AUTHENTICATION OF AMENDMENT TO FINAL REPORT

13F-SFA-MONOMER:

ACUTE DERMAL IRRITATION IN THE RABBIT

PROJECT NUMBER: 1458/0062

REASON FOR AMENDMENT

At the request of the Sponsor, the results were interpreted according to the Globally Harmonized System of Classification and Labelling of Chemicals.

DETAILS OF AMENDMENT

The sentence "The test material does not meet the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals" was added to the conclusion of the report. The sentence "The results were also evaluated according to the Globally Harmonized System of Classification and Labelling of Chemicals" was inserted into the Interpretation of Results section of the report.

Pages 5, 9 and10 are hereby amended.

This amendment does not affect the validity or interpretation of the data.

A. Pooles ..... DATE: 3/8/10 .....

A Pooles
Study Director

This amendment has been audited by the Quality Assurance Unit and is considered to be an accurate account of the project.

G. Wren ..... DATE: 04 AUG 2010 .....

For the Quality Assurance Unit*

***Authorised QA Signatures:**
Senior Audit Staff: J G Riley BSc (Hons) MRQA, J M Crowther MIScT MRQA,
G Wren ONC MRQA, S Bevan BSc (Hons) MRQA, L Blaney MRQA

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SUMMARY

Introduction. The study was performed to assess the irritancy potential of the test material to the skin of the New Zealand White rabbit. The method was designed to meet the requirements of the following:

- OECD Guidelines for the Testing of Chemicals No. 404 "Acute Dermal Irritation/Corrosion" (adopted 24 April 2002)
- Method B4 Acute Toxicity (Skin Irritation) of Commission Directive 2004/73/EC

Results. A single 4-hour, semi-occluded application of the test material to the intact skin of three rabbits produced very slight erythema. One treated skin site appeared normal at the 24-hour observation and the remaining two treated skin sites appeared normal at the 72-hour observation.

3-minute and 1-hour semi-occluded applications of the test material to the intact skin of one rabbit produced no evidence of skin irritation.

Conclusion. The test material produced a primary irritation index of 0.3 and was classified as a mild irritant to rabbit skin according to the Draize classification scheme.

The test material does not meet the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals.

3.3 Interpretation of Results

Calculation of Primary Irritation Index and Grading of Irritancy Potential Using the Draize Scheme

The scores for erythema and oedema at the 24 and 72-hour readings were totalled for the three test rabbits (12 values) and this total was divided by six to give the primary irritation index of the test material. The test material was classified according to the following scheme devised by Draize J H (1959) "Dermal Toxicity" In: Appraisal of the Safety of Chemicals in Foods, Drugs and Cosmetics. Association of Food and Drug Officials of the United States, Austin, Texas, p.47:

Primary Irritation Index	Classification of Irritancy
0	Non-irritant
> 0 to 2	Mild irritant
> 2 to 5	Moderate irritant
> 5 to 8	Severe irritant

If irreversible alteration of the dermal tissue is noted in any rabbit, as judged by the Study Director, which include ulceration and clear necrosis or signs of scar tissue, the test material is classified as corrosive to rabbit skin. Classification according to Draize may, therefore, not be applicable.

The results were also evaluated according to the Globally Harmonized System of Classification and Labelling of Chemicals.

4. ARCHIVES

Unless instructed otherwise by the Sponsor, all original data and the final report will be retained in the Safepharm archives for five years, after which instructions will be sought as to further retention or disposal.

5. RESULTS

5.1 4-Hour Exposure Period

The individual scores for erythema/eschar and oedema are given in Table 1.

Very slight erythema was noted at two treated skin sites one hour after patch removal and at two treated skin sites at the 24 and 48-hour observations.

One treated skin site appeared normal at the 24-hour observation and the remaining two treated skin sites appeared normal at the 72-hour observation.

5.2 1-Hour Exposure Period

The individual scores for erythema/eschar and oedema are given in Appendix 1.

No evidence of skin irritation was noted during the study.

5.3 3-Minute Exposure Period

The individual scores for erythema/eschar and oedema are given in Appendix 1.

No evidence of skin irritation was noted during the study.

6. CONCLUSION

The test material produced a primary irritation index of 0.3 and was classified as a MILD IRRITANT to rabbit skin according to the Draize classification scheme. No corrosive effects were noted.

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