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June 23, 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

10 JUN 23 PM 1:45

RECEIVED

Re: Valspar Corporation; TSCA Section 8(e) Submission for Isobutyl Methacrylate (IBMA) (CAS Reg. No: 97-86-9)

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 and chromosomal aberration test using the test substance isobutyl methacrylate (IBMA) (CAS Reg. No. 97-86-9). We are enclosing tables that summarize the test results.

Although this submission is being 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 IBMA 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

Mouse Lymphoma (MLA) Test

The test substance IBMA was examined for its potential to induce gene mutations at the TK-locus of cultured mouse lymphoma L5178Y cells, in both the absence and the presence of a metabolic activation system (S9-mix). One assay was conducted in which 13 single cultures were treated for 24 hours and 4 hours in the absence and presence of S9-mix, respectively.

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Limited by cytotoxicity, the highest concentrations evaluated for mutagenicity were 1.1 and 5.0 mmol/l in the absence and presence of S9-mix respectively. The relative total growth (RTG) at these conditions were 12% and 30%, respectively, which corresponds with 88 and 70% cytotoxicity. In the absence of S9-mix, this is as required by the guidelines (RTG should be between 10 and 20%); in the presence of S9-mix, higher concentrations might have been tested.

In both the absence and presence of S9-mix, a dose related and significant increase in mutant frequency was observed. In the absence of S9-mix, the mutant frequencies (MF) at 0.67, 0.78, 0.92 and 1.1 mmol/l were increased by respectively 92, 97, 176 and 345 mutants per 1,000,000 clonable cells compared to the negative control. In the presence of S9-mix at 5 mmol/l, the MF was increased by 195 mutants.

Because the positive (increase of MF>126) and equivocal responses (increase MF>88) were observed at several concentrations and also dose-related, the conducting laboratory concluded that there is no need to repeat the assay and that under the conditions used in the study the test substance IBMA is mutagenic.

Chromosomal Aberration (CAT) Study

In the chromosomal aberration test with the test substance IBMA, in both the absence and presence of a metabolic activation system (S9-mix), the treatment/harvesting times were 4/18 hours (pulse treatment).

In both the absence and presence of S9-mix, a dose-related increase in cytotoxicity was observed. In both, three dose levels of the test substance (400, 800 and 1572 µg/ml) were selected for chromosomal aberration analysis. In both the absence and presence of the S9-mix, the test substance induced a dose-related statistically significant increase in the number of cells with structural aberration when compared to the number of cells in the concurrent negative control cultures.

The numbers of cells with structural aberrations observed in the vehicle control (DMSO) cultures were within the historical range. The positive controls induced the expected statistically significant increases in the incidence of structural aberrations.

From the results obtained in the first chromosomal aberration test and under the conditions used in this study, the conducting laboratory concluded that test substance IBMA is clastogenic to the cultured human lymphocytes.

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

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Sincerely,

Thomas C. Berger / P.O.B.

