

**AUTHENTICATION OF AMENDMENT  
TO FINAL REPORT**

**13F-SFA-MONOMER:**

**ACUTE EYE IRRITATION IN THE RABBIT**

**PROJECT NUMBER: 1458/0063**

**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 and 10 are hereby amended.

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

..... DATE: 31/8/10 .....

Study Director

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

..... DATE: 04 AUG 2010 .....

For the Quality Assurance Unit\*

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\*Authorised QA Signatures:  
Senior Audit Staff:

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**ACUTE EYE IRRITATION IN THE RABBIT**

**SUMMARY**

**Introduction.** The study was performed to assess the irritancy potential of the test material to the eye 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. 405 "Acute Eye Irritation/Corrosion" (adopted 24 April 2002)
- Method B5 Acute Toxicity (Eye Irritation) of Commission Directive 2004/73/EC

**Result.** A single application of the test material to the non-irrigated eye of three rabbits produced minimal conjunctival irritation. All treated eyes appeared normal at the 48-hour observation.

**Conclusion.** The test material produced a maximum group mean score of 6.0 and was classified as a minimal irritant (Class 3 on a 1 to 8 scale) to the rabbit eye according to a modified Kay and Calandra classification system.

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

If evidence of irreversible ocular damage is noted, the test material will be classified as corrosive to the eye.

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**

Individual and group mean scores for ocular irritation are given in Table 1 and Table 2.

No corneal or iridial effects were noted during the study.

Minimal conjunctival irritation was noted in all treated eyes at the 1 and 24-hour observations.

All treated eyes appeared normal at the 48-hour observation.

## **6. CONCLUSION**

The test material produced a maximum group mean score of 6.0 and was classified as a MINIMAL IRRITANT (CLASS 3 ON A 1 TO 8 SCALE) to the rabbit eye according to a modified Kay and Calandra classification system.

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