

Appendix C

***In Vitro* Data for Substances Tested in the IRE Test Method**

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Appendix C1

Balls et al. (1995) Data Sorted by Reference

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Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Liquid	IREA 26	3	2	10	25	Severe	Severe
Liquid	IREA 23	3	2	32.6	76.3	Severe	
Liquid	IREA 28	3.7	0.2	5.5	11.3	Nonsevere	
Liquid	IREA 29	2	0	13	15	Nonsevere	
Solid	IREA 26	0	0	10	25	Severe	Nonsevere
Solid	IREA 23	0	0	3	3	Nonsevere	
Solid	IREA 28	0	0	9.1	12.7	Nonsevere	
Solid	IREA 29	0	0	7	0	Nonsevere	
Solid	IREA 26	0	0	5	5	Nonsevere	Nonsevere
Solid	IREA 23	0	0	0	0	Nonsevere	
Solid	IREA 28	0	0	9.2	15.3	Nonsevere	
Solid	IREA 29	1	1	6	4	Nonsevere	
Solution	IREA 26	2	3	20	80	Severe	Severe
Solution	IREA 23	2	3	41.7	62.9	Severe	
Solution	IREA 28	1	2	24	37.4	Severe	
Solution	IREA 29	1.7	2	60	112	Severe	
Solution	IREA 26	2	2	29.2	66.4	Severe	Severe
Solution	IREA 23	2	2.7	21.5	115.6	Severe	
Solution	IREA 28	0	1.3	27.6	114.9	Severe	
Solution	IREA 29	1.3	1	51	100	Severe	
Solution	IREA 26	1	0	20.8	20.8	Severe	Severe
Solution	IREA 23	2	0	18.8	61.7	Severe	
Solution	IREA 28	0.7	0	24.8	47.8	Severe	
Solution	IREA 29	0	0	31	81	Severe	
Liquid	IREA 26	0	0	0	5	Nonsevere	Nonsevere
Liquid	IREA 23	0	0	9.4	29.1	Severe	
Liquid	IREA 28	0	0.7	5.8	7.8	Nonsevere	
Liquid	IREA 29	0	0.7	11	17	Nonsevere	
Liquid	IREA 26	1	3	19.3	29.1	Severe	Severe
Liquid	IREA 23	0	2	27.4	49.6	Severe	
Liquid	IREA 28	0	1	20	30.6	Severe	
Liquid	IREA 29	0	0.7	19	44	Severe	
Solid	IREA 26	2	2	0	10	Nonsevere	Nonsevere

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Solid	IREA 23	0	1.7	12	31.6	Severe	
Solid	IREA 28	0	0	8.9	13.4	Nonsevere	
Solid	IREA 29	1	0.3	5	20	Nonsevere	
Solid	IREA 26	0	0	5	5	Nonsevere	Nonsevere
Solid	IREA 23	0	0	11.1	25.6	Severe	
Solid	IREA 28	0	0.7	2.8	13.2	Nonsevere	
Solid	IREA 29	1	1	6	8	Nonsevere	
Solution	IREA 26	1	2	23.7	31.6	Severe	Severe
Solution	IREA 23	2	3	23	87.4	Severe	
Solution	IREA 28	0	1	11.7	30.1	Severe	
Solution	IREA 29	0.33	0.7	13	25	Severe	
Solution	IREA 26	1	2	30	30	Severe	Severe
Solution	IREA 23	0	2.7	28.1	46.7	Severe	
Solution	IREA 28	0.3	1.3	13.6	26.3	Severe	
Solution	IREA 29	1	1	14	25	Severe	
Solution	IREA 26	0	0	24.2	25	Severe	Severe
Solution	IREA 23	0	0	14.9	30.6	Severe	
Solution	IREA 28	0	0	8.6	8.6	Nonsevere	
Solution	IREA 29	0	0	11	15	Nonsevere	
Solid	IREA 26	3	4	*	*	Severe	Severe
Solid	IREA 23	0	2	19.4	37.8	Severe	
Solid	IREA 28	1	2.7	17	54.7	Severe	
Solid	IREA 29	1	2	44	115	Severe	
Liquid	IREA 26	2	3	13.8	68.1	Severe	Severe
Liquid	IREA 23	0	2	18.4	60.3	Severe	
Liquid	IREA 28	1	2	29	103	Severe	
Liquid	IREA 29	1.33	3	36	97	Severe	
Solid	IREA 26	3	3	50	50	Severe	Nonsevere
Solid	IREA 23	0	2.3	5.9	13.3	Nonsevere	
Solid	IREA 28	0	0.3	11.8	16.7	Nonsevere	
Solid	IREA 29	1	2	5	18	Nonsevere	
Solid	IREA 26	1	1	5.1	5.1	Nonsevere	Nonsevere
Solid	IREA 23	0	2	7.4	25.9	Severe	
Solid	IREA 28	0	1	14.6	20.8	Nonsevere	
Solid	IREA 29	1	0.3	11	14	Nonsevere	
Liquid	IREA 26	1	2.3	3.3	9.9	Nonsevere	Nonsevere

