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TSCA Document Processing Center (TS-790)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, SW
Washington, DC 20460

April 28, 2000

RETURN RECEIPT REQUESTED
P 255 369 560

Attention: Section 8(e) Coordinator

Company Sanitized

Dear Sir or Madam:

This information is being submitted under the provisions of the Toxic Substances Control Act, 90 Stat. 2029, 15 USC 2607, Section 8(e). Attached are Final Report Summary sheets of a report currently being drafted which reflects the skin sensitization potential of a commercial grade of hexanedioic acid, polymer with N-(2-aminoethyl)-1,2-ethanediamine, N-(1-oxohexyl) derivs., epichlorohydrin-quaternized (CASRN 236400-71-8), and the immediate chemical precursor, i.e. hexanedioic acid, polymer with N-(2-aminoethyl)-1,2-ethanediamine, N-(1-oxohexyl) derivs., CASRN 236400-59-2. These data were provided by the performing laboratory via facsimile transmission to [company name sanitized] on April 7, 2000. Copies of the full final reports have not yet been received.

The Final Report Summaries (see attached) can be summarized as follows.

- CASRN 236400-71-8 (@ 20% solids, the highest nonirritating dose) elicited sensitization in 10/10 test animals.
- Paper treated with 0.2% CASRN 236400-71-8 did not elicit sensitization in guinea pigs that were previously challenged with CASRN 236400-71-8.
- 1,3-Dichloro-2-propanol (i.e. DCP) @ 0.75% in distilled water elicited sensitization in 1/10 guinea pigs that had been previously challenged with CASRN 236400-71-8. DCP is a known by-product in the manufacture of CASRN 236400-71-8 and is present in the commercial sample at ca. 1.5%.
- The prepolymer of CASRN 236400-71-8, i.e. CASRN 236400-59-2 (@ 20% solids in water), elicited sensitization in 7/10 previously challenged guinea pigs.
- 1,3-Dichloro-2-propanol @ 0.75% in corn oil, elicited sensitization in 1/10 guinea pigs that were previously challenged with CASRN 236400-71-8.

At this point it is unclear whether the skin sensitization being elicited is attributable to the polymer *per se* or to lower molecular weight species which have not been characterized. Never the less, due to the incidence and the severity of the responses, we believe that

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these data constitute substantial risk information under Section 8(e) of TSCA. The full report of these data will be provided to EPA on receipt by this office.

Sincerely,

[*sanitized*]
Director, Regulatory Affairs

attachments

A 05

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Consumer Product Testing Co.

EST. 1975

Final Report Summary

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CLIENT: []
 STUDY NO.: T00-0005
 REFERENCE: []
 TEST ARTICLE: *[Aminopolyamide]*
 TEST ARTICLE RECEIPT DATE: January 11, 2000
 EXPERIMENTAL INTERVAL (Screens through Challenge): February 15, 2000 to March 17, 2000

Guinea Pig Maximization Test

Method: Ten (5M:5F) Hartley-strain guinea pigs, 382 - 489 grams, were utilized as the test group. An additional ten (5M:5F) Hartley-strain guinea pigs, 368 - 450 grams, were utilized as the control group. For induction, each animal in the test group received three (3) pairs of intradermal injections, with and without the test article. During the second week of the induction phase, topical applications of the test article were made to the induction site of each animal in the test group. Two (2) weeks after the topical induction applications, the challenge applications were made. These 24 hour challenge applications were made to virgin sites on the flank of each animal in the test and control groups, at the screen determined, highest non-irritating concentration of 50%. Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications.

Results:	Index: Group	Challenge	
		<u>Incidence Test/Control</u>	<u>Severity Test/Control</u>
Scoring Interval:			
48 Hours:		1.00/0.30	2.10/0.30
72 Hours:		0.90/0.10	1.50/0.10

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Conclusion: This test article is a sensitizer in guinea pigs under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
 Severity Index = The sum of the erythema scores, 1 or greater, divided by the number of animals observed at challenge.



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Final Report Summary (continued)

CLIENT: []

STUDY NO.: T00-0005

REFERENCE: []

TEST ARTICLE: Paper Treated with 0.5% [aminopolyamide]

TEST ARTICLE RECEIPT DATE: February 16, 2000

EXPERIMENTAL INTERVAL (Rechallenge): March 21, 2000 to March 24, 2000

Guinea Pig Maximization Test

Method:

The ten (5M:5F) original test animals were rechallenged one (1) week after the initial challenge. An additional ten (5M:5F), previously untreated, Hartley-strain guinea pigs, 467 - 652 grams at the time of rechallenge, were utilized as the control group. These 24 hour rechallenge applications were made to virgin sites on the flank of each animal in the test and control groups. Each dosage consisted of approximately one (1) square inch of the test article moistened with saline. Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications.

