Appendix G2

Dataset Received from S.C. Johnson & Son, Inc. in Support of Cuellar et al. (2002) Poster Presentation

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SC Johnson
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S.C. Johnson & Son, Inc.
Worldwide Consumer Products, RD & E
Global Safety Assessment and Regulatory Affairs, Product Toxicology
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September 3, 2004

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Christina,

Hi! How are you? I am happy to be submitting the data on benchmark and fragrance formulations, which were partially discussed in the poster citation listed below:

Cuellar, N., Merrill, J.C., Clear, M.L.,. Mun G., and Harbell J.W. 2002. The application of benchmarks for the evaluation of the potential ocular irritancy of aerosol fragrances. The Toxicologist 66(1-S): 243-244.

Included with this submission are the following documents:

1. Cover letter
2. Data spreadsheet
3. Fragrance graphs
4. Coded formula spreadsheet

Study Protocols:

Standard Draize protocol was used for 4 of the in-vivo studies. The EPA aerosol protocol was used for test material #3. Standard BCOP protocol was used for the in-vitro work at IIVS. BCOP exposure times were 3 and 10 minutes with post exposure of 2 hours.

Formula Spreadsheet:

The formulas listed in this spreadsheet are coded similarly to past submissions. For benchmarks, test material number is the unique sample number whereas the group description is referenced in the poster as type of benchmark. Test material #3 and #4 (Alcohol-based benchmark) is not listed in the poster. For fragrance formulas, test material denotes the category (formula) whereas the group describes the formula form (i.e aerosol vs membrane (gel). Fragrances formulas are referenced in the poster. For both benchmarks and formulations, raw materials are listed followed by their percentages.

Poster:

Benchmark poster not included. John Harbell previously sent it to you.

Graphs:

Graphs plot the BCOP total score per each unique fragrance formulation. Graphs include reference benchmarks (see formula spreadsheet) and the ethanol control. The bars show one standard deviation from the mean value for each benchmark and the ethanol. Please not that the ethanol values displayed on the 3-minute exposure graphs are for a 3-minute exposure to ethanol (not the 10-minute exposure ethanol that was performed as the positive control). There are 9 tabs in this spreadsheet. Graphs are labeled per form ((2 for aerosol and 2 for membrane (gel)) and exposure time (3 or 10 minutes) in tabs 1-8. The first two graphs refer to the aerosol formulas and the second two graphs refer to the membrane. Each graph includes the corresponding raw data in the next tab. There are 44 aerosol formulas depicted in the aerosol graphs and 36 membrane formulas depicted in the membrane graphs. The final tab describes the basic statistics on the ethanol control and each benchmark by exposure time.

Data Worksheet:

The data worksheet consists of 4 tabs at the bottom of the page. We are including all tabs to clearly demonstrate how we analyzed the data into the GHS and EPA categories in the summary spreadsheet shown in tab #4.

Summary spreadsheet:

The summary spreadsheet is sorted by test material. The test material number refers to the benchmark formula or ethanol listed in the formula spreadsheet. GHS and EPA categories are in the next 8 columns in yellow. The last 2 columns consist of the mean BCOP total scores (3 and 10 minute) in blue. EPA and GHS criteria are summarized in this spreadsheet.

Data was analyzed per formula. Raw data scores from the first three days and days to clear per each of 6 rabbits were randomly put into combinations of three and categorized accordingly based on EPA or GHS criteria. This analysis resulted in a total of 20 combinations per formula. Each combination was listed in the appropriate GHS or EPA category. Scoring assumptions are also listed in this spreadsheet based on protocol differences.

Protocol used for the BCOP assay was the same for all benchmarks and ethanol formulas. In-vivo studies were conducted using the standard Draize protocol with the exception of the ethanol/fragrance benchmark. The ethanol/fragrance benchmark utilized the EPA aerosol dosing Draize protocol.

The ethanol/fragrance benchmark is used to evaluate specific aerosol formulations. This benchmark shows that even though the formulation would be irritating in the standard Draize Assay, the product is provided in a form that restricts exposure to the aerosol route by limiting exposure via a metered dose. The metered dosing approach demonstrates that new formulations would not exceed the irritation potential of the benchmark.

As shown in the graphs and the summary table, the BCOP is able to rank irritation of a variety of formulations in comparison to the benchmarks. Severe irritants can be identified using this methodology. The fragrance level in the formula does impact the irritation potential of the formula.

These data demonstrate the importance of assessing all new formulations relative to an appropriate fixed benchmark.