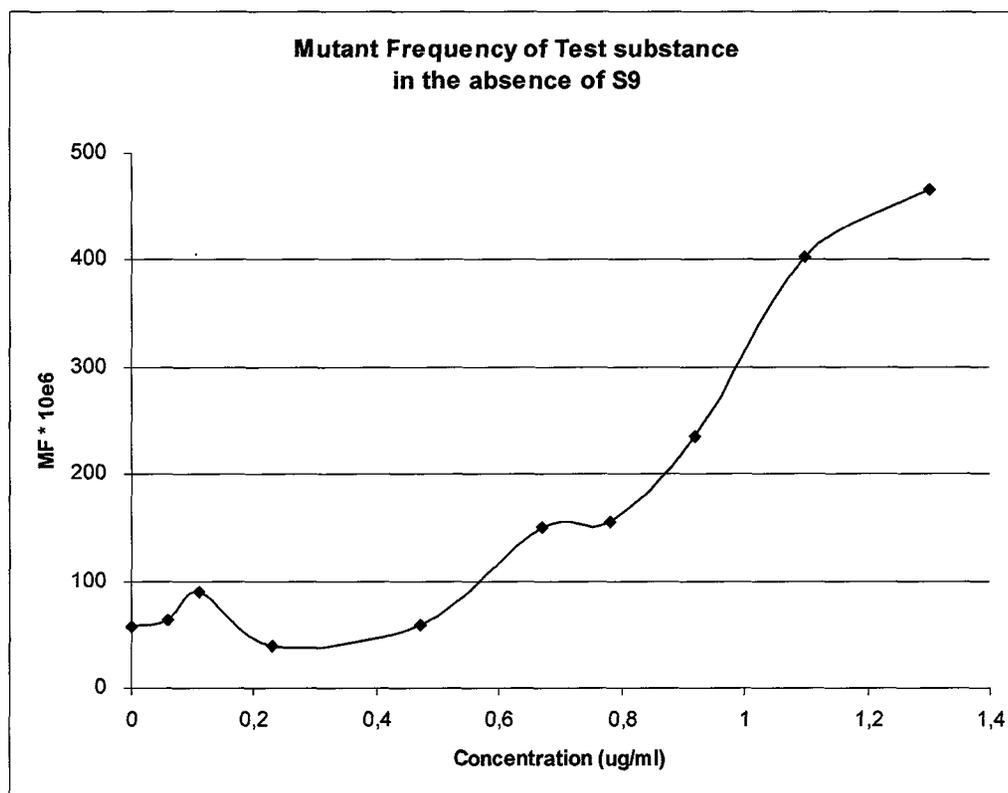
Thomas C. Berger

Enclosures

Results of Gene mutation test with IBMA (8803/08)

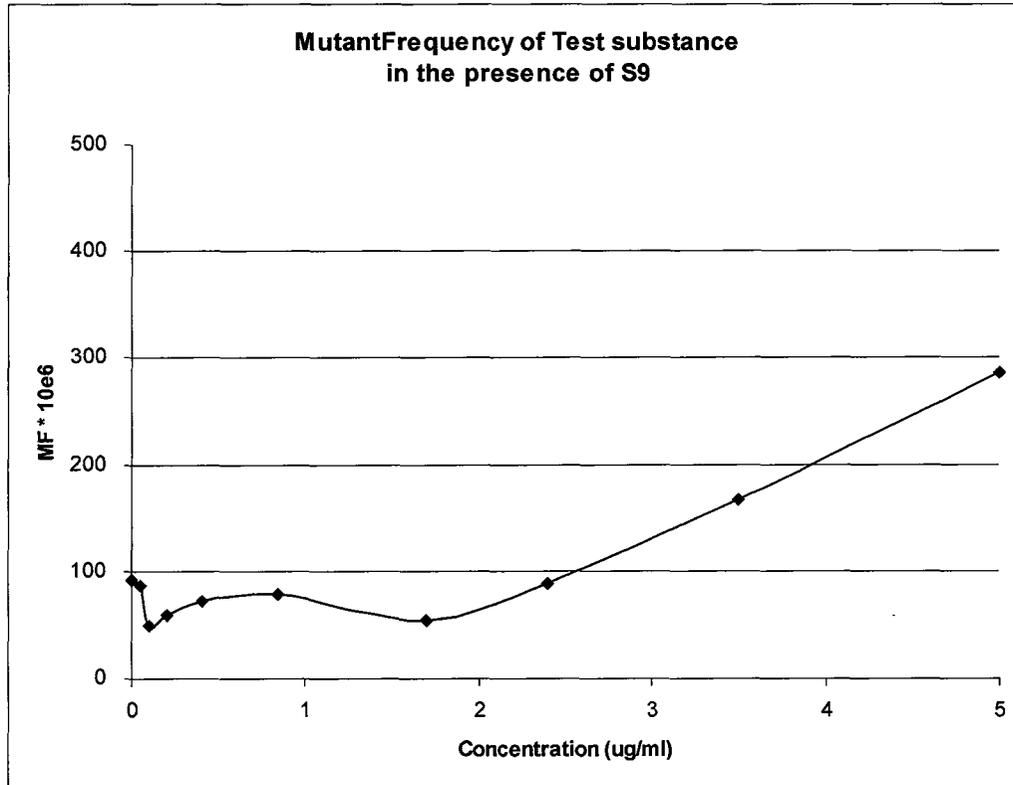
Mutant frequency in the absence of S9 (24h exposure)

