anlaysis was performed on these data.

Discussion/Results

The test animal receiving the 5% mixture in food and water refused the test feed and did not drink the water suspension of the test material. After 48 hours the animal was placed back on unadulterated feed and water.

All other test animals exhibited emesis. Six of these animals died due to the test material during the 21-day observation period. Examination of post-mortem animals revealed hemorrhage in the gastrointestinal tract. Autopsy of test survivors revealed no pathology attributable to test material. (See table).

The six animals which died did not eat from the time of dosing until the time of death. No adverse effects on food consumption were noted in any of the other test animals.

Group	Sex	Dose Level mg/Kg	Method of Administration	Time of Emesis following dosing (min)	Time of death following dosing	Post-Mortem
Control	F	Sham	Gavage	None	None	Normal
I	M	10,000	(1 Capsule, 1 Gavage)	20	--	Normal
	F	10,000		5	20 hours (17 5/6 h.)	Multiple hemorrhage of proventriculus and duodenum.
II	M	6,810	Gavage	5	19 3/4 hours (17 5/6 h.)	Convulsions. Multiple hemorrhage of proventriculus and duodenum.
	M	6,810	Gavage	5	4 days	(Heart auricles enlarged slightly). Other organs normal.
III	M	2,150	Capsule	35	———	Normal
IV	M	1,000	Capsule	40	———	Normal
	F	1,000	Capsule	40	———	Normal
	M	1,000	Capsule	40	———	Normal
V	F	681	Capsule	35	23 hours	Convulsions. Heart auricles slightly enlarged.
	M	681	Capsule	35	———	Normal
VI	M	464	Capsule	35	24 hours	Heart auricles slightly enlarge. Massive hemorrhage of proventriculus.
	F	464	Capsule	40	—	Normal
VII	M	316	Capsule	30	—	Normal
	F	316	Capsule	30	—	Normal
VIII	M	215	Capsule	35	—	Normal
	F	215	Capsule	35	—	Normal

Group	Sex	Dose Level mg/Kg	Method of Administration	Time of Emesis following dosing (min)	Time of death following dosing	Post-Mortem
IX	M	147	Capsule	35	6 days	Three 1.2 mm area hemorrhage in gizzard. General slight hemorrhage of proventriculus
X	M	100	(2 Capsule, 1 Gavage)	40	—	Normal
	F	100		75	—	Normal
	M	100		125	—	Normal
XI	F	82.6	Gavage	125	—	Normal
XII	M	68.1	(1 capsule, 1 Gavage)	45	—	Normal
	F	68.1		7	—	Normal
XIII	M	21.5	Gavage	50	—	Normal
XIV	M	10.0	(1 Capsule, 1 Gavage)	90	—	Normal
	M	10.0		15hr	—	Normal
XV	F	2.15	Gavage	120	—	Normal
XVI	M	1.47	Gavage	110	—	Normal
XVII	F	1.00	Gavage	105	—	Normal
XVIII	M	10,000 (Intended level in food and water)	—	None	—	Normal

Reviewer's Evaluation

A. Test Procedure

This study is essentially a range-finding test; 17 dose levels with only one to three test birds at each level were used. An LD_{50} can not be determined from these results due to the fact that the test material caused emesis at all dose levels.

During the audit of this study, several discrepancies between the report and the supporting data were brought to light:

1. The method of compound administration via gavage or capsule could not be determined from the raw data for test groups III-IX and test groups XII and XIV.

2. Page six of the report states that observations were made daily for 21 days after dosing. This is incorrect as a number of the birds were sacrificed as early as 10 days and as late as 27 days after dosing.

3. Two minor discrepancies were noted between the report and the raw data concerning time of death following dosing. In addition, a post-mortem observation was omitted from the report. Corrected times and the post-mortem observation have been added to the table (in parentheses).

None of the above discrepancies affect the scientific validity of the study. Although the protocol was not followed and an LD_{50} can not be determined, it is still possible to draw certain conclusions from this study. The test material was unpalatable when mixed with food and water and, when administered by capsule or gavage, caused toxic effects (emesis) at all levels. The lowest dose level at which mortality occurred was 147 mg/kg. For the animals which survived, however, no apparent adverse effect was noted on food consumption although daily measurements were not taken. These animals also gained weight normally.

B. Statistical Analysis

No statistical analysis was performed on these data.

C. Conclusions

1. Category: Supplemental

2. Rationale: An LD_{50} can not be determined from the results of this study.

3. Repairability: No

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