If you have any questions or comments on this data set, please feel free to contact either Judith Swanson or myself at the following:

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Sincere regards,

/s/

Nicole Cuellar
Sr. Research Toxicologist

In Vivo Data - S.C. Johnson Submission Dated September 3, 2004

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	CONJUNCTIVAL REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	F38948	#1	24	1	2	1	2	2	2	27	EPA
			48	1	1	0	2	1	0	11	14
			72	1	1	0	0	1	0	7	GHS
			7 days	0	0	0	2	0	0	4	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	

	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
GHS Tissue	F38948	#1	27	1.0	1.3	0.3	1.3	1.3	0.7	14	14
	ANIMAL ID										
Summary	1	#1	27	1.0	1.3	0.3	1.3	1.3	0.7	14	14
block used	2	#1	34	0.7	1.3	0.3	2.3	1.3	0.7	14	14
analysis of	3	#1	37	0.7	2.0	0.3	2.0	1.3	0.7	7	14
the twenty	4	#1	35	1.0	2.3	1.0	2.0	1.3	0.3	7	14
combinations	5	#1	39	1.0	2.7	1.0	2.7	1.3	2.0	14	14
	6	#1	30	1.0	1.7	1.0	2.7	1.3	0.3	14	14
	Dose Vol	0.1									

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	CONJUNCTIVAL REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	R2266	#2	24	0	0	0	1	0	0	2	EPA
			48	0	0	0	0	0	0	0	0
			72							0	GHS
			7 days							0	2
			14 days							0	
			21 days							0	

	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
GHS Tissue	R2266	#2	2	0.0	0.0	0.0	0.5	0.0	0.0	0	2
	ANIMAL ID										
Summary	1	#2	2	0.0	0.0	0.0	0.5	0.0	0.0	0	2
block used	2	#2	2	0.0	0.0	0.0	0.5	0.0	0.0	0	2
analysis of	3	#2	4	0.0	0.0	0.0	0.7	0.3	0.0	0	3
the twenty	4	#2	2	0.0	0.0	0.0	0.7	0.0	0.0	0	3
combinations	5	#2	2	0.0	0.0	0.0	0.7	0.0	0.0	0	3
	6	#2	4	0.0	0.0	0.0	0.7	0.7	0.0	0	3
	Dose Vol	0.1									

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Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	F38949	#1	24	1	3	1	3	2	2	34	EPA
			48	1	1	0	2	1	0	11	14
			72	0	0	0	2	1	0	6	GHS
			7 days	1	1	0	1	0	0	7	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	F38949	#1	34	0.666667	1.333333	0.333333	2.333333333	1.333333333	0.666666667	14	14
	Combinations	Opacity	Iris	Redness	Chemosis	DtC EPA	DtC GHS		Combinations	Opacity	Iris
Combination block #1	1,2,3	0.833333	0.333333	2.166667	1.333333	14	14	Combination block #2	1,3,4	1	0.666667
	GHS Rating	4	4	2	4	14	14		GHS Rating	2	4
	1,2,4	1	0.666667	2.166667	1.333333	14	14		1,3,5	1	0.666667
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	4
	1,2,5	1	0.666667	2.5	1.333333	14	14		1,3,6	1	0.666667
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	4
	1,2,6	1	0.666667	2.5	1.333333	14	14		1,4,5	1	1
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	4

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	R2317	#2	24	0	0	0	1	0	0	2	EPA
			48	0	0	0	0	0	0	0	0
			72							0	GHS
			7 days							0	2
			14 days							0	
			21 days							0	
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	R2317	#2	2	0	0	0	0.5	0	0	0	2
	Combinations	Opacity	Iris	Redness	Chemosis	DtC EPA	DtC GHS		Combinations	Opacity	Iris
Combination block #1	1,2,3	0	0	0.583333	0.166667	0	3	Combination block #2	1,3,4	0	0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4
	1,2,4	0	0	0.583333	0	0	3		1,3,5	0	0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4
	1,2,5	0	0	0.583333	0	0	3		1,3,6	0	0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4
	1,2,6	0	0	0.583333	0.333333	0	3		1,4,5	0	0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4

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		TEST		CORNEAL				CONJUNCTIVAL			DAYS-TO-
Volume	ANIMAL ID	MATL	TIME	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DRAIZE	CLEAR
0.1	F38950	#1	24	1	4	1	2	2	2	37	EPA
			48	1	2	0	2	1	0	16	7
			72	0	0	0	2	1	0	6	GHS
			7 days	0	0	0	1	0	0	2	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	F38950	#1	37	0.666667	2	0.333333	2	1.33333333	0.666666667	7	14
Redness	Chemosis	DtC EPA	DtC GHS		Combinatio Opacity		Iris	Redness	Chemosis	DtC EPA	DtC GHS
2	1.333333	14	14	Combina-	1,4,6	1.0	1.0	2.3	1.3	14	14
2	4	14	14	tion block	GHS Rating	2	4	2	4	14	14
2.333333	1.333333	14	14	#3	1,5,6	1.0	1.0	2.7	1.3	14	14
2	4	14	14		GHS Rating	2	4	2	4	14	14
2.333333	1.333333	14	14		2,3,4	0.8	0.7	2.2	1.3	14	14
2	4	14	14		GHS Rating	4	4	2	4	14	14
2.333333	1.333333	14	14		2,3,5	0.8	0.7	2.5	1.3	14	14
2	4	14	14		GHS Rating	4	4	2	4	14	14

