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FROM: T. G. Grumbles

DATE: March 1, 1989

VISTA

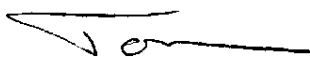
Interoffice
Communication

SUBJ: COMPARATIVE ETHER SULFATE EYE AND SKIN IRRITATION TESTING

Eye and skin irritation testing was done to compare the relative irritation potential of Novel vs. "regular" 1214 GC-20, 1214 GC-30 and 1214 GC-40 Ether Sulfate. Attached is a comparative data table and the summary pages from the study reports.

In general it appears the novel ether sulfates are more irritating to the eyes than the standard ether sulfates. However, with only one exception, Novel 1214 GC-20, the eye irritation scores are all in the "moderate" rating class. In other words although the scores differ, the irritation classification is the same. The exception, Novel 1214 GC-20 is classed as a severe irritant. This is an artifact of the classification scheme (attached) and is not significant. It was the result of one animal having a score of 31 when no animal can exceed a score of 30 to maintain the moderate classification. Also, it should be noted that the washed eyes exhibit a higher irritation than the unwashed eyes, which seems intuitively opposite of the expected result. However, the laboratory tells me this is not unexpected.

The skin irritation results are variable, with Novel 1214 GC-20 and 40 being less irritating than the normal ether sulfates and Novel 1214 GC-30 being more irritating than normal ether sulfate. However, the score differences are within expected variability for acute dermal irritation testing, and all results are within the moderate irritant category.



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dlj
.570

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VVV 000006900

TEST RESULTS

<u>Product</u>	<u>Primary Dermal Irritation</u>	<u>Primary Eye Irritation</u>	
		<u>Washed</u>	<u>Nonwashed</u>
Novel 1214 GC-20	3.7	38.7	25.8
1214 GC-20	4.2	20.0	15.7
Novel 1214 GC-30	4.3	25.3	19.0
1214 GC-30	4.0	19.0	24.8
Novel 1214 GC-40	3.8	34.2	45.7
1214 GC-40	4.0	15.0	28.3

VVV 000006901

I. SUMMARY

An eye irritation study was conducted on nine albino rabbits using test material ALFONIC 1214GC-30 Ether Sulfate Sample No. V2769C, hereafter referred to as ALFONIC 1214GC-30 Ether Sulfate.

Actual undiluted test material (0.1 ml) was placed into the conjunctival sac of the left eye of each animal selected for testing. The treated eyes of three of the animals were each washed with room temperature deionized water for 1 minute beginning 30 seconds after treatment.

ALFONIC 1214GC-30 Ether Sulfate was rated as moderately irritating in nonwashed eyes and moderately irritating in washed eyes with maximum average irritation scores of 24.8 and 19.0, respectively. The test material is categorized as Toxicity Category I for nonwashed eyes and Toxicity Category II for washed eyes.

Corneal opacity and/or invasion of the cornea by blood vessels was present in one nonwashed eye on Day 21. Corneal opacity and/or invasion of the cornea by blood vessels was not present in any washed eyes on Day 21.

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VVV 000006902

I. SUMMARY

A skin irritation study was conducted on six albino rabbits using test material NOVEL 1214GC-30 Ether Sulfate Sample No. V2717C, hereafter referred to as NOVEL 1214GC-30.

There was one intact skin test site per animal. Each test site was treated with 0.5 ml of actual undiluted test material. The test sites were occluded for 4 hours. Observations for dermal irritation and defects were made at 1, 24, 48, and 72 hours and on Days 7, 10, 14, and 17 after the occlusion period.

NOVEL 1214GC-30 produced a maximum irritation score of 4.3 and was given a descriptive rating of moderate irritant.

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VVV 000006903

I. SUMMARY

A skin irritation study was conducted on six albino rabbits using test material ALFONIC 1214GC-30 Ether Sulfate Sample No. V2769C, hereafter referred to as ALFONIC 1214GC-30 Ether Sulfate.

There was one intact skin test site per animal. Each test site was treated with 0.5 ml of actual undiluted test material. The test sites were occluded for 4 hours. Observations for dermal irritation and defects were made at 1, 24, 48, and 72 hours and on Days 7, 10, 14, and 17 after the occlusion period.

ALFONIC 1214GC-30 Ether Sulfate produced a maximum irritation score of 4.0 and was given a descriptive rating of moderate irritant.

