

Sponsor:

Lear Chemical Research Corporation
Mississauga, Ontario

FINAL REPORT

Study Title:

Primary Eye Irritation Study of
ACF-50 Lubricant in Rabbits
(FHSA Regulations)

Author:

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Study Completion Date:

December 4, 1990

Performing Laboratory:

Hazleton Wisconsin, Inc.
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Laboratory Project Identification:

HWI 00904815

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Table 1
Individual Eye Irritation Scores

Animal Number	Sex	Cornea		Iris	Conjunctivae			Total Score*
		A	B	C	D	E	F	
<u>24 Hours</u>								
F34375	M	0	0	0	1	0	0	2
F34376	M	0	0	0	0	0	0	0
F34377	M	0	0	0	1	0	0	2
F34378	F	0	0	0	0	0	0	0
F34379	F	0	0	0	0	0	0	0
F34380	F	0	0	0	1	0	0	2
Mean								1.0
<u>48 Hours</u>								
F34375	M	0	0	0	0	0	0	0
F34376	M	0	0	0	0	0	0	0
F34377	M	0	0	0	1	0	0	2
F34378	F	0	0	0	0	0	0	0
F34379	F	0	0	0	0	0	0	0
F34380	F	0	0	0	1	0	0	2
Mean								0.7
<u>72 Hours</u>								
F34375	M	0	0	0	0	0	0	0
F34376	M	0	0	0	0	0	0	0
F34377	M	0	0	0	0	0	0	0
F34378	F	0	0	0	0	0	0	0
F34379	F	0	0	0	0	0	0	0
F34380	F	0	0	0	0	0	0	0
Mean								0.0

Cornea

A - Degree of opacity
B - Area of involvement

Iris

C - Degree of iridal
irritation

Conjunctivae

D - Redness
E - Chemosis
F - Discharge

$$* = (A \times B \times 5) + (C \times 5) + (D + E + F) \times 2$$

Table 2
Sodium Fluorescein Examination

Animal Number	Observation Period	
	Preinitiation	72 Hour
F34375	NEG	NEG
F34376	NEG	NEG
F34377	NEG	NEG
F34378	NEG	NEG
F34379	NEG	NEG
F34380	NEG	NEG

NEG - No stain retention.

Comments

No pain response was elicited from any animal following instillation of the test material.

No corneal or iridal involvement was observed in any animal during the study.

DISCUSSION

The test material, ACF-50 Lubricant, when evaluated for its primary eye irritation potential in rabbits, produced only very slight conjunctival irritation in three of the six animals. All conjunctival irritation cleared within 72 hours of instillation of the test material. None of the animals exhibited a positive response according to the FHSA criteria.

CONCLUSION

Based on the results of this study, this test material is not considered to be a primary eye irritant.