		TEST		CORNEAL				CONJUNCTIVAL			DAYS-TO-
Volume	ANIMAL ID	MATL	TIME	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DRAIZE	CLEAR
0.1	R2314	#2	24	0	0	0	1	1	0	4	EPA
			48	0	0	0	1	0	0	2	0
			72	0	0	0	0	0	0	0	GHS
			7 days							0	3
			14 days							0	
			21 days							0	
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	R2314	#2	4	0	0	0	0.666666667	0.33333333	0	0	3
Redness	Chemosis	DtC EPA	DtC GHS		Combinatio Opacity		Iris	Redness	Chemosis	DtC EPA	DtC GHS
0.666667	0.166667	0	3	Combina-	1,4,6	0.0	0.0	0.7	0.3	0	3
4	4	0	3	tion block	GHS Rating	4	4	4	4	0	3
0.666667	0.166667	0	3	#3	1,5,6	0.0	0.0	0.7	0.3	0	3
4	4	0	3		GHS Rating	4	4	4	4	0	3
0.666667	0.5	0	3		2,3,4	0.0	0.0	0.7	0.2	0	3
4	4	0	3		GHS Rating	4	4	4	4	0	3
0.666667	0	0	3		2,3,5	0.0	0.0	0.7	0.2	0	3
4	4	0	3		GHS Rating	4	4	4	4	0	3

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Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	F38951	#1	24	1	4	1	2	2	1	35	EPA
			48	1	2	1	2	1	0	21	7
			72	1	1	1	2	1	0	16	GHS
			7 days	0	0	0	1	0	0	2	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	

	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	F38951	#1	35	1	2.333333	1	2	1.333333333	0.333333333	7	14
	Combinatio Opacity		Iris	Redness	Chemosis	DtC EPA	DtC GHS		Combinations	Opacity	Iris
Combina-	2,3,6	0.8	0.7	2.5	1.3	14	14	Combina-	3,4,5	1.0	1.0
tion block	GHS Rating	4	4	2	4	14	14	tion block	GHS Rating	2	4
#4	2,4,5	1.0	1.0	2.5	1.3	14	14	#5	3,4,6	1.0	1.0
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	4
	2,4,6	1.0	1.0	2.5	1.3	14	14		3,5,6	1.0	1.0
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	4
	2,5,6	1.0	1.0	2.7	1.3	14	14		4,5,6	1.0	1.0
	GHS Rating	2	4	2	4	14	14		GHS Rating	2	2

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	R2299	#2	24	0	0	0	1	0	0	2	EPA
			48	0	0	0	1	0	0	2	0
			72	0	0	0	0	0	0	0	GHS
			7 days							0	3
			14 days							0	
			21 days							0	

	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	R2299	#2	2	0	0	0	0.66666667	0	0	0	3
	Combinatio Opacity		Iris	Redness	Chemosis	DtC EPA	DtC GHS		Combinations	Opacity	Iris
Combina-	2,3,6	0.0	0.0	0.7	0.5	0	3	Combina-	3,4,5	0.0	0.0
tion block	GHS Rating	4	4	4	4	0	3	tion block	GHS Rating	4	4
#4	2,4,5	0.0	0.0	0.7	0.0	0	3	#5	3,4,6	0.0	0.0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4
	2,4,6	0.0	0.0	0.7	0.3	0	3		3,5,6	0.0	0.0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4
	2,5,6	0.0	0.0	0.7	0.3	0	3		4,5,6	0.0	0.0
	GHS Rating	4	4	4	4	0	3		GHS Rating	4	4

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	CONJUNCTIVAL REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	F38952	#1	24	1	4	1	2	2	3	39	EPA
			48	1	3	1	3	1	2	32	14
			72	1	1	1	3	1	1	20	GHS
			7 days	1	1	0	1	1	0	9	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	

ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
F38952	#1	39	1	2.666667	1	2.66666667	1.333333333	2	14	14

Redness	Chemosis	DtC EPA	DtC GHS	Summary			
2.3	1.3	14	14	#1	1,2,3	2	14
2	4	14	14		1,2,4	2	14
2.3	1.3	14	14		1,2,5	2	14
2	4	14	14		1,2,6	2	14
2.7	1.3	14	14		1,3,4	2	14
2	4	14	14		1,3,5	2	14
2.7	1.3	14	14		1,3,6	2	14
2	4	14	14		1,4,5	2	14
					1,4,6	2	14
					1,5,6	2	14

