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ABBREVIATED PRIMARY EYE IRRITATION STUDY OF
[REDACTED] IN RABBITS

Study No. 1588
Test Article No. 665

Treatment Initiation Date: October 2, 1990
Biophase Termination Date: October 5, 1990
Amoco LD. Number: ATTA 90-32

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OCT 1990
TOXICOLOGY

SUMMARY

was placed in the right eye of each of three rabbits at a dose of 0.1 ml, with the left eye serving as an untreated control. The treated eye of each rabbit was scored for irritation at 1, 24, 48, and 72 hours following test article application. The control eye was used for comparison.

According to the specific requirements of the Sponsor and/or the general criteria of the European Economic Community (EEC), [REDACTED] was found to be an irritant. The maximum eye irritation score of 69.0/110.0 was obtained 72 hours after application of the test article.

STUDY PARTICIPANTS:

Christopher Lord, Experimentalist

This summary was prepared by J. Fred Krueger, M.S., Technical Editor

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TABLE 1

SUMMATION OF OECD EYE IRRITATION SCORES

Cornea (Density of Opacity)

Animal Number	Sex	Scoring Interval				Mean ^a
		1 hr	24 hr	48 hr	72 hr	
869	M	0	2	2	2	2.0
870	F	0	2	2	2	2.0
871	F	0	2	2	3	2.3

Iris

Animal Number	Sex	Scoring Interval				Mean ^a
		1 hr	24 hr	48 hr	72 hr	
869	M	0	1	1	1	1.0
870	F	1	1	1	1	1.0
871	F	1	1	1	1	1.0

Conjunctiva

Animal Number	Sex	Scoring Interval								Mean ^a	
		1 hr		24 hr		48 hr		72 hr		A	B
		A ^b	B ^c	A	B	A	B	A	B		
869	M	3	3	3	4	3	4	3	4	3.0	4.0
870	F	3	3	3	3	3	3	3	3	3.0	3.0
871	F	3	3	3	4	3	4	3	4	3.0	4.0

^a Excludes the 1-hr scores, as per the EEC criteria.

^b A - Erythema

^c B - Chemosis .

TABLE 2

SUMMATION OF DRAIZE EYE IRRITATION SCORES

Cornea (A - Density of Opacity, B - Area of Opacity)									
Animal Number	Sex	Scoring Interval							
		1 hr		24 hr		48 hr		72 hr	
		A	B	A	B	A	B	A	B
869	M	0	0	2	4	2	4	2	4
870	F	0	0	2	4	2	4	2	4
871	F	0	0	2	4	2	4	3	4

Iris									
Animal Number	Sex	Scoring Interval							
		1 hr		24 hr		48 hr		72 hr	
		A	B	A	B	A	B	A	B
869	M	0		1		1		1	
870	F	1		1		1		1	
871	F	1		1		1		1	

Conjunctiva (A - Erythema, B - Chemosis, C - Discharge)													
Animal Number	Sex	Scoring Interval											
		1 hr			24 hr			48 hr			72 hr		
		A	B	C	A	B	C	A	B	C	A	B	C
869	M	3	3	3	3	4	3	3	4	3	3	4	1
870	F	3	3	3	3	3	3	3	3	2	3	3	2
871	F	3	3	3	3	4	3	3	4	3	3	4	3

TOTAL EYE IRRITATION SCORES

Formula: TOTAL SCORE (TS) = I+II+III, where:

- I - Cornea Score - [Density(A) X Area(B)] X 5
 II - Iris Score - [Severity(A)] X 5
 III - Conjunctival Score - [Erythema(A) + Chemosis(B) + Discharge(C)] X 2

Scoring Interval	TOTAL IRRITATION SCORE			MEAN IRRITATION SCORE
	869	870	871	
1 hr	18	23	23	21.3
24 hr	65	63	65	64.3
48 hr	65	61	65	63.7
72 hr	61	61	85	69.0

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