MB Research Laboratories

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Study Title	:	Single Dose Oral Toxicity in Rats
Test Article	:	ZEOLITE PURE, Lot/Batch# 1105248
Author	:	Blair Yasso, B.S., Study Director
Study Completed On	:	18 Jan 2012
Performing Laboratory	:	MB Research Laboratories 1765 Wentz Road P.O. Box 178 Spinnerstown, PA 18968
MB Research Project #	:	MB 11-20448.01
MB Research Protocol #	:	3000-01
Sponsor	:	ZEO Health Ltd. 159 Route 303 Valley Cottage, NY 10989
Citation	:	Blair Yasso, B.S. (2012) Unpublished Report by MB Research Laboratories

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GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practices of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58, and as specified in Principles on Good Laboratory Practices, published by the Organization for Economic Cooperation & Development (OECD), 1997, with the following exceptions:

Test article characterization information did not include certain parameters that the Sponsor indicated are proprietary. Accordingly, the test article characterization was incomplete. See Appendix A for information that was provided. The effect of the lack of full test article characterization information cannot be fully assessed.

Test article characterization information was not conducted according to the Good Laboratory Practices. This is not expected to have an impact on the outcome of the study.

STUDY DIRECTOR:

18JAN2012

Blair Yasso, B.S. Date
MB RESEARCH LABORATORIES

PROJECT NUMBER : MB 11-20448.01
TEST ARTICLE : ZEOLITE PURE, Lot/Batch# 1105248
SPONSOR : ZEO HEALTH LTD.
TITLE : Single Dose Oral Toxicity in Rats
PROTOCOL # : 3000-01

A B S T R A C T

Objective: To determine the potential for toxicity of the test article when administered orally. This study was designed to comply with the standards set forth by the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act, 16 CFR Part 1500.3(c)(2)(i)(A).

Method Synopsis: Ten healthy male Sprague Dawley rats were dosed orally with ZEOLITE PURE, Lot/Batch# 1105248, at 5000 mg/kg of body weight. Mortality and systemic observations were recorded 3-4 hours post dose and once daily thereafter for 14 days. Body weights were recorded pre-test.

Summary: All ten male rats survived the single 5000 mg/kg oral dose.

Diarrhea was observed in one animal within 4 hours post dose. Otherwise, no abnormal physical signs were observed.

Conclusion: The oral LD_{50} of ZEOLITE PURE, Lot/Batch# 1105248, is greater than 5000 mg/kg of body weight in male rats. Therefore, the test article is not toxic as defined in 16 CFR 1500.3(c)(2)(i).

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OBJECTIVE

To determine the potential for toxicity of the test article when administered orally. This study was designed to comply with the standards set forth by the Consumer Product Safety Commission issued pursuant to and for the implementation of the Federal Hazardous Substances Act, 16 CFR Part 1500.3(c)(2)(i)(A).

TEST ARTICLE

Identity	:	ZEOLITE PURE, Lot/Batch# 1105248
Test Article Characterization	:	See Appendix A for Test Article Characterization.
Stability	:	Not supplied by the Sponsor.
Supplied By	:	ZEO Health Ltd.
Date Received	:	14 Nov 2011
Storage	:	Room temperature and humidity
Description	:	Off-white powder
Sample Preparation	:	24 grams of the test article were brought to a volume of 60 ml with distilled water and mixed to yield a 0.40 g/ml suspension (brown suspension).

TEST DATES

Study Initiation	(date protocol signed)	:	15 Nov 2011
Experimental Start Date	(1st exposure to test substance)	:	29 Nov 2011
Experimental Term Date	(last date data collected)	:	13 Dec 2011
Draft Report Submitted	(if applicable)	:	30 Dec 2011
Final Report Signed	(study completion)	:	18 Jan 2012

EXPERIMENTAL DESIGN

Test Animals

Animals were received from SAGE Labs, Boyertown, PA on 22 Nov 2011. Following an acclimation period of at least one week, ten healthy male Sprague Dawley rats were selected for this test without conscious bias from a larger group.

The animals were born the week of 04 Oct 2011. The pretest body weight range was 227 - 272 grams. Animals were identified by cage notation. The animals were housed 5 per cage in suspended cages. Absorbent paper bedding was placed beneath the cages and changed at least three times per week. Fresh PMI Rat Chow (Diet #5012) was freely available except for 16-20 hours prior to dosing. Water was available *ad libitum*. The animal room, reserved exclusively for rats on acute tests, was temperature controlled, had a 12-hour light/dark cycle and was kept clean and vermin free.

