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July 13, 2010

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TSCA Confidential Business Information Center (7407M)
EPA East - Room 6428 Attn: Section 8(e)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

8EHQ-0710-18037A
DCN: 88100000362



**Re: Valspar Corporation; TSCA Section 8(e) Submission for Hydroquinone
Diglycidyl Ether (HQDGE) (CAS Reg. No. 2425-01-6)**

Dear Sir or Madam:

On behalf of our client, Valspar Corporation (Valspar), we are delivering to the U.S. Environmental Protection Agency (EPA) under section 8(e) of the Toxic Substances Control Act (TSCA) results of a mouse lymphoma forward mutation screen using the test substance hydroquinone diglycidyl ether (HQDGE) (CAS Reg. No. 2425-01-6). We are enclosing a summary report of the results.

Although this submission is made in accordance with EPA's Section 8(e) *Notification of Substantial Risk; Policy Clarification and Reporting Guidance* (68 Fed. Reg. 33,129, Jun. 3, 2003), Valspar does not consider the results particularly remarkable nor does Valspar necessarily consider positive *in vitro* data in and of themselves reportable under section 8(e), particularly when the test substance is only at the research and development (R&D) stage, as is the case here. Valspar currently is developing HQDGE solely for FDA-regulated food contact use. Valspar is making this submission at this time to cover the possibility that in the future one or more non-exempt applications for this substance may evolve, and, thus, Valspar is submitting this information out of an abundance of caution.

Summary of Results

L5178Y TK^{+/+} Mouse Lymphoma Forward Mutation Screen with Three Treatment Conditions

HQDGE was evaluated in the L5178Y TK^{+/+} Mouse Lymphoma Forward Mutation Screen with Three Treatment Conditions as indicated in Trial 8228874-B3 (*see* attached Tables 1 to 3). As noted by the conducting laboratory, increases in the frequency of TFT^r mutants were observed under all three treatment conditions. These increases also appeared to be dose-dependent. However, only one dose level with acceptable cytotoxicity was available for the 4-hour treatment without S9. In addition, the maximal responses observed for each treatment

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condition exceeded the criteria for a positive response (a net increase ≥ 90 TFT^r mutants/ 10^6 clonable cells above the average concurrent vehicle control mutant frequency).

Two trials were terminated early – prior to selection – due to excessive cytotoxicity. Valspar has confirmed with the laboratory that, for the terminated trials, a ten-fold dose formulation error left the testing laboratory with insufficient remaining dose levels for an acceptable assay. As a result, no mutagenicity results were obtained for the terminated trials and results have not been replicated in the subject study.

The results in Tables 1 -3 indicate that HQDGE was positive in the L5178Y TK^{+/-} Mouse Lymphoma Forward Mutation Screen with Three Treatment Conditions under the conditions, and according to the criteria, of the protocol.

* * *

We thank you in advance for your consideration of this information. If you have any questions regarding this submission, you may contact:

Ms. Lynn Rutkowski
Regulatory Affairs Supervisor
Valspar Corporation
2001 Tracy Street
Pittsburgh, Pennsylvania 15233
Tel: 412-734-8583
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E-mail: lrutkowski@valspar.com

Sincerely,

Thomas C. Berger / P.O.B.

Thomas C. Berger

Enclosure

Report

Study Title L5178Y TK⁺ Mouse Lymphoma Forward
Mutation Screen with Three Treatment
Conditions

Study Director Leon F. Stankowski, Jr., PhD

Sponsor Valspar Packaging Coatings Group
2001 Tracy Street
Pittsburgh, Pennsylvania 15233
United States of America

Sponsor's Authorized Representative Janet Bliss

Testing Facility Covance Laboratories Inc.
9200 Leesburg Pike
Vienna, Virginia 22182
United States of America

Covance Study Number 8228874

Covance Client Code 1006888

Genetic Toxicology Protocol Modifier 431SC, Design 2

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STUDY INFORMATION

Test Article

The test article was supplied by the Sponsor on 10 May 2010 as a white flocculent powder with the following information/characteristics.

Test article	Lot No.	Storage	Purity	Expiration Date
Hydroquinone diglycidyl ether (HQDGE)	AL 634-74	room temperature with desiccant	99.4%	NP

NP = Not provided

Study Timetable

Experimental Start Date 18 May 2010
Experimental Completion Date 17 June 2010

DATA INTERPRETATION

HQDGE was evaluated in the L5178Y TK^{+/+} Mouse Lymphoma Forward Mutation Screen with Three Treatment Conditions as indicated in Trial 8228874-B3 (Tables 1 to 3; two earlier trials were terminated due to excessive cytotoxicity at higher concentrations or due to technical error; not shown). Increases in the frequency of TFT^r mutants were observed under all three treatment conditions. These increases also appeared to be dose dependent (however, only one dose level with acceptable cytotoxicity was available for the 4-hour treatment without S9). In addition, the maximal responses observed for each treatment condition exceeded the criteria for a positive response (a net increase ≥ 90 TFT^r mutants/ 10^6 clonable cells above the average concurrent vehicle control mutant frequency).