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	CONJUNCTIVAL REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	R2275	#2	24	0	0	0	1	0	0	2	EPA
			48	0	0	0	1	0	0	2	0
			72	0	0	0	0	0	0	0	GHS
			7 days							0	3
			14 days							0	
			21 days							0	

ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
R2275	#2	2	0	0	0	0.66666667	0	0	0	3

Redness	Chemosis	DtC EPA	DtC GHS	Summary			
0.7	0.2	0	3	#2	1,2,3	4	3
4	4	0	3		1,2,4	4	3
0.7	0.5	0	3		1,2,5	4	3
4	4	0	3		1,2,6	4	3
0.7	0.5	0	3		1,3,4	4	3
4	4	0	3		1,3,5	4	3
0.7	0.3	0	3		1,3,6	4	3
4	4	0	3		1,4,5	4	3
					1,4,6	4	3
					1,5,6	4	3

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	F38953	#1	24	1	3	1	2	2	1	30	EPA
			48	1	1	1	3	1	0	18	14
			72	1	1	1	3	1	0	18	GHS
			7 days	0	0	0	2	1	0	6	14
			14 days	0	0	0	0	0	0	0	
			21 days							0	

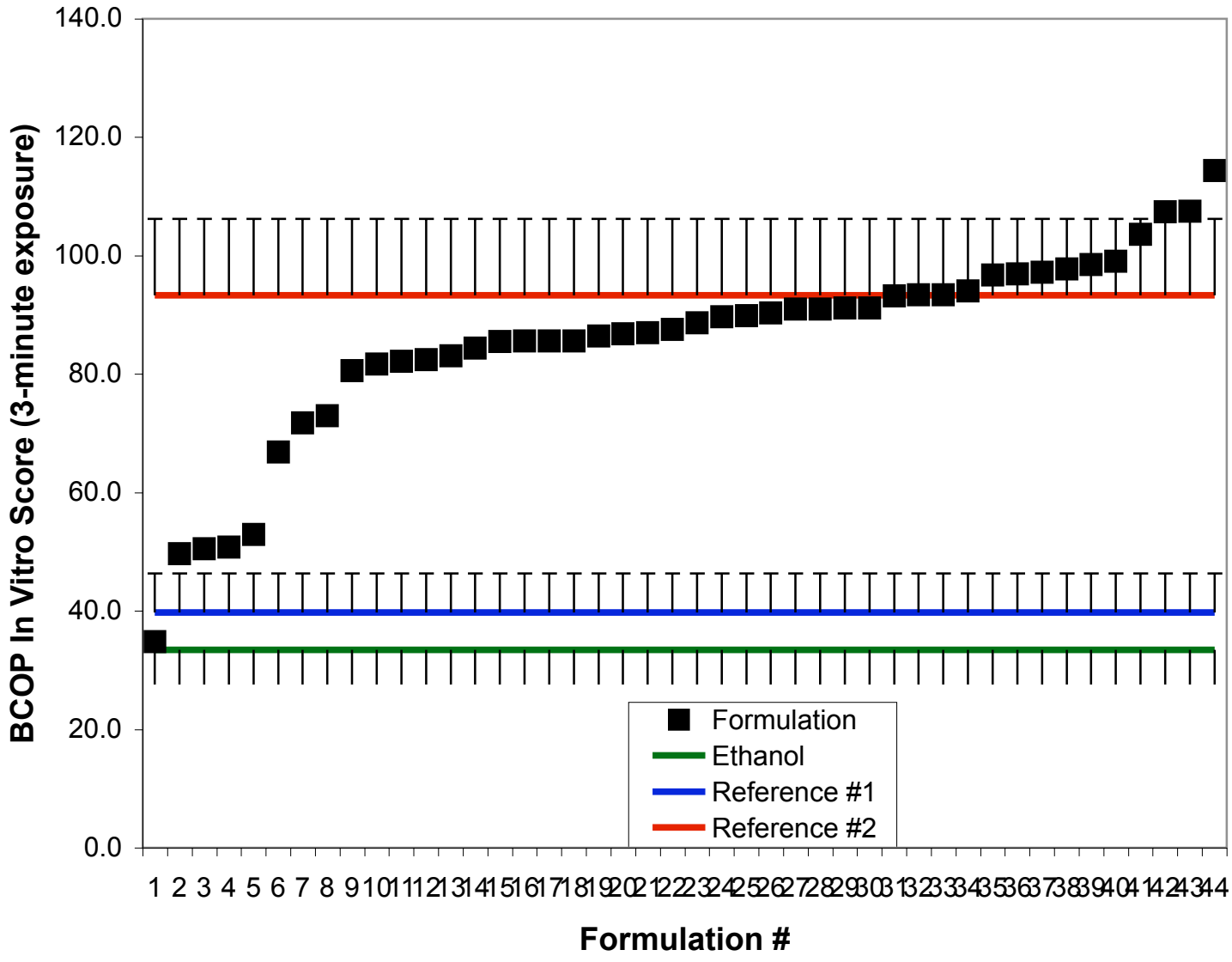
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	F38953	#1	30	1	1.666667	1	2.66666667	1.333333333	0.333333333	14	14
14		2,3,4	2	14		14					
14		2,3,5	2	14		14					
14		2,3,6	2	14		14					
14		2,4,5	2	14		14					
14		2,4,6	2	14		14					
14		2,5,6	2	14		14					
14		3,4,5	2	14		14					
14		3,4,6	2	14		14					
14		3,5,6	2	14		14					
14		4,5,6	2	14		14					

