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BIOMED

BIOMED, INCORPORATED

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LABORATORY REPORT

CUSTOMER:

Wayne Slater
Battelle, Pacific Northwest Laboratories
P.O. Box 999
Richland, WA 99352

LABORATORY USE ONLY	
LAB #:	11872
REPORT DATE	12/13/89
CUSTOMER P.O. #	
APPROVED	

JAN 1995 RECEIVED EDMC

RAT TOXICITY TEST
BIOMED NO. 11872

Received in support of PO 084075-AKS
W Wayne Slater 12/21/89

SUBJECT:

14 Day Acute Oral Rat Toxicity Test on Battelle Sample (PWO-composite 2, BNW 5X2877) Biomed No. 11872.

KWS 12/21/89

METHODS:

The sample was tested for its toxicity to male albino Sprague Dawley rats. Testing was in accordance with guidelines in the State of Washington's Biological Testing Methods DOE 80-12, revised July, 1981. The test groups included 10 rats gavaged at 5000 mg per kilo body weight, 10 rats at 500 mg per kilo body weight. A control group of 10 rats were gavaged with 2 ml of the diluent used for the test samples. The diluent was distilled water. The animals were randomized according to a random number table. The animals were weighed and gavaged on day 1. They were weighed on day 7 and 14. At the termination of the test all animals were necropsied.

RESULTS AND CONCLUSIONS:

Table I. Summarizes the daily observations and weekly weights of the rats receiving PWO-composite 2 at 5000 mg (5g) per kilo body weight.

Table II. Summarizes the daily observations and weekly weights of the rats receiving PWO-composite 2 at 500 mg (0.5g) per kilo body weight.

Table III. Summarizes the daily observations and weekly weights of the rats receiving the vehicle (distilled water) at 2 ml per rat.

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Table IV. Compares the average body weight gains of the rats receiving 5000 mg, 500 mg, and 0 mg per kilo body weight of the test material PWO-composite 2.

There was 1 mortality during the test period. Rat no. 136 gavaged with 5000 mg per kilo body weight died three days after treatment. The animal on necropsy showed a perforated oesophagus with the test material in the lung cavity. The weight gain averages the 5000 mg dose group was based on 9 animals. There were no other mortalities. All of the animals were healthy and showed positive weight gains during the study. Compared to the control group, the weight gains were similar in both treated groups (Table IV.) this indicates a lack of toxicity to the test material at 5000 mg per kilo body weight. Due to its lack of toxicity, Biomed sample No. 11872 is considered not to be a dangerous waste.

Respectfully submitted,

John J. Majnarich

John J. Majnarich, Ph.D.
Scientific Director

Warren Ladiges

Warren Ladiges, DVM
Diplomate American College
of Laboratory Medicine

DATA SHEET FOR ACUTE ORAL RAT TOXICITY TEST

TABLE I.

INDUSTRY/TOXICANT Puic-Composite 2 BIOMED RESEARCH LABORATORIES, INC. # 11972

ADDRESS Battelle ANALYST MAINARich + Ladiges

COLLECTOR Wayne Slater BEGINNING TIME & DATE 11/17/89 11:10 A.M.

DATE SAMPLE COLLECTED ENDING TIME & DATE 12/1/89

TEST ORGANISM Male Sprague-Dawley Rats DOSAGE LEVEL 5000mg. (sg)/kg.

RAT #	WEIGHT 11/17 0	WEIGHT 11/24 7	WEIGHT 12/1 14	DOSE ml	OBSERVATIONS AND DATES 11/17 4HR	11/19	11/19	11/20	11/21	11/22	11/23	11/24	11/25	11/26	11/27	11/28	11/29	11/30	12/1	COMMEN Necrop
131	211	244	290	2.11	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
132	212	254	325	2.12	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
133	212	266	290	2.12	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
134	188	333	265	1.98	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
135	229	302	347	2.21	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
136	196	272	310	1.96	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
137	229	dead	Test material in lung cavity 11/21/89 (Perforated oesophagus)	2.29																—
138	237	288	339	2.37	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
139	196	229	259	1.96	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
140	230	297	332	2.3	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
INITIALS																				

DATA SHEET FOR ACUTE ORAL RAT TOXICITY TEST

TABLE II.

INDUSTRY/TOXICANT PWU-Composite 2 BIOMED RESEARCH LABORATORIES, INC. # 11972

ADDRESS Battelle ANALYST MainArich + Ladigas

COLLECTOR Wayne Slater BEGINNING TIME & DATE 11/17/89 10:45

DATE SAMPLE COLLECTED ENDING TIME & DATE 12/1/89

TEST ORGANISM Male Sprague-Dawley Rats DOSAGE LEVEL 500mg (0.5g)/kg

RAT #	WEIGHT 11/17 0	WEIGHT 11/24 7	WEIGHT 12/1 14	DOSE Ml.	OBSERVATIONS AND DATES 11/17 4HR	11/18	11/19	11/20	11/21	11/22	11/23	11/24	11/25	11/26	11/27	11/28	11/29	11/30	12/1	COMMENTS Necropsy
121	196	250	292	0.96	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
122	223	296	339	1.11	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
123	232	301	338	1.16	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
124	209	259	283	1.04	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
125	204	252	267	1.02	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
126	197	264	297	0.96	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
127	212	269	304	1.06	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
128	216	287	312	1.08	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
129	214	278	317	1.07	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
130	193	239	285	0.96	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
INITIALS	JM	MK	JM	JM	JM	JM	JM	JM	JM	JM	JM	MK	JM	JM	JM	JM	JM	JM	JM	JM

DATA SHEET FOR ACUTE ORAL RAT TOXICITY TEST

TABLE III.

INDUSTRY/TOXICANT Control — BIOMED RESEARCH LABORATORIES, INC. #Controls for 11871 & 11872

ADDRESS — ANALYST MAJWARich + Ladiges

COLLECTOR — BEGINNING TIME & DATE 11/17/89 11:45 A.M.

DATE SAMPLE COLLECTED 11/17/89 — ENDING TIME & DATE 12/1/89

TEST ORGANISM Male Sprague-Dawley Rats — DOSAGE LEVEL 2 Ml Distilled water/Rat (Controls)

RAT #	WEIGHT 11/17 0	11/24 7	12/1 14	DOSE Ml.	OBSERVATIONS AND DATES 11/17 4HR	11/18	11/19	11/20	11/21	11/22	11/23	11/24	11/25	11/26	11/27	11/28	11/29	11/30	12/1	COMMENTS: Necrops:
141	215	266	293	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg
142	214	273	305	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
143	203	264	273	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
144	157	230	278	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg
145	215	257	270	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg
146	233	300	321	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
147	221	292	330	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg
148	216	257	326	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg
149	217	296	317	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
150	207	262	301	2	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	neg.
INITIALS	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm	gm

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Table IV.

Comparison of the average body weights of the rats receiving by gavage PWO-composite 2 at 5000 mg, 500mg and 0 mg per kilo body weight. The 0 group received 2 ml of distilled water, the diluent used for the other samples.

Test compound	dose mg/kg	No. Rats	Initial wt. g.	7 day wt. g.	14 day wt. g.
PWO-composite 2	5000	9	212.3	265.0	306.3
PWO-composite 2	500	10	209.5	269.5	302.4
Distilled water	2 ml	10	210.0	271.7	301.4