Results:

Index: Group	Incidence <u>Test/Control</u>	Challenge Severity <u>Test/Control</u>
Scoring Interval:		
48 Hours:	0.00/0.00	0.00/0.00
72 Hours:	0.00/0.00	0.00/0.00

Conclusion: This test article did not elicit a sensitization reaction in this particular group of previously treated guinea pigs, under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
Severity Index = The sum of the erythema scores, 1 or greater, divided by the number of animals observed at challenge.



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Final Report Summary (continued)

CLIENT: []
 STUDY NO.: T00-0005
 REFERENCE: []
 TEST ARTICLE: 1,3-Dichloro-2-Propanol
 TEST ARTICLE RECEIPT DATE: March 28, 2000 (Aldrich Chemicals)
 EXPERIMENTAL INTERVAL (Rechallenge): March 28, 2000 to March 31, 2000

Guinea Pig Maximization Test

Method: The ten (5M:5F) original test animals were again rechallenged two (2) weeks after the initial challenge. An additional four (4), male, previously untreated, Hartley-strain guinea pigs, 556 - 688 grams at the time of rechallenge, were utilized as the control group. These 24 hour rechallenge applications were made to sites on the flank of each animal in the test and control groups. Each dosage consisted of the test article at 0.75% suspended in distilled water. Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications.

Results:	Index: Group	Challenge	
		<u>Incidence Test/Control</u>	<u>Severity Test/Control</u>
Scoring Interval:			
48 Hours:		0.10/0.00	0.20/0.00
72 Hours:		0.10/0.00	0.20/0.00

Conclusion: This test article elicited a sensitization reaction in one (1) animal in this particular group of previously treated guinea pigs, under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
 Severity Index = The sum of the erythema scores, 1 or greater, divided by the number of animals observed at challenge.



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Final Report Summary (continued)

CLIENT: []
 STUDY NO.: T00-0005
 REFERENCE: []
 TEST ARTICLE: 1,3-Dichloro-2-Propanol
 TEST ARTICLE RECEIPT DATE: March 28, 2000 (Aldrich Chemicals)
 EXPERIMENTAL INTERVAL (Rechallenge): April 4, 2000 to April 7, 2000

Guinea Pig Maximization Test

Method: The ten (5M:5F) original test animals were again rechallenged three (3) weeks after the initial challenge. An additional three (3), male, previously untreated, Hartley-strain guinea pigs, 586 - 650 grams at the time of rechallenge, were utilized as the control group. These 24 hour rechallenge applications were made to sites on the left flank of each animal in the test and control groups. Each dosage consisted of the test article at 0.75% suspended in corn oil. Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications.

Results:	Index: Group	Challenge	
		<u>Incidence Test/Control</u>	<u>Severity Test/Control</u>
Scoring Interval:			
	48 Hours:	0.10/0.00	0.20/0.00
	72 Hours:	0.10/0.00	0.10/0.00

Conclusion: This test article elicited a sensitization reaction in one (1) animal in this particular group of previously treated guinea pigs, under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
 Severity Index = The sum of the erythema scores, 1 or greater, divided by the number of animals observed at challenge.



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Final Report Summary (continued)

CLIENT: []
 STUDY NO.: T00-0005
 REFERENCE: []
 TEST ARTICLE: [aminopolyamide]
 TEST ARTICLE RECEIPT DATE: April 3, 2000
 EXPERIMENTAL INTERVAL (Rechallenge): April 4, 2000 to April 7, 2000

Guinea Pig Maximization Test

Method: The ten (5M:5F) original test animals were again rechallenged three (3) weeks after the initial challenge. An additional three (3), male, previously untreated, Hartley-strain guinea pigs, 586 - 650 grams at the time of rechallenge, were utilized as the control group. These 24 hour rechallenge applications were made to sites on the right flank of each animal in the test and control groups. Each dosage consisted of the test article at 50% suspended in distilled water. Observations of erythema, edema and other effects were recorded 48 and 72 hours after the challenge applications.

Results:	Index: Group	Challenge	
		<u>Incidence Test/Control</u>	<u>Severity Test/Control</u>
Scoring Interval:			
	48 Hours:	0.70/0.00	1.90/0.00
	72 Hours:	0.60/0.00	1.40/0.00

Conclusion: This test article elicited a sensitization reaction in the animals in this particular group of previously treated guinea pigs, under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
 Severity Index = The sum of the erythema scores, 1 or greater, divided by the number of animals observed at challenge.