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Liquid	IREA 23	0	2	21.6	36.3	Severe	
Liquid	IREA 28	1	2.3	5.2	24.2	Nonsevere	
Liquid	IREA 29	1	1	4	14	Nonsevere	
Liquid	IREA 26	3	3	29.8	45.6	Severe	Severe
Liquid	IREA 23	3	3	41.5	72.6	Severe	
Liquid	IREA 28	3	2.3	34	76	Severe	
Liquid	IREA 29	2	2.7	29	78	Severe	
Solid	IREA 26	1	1	35	35	Severe	Nonsevere
Solid	IREA 23	0	0	10.3	14	Nonsevere	
Solid	IREA 28	0	0	5.9	11.8	Nonsevere	
Solid	IREA 29	0.33	0.7	10	5	Nonsevere	
Liquid	IREA 26	2	3	50	60.8	Severe	Severe
Liquid	IREA 23	1	3	14.2	48.5	Severe	
Liquid	IREA 28	1.2	2.3	17.8	41	Severe	
Liquid	IREA 29	2.67	2	25	60	Severe	
Liquid	IREA 26	0	2	6.5	13.7	Nonsevere	Severe
Liquid	IREA 23	0	2	18	45.1	Severe	
Liquid	IREA 28	0	0.7	19.8	38.7	Severe	
Liquid	IREA 29	0	1	14	25	Severe	
Liquid	IREA 26	1	1	16.7	16.7	Nonsevere	Nonsevere
Liquid	IREA 23	0	1	5.9	20.7	Nonsevere	
Liquid	IREA 28	0	1.7	8.3	24.7	Nonsevere	
Liquid	IREA 29	0	2	12	19	Nonsevere	
Liquid	IREA 26	0	1	2.5	5	Nonsevere	Severe
Liquid	IREA 23	1	2.7	25.2	29.4	Severe	
Liquid	IREA 28	0	2	25.5	36.5	Severe	
Liquid	IREA 29	0.67	1	12	14	Nonsevere	
Liquid	IREA 26	0	1	5.3	10.5	Nonsevere	Nonsevere
Liquid	IREA 23	0	2	14.3	19.3	Nonsevere	
Liquid	IREA 28	0	0.3	2.9	13.3	Nonsevere	
Liquid	IREA 29	0	0	4	5	Nonsevere	
Solid	IREA 26	3	3	25	25	Severe	Severe
Solid	IREA 23	0	1.7	2.3	29.3	Severe	
Solid	IREA 28	0	0	5.5	12	Nonsevere	
Solid	IREA 29	0.33	0	4	-1	Nonsevere	
Liquid	IREA 26	0	1	9.2	10	Nonsevere	Nonsevere