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VVV 000006904

Legend to Table 2
RABBIT EYE IRRITATION
Rating of Test Material Based on Eye Irritation

<u>Rating</u>	<u>Maximum Average Score</u>	<u>Definition</u>
Non-Irritating	0.0 - 0.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this category, all scores at the 72-hour reading must be zero; otherwise, increase category one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this category, scores at the 7-day reading must be zero; otherwise, increase category one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this category, scores at the 7-day reading must be less than or equal to 10 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 20. If the 7-day mean score is less than or equal to 20, but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if category is to be maintained; otherwise, increase category one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this category, scores at the 7-day reading must be less than or equal to 30 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 40. If the 7-day mean score is less than or equal to 40, but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if category is to be maintained; otherwise, increase category one level.
Extremely Irritating	Greater than 80.0 - 110.0	

NOTE: The category of the test material is not to be increased more than one level above its maximum average score.

VVV 000006905

Legend to Table 2 (cont.)

RABBIT EYE IRRITATION

Criteria of Eye Irritation for Classification into Toxicity Categories

<u>Category</u>	<u>Criteria</u>
I	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or conjunctival irritation persisting through Day 21.
II	Corneal involvement or conjunctival irritation clearing in 8 - 21 days.
III	Corneal involvement or conjunctival irritation clearing in 7 days or less.
IV	Minimal effects clearing in less than 24 hours.

VVV 000006906

I. SUMMARY

A skin irritation study was conducted on six albino rabbits using test material NOVEL 1214GC-40 Ether Sulfate Sample No. V2718C, hereafter referred to as NOVEL 1214GC-40.

There was one intact skin test site per animal. Each test site was treated with 0.5 ml of actual undiluted test material. The test sites were occluded for 4 hours. Observations for dermal irritation and defects were made at 1, 24, 48, and 72 hours and on Days 7, 10, 14, 17, and 21 after the occlusion period.

NOVEL 1214GC-40 produced a maximum irritation score of 3.8 and was given a descriptive rating of moderate irritant. The death of one animal on Day 9 of the study was not believed to be related to the administration of the test material.

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VVV 000006907

I. SUMMARY

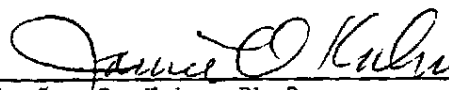
An eye irritation study was conducted on nine albino rabbits using test material NOVEL 1214GC-30 Ether Sulfate Sample No. V2717C, hereafter referred to as NOVEL 1214GC-30.

Actual undiluted test material (0.1 ml) was placed into the conjunctival sac of the left eye of each animal selected for testing. The treated eyes of three of the animals were each washed with room temperature deionized water for 1 minute beginning 30 seconds after treatment.

NOVEL 1214GC-30 was rated as moderately irritating in nonwashed eyes and moderately irritating in washed eyes with maximum average irritation scores of 19.0 and 25.3, respectively. The test material is categorized as Toxicity Category I.

Corneal opacity and/or invasion of the cornea by blood vessels was not present in any nonwashed eyes on Day 21. Corneal opacity and/or invasion of the cornea by blood vessels was present in one washed eye on Day 21.

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VVV 000006908

Legend to Table 2

RABBIT EYE IRRITATION

Rating of Test Material Based on Eye Irritation

<u>Rating</u>	<u>Maximum Average Score</u>	<u>Definition</u>
Non-Irritating	0.0 - 0.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this category, all scores at the 72-hour reading must be zero; otherwise, increase category one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this category, scores at the 7-day reading must be zero; otherwise, increase category one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this category, scores at the 7-day reading must be less than or equal to 10 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 20. If the 7-day mean score is less than or equal to 20, but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if category is to be maintained; otherwise, increase category one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this category, scores at the 7-day reading must be less than or equal to 30 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 40. If the 7-day mean score is less than or equal to 40, but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if category is to be maintained; otherwise, increase category one level.
Extremely Irritating	Greater than 80.0 - 110.0	

NOTE: The category of the test material is not to be increased more than one level above its maximum average score.

VVV 000006909

Legend to Table 2 (cont.)

RABBIT EYE IRRITATION

Criteria of Eye Irritation for Classification into Toxicity Categories

<u>Category</u>	<u>Criteria</u>
I	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or conjunctival irritation persisting through Day 21.
II	Corneal involvement or conjunctival irritation clearing in 8 - 21 days.
III	Corneal involvement or conjunctival irritation clearing in 7 days or less.
IV	Minimal effects clearing in less than 24 hours.