Volume	ANIMAL ID	TEST MATL	TIME	CORNEAL OPACITY	CORNEAL AREA	IRIS	REDNESS	CONJUNCTIVAL CHEMOSIS	CONJUNCTIVAL DISCHARGE	DRAIZE	DAYS-TO-CLEAR
0.1	R2267	#2	24	0	0	0	1	1	0	4	EPA
			48	0	0	0	1	1	0	4	0
			72	0	0	0	0	0	0	0	GHS
			7 days							0	3
			14 days							0	
			21 days							0	

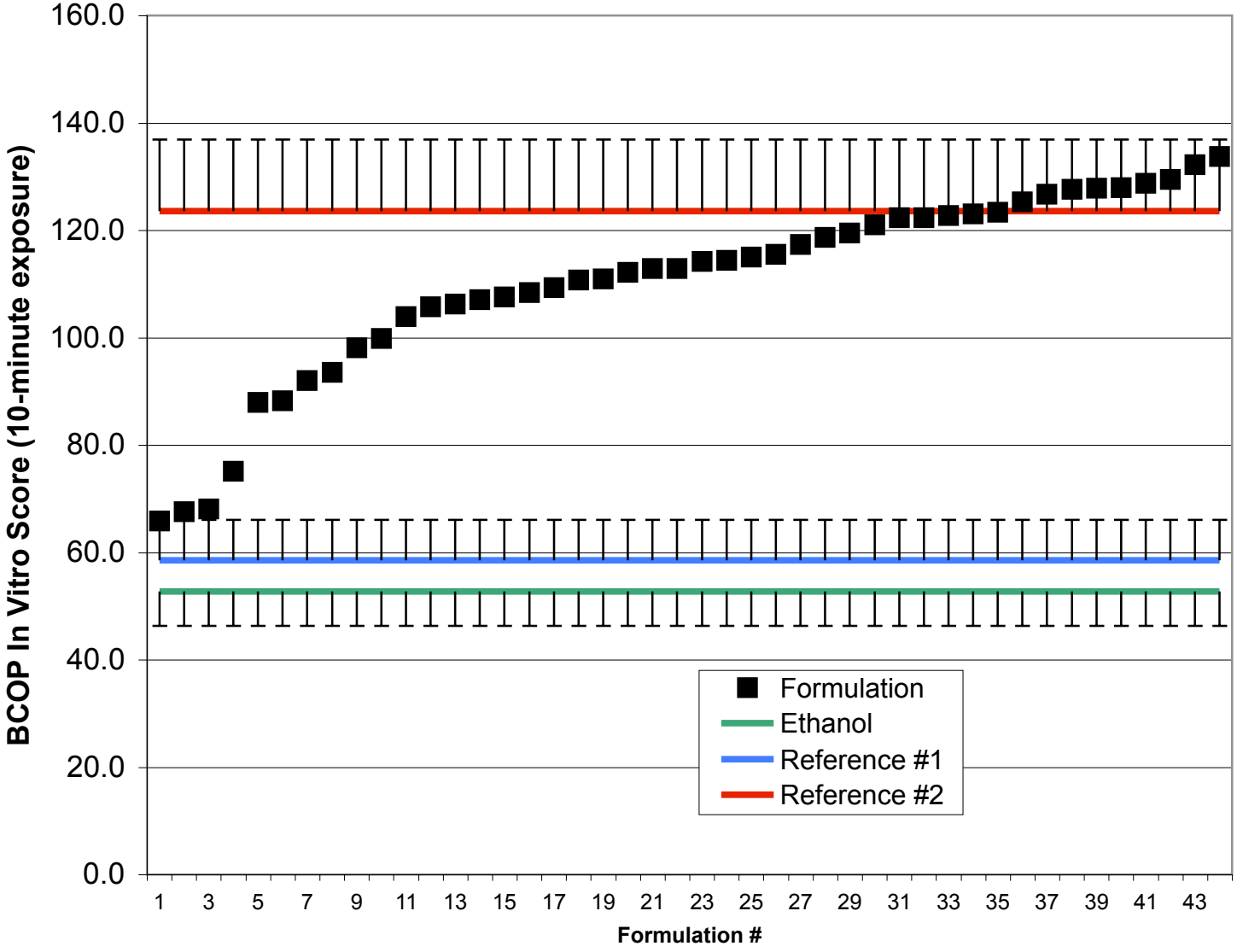
	ANIMAL ID	MATL	MAS	OPACITY	AREA	IRIS	REDNESS	CHEMOSIS	DISCHARGE	DtC EPA	DtC GHS
	R2267	#2	4	0	0	0	0.66666667	0.666666667	0	0	3
0		2,3,4	4	3		0					
0		2,3,5	4	3		0					
0		2,3,6	4	3		0					
0		2,4,5	4	3		0					
0		2,4,6	4	3		0					
0		2,5,6	4	3		0					
0		3,4,5	4	3		0					
0		3,4,6	4	3		0					
0		3,5,6	4	3		0					
0		4,5,6	4	3		0					

