MB RESEARCH LABORATORIES

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T R A N S M I T T A L F O R M

DATE : **April 20, 2006**

TO : **Mr. David J. Kelly**

COMPANY : WT Burnett
2112 Montevideo Road
Jessup, MD 20794

FROM : Barbara Kweder

Transmitted herewith are the following:

- ☒ DRAFT REPORT (s)
- ☐ FINAL REPORT
- ☐ INVOICE (s)
- ☐ RAW DATA
- ☒ PROTOCOL SIGNATURE PAGE (s)
- ☐ SPECIMEN DISPOSITION MEMO
- ☐ OTHER

PROTOCOL	STUDY TITLE	TEST ARTICLE	MB PROJECT #
3130	Dermal Irritation in Rabbits	1.8C Polyester Pollyurethane Foam	06-14418.03

PLEASE RESPOND WITH YOUR APPROVAL FOR FINAL REPORT VIA FAX, PHONE OR EMAIL.

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VOLUME I

Study Title	:	Primary Dermal Irritation in Rabbits
Test Article	:	1.8C Polyester Polyurethane Foam (RUN 52-30)
Author	:	Daniel R. Cerven, M.S., Study Director
Study Completed On	:	
Performing Laboratory	:	MB Research Laboratories 1765 Wentz Road P.O. Box 178 Spinnerstown, PA 18968
MB Research Project #	:	MB 06-14418.03
MB Research Protocol #	:	3130
Sponsor	:	WT Burnett 2112 Montevideo Road Jessup, MD 20794
Citation	:	Daniel R. Cerven, M.S. (2006) Unpublished Report by MB Research Laboratories

A030 is dap no. patch test

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
Test article : 1.8C Polyester Polyurethane Foam
Protocol : 3130

GOOD LABORATORY PRACTICES COMPLIANCE STATEMENT

This study was conducted in accordance with the Good Laboratory Practice requirements of the EPA, 40 CFR 160 and 792, FDA 21 CFR 58, and the OECD, The Testing of Chemicals, 1997.

The Test Article Characterization was supplied by the sponsor prior to study initiation. However, it was not conducted under Good Laboratory Practices.

STUDY DIRECTOR :

_____
Daniel R. Cerven, M.S. Date
MB RESEARCH LABORATORIES

PROJECT NUMBER	:	**MB 06-14418.03**
TEST ARTICLE	:	**1.8C Polyester Polyurethane Foam**
SPONSOR	:	**WT BURNETT**
TITLE	:	**Primary Dermal Irritation in Rabbits**
PROTOCOL #	:	**3130**

A B S T R A C T

Objective: To determine the irritation potential of the test article when applied dermally. This study was designed to comply with the FHSA standards set forth by 16 CFR 1500.41.

Method Synopsis: Six healthy New Zealand White rabbits were dosed dermally with 1.8C Polyester Polyurethane Foam. The test article (a 2.5 x 2.5 cm square) was applied to one intact and one abraded site on the clipped back of each rabbit. The sites were occluded for 24 hours. Skin reactions were evaluated by the Draize technique at 24 and 72 hours after dosing. The Primary Irritation Index was calculated. Body weights were recorded pretest.

Summary:

There was no erythema or edema noted at any observation period.

There were no abnormal physical signs noted during the observation period.

Conclusion: The Primary Irritation Index is 0. Therefore, 1.8C Polyester Polyurethane Foam is not a dermal irritant as defined in 16 CFR 1500.41 and 16 CFR 1500.3(c)(4).

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
Test article : 1.8C Polyester Polyurethane Foam
Protocol : 3130

OBJECTIVE

To determine the irritation potential of the test article when applied dermally. This study was designed to comply with the FHSA standards set forth by 16 CFR 1500.41.

TEST ARTICLE

Identity	: 1.8C Polyester Polyurethane Foam
Test Article Characterization	: See Appendix A for Test Article Characterization.
Stability	: According to the Test Article Characterization, the test article is stable.
Supplied By	: WT Burnett
Date Received	: 03/13/06
Description	: Blue foam
Storage	: Room temperature and humidity
Sample Preparation	: The test article was cut into 2.5 x 2.5 cm squares.

TEST DATES

Study Initiation:	(date protocol signed)	: 03/29/06
Experimental Start Date	(1st exposure to test substance)	: 04/04/06
Experimental Term Date	(last date data collected)	: 04/07/06
Draft Report Signed	(if applicable)	: 04/18/06
Final Report Signed	(study completion)	:

EXPERIMENTAL DESIGN

Test Animals

Animals were received from Millbrook Breeding Labs, Amherst, MA on 02/08/06 and 03/29/06. Following an equilibration period of at least one week, six healthy New Zealand White rabbits were selected for this test from a larger group without conscious bias.

The animals were born the weeks of 11/20/05 and 01/08/06. Pretest body weight range was 2.4 - 3.8 kg.

The animals were identified by cage notation and a uniquely numbered metal eartag. The animals were housed 1/cage in suspended cages. Bedding, placed beneath the cages, was changed at least three times/week. Fresh PMI Rabbit Chow (Diet #5321) was provided daily. Water was available ad libitum. The animal room, reserved exclusively for rabbits on acute tests, was temperature controlled, had a 12 hour light/dark cycle and was kept clean and vermin free.

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
Test article : 1.8C Polyester Polyurethane Foam
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EXPERIMENTAL DESIGN (continued)

Site Preparation

Prior to application of the test article, the back and sides of each animal were clipped free of hair. The left side of each animal was abraded with a bent tip needle. Three abrasions, approximately 2-3 cm apart, extending the length of the exposure site were made. The abrasions were sufficiently deep to penetrate the stratum corneum, but not deep enough to produce bleeding. The right side of each animal remained intact.