Dose (mmol/l)	MF 1	MF 2	Mean	Increase	RTG
1.3	467		467	409	5
1.1	403		403	345	12
0.92	234		234	176	24
0.78	155		155	97	28
0.67	150		150	92	36
0.47	58		58	0	52
0.23	39		39	-18	72
0.11	89		89	32	63
0.06	64		64	6	94
0	56	59	58	0	100



Mutant frequency in the presence of S9 (4 h exposure)

Dose (mmol/l)	MF 1	MF 2	Mean	Increase	RTG
5	286		286	195	30
3.5	166		166	75	56
2.4	88		88	-3	67
1.7	53		53	-38	99
0.84	78		78	-12	95
0.41	72		72	-19	114
0.2	58		58	-32	110
0.1	50		50	-41	111
0.05	87		87	-4	101
0	71	110	91	0	100



Results of the Chromosomal Aberration Analysis of the study 8802/02 Test 1

Table 1 ► Pulse treatment method with S9-mix

Treatment / harvest time (h)	Dose level (µg/ml)	Number of cells showing structural chromosome aberrations								Statistics ²⁾	Number of cells with only gaps ¹⁾	Relative Mitotic index (%)
		cells observed	chromatid break	chromatid exchange	chromosome break	chromosome exchange	others	Number of cells showing aberrations (%)				
4/24 (+ S9)	neg. control (DMSO)	100	0	0	0	0	0	0	-	0	100	
		100	0	0	0	0	0	0		1		
		200	0	0	0	0	0	0 (0.0)		1		
	400	100	0	1	0	0	0	1	p0.500	0	94	
		100	0	0	1	0	0	0		0		
		200	0	1	1	0	0	1 (0.5)		0		
	800	100	2	1	0	0	0	3	*p<0.05	0	71	
		100	0	0	2	0	0	2		0		
		200	2	1	2	0	0	5 (2.5)		0		
	1572	100	13	4	1	0	0	17	***p<0.001	0	51	
		100	9	2	0	0	0	9		0		
		200	22	6	1	0	0	26 (13.0)		0		
	pos. control cyclophosphamide (25.0)	100	14	9	2	0	0	24	***p<0.001	0	50	
		100	16	8	4	0	0	23		0		
		200	30	17	6	0	0	47 (23.5)		0		

¹⁾ Gap(g) - total number of cells showing only (chromatid-type and chromosome-type) gaps, ²⁾ Fisher's exact probability test (one-sided): *** p<0.001

Results of the Chromosomal Aberration Analysis of the study 8802/02 Test 1

Table 2 ► Pulse treatment method without S9-mix

Treatment / harvest time (h)	Dose level (µg/ml)	Number of cells showing structural chromosome aberrations							Statistics ²⁾	Number of cells with only gaps ¹⁾	Relative Mitotic index (%)
		cells observed	chromatid break	chromatid exchange	chromo-some break	chromo-some exchange	others	Number of cells showing aberrations (%)			
4/24 (- S9)	neg. control (DMSO)	100	1	0	0	0	0	1	-	0	100
		100	0	0	0	0	0	0		0	
		200	1	0	0	0	0	1 (0.5)		0	
	400	100	0	0	0	0	0	0	p0.500	0	91
		100	1	0	1	0	0	2		0	
		200	1	0	1	0	0	2 (1.0)		0	
	800	100	1	0	0	0	0	1	p0.751	0	61
		100	0	0	0	0	0	0		1	
		200	1	0	0	0	0	1 (0.5)		1	
	1572	100	6	3	1	0	0	8	***p<0.001	1	49
		100	17	8	1	0	0	22		0	
		200	23	11	2	0	0	30 (15.0)		1	
	pos.control mitomycin C (0.4)	100	13	20	2	0	0	33	***p<0.001	0	69
		100	15	18	3	0	0	31		0	
		200	28	38	5	0	0	64(32.0)		0	

¹⁾ Gap(g) - total number of cells showing only (chromatid-type and chromosome-type) gaps

²⁾ Fisher's exact probability test (one-sided): *** p<0.001