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1															
2					Test				Count per Category					BCOP Mean In Vitro Score	
3					Material #	GHS 1	GHS 2a	GHS 2b	GHS NI	EPA 1	EPA 2	EPA 3	EPA 4	3-minute	10-minute
4	Note #1	Fragrance Benchmark #3			#1	0	20	0	0	0	20	0	0	50.1	90.1
5	Note #2	Ethanol/Fragrance Benchmark #2			#2	0	0	0	20	0	0	0	20	93.3	123.6
6	Note #3	Alcohol-based Benchmark #1			#3	10	10	0	0	10	10	0	0	39.7	58.9
7	Note #4	Alcohol-based Benchmark #1			#4	20	0	0	0	20	0	0	0	39.7	58.9
8	Note #5	Ethanol			#5	10	10	0	0	10	10	0	0	33.4	52.7
9															
10	reference #s refer to the benchmark study														
11	data and figures														
12															
13	Note #1	Full volume rabbit eye irritation test													
14	Note #2	Aerosol protocol where eye is sprayed for one second at a distance of 10 cm							**Not a normal installation Draize test**						
15	Note #3	Full volume eye test. Details of BCOP Reference #1 provided in the earlier submission of ethanol containing formulations													
16	Note #4	second study also reported with the ethanol containing formulations													
17	Note #5	Full volume eye test. Data reported with ethanol formulations													
18															
19	Raw animal data already provided for Reference #1 and ethanol														
20															
21															
22		Opacity	Iris	Conjunct	Days to Clear		Notes:	GHS							
23	GHS 1	3 or >	1.5 or >	NA	>21		Tissue scores for 2 most irritated rabbits								
24	GHS 2a	1 or >	1 or >	2 or >	<21		Days to clear for the last rabbit to clear (all tissues)								
25	GHS 2b	1 or >	1 or >	2 or >	7 or <		(i.e., tissue scores of 0)								
26	GHS NI	<1	<1	<2	<21		Discharge not scored								
27								EPA							
28	EPA 1				>21		Rabbit has cleared if:								
29	EPA 2				<21		Opacity	Iris	Conjunct						
30	EPA 3				7 or <		<1	<1	<2						
31	EPA 4				1 or <		Discharge not scored								
32															
33															