Dosing

The test article (a 2.5 x 2.5 cm square) was applied to two areas, 1 intact and 1 abraded, on the prepared site, on the back of each of six rabbits.

The test article was placed under 2.5 x 2.5 cm, 4 ply, surgical gauze patches which were secured with non-irritating adhesive tape. The torso was wrapped with plastic in a semi-occlusive manner which was secured with non-irritating adhesive tape. The sites were occluded for 24 hours at which time the patches were removed. The test article was removed from the test site at the end of the exposure period, prior to scoring for dermal reactions.

Type and Frequency of Observations

Animals were observed for skin reactions at 24 and 72 hours following application of the test article. Erythema and edema were scored according to the numerical Draize technique below (Draize, J. H. et al., J. Pharm. Exp. Ther. 82:377-390, 1944).

Erythema and Eschar

No erythema	0
Very slight erythema (barely perceptible)	1
Well defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Edema

No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1.0 mm)	3
Severe edema (raised more than 1.0 mm, extending beyond the area of exposure)	4

Body weights were recorded pretest.

The general health of the animals was monitored at each observation time. All animals were humanely sacrificed using CO_2 following study termination.

EXPERIMENTAL DESIGN (continued)

Analysis of Data

The Primary Irritation Index was calculated by adding the mean values (6 rabbits) for erythema/eschar and edema on intact and abraded skin at 24 and 72 hours (a total of 8 values) and dividing the sum by 4.

A primary irritant is defined as a substance which is not corrosive but which results in an empirical score of 5 or more (16 CFR 1500.3(c)(4)).

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.

The test article will be returned to the sponsor following submission of the report.

Amendment to the Protocol

There were no amendments to the protocol.

Deviation to Good Laboratory Practices

The Test Article Characterization was supplied by the sponsor prior to study initiation. However, it was not conducted under Good Laboratory Practices. The impact this has on the study cannot be fully assessed.

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
Test article : 1.8C Polyester Polyurethane Foam
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RESULTS

Table 1: Dermal Observations, Body Weights and Systemic Observations

	Rabbit Eartag	G8462	G8464	G8465	G8460	G8512	G8513	
	Sex	F	F	F	F	M	M	
Pretest Body Weight - kg		3.8	3.8	3.8	3.7	2.8	2.4	
Time: Postdose				**Erythema & Eschar Formation**				**Mean Scores**
Intact skin	24 hours	0	0	0	0	0	0	0.00
	72 hours	0	0	0	0	0	0	0.00
Abraded skin	24 hours	0	0	0	0	0	0	0.00
	72 hours	0	0	0	0	0	0	0.00
				Edema				
Intact skin	24 hours	0	0	0	0	0	0	0.00
	72 hours	0	0	0	0	0	0	0.00
Abraded skin	24 hours	0	0	0	0	0	0	0.00
	72 hours	0	0	0	0	0	0	0.00
						Sum of Mean Scores =		0.00
				Primary Dermal Irritation Index (PII) = Sum of Mean Scores/4 =				0.00
				Systemic Observations				
	24 hours	A	A	A	A	A	A	
	72 hours	A	A	A	A	A	A	

A = Normal

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
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DISCUSSION

1. **Dermal Observations (Table 1)**
   There was no erythema or edema noted at any observation period.

2. **Systemic Observations (Table 1)**
   There were no abnormal physical signs noted during the observation period.

CONCLUSION

The Primary Irritation Index is 0. Therefore, 1.8C Polyester Polyurethane Foam is not a dermal irritant as defined in 16 CFR 1500.41 and 16 CFR 1500.3(c)(4).

DRAFT REPORT

Approved by: _____ 18 Apr 06
Daniel R. Cerven, M.S. Date
Study Director

Upon approval of this draft report by the sponsor, a final report with full signatures will be issued.

Study Title : Dermal Irritation in Rabbits
Project # : MB 06-14418.03
Test article : 1.8C Polyester Polyurethane Foam
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QUALITY ASSURANCE EVALUATION

The Quality Assurance Unit has inspected an in-life 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. No changes/modifications from the approved protocol or Standard Operating Procedures were made without proper authorization and documentation. A summary of the compliance inspections is presented below.

Date of Inspection	Phase	Performed By	Date Findings Reported to Mgmt.	Sty. Dir.
04/05/06	Scoring	William J. Kintigh		
04/12/06	Raw data audit	William J. Kintigh		
04/18/06	Draft report audit	William J. Kintigh		
	Final report audit			

A complete Quality Assurance Evaluation statement will be included with the final report.

William J. Kintigh, B.S. Date
Quality Assurance Unit

MB Research Laboratories

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TEST ARTICLE CHARACTERIZATION INFORMATION

In compliance with Good Laboratory Practice (GLP) regulations, a characterization of the test article is required in support of data submissions and should include identity, strength, purity, composition, stability and uniformity. This data must be reviewed by the Study Director prior to study initiation and 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.

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

Test Article Identity	:	Polyurethane foam, Grade 1.8C run # 52
Strength	:	100%
Purity	:	100%
Composition	:	polyester-polyurea cellular polymer
Stability	:	Stable 5°-20° years @ R.Temp + 10-60% R.H.
Uniformity	:	Uniform

☐ This characterization **was** conducted under GLPs *(or)*

☑ This characterization **was not** conducted under GLPs

BY: Walter V. V. Gruber (signature) FOR: Wm. T. Burnett & Co. (company) Foam Division

3/10/06 (date)