EXPERIMENTAL DESIGN (continued)

Dosing

The test article was mixed with distilled water to make dosing by gavage possible. The dose was based on the dry weight of the test article. A single dose was administered orally by syringe and dosing needle at a dose level of 5000 mg/kg.

Type and Frequency of Observations

In Vivo: Animals were observed 3-4 hours post dose and once daily thereafter for 14 days for mortality, toxicity and pharmacological effects. Body weights were recorded pretest.

Post Mortem: All animals were humanely sacrificed using CO_2 following study termination.

Analysis of Data

The test article is not considered to be toxic if less than one half (1/2) of the animals die at a dose of 5000 mg/kg (16 CFR 1500.3(c)(2)(i)).

Retention of Data

Upon signing the final report, all raw data, supporting documentation and reports are submitted to the Archivist by the Study Director. The raw data is filed at MB Research by project number. The final report is filed at MB Research by Sponsor name and MB project number.

All data generated during the conduct of this study are archived at MB Research for at least 10 years from the date of the final report. The Sponsor will be contacted in writing to determine final disposition of the records. If the Sponsor fails to respond within the 90 days, the archived material will be promptly discarded.

Any remaining test article will be discarded following submission of the report.

Amendment to the Protocol

There were no amendments to the protocol.

RESULTS & DISCUSSION

1. **LD_{50}**
   The oral LD_{50} is greater than 5000 mg/kg of body weight in male rats.

2. **Mortality**
   All ten male rats survived the single 5000 mg/kg oral dose.

3. **Systemic Observations**
   Diarrhea was observed in one animal within 4 hours post dose. Otherwise, no abnormal physical signs were observed.

CONCLUSION

The oral LD_{50} of ZEOLITE PURE, Lot/Batch# 1105248 is greater than 5000 mg/kg of body weight in male rats. Therefore, the test article is not toxic as defined in 16 CFR 1500.3(c)(2)(i).

FINAL REPORT

Approved by:

Blair Yasso, B.S.
Study Director

18JAN2012
Date

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QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected a critical phase of this study, audited the raw data and the report and determined that the methods and results contained herein accurately reflect the raw data. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Inspection Results Reported	
			Sty. Dir.	Mgmt.
29 Nov 2011	Dose Administration	Tanja Vaneman	29 Nov 2011	29 Nov 2011
14 Dec 2011	Raw data audit	Matt Lowrie	14 Dec 2011	14 Dec 2011
26 Dec 2011	Draft report audit	Matt Lowrie	26 Dec 2011	17 Jan 2012
17 Jan 2012	Final report audit	Matt Lowrie	17 Jan 2012	17 Jan 2012

Matt Lowrie 17JAN12

Matt Lowrie, B.S. Date
Quality Assurance Unit

MB Research Laboratories

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SPONSOR
TEST ARTICLE CHARACTERIZATION INFORMATION

In compliance with Good Laboratory Practice (GLP) regulations, a characterization of the test article is required and should include identity, strength, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and will be included in the final report. (EPA 40 CFR 160.105 and 792.105; FDA 21 CFR 58.105, OECD 6.2).

In addition, the test article characterization should be performed in compliance with the Good Laboratory Practices.

Any exceptions to the GLP requirements will be indicated in the Compliance Statement of the final report.

Accordingly, please supply the following information for each test article submitted:

Proprietary is defined for this form as known by the Sponsor, but confidential.

Please do not use NA for any portion of this form.

Test Article Identity ZEOLITE PURE Lot/Batch# 1105248

Storage X Room Temperature ☐ Refrigerate(2-8°C) ☐ Other: _____

Stability _____ ☐ unknown ☐ proprietary

Purity _____ X unknown ☐ proprietary

Strength _____ ☐ unknown ☐ proprietary

Composition Clinoptilolite Zeolite ☐ unknown ☐ proprietary

Uniformity _____ ☐ unknown ☐ proprietary

☐ This characterization **was** conducted under GLPs

☐ This characterization **was** conducted under GMPs

☐ This characterization **was not** conducted under GLPs **or** GMPs.

BY: _____ FOR: ZEO Health Ltd
(signature) (company)

11-09-11
(date)

Per conversation with Micah Portney on 15 November 2011 @ 1:25pm Storage: Stability, strength and uniformity are proprietary. Also, the characterization was not conducted under GLPs or GMPs. BJC 15 Nov 2011