All positive and vehicle control values were within acceptable ranges, and all criteria for a valid study were met.

CONCLUSION

These results indicate HQDGE was positive in the L5178Y TK^{+/+} Mouse Lymphoma Forward Mutation Screen with Three Treatment Conditions under the conditions, and according to the criteria, of the protocol.

Study Director:



Leon F. Stankowski, Jr., PhD
Genetic and Molecular Toxicology
Covance-Vienna

25 JUN 2010

Date

Table 1
Mutation Screen (4-Hour Treatment with S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE)
B. Study No.: 8228874
C. Vehicle: Dimethylsulfoxide (DMSO)
D. Selective Agent: TFT 3.0 µg/mL

E. Treatment Date: 06/01/2010
F. Cells Analyzed: 3×10^6
G. Treatment Period: ~4 hours
H. Expression Period: 2 days

Test Condition	Daily Cell Density/mL ($\times 10^5$)		Cumulative RSG ^a		Total Mutant Colonies	Total Viable Colonies	Cloning Efficiency ^b	Relative Growth (%) ^c	Mutant Frequency ($\times 10^{-6}$) ^d
	Day 1	Day 2	AVG VC				AVG VC		
Activation Controls ^e									
Vehicle Control	8.3	12.1	11.2		78	526	87.7	130.9	29.7
Vehicle Control	7.7	11.7	10.0		57	388	64.6	86.5	29.4
Vehicle Control	7.9	11.3	9.9	10.4	92	385	64.2	85.2	48.0
MCA 2.00 µg/mL	4.5	9.7	4.8		442	194	32.4	21.0	454.9 ^f
MCA 4.00 µg/mL	3.4 ^g	7.6	2.5		364	187	31.2	10.6	388.6 ^f
Test Article (µg/mL)			Relative to Vehicle Control (%)				Relative to Vehicle Control (%)		
1.00	8.5	10.6	96.6		72	423	97.7	94.4	34.2
10.0	5.8	12.4	77.1		98	363	83.8	64.6	54.2
20.0	4.1	9.5	41.8		140	165	38.0	15.9	169.8 ^f
25.0	4.0	6.3	27.0		^h	47	10.9	2.2	ⁱ
30.0	3.1 ^g	4.3	13.8		^h	15	3.6	0.5	ⁱ

^aRSG = (Day 1 Count/3) x (Day 2 Count)/3 (or Day 1 Count if not subcultured)

^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100

^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100

^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2×10^{-4})

Decimal is moved to express the frequency in units of 10^{-6}

^eVehicle Control = 1% DMSO

Positive Control: MCA = Methylcholanthrene

^fMutagenic. Exceeds Minimum Criterion of 125.7×10^{-6}

^gNot subcultured.

^hNot scored due to excessive cytotoxicity.

ⁱInsufficient data for calculations.

Table 2
Sizing Data for Mutation Screen (4-Hour Treatment with S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE)

B. Study No.: 8228874

C. Vehicle; Dimethylsulfoxide (DMSO)

D. Selective Agent: TFT 3.0 µg/mL

E. Treatment Date: 06/01/2010

Test Condition	Conc.	Cum. RSG (%) ^a		Cloning Efficiency ^b		Relative Growth ^c (%)	Mutant Frequency (x 10 ⁻⁶) ^d		
		Day 1	Day 2	Abs %	Rel %		Total	Small	Large
Vehicle Control ^e	1%	104.2	107.7	87.7	121.5	130.9	29.7	9.5	20.3
	1%	96.7	96.6	64.6	89.5	86.5	29.4	12.8	16.5
	1%	99.2	95.7	64.2	89.0	85.2	48.0	15.4	32.6
MCA ^f (µg/mL)	2.00	56.5	46.8	32.4	44.9	21.0	454.9	234.1	220.7
	4.00	42.7	24.4	31.2	43.2	10.6	388.6	191.1	197.5
Test Article (µg/mL)	1.00	106.7	96.6	70.5	97.7	94.4	34.2	18.5	15.7
	10.0	72.8	77.1	60.5	83.8	64.6	54.2	22.2	32.0
	20.0	51.5	41.8	27.5	38.0	15.9	169.8	86.3	83.5