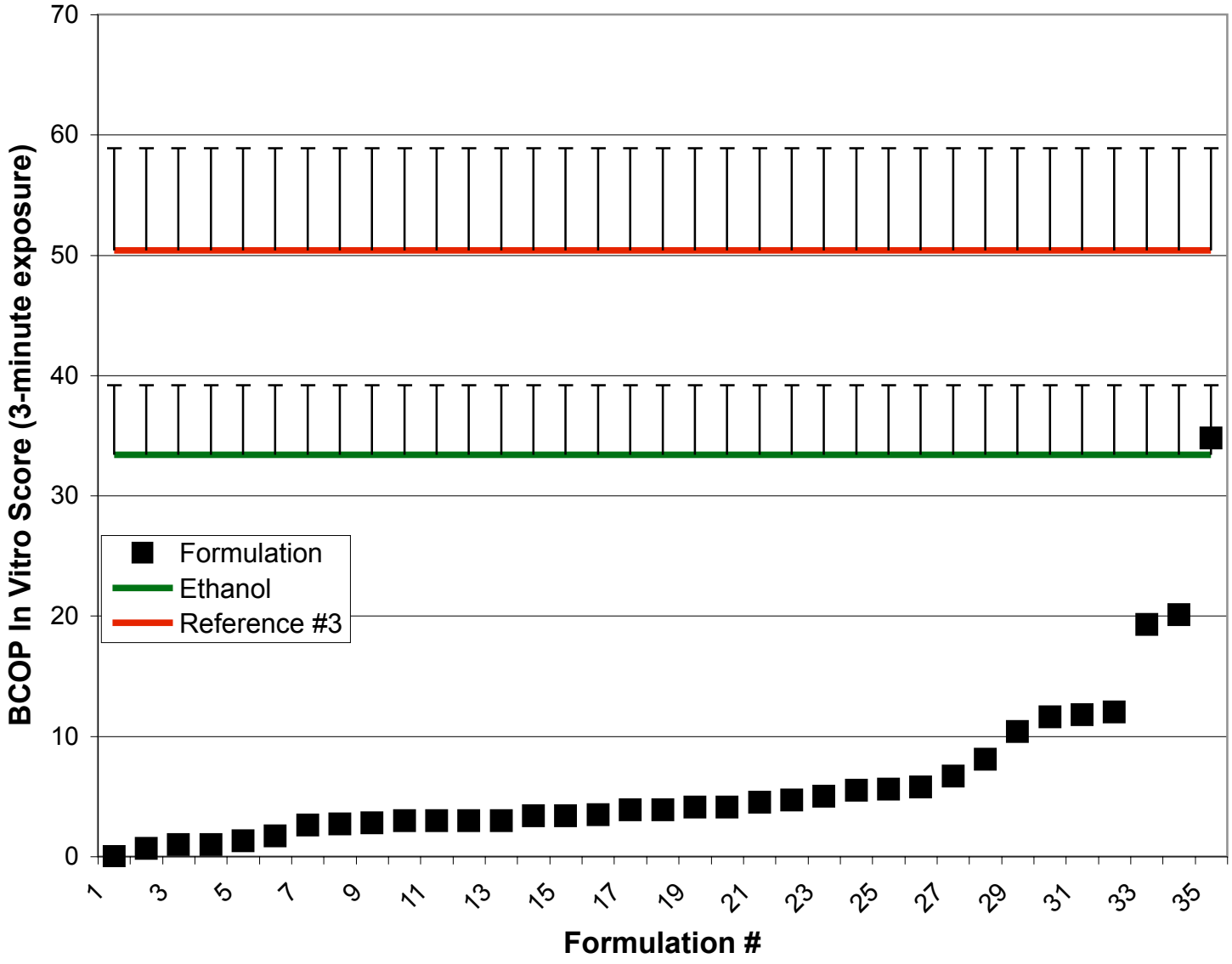
Fragrance Graphs for
SC Johnson Submission
Dated September 3, 2004