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Liquid	IREA 23	0	0	5.2	5.2	Nonsevere	
Liquid	IREA 28	0	0.3	11.3	11.3	Nonsevere	
Liquid	IREA 29	0	0	5	4	Nonsevere	
Liquid	IREA 26	1.3	2	20.5	38.5	Severe	Severe
Liquid	IREA 23	0	3	13.7	43.6	Severe	
Liquid	IREA 28	0	2.7	19.1	62.1	Severe	
Liquid	IREA 29	1.33	3	21	49	Severe	
Solid	IREA 26	2	3	50	80	Severe	Severe
Solid	IREA 23	3	3	45.5	75.8	Severe	
Solid	IREA 28	3	3	45.8	63.2	Severe	
Solid	IREA 29	2	2	38	80	Severe	
Liquid	IREA 26	2	3	20	85	Severe	Severe
Liquid	IREA 23	0	2	14.5	47	Severe	
Liquid	IREA 28	2	3	26	78.9	Severe	
Liquid	IREA 29	1.33	2	40	91	Severe	
Liquid	IREA 26	1.7	3	4	22.4	Severe	Severe
Liquid	IREA 23	2	2.3	30.9	65.5	Severe	
Liquid	IREA 28	0	0.7	13.1	23.4	Nonsevere	
Liquid	IREA 29	1.67	1.7	16	32	Severe	
Solid	IREA 26	3	2	49.2	52.5	Severe	Severe
Solid	IREA 23	0	2	29.9	37.3	Severe	
Solid	IREA 28	1	0	10.8	16.5	Nonsevere	
Solid	IREA 29	0	0	6	0	Nonsevere	
Liquid	IREA 26	1	3	21	49.6	Severe	Severe
Liquid	IREA 23	0	0	12	18.8	Nonsevere	
Liquid	IREA 28	1	1.7	12.2	28.1	Severe	
Liquid	IREA 29	0	1.7	15	26	Severe	
Liquid	IREA 26	0	0	5.1	5.1	Nonsevere	Nonsevere
Liquid	IREA 23	0	2	5.8	8.7	Nonsevere	
Liquid	IREA 28	0	0.3	2.9	6.8	Nonsevere	
Liquid	IREA 29	0.33	0.3	6	7	Nonsevere	
Liquid	IREA 26	0	0	7.4	7.4	Nonsevere	Nonsevere
Liquid	IREA 23	0	0	17.6	21	Nonsevere	
Liquid	IREA 28	0	0	2.8	5.6	Nonsevere	
Liquid	IREA 29	0	0	5	4	Nonsevere	
Liquid	IREA 26	2	3	20.8	91.7	Severe	Severe

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Liquid	IREA 23	1	2	20.7	56.3	Severe	
Liquid	IREA 28	0	2.3	29.4	51	Severe	
Liquid	IREA 29	0.67	2.3	14	46	Severe	
Liquid	IREA 26	1	2	34.5	40.4	Severe	Severe
Liquid	IREA 23	0	3	29.3	64.6	Severe	
Liquid	IREA 28	0	1.3	0	8.7	Nonsevere	
Liquid	IREA 29	0	0	9	23	Nonsevere	
Solid	IREA 26	0	0.3	15	15	Nonsevere	Nonsevere
Solid	IREA 23	0	2.3	21.9	24.1	Nonsevere	
Solid	IREA 28	0	0	1	2.8	Nonsevere	
Solid	IREA 29	1	1	10	13	Nonsevere	
Solid	IREA 26	2	3	67	108.7	Severe	Severe
Solid	IREA 23	0	2.7	16.1	41.6	Severe	
Solid	IREA 28	0	3	61	125.1	Severe	
Solid	IREA 29	2	2	84	155	Severe	
Liquid	IREA 26	0	1	4.4	14.8	Nonsevere	Severe
Liquid	IREA 23	0	2	17.6	26.1	Severe	
Liquid	IREA 28	0	1.8	14.2	29.9	Severe	
Liquid	IREA 29	0	1	11	16	Nonsevere	
Liquid	IREA 26	2	2	25	55	Severe	Severe
Liquid	IREA 23	0	2	27.4	63.7	Severe	
Liquid	IREA 28	1.3	3	33.7	68.7	Severe	
Liquid	IREA 29	1.67	2.2	25	70	Severe	
Liquid	IREA 26	1	1	29.4	31.1	Severe	Severe
Liquid	IREA 23	0	1	20.7	27.4	Severe	
Liquid	IREA 28	0	0	6	12.8	Nonsevere	
Liquid	IREA 29	0	0	4	-1	Nonsevere	
Solid	IREA 26	0	0	9.1	9.1	Nonsevere	Nonsevere
Solid	IREA 23	0	0	1.5	1.5	Nonsevere	
Solid	IREA 28	0	0	5.3	11.5	Nonsevere	
Solid	IREA 29	0	0	5	-1	Nonsevere	
Solid	IREA 26	2	2	17.5	45	Severe	Severe
Solid	IREA 23	1	3	76.1	117.1	Severe	
Solid	IREA 28	1	2.3	20.8	86.9	Severe	
Solid	IREA 29	2	2	62	110	Severe	
Liquid	IREA 26	1	3	18.2	53.7	Severe	Severe

