

ORIGINAL

TSCA NON-CONFIDENTIAL BUSINESS INFORMATION

DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
BEHQ-10-18056	88100000381	8/2/10

COMMENTS:

DOES NOT CONTAIN CBI

114328872

8EHQ-0710-18056A



10 AUG -2 11:10:28

July 29, 2010

TSCA Confidential Business Information Center (7407M)
EPA East – Room 6428
Attn: Section 8(e)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001

Re: TSCA Section 8(e) Notification of Substantial Risk: Dow Corning® APZ-3

Dear TSCA Section 8(e) Coordinator:

In accordance with the provisions of Section 8(e) of the Toxic Substances Control Act (TSCA), as interpreted in the TSCA Section 8(e) Policy Statement and Guidance, Fed. Reg. 33129 (June 3, 2003) and other Agency guidance, Dow Corning Corporation submits information concerning a study with Dow Corning® APZ-3.

Submission of this report at this time is driven by a recent review of existing study reports for materials that share structural similarity with a material of commercial interest. This report was previously submitted to EPA pursuant to TSCA §5 obligations.

Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by the study findings.

Chemical Substance

Dow Corning® APZ-3

Composition:

> 60% proprietary siloxane

1.0 – 5.0 wt% Glycidoxypropyl trimethoxysilane (CAS Number: 2530-83-8)

DCN:8810000381



CONTAINS NO CBI

Study Title

Genetic Evaluaton of Dow Corning® APZ-3 In Bacterial Reverse Mutation Assays
(Report number: 1987-I0005-1631)

Summary

The test article was evaluated for genetic activity in the Salmonella typhimurium and Escherichia coli Reverse Mutation assays as outlined in the “O.E.C.D. Guidelines for Testing of Chemicals”. Under the conditions of this study the test article was determined to be mutagenic.

Details

Study Design:

The objective of this study was to evaluate the test material for genetic activity in the Salmonella typhimurium and Escherichia coli Reverse Mutation assays as part of the Minimum Premarket Data Set for new chemicals. The following strains were tested Salmonella typhimurium strains TA1535, TA-1537, TA-98, and TA-100 and Escherichia coli strain WP2. Bacteria were exposed to the five concentrations of test article (312.5, 625, 1250, 2500, and 5000 µg per plate) in the presence and absence of a mammalian activation mixture (S-9 mix). The solvent used was dimethylsulfoxide (DMSO). The concentration of test article, solvent control, or positive control and tester strain were added to 2 mL top agar held at 45°C, which was then pour-plated immediately on the surface of hardened minimal agar. In the non-activation assay, 0.5 mL phosphate buffer was added just prior to plating while 0.5 mL S-9 activation mix was added for the activation assay. Positive control assays were conducted with each experiment and consisted of direct-acting mutagens for non-activation assays and mutagens that require metabolic biotransformation in activation assays. Negative control, DMSO, consisted of the test article solvent in the overlay agar together with the other essential components. Plates were incubated for 72 hours and counted. All testing was done in triplicate.

Results

The test article elicited a dose related positive response to strain TA-1535 with S-9 activation. A weak dose related response was also obtained with strain TA-100 in the presence of an S-9 activation mix. The test article, therefore, was considered mutagenic under the experimental conditions. The mutagenicity observed is consistent with and corroborates with the known mutagenic potential of glycidoxypopyl trimethoxysilane, a component of APZ-3.

Actions

Dow Corning has not made a determination at this time that any significant risk of injury to human health or the environment is presented by these findings. Dow Corning Corporation will notify EPA of any further relevant information that may be developed concerning this product. A copy of the final report is attached to this letter.

If you have any questions concerning this submission, please contact me at (989) 496-8046, kathy.plotzke@dowcorning.com, or at the address provided herein.

Sincerely,



Kathleen Plotzke, Ph.D.
Director, Health and Environmental Sciences

DOW CORNING CORPORATION
Toxicology Department

File No.:

GENETIC EVALUATION OF DOW CORNING®
APZ-3* IN BACTERIAL REVERSE
MUTATION ASSAYS

Reference No.: TX-87-9964-07

Series No.: I-0005-1631

Authors:

Lot No.:

GLP/QAU:

Submitted By:

Reported By:

Checked By:

Date: July 22, 1987

This summary of data and conclusions is based upon the sample received.
Additional studies may be required as specific uses and formulations are
developed or if process changes occur.