Fragrance Graphs for
SC Johnson Submission
Dated September 3, 2004



Fragrance Graphs for
SC Johnson Submission
Dated September 3, 2004



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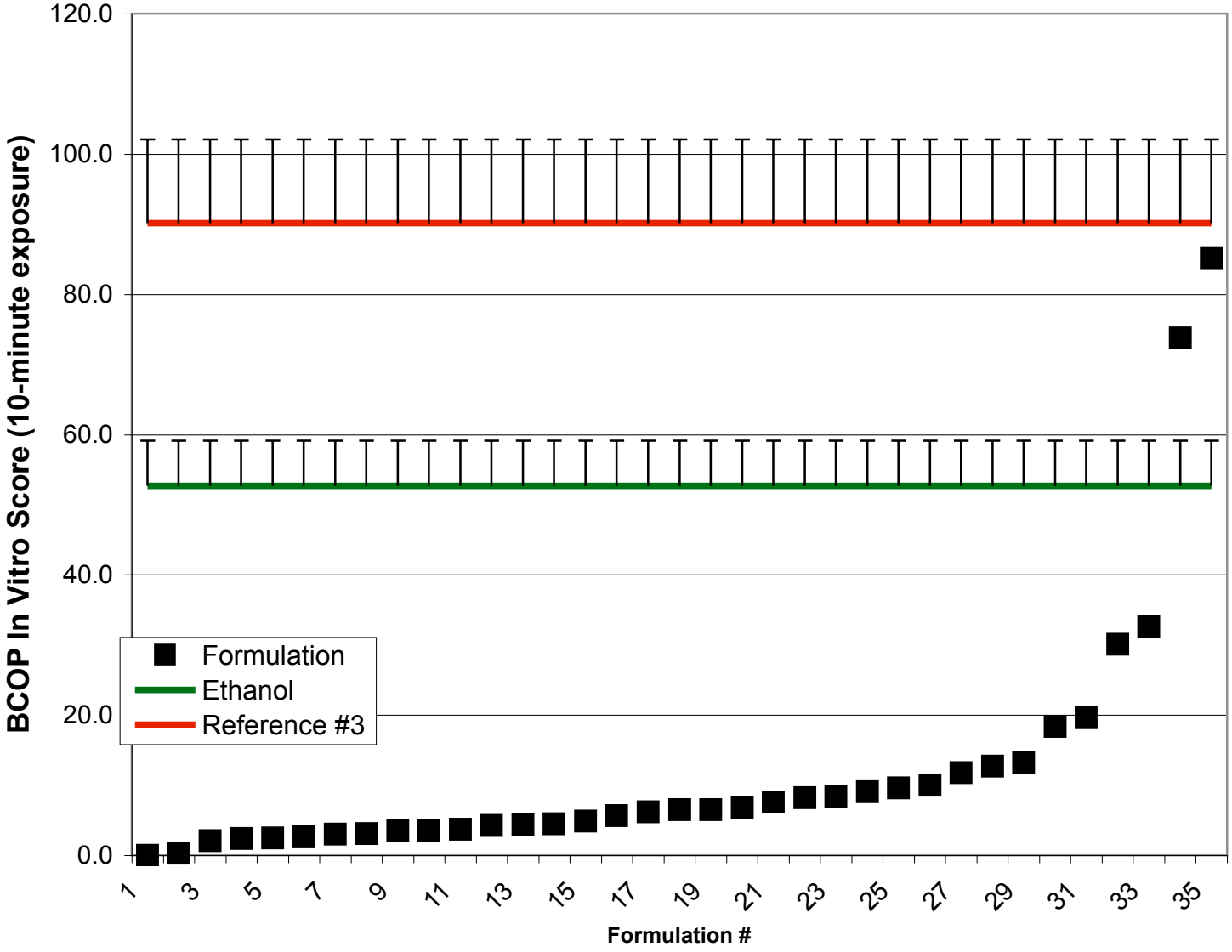
Dated September 3, 2004



Ethanol 3-minute exposure

	Opacity	OD490	In Vitro Score
Mean	21.1	0.820	33.4
STD	2.9	0.238	5.8
CV	13.7%	29.0%	17.5%

n=7

Ethanol 10-minute exposure (normal positive control)

	Opacity	OD490	In Vitro Score
Mean	31.2	1.422	52.7
STD	4.8	0.345	6.4
CV	15.3%	24.3%	12.1%

n = 632
Oct 1997 to the present

Reference #1 Alcohol-based benchmark
3-minute exposure

Used as the first benchmark formulation for the aerosol formulations

	Opacity	OD490	IV Score
Mean	20.6	1.270	39.7
STD	3.5	0.308	6.6
CV	16.8%	24.2%	16.7%

n=21
10-minute exposure

	Opacity	OD490	IV Score
Mean	28.6	2.001	58.5
STD	4.1	0.415	7.6
CV	14.3%	20.7%	13.0%

n=43

Reference #2 Ethanol Fragrance benchmark
3-minute exposure

	Opacity	OD490	IV Score
Mean	53.7	2.6	93.3
STD	8.5	0.5	12.9
CV	15.8%	20.0%	13.8%

n=32

10-minute exposure

	Opacity	OD490	IV Score
Mean	81.5	2.805	123.6
STD	11.9	0.520	13.3
CV	14.6%	18.5%	10.8%

n=32

Reference #3 Fragrance benchmark (no ethanol)

3-minute exposure

	Opacity	OD490	IV Score
Mean	39.9	0.693	50.4
STD	6.0	0.238	8.5
CV	14.9%	34.3%	16.8%

n=84

10-minute exposure

	Opacity	OD490	IV Score
Mean	61.0	1.941	90.1
STD	7.9	0.459	12.0
CV	12.9%	23.7%	13.3%

n=90

FORMULAS

Test Material #	Group	Raw Material	Percentage
1	Fragrance Benchmark (Reference #3)	Fragrance	95-100
		Thickener	0-5
2	Ethanol/ Fragrance Benchmark (Reference #2)	Ethanol	70-75
		Fragrance	25-30
3, 4	Alcohol-based Benchmark (Reference #1)	Alcohol	85-90
		Active	10-15
		Dimethicone	1-5
		Fragrance	< 1
5	Ethanol	Ethanol	100
Fragrance Formulas	Membrane Formula	Fragrance	95-100
		Thickener	0-5
Fragrance Formulas	Aerosol Formula-1[1]	Alcohol	70-75
		Fragrance	25-30
Fragrance Formulas	Aerosol Formula-2	Alcohol	80-85
		Fragrance	15-20
Fragrance Formulas	Aerosol Formula-3	Alcohol	90-95
		Fragrance	5-10

[1]Most aerosol formulas fall within this category