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Liquid	IREA 23	2	3	10.3	48.5	Severe	
Liquid	IREA 28	2	3	34.9	42.4	Severe	
Liquid	IREA 29	2.33	2.3	40	75	Severe	
Solid	IREA 26	0	0	10.5	10.5	Nonsevere	Nonsevere
Solid	IREA 23	0	0	0	0.7	Nonsevere	
Solid	IREA 28	0	0.7	13	16.7	Nonsevere	
Solid	IREA 29	0	0	5	4	Nonsevere	
Solution	IREA 26	3	4	86	110.5	Severe	Severe
Solution	IREA 23	3	4	107.8	144.3	Severe	
Solution	IREA 28	3.7	4	*	*	Severe	
Solution	IREA 29	2	4	111	160	Severe	
Solution	IREA 26	1.3	2	40	85	Severe	Severe
Solution	IREA 23	0	3	41.7	65.2	Severe	
Solution	IREA 28	1	3	57.1	121.9	Severe	
Solution	IREA 29	1.67	3	62	102	Severe	
Solution	IREA 26	0	1	21.1	21.1	Nonsevere	Nonsevere
Solution	IREA 23	0	2	13.5	26.3	Severe	
Solution	IREA 28	0	0.3	14.5	22.3	Nonsevere	
Solution	IREA 29	0.33	2	16	24	Nonsevere	
Solution	IREA 26	0	1	5.3	15.8	Nonsevere	Nonsevere
Solution	IREA 23	0	0	13.4	22.4	Nonsevere	
Solution	IREA 28	0	0	8.4	9.3	Nonsevere	
Solution	IREA 29	0	1	12	14	Nonsevere	
Solid	IREA 26	0	0	5	5	Nonsevere	Nonsevere
Solid	IREA 23	0	0	0.8	6.7	Nonsevere	
Solid	IREA 28	0	0	17.3	22	Nonsevere	
Solid	IREA 29	0	0	6	5	Nonsevere	
Solid	IREA 26	0	0	5	5	Nonsevere	Nonsevere
Solid	IREA 23	0	0	0.8	2.3	Nonsevere	
Solid	IREA 28	0	0	2.9	14.7	Nonsevere	
Solid	IREA 29	0	0	4	0	Nonsevere	
Solid	IREA 26	2	1	12.5	25	Severe	Nonsevere
Solid	IREA 23	0	0	0.7	4.4	Nonsevere	
Solid	IREA 28	0	0	1	2.9	Nonsevere	
Solid	IREA 29	1	2	3	9	Nonsevere	
Solid	IREA 26	0	0	10	10	Nonsevere	Nonsevere

Form Tested	Testing Lab	Opacity		Swelling		In Vitro Irritancy Classification	Overall In Vitro Irritancy Classification
		1 Hr	4 Hr	1 Hr	4 Hr		
Solid	IREA 23	0	0	5.1	5.1	Nonsevere	
Solid	IREA 28	0	0	5.7	5.7	Nonsevere	
Solid	IREA 29	0	0.7	7	4	Nonsevere	
Liquid	IREA 26	1	1	28.3	30	Severe	Severe
Liquid	IREA 23	0	0	11.1	37.6	Severe	
Liquid	IREA 28	0.7	1	10.1	17.5	Nonsevere	
Liquid	IREA 29	1	0	8	6	Nonsevere	
Solution	IREA 26	4	4	*	*	Severe	Severe
Solution	IREA 23	3	4	44	100.8	Severe	
Solution	IREA 28	3.7	3.7	*	*	Severe	
Solution	IREA 29	3	3	4	54	Severe	
Solution	IREA 26	0	1	6	6	Nonsevere	Nonsevere
Solution	IREA 23	1	2	12.1	36.2	Severe	
Solution	IREA 28	0.7	0	7.2	20.6	Nonsevere	
Solution	IREA 29	1	0	7	11	Nonsevere	
Solution	IREA 26	2	3	8.8	19.2	Severe	Severe
Solution	IREA 23	0	2	24.2	32.6	Severe	
Solution	IREA 28	0	2	36.2	95.3	Severe	
Solution	IREA 29	0.67	2.3	39	80	Severe	
Solution	IREA 26	2	3	25.4	31.6	Severe	Severe
Solution	IREA 23	0	2	23.3	30.1	Severe	
Solution	IREA 28	0	1.3	10	25.2	Severe	
Solution	IREA 29	0.33	1.5	20	45	Severe	
Liquid	IREA 26	0	0	12.6	15.1	Nonsevere	Nonsevere
Liquid	IREA 23	0	1	28.1	29.6	Severe	
Liquid	IREA 28	0	0	6.4	14.7	Nonsevere	
Liquid	IREA 29	0	0	7	4	Nonsevere	