^aCum. RSG = Cumulative Suspension Growth Relative to the Average Vehicle Control Suspension Growth^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2 x 10⁻⁴)Decimal is moved to express the frequency in units of 10⁻⁶

Expressed as Total Mutant Frequency, Small Colony Mutant Frequency and Large Colony Mutant Frequency

^eVehicle Control = DMSO^fPositive Control: MCA = Methylcholanthrene

Table 3
Mutation Screen (4-Hour Treatment without S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE) E. Treatment Date: 06/01/2010
 B. Study No.: 8228874 F. Cells Analyzed: 3×10^6
 C. Vehicle: Dimethylsulfoxide (DMSO) G. Treatment Period: ~4 hours
 D. Selective Agent: TFT 3.0 $\mu\text{g/mL}$ H. Expression Period: 2 days

Test Condition	Daily Cell Density/mL ($\times 10^5$)		Cumulative RSG ^a	Total Mutant Colonies	Total Viable Colonies	Cloning Efficiency ^b	Relative Growth (%) ^c	Mutant Frequency ($\times 10^{-6}$) ^d
	Day 1	Day 2						
Nonactivation Controls ^e								
			AVG VC				AVG VC	
Vehicle Control	10.7	9.9	11.8	97	509	84.8	109.5	38.2
Vehicle Control	10.6	9.4	11.1	72	424	70.7	86.0	34.1
Vehicle Control	10.0	10.8	12.0	69	479	79.8	78.4	28.7
MMS 15.0 $\mu\text{g/mL}$	7.5	7.8	6.5	197	145	24.1	17.2	272.1 ^f
MMS 20.0 $\mu\text{g/mL}$	8.9	5.3	5.2	138	78	13.0	7.5	351.5 ^f
Test Article ($\mu\text{g/mL}$)			Relative to Vehicle Control (%)			Relative to Vehicle Control (%)		
0.25	10.2	9.6	93.7	193	281	59.7	55.9	137.6 ^f
1.00	6.5	7.4	46.0	g	52	11.1	5.1	h
2.00	5.6	6.1	32.7	g	5	1.0	0.3	h
4.00	4.8	4.7	21.6	g	h	h	h	h
5.00	4.1	4.7	18.4	g	h	h	h	h

^aRSG = (Day 1 Count/3) x (Day 2 Count)/3 (or Day 1 Count if not subcultured)

^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100

^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100

^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2×10^{-4})

Decimal is moved to express the frequency in units of 10^{-6}

^eVehicle Control = 1% DMSO

Positive Control: MMS = Methyl methanesulfonate

^fMutagenic. Exceeds Minimum Criterion of 123.7×10^{-6}

^gNot scored due to excessive cytotoxicity.

^hInsufficient data for calculations.

Table 4
Sizing Data for Mutation Screen (4-Hour Treatment without S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE)
 B. Study No.: 8228874
 C. Vehicle: Dimethylsulfoxide (DMSO)
 D. Selective Agent: TFT 3.0 µg/mL
 E. Treatment Date: 06/01/2010

Test Condition	Conc.	Cum. RSG (%) ^a		Cloning Efficiency ^b		Relative Growth ^c (%)	Mutant Frequency (x 10 ⁻⁶) ^d		
		Day 1	Day 2	Abs %	Rel %		Total	Small	Large
Vehicle Control ^e	1%	102.6	101.3	84.8	108.1	109.5	38.2	16.3	21.9
	1%	101.6	95.3	70.7	90.2	86.0	34.1	15.6	18.4
	1%	95.8	103.3	79.8	101.8	105.1	28.7	11.9	16.8
MMS ^f (µg/mL)	15.0	71.9	56.0	24.1	30.7	17.2	272.1	170.5	101.6
	20.0	85.3	45.1	13.0	16.6	7.5	351.5	203.0	148.5
Test Article (µg/mL)	0.25	97.8	93.7	46.8	59.7	55.9	137.6	82.7	54.9

^aCum. RSG = Cumulative Suspension Growth Relative to the Average Vehicle Control Suspension Growth

^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100

^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100

^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2 x 10⁻⁴)

Decimal is moved to express the frequency in units of 10⁻⁶

Expressed as Total Mutant Frequency, Small Colony Mutant Frequency and Large Colony Mutant Frequency

^eVehicle Control = DMSO

^fPositive Control: MMS = Methyl methanesulfonate

Table 5
Mutation Screen (24-Hour Treatment without S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE)
B. Study No.: 8228874
C. Vehicle: Dimethylsulfoxide (DMSO)
D. Selective Agent: TFT 3.0 µg/mL