ABSTRACT

The test material was evaluated for genetic activity in the Salmonella typhimurium and Escherichia coli Reverse Mutation assays as outlined in "O.E.C.D. Guidelines for Testing of Chemicals" - Draft Protocol Nos. 419 and 420. The test material elicited a strong dose related positive response to strain TA-1535 with activation. A weak dose related response was also obtained with strain TA-100 in the presence of activation mix. The test material, therefore, is mutagenic under the conditions of this test.

*Siloxanes and silicones, dimethyl, methylvinyl, hydroxy terminated, reaction products with trimethoxy [3-(oxiranylmethoxy)propyl] silane

Distribution

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TABLES - Overlay Plate Test Results

<u>Salmonella typhimurium</u>	TA-1535 - Table I
	TA-1537 - Table II
	TA-98 - Table III
	TA-100 - Table IV
<u>Escherichia coli</u> WP2	uvr A - Table V

OBJECTIVE

The objective of this study was to evaluate the test material for genetic activity in the Salmonella typhimurium and Escherichia coli Reverse Mutation Assays as outlined in O.E.C.D. GUIDELINES FOR TESTING OF CHEMICALS (CRF 46 (162)/8-21-81) as part of the Minimum Premarket Data Set for new chemicals.

MATERIALS

A. Test Material

TX-87-9964-07

B. Indicator Microorganisms

<u>Salmonella typhimurium</u> , str.	TA-1535	TA-98
	TA-1537	TA-100
<u>Escherichia coli</u> , str.	WP2	

C. Activation System

Bacteria were exposed to the test substance both in the presence and absence of a mammalian activation mixture (S-9 mix) prepared in accordance with published protocols (Ames, et al., 1975; Matsushima, et al., 1976), using a 9000 x g supernatant prepared from Sprague-Dawley adult male rat liver induced by AROCLOR 1254 five days prior to kill

D. Positive Control Chemicals

Chemicals used for positive controls in the non-activation and activation assays.

<u>Assay</u>	<u>Chemical*</u>	<u>µg/plate</u>	<u>Bacterial Strain</u>
Non-activation	Sodium Azide (AZ)	10	TA-1535, TA-100
	9-Amino Acridine (AA)	50	TA-1537
	2-Nitrofluorene (NF)	10	TA-98
	N-Methyl-N-nitro-N-nitrosoquinidine (MNNG)	10	WP2
Activation	2-Anthramine (ANTH)	10	All Strains

E. Solvent

Dimethylsulfoxide (DMSO) was used to prepare dilutions of the test material.

EXPERIMENTAL DESIGN

Five concentrations of the test material, separated by half-log intervals, were evaluated with and without metabolic activation. Concentration of test chemical (concentrations used are given in each data table) and appropriate testor strain were added to 2 ml top agar held at 45°C, which was then poured immediately on the surface of hardened minimal agar. In the non-activation assay, 0.5 ml phosphate buffer was added just prior to plating while 0.5 ml S-9 activation mix was added for the activation assay. Positive and negative control assays were conducted with each experiment and consisted of direct-acting mutagens for nonactivation assays and mutagens that require metabolic biotransformation in activation assays. Negative controls consisted of the test article solvent in the overlay agar together with the other essential components. Plates were incubated for 72 hours and counted. All testing was done in triplicate.

RESULTS

See attached Tables I-V for results. The test material elicited a strong dose related positive response to strain TA-1535 with activation. A weak dose related response was also obtained with strain TA-100 in the presence of activation mix. The test material, therefore, is mutagenic under the conditions of this test.

DATA

The data are presented as the number of revertant colonies per plate. The number of revertant colonies on both negative (solvent) and positive control plates are also presented. The mean (x) number of revertants per plate and standard deviation are also given.

REFERENCES

- Ames, B. N., McCann, J. and Yamasaki, E.: Methods for detecting carcinogens and mutagens with the Salmonella/mammalian-microsome mutagenicity test. Mutation Res. 31, 347-364, 1975
- Brusick, D. J., Simmon, V. F., Rosenkranz, H. S., Ray, V. A. and Stafford, R. S.: An evaluation of the Escherichia coli WP2 and WP2 uvrA reverse mutation assay. Mutation Res., 76:169-190, 1980.
- de Serres, F. J. and Shelby, M. D.: Science, 203:563-565, 1979.
- Green, M. H. C. and Muriel, W. J.: Mutation Res., 38:3-32, 1976.
- Matsushima, T., Sawamura, M., Hara, K. and Sugimura, T.: In, In vitro metabolic activation in mutagenesis testing. F. J. de Serres, J. R. Fouts, J. R. Bend and R. M. Philpot, (eds.), Elsevier/North-Holland Biomedical Press, Amsterdam, pp.85-88, 1976.