Legend to Table 2
 RABBIT EYE IRRITATION
 Rating of Test Material Based on Eye Irritation

<u>Rating</u>	<u>Maximum Average Score</u>	<u>Definition</u>
Non-Irritating	0.0 - 0.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this category, all scores at the 72-hour reading must be zero; otherwise, increase category one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this category, scores at the 7-day reading must be zero; otherwise, increase category one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this category, scores at the 7-day reading must be less than or equal to 10 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 20. If the 7-day mean score is less than or equal to 20, but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if category is to be maintained; otherwise, increase category one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this category, scores at the 7-day reading must be less than or equal to 30 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 40. If the 7-day mean score is less than or equal to 40, but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if category is to be maintained; otherwise, increase category one level.
Extremely Irritating	Greater than 80.0 - 110.0	

NOTE: The category of the test material is not to be increased more than one level above its maximum average score.

VVV 000006911

Legend to Table 2 (cont.)

RABBIT EYE IRRITATION

Criteria of Eye Irritation for Classification into Toxicity Categories

<u>Category</u>	<u>Criteria</u>
I	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or conjunctival irritation persisting through Day 21.
II	Corneal involvement or conjunctival irritation clearing in 8 - 21 days.
III	Corneal involvement or conjunctival irritation clearing in 7 days or less.
IV	Minimal effects clearing in less than 24 hours.

VVV 000006912

Legend to Table 2
RABBIT EYE IRRITATION
Rating of Test Material Based on Eye Irritation

<u>Rating</u>	<u>Maximum Average Score</u>	<u>Definition</u>
Non-Irritating	0.0 - 0.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this category, all scores at the 72-hour reading must be zero; otherwise, increase category one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this category, scores at the 7-day reading must be zero; otherwise, increase category one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this category, scores at the 7-day reading must be less than or equal to 10 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 20. If the 7-day mean score is less than or equal to 20, but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if category is to be maintained; otherwise, increase category one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this category, scores at the 7-day reading must be less than or equal to 30 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 40. If the 7-day mean score is less than or equal to 40, but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if category is to be maintained; otherwise, increase category one level.
Extremely Irritating	Greater than 80.0 - 110.0	

NOTE: The category of the test material is not to be increased more than one level above its maximum average score.

VVV 000006913

Legend to Table 2 (cont.)

RABBIT EYE IRRITATION

Criteria of Eye Irritation for Classification into Toxicity Categories

<u>Category</u>	<u>Criteria</u>
I	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or conjunctival irritation persisting through Day 21.
II	Corneal involvement or conjunctival irritation clearing in 8 - 21 days.
III	Corneal involvement or conjunctival irritation clearing in 7 days or less.
IV	Minimal effects clearing in less than 24 hours.

VVV 000006914

Legend to Table 2

RABBIT EYE IRRITATION

Rating of Test Material Based on Eye Irritation

Rating	Maximum Average Score	Definition
Non-Irritating	0.0 - 0.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Practically Non-Irritating	Greater than 0.5 - 2.5	To maintain this category, all scores at the 24-hour reading must be zero; otherwise, increase category one level.
Minimally Irritating	Greater than 2.5 - 15.0	To maintain this category, all scores at the 72-hour reading must be zero; otherwise, increase category one level.
Mildly Irritating	Greater than 15.0 - 25.0	To maintain this category, scores at the 7-day reading must be zero; otherwise, increase category one level.
Moderately Irritating	Greater than 25.0 - 50.0	To maintain this category, scores at the 7-day reading must be less than or equal to 10 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 20. If the 7-day mean score is less than or equal to 20, but less than 60% of the animals show scores less than 10, then no animal among those showing scores greater than 10 can exceed a score of 30 if category is to be maintained; otherwise, increase category one level.
Severely Irritating	Greater than 50.0 - 80.0	To maintain this category, scores at the 7-day reading must be less than or equal to 30 for 60% or more of the animals. Also, the 7-day mean score must be less than or equal to 40. If the 7-day mean score is less than or equal to 40, but less than 60% of the animals show scores less than or equal to 30, then no animal among those showing scores greater than 30 can exceed a score of 60 if category is to be maintained; otherwise, increase category one level.
Extremely Irritating	Greater than 80.0 - 110.0	

NOTE: The category of the test material is not to be increased more than one level above its maximum average score.

VVV 000006915

Legend to Table 2 (cont.)

RABBIT EYE IRRITATION

Criteria of Eye Irritation for Classification into Toxicity Categories

<u>Category</u>	<u>Criteria</u>
I	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or conjunctival irritation persisting through Day 21.
II	Corneal involvement or conjunctival irritation clearing in 8 - 21 days.
III	Corneal involvement or conjunctival irritation clearing in 7 days or less.
IV	Minimal effects clearing in less than 24 hours.

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