E. Treatment Date: 06/01/2010
F. Cells Analyzed: 3×10^6
G. Treatment Period: ~24 hours
H. Expression Period: 2 days

Test Condition	Daily Cell Density/mL (x 10 ⁵)			Cumulative RSG ^a	Total Mutant Colonies	Total Viable Colonies	Cloning Efficiency ^b	Relative Growth (%) ^c	Mutant Frequency (x 10 ⁻⁶) ^d	
	Day 1	Day 2	Day 3							
Nonactivation Controls ^e				AVG VC			AVG VC			
Vehicle Control	11.0	11.5	8.5	39.8	70	407	67.8	110.7	34.4	
Vehicle Control	11.7	10.4	9.2	41.5	64	326	54.3	92.4	39.3	
Vehicle Control	10.5	8.6	8.1	27.1	36.1	120	80.4	67.5	49.6	
MMS 6.50 µg/mL	8.8	7.0	5.6	12.8		258	140	23.3	12.2	369.5 ^f
MMS 10.0 µg/mL	7.2	5.7	4.6	7.0		141	39	6.5	1.9	721.2 ^f
Test Article (µg/mL)				Relative to Vehicle Control (%)			Relative to Vehicle Control (%)			
0.050	9.9	11.6	9.0	106.0	140	301	74.3	78.8	92.9	
0.075	8.9	11.1	8.3	84.1	140	289	71.4	60.0	96.7	
0.100	8.2	11.1	7.6	70.9	174	203	50.0	35.5	171.9 ^f	
0.250	8.3	8.6	4.6	33.7	204	133	32.8	11.0	307.1 ^f	
0.500	7.5	5.1	3.7	14.5	^g	17	4.1	0.6	^h	

^aRSG = [Treatment termination (Day 1) cell density/3] x [Day 2 cell density/3 or Day 1 density if not split back] x [Day 3 cell density/3 or Day 2 density if not split back]

^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100

^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100

^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2×10^{-4})

Decimal is moved to express the frequency in units of 10^{-6}

^eVehicle Control = 1%DMSO

Positive Control: MMS = Methyl methanesulfonate

^fMutagenic. Exceeds Minimum Criterion of 131.1×10^{-6}

^gNot scored due to excessive cytotoxicity.

^hInsufficient data for calculations.

Table 6
Sizing Data for Mutation Screen (24-Hour Treatment without S9)

A. Test Article: Hydroquinone diglycidyl ether (HQDGE)
 B. Study No.: 8228874
 C. Vehicle: Dimethylsulfoxide (DMSO)
 D. Selective Agent: TFT 3.0 µg/mL
 E. Treatment Date: 06/01/2010

Test Condition	Conc.	Cum. RSG (%) ^a			Cloning Efficiency ^b		Relative Growth ^c (%)	Mutant Frequency (x 10 ⁻⁶) ^d		
		Day 1	Day 2	Day 3	Abs %	Rel %		Total	Small	Large
Vehicle Control ^e										
	1%	99.4	112.1	110.2	67.8	100.4	110.7	34.4	14.6	19.8
	1%	105.7	107.8	114.8	54.3	80.5	92.4	39.3	10.9	28.4
	1%	94.9	80.0	75.0	80.4	119.1	89.3	49.6	11.8	37.8
MMS ^f (µg/mL)										
	6.50	79.5	54.6	35.4	23.3	34.5	12.2	369.5	216.9	152.5
	10.0	65.1	36.4	19.4	6.5	9.7	1.9	721.2	381.8	339.4
Test Article (µg/mL)										
	0.050	89.5	101.8	106.0	50.2	74.3	78.8	92.9	45.7	47.2
	0.075	80.4	87.6	84.1	48.2	71.4	60.0	96.7	38.5	58.2
	0.100	74.1	80.7	70.9	33.8	50.0	35.5	171.9	70.2	101.8
	0.250	75.0	63.3	33.7	22.1	32.8	11.0	307.1	173.2	133.9

^aCum. RSG = Cumulative Suspension Growth Relative to the Average Vehicle Control Suspension Growth

^bCloning Efficiency = Total Viable Colony Count/Number of Cells Seeded x 100

^cRelative Growth = (Relative Suspension Growth x Relative Cloning Efficiency) / 100

^dMutant Frequency = (Total Mutant Colonies/Total Viable Colonies) x (2 x 10⁻⁴)

Decimal is moved to express the frequency in units of 10⁻⁶

Expressed as Total Mutant Frequency, Small Colony Mutant Frequency and Large Colony Mutant Frequency

^eVehicle Control = DMSO

^fPositive Control: MMS = Methyl methanesulfonate