Matsushima, T., Sugimura, T., Nagao, M., Yahagi, T., Shirai, A. and Sawamura, M.: In Short-term test systems for detecting carcinogens. K. H. Norpoth and R. C. Garner, (eds.), Springer-Verlag, Berlin Heidelberg New York, pp.273-285, 1980.

Matsushima, T., Talamoto, Y., Shirai, A., Sawamura, M. and Sugimura, T.: The reverse mutation test on 42 coded compounds with the Escherichia coli WP2 system. In press, 1981.

McCann, J., Choi, E., Yamasaki, E. and Ames, B. N.: Detection of carcinogens as mutagens in the Salmonella/microsome test: Assay of 300 chemicals. Proc. Nat. Acad. Sci. 72:5135-5139, 1975.

Vogel, H. J. and Bonner, D. M.: J. Biol. Chem., 218:97-106, 1956.

This report constitutes pages 1-7 and Tables I-V.

Authors: Richard T. Pennell Date: 7/6/87
Study Director/Principal Investigator

Jennifer M. Muntz Date: 7-6-87
Associate Biologist

Approved By: [Signature] Date: 7-14-87
Toxicology Department

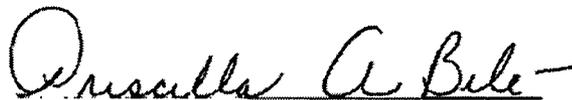
Typed By:

[Signature]

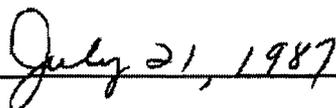
QUALITY ASSURANCE STATEMENT

This report represents data generated by the Toxicology Department,
This study was conducted according to
EPA Toxic Substances Control; Good Laboratory Practices Regulations; 40 CFR,
Part 792, Vol. 48, No. 230. The results reported accurately reflect the data
generated. All raw data is located at

Study Started: June 26, 1987
Study Completed: June 29, 1987
Date Audited: June 26, 1987
Report Issued: July 22, 1987



Quality Assurance
Health & Environmental Sciences

Date: 

Ames' test data

```

=====
Name
Master #      APZ-3
Study number  TX-B7-9964-07
Date - Time   06-29-1987  08:04:50
Program name  Artek/AMES  2.0      Vdate 04-16-85
=====
    
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Strain TA1535

No.	Plate Label	Cnt1	Cnt2	Cnt3	Mean Cnt	+/- Std Dev
1	PC -	641	684	635	653.33	26.73
2	SC -	28	16	21	21.67	6.03
3	312.5 -	31	22	22	25.00	5.20
4	625 -	29	24	21	24.67	4.04
5	1250 -	22	24	33	26.33	5.86
6	2500 -	33	32	36	33.67	2.08
7	5000 -	64	45	50	53.00	9.85
8	PC +	112	121	118	117.00	4.58
9	SC +	28	20	16	21.33	6.11
10	312.5 +	81	68	52	67.00	14.53
11	625 +	103	110	117	110.00	7.00
12	1250 +	156	143	156	151.67	7.51
13	2500 +	250	180	204	211.33	35.57
14	5000 +	310	279	278	289.00	18.19

Ames test data

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=====
Name
Master #      APZ-3
Study number  TX-87-9964-07
Date - Time   06-29-1987 10:12:01
Program name  Artek/AMES 2.0   Vdate 04-16-85
=====
  
```

Strain TA1537

No.	Plate Label		Cnt1	Cnt2	Cnt3	Mean Cnt	+/- Std Dev
1	PC	-	448	239	352	346.33	104.62
2	5C	-	10	6	13	9.67	3.51
3	312.5	-	14	15	18	15.67	2.08
4	625	-	11	15	14	13.33	2.08
5	1250	-	14	17	14	15.00	1.73
6	2500	-	12	13	11	12.00	1.00
7	5000	-	9	11	7	9.00	2.00
8	PC	+	85	77	93	85.00	8.00
9	5C	+	14	12	20	15.33	4.16
10	312.5	+	19	16	22	19.00	3.00
11	625	+	14	24	14	17.33	5.77
12	1250	+	16	12	12	13.33	2.31
13	2500	+	15	12	12	13.00	1.73
14	5000	+	18	13	12	14.33	3.21

Ames' test data

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=====
Name
Master #      APZ-3
Study number  TX-87-9964-07
Date - Time   04-29-1987  10:43:51
Program name  Artek/AMES  2.0      Vdate 04-16-85
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Strain TA98

No.	Plate Label		Cnt1	Cnt2	Cnt3	Mean Cnt	+/- Std Dev
1	PC	-	730	707	912	783.00	112.31
2	3C	-	23	23	19	21.67	2.31
3	312.5	-	26	23	25	24.67	1.53
4	625	-	20	23	25	22.67	2.52
5	1250	-	18	31	23	24.00	6.56
6	2500	-	23	24	24	23.67	.58
7	5000	-	15	16	30	20.33	8.39
8	PC	+	1118	955	973	1015.33	89.37
9	3C	+	36	29	24	29.67	6.03
10	312.5	+	30	22	27	26.33	4.04
11	625	+	39	32	36	35.67	3.51
12	1250	+	25	34	28	29.00	4.58
13	2500	+	34	32	25	30.33	4.73
14	5000	+	39	23	36	32.67	8.50

Ames' test data

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=====
Name
Master #      APZ-3
Study number  TX-B7-9964-07
Date - Time   06-29-1987  10:55:19
Program name  Artek/AMES  2.0      Vdate 04-16-85
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Strain TA100

No.	Plate Label		Cnt1	Cnt2	Cnt3	Mean Cnt	+/- Std Dev
1	PC	-	768	748	779	765.00	15.72
2	SC	-	123	125	136	128.00	7.00
3	312.5	-	133	137	137	135.67	2.31
4	625	-	170	127	136	144.33	22.68
5	1250	-	150	146	143	146.33	3.51
6	2500	-	141	166	137	148.00	15.72
7	5000	-	142	150	147	146.33	4.04
8	PC	+	1321	953	796	1023.33	269.47
9	SC	+	131	166	140	145.67	18.18
10	312.5	+	191	159	174	174.67	16.01
11	625	+	150	168	186	168.00	18.00
12	1250	+	204	202	201	202.33	1.53
13	2500	+	239	236	247	240.67	5.69
14	5000	+	342	273	274	296.33	39.55

Ames' test data

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=====
Name
Master #      APZ-3
Study number  TX-87-9964-07
Date - Time   06-29-1987  11:05:28
Program name  Artek/AMES  2.0      Vdate 04-16-85
=====
  
```

Strain WP2

No.	Plate Label		Cnt1	Cnt2	Cnt3	Mean Cnt	+/- Std Dev
1	PC	-	116	76	102	98.00	20.30
2	5C	-	24	31	27	27.33	3.51
3	312.5	-	51	34	24	36.33	13.65
4	625	-	34	26	25	28.33	4.93
5	1250	-	43	29	32	34.67	7.37
6	2500	-	27	33	19	26.33	7.02
7	5000	-	35	35	32	34.00	1.73
8	PC	+	98	107	68	91.00	20.42
9	5C	+	29	32	38	33.00	4.58
10	312.5	+	34	30	31	31.67	2.08
11	625	+	23	36	28	29.00	6.56
12	1250	+	25	24	32	27.00	4.36
13	2500	+	33	35	32	33.33	1.53
14	5000	+	28	28	29	28.33	.58

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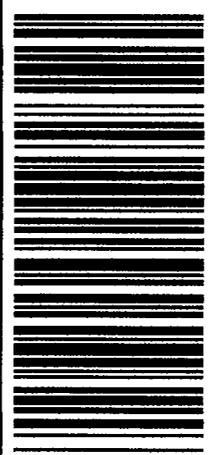
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<p>MARY SMALL 989 4964949 DOW CORNING CORPORATE 2200 W. SALZBURG RD. MIDLAND MI 48686</p> <p>SHIP TO: DOCUMENT CONTROL OFFICE (7407) U.S. E.P.A. 1200 PENNSYLVANIA AVE NW OFFICE OF POLLUTION PREVENTION & TO TSCA DATA PROCESSING CENTER CBIC WASHINGTON DC 20460-0001</p>	<p style="text-align: right;">0.0 LBS LTR</p> <p style="text-align: right;">1 OF 1</p>	<p style="font-size: 2em; font-weight: bold;">MD 201 9-80</p> 	<p style="font-size: 2em; font-weight: bold;">UPS NEXT DAY AIR</p> <p style="font-size: 3em; font-weight: bold;">1</p> <p>TRACKING #: 1Z 464 696 01 9954 1666</p> 	<p style="text-align: right;">BILLING: P/P</p>  <p style="font-size: 8px; text-align: right;">UIS 12.6.16. WPB60 06.0A 07/2010</p>
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