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Appendix C2

Guerriero et al. (2004) Data Sorted by Substance

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Substance	CASRN	Form Tested	Testing Lab	Maximum Corneal Opacity		Maximum Fluorescein Uptake	
				Cloudiness	Area	Intensity	Area
Acetanilide (F22)	NA	Solid	GSK	0	0	0	0
Acetone (F33)	67-64-1	Liquid	GSK	2	3	3	4
Acetophenone (F27)	98-86-2	Solid	GSK	0	0	0	0
Dimethyl carbonate (F30)	616-38-6	Solid	GSK	0	0	0	0
Allyl alcohol (F34)	107-18-6	Liquid	GSK	3	3	4	4
Ammonium nitrate (F36)	6484-52-2	Solid	GSK	0	0	0	0
di-Isopropyl aminoethyldiphenyl acetamide (F15)	NA	Solid	GSK	0	0	0	0
3,4-Dimethoxybenzaldehyde (F19)	NA	Solid	GSK	0	0	0	0
5-Chloro-N-[4-methoxy-3-(1-piperazinyl)phenyl]-3-methylbenzo[B]thiophene-2-sulfonamide monohydrochloride (F4)	NA	Solid	GSK	2	3	2	1
2,6-Dichlorobenzenesulfonyl chloride (F1)	NA	Solid	GSK	3	4	2	3
(S)-1-Phenyl-N-propylamine (F13)	NA	Liquid	GSK	2	4	2	4
n-Butanol (F35)	71-36-3	Liquid	GSK	3	4	3	4
n-Butyl acetate (F39)	123-86-4	Liquid	GSK	1	3	2	1
gamma-(Aminocarbonyl)-N-methyl-N,N-bis(1-methylethyl)-gamma-phenyl-, iodide (F14)	NA	Solid	GSK	0	0	0	0
Cetylpyridium bromide (F37)	140-72-7	Solid	GSK	2	3	3	3
3,4-Dichloroaniline hydrochloride (F11)	NA	Solid	GSK	4	4	3	4
Sodium dicyanamide (F3)	NA	Solid	GSK	2	3	2	2
Isopropyl dicyanamide (F9)	35695-36-4	Solid	GSK	3	4	3	4
Glycerol (F41)	56-81-5	Liquid	GSK	0	0	0	0
1-(3,4-Dichlorophenyl)-5-isopropylbiguanide HCl (F6)	537-21-3	Solid	GSK	2	3	4	2

Substance	CASRN	Form Tested	Testing Lab	Maximum Corneal Opacity		Maximum Fluorescein Uptake	
				Cloudiness	Area	Intensity	Area
2-(4-Oxopentyl)-1H-isoindole-1,3 (2H)-dione (F26)	3197-25-9	Solid	GSK	0	0	1	3
4,4'-Methylenebis-(2,6-di-tert-butylphenol) (F43)	118-82-3	Solid	GSK	0	0	0	0
1H-Indole-2,3-dione (F28)	91-56-5	Solid	GSK	0	0	0	0
Methyl ethyl ketone (F38)	78-93-3	Liquid	GSK	3	4	4	3
1-(5-Amino-2-methoxyphenyl) piperazine hydrochloride (F20)	NA	Solid	GSK	2	2	2	2
1-(2-Methoxyphenyl)piperazine hydrogen sulfate (F2)	NA	Solid	GSK	1	4	1	4
Polyethylene glycol 400 (F44)	25322-68-3	Liquid	GSK	0	0	0	0
Propylene glycol (F42)	57-55-6	Liquid	GSK	0	0	0	0
Iodine chloride with pyridine (1:1) (F10)	6443-90-9	Solid	GSK	2	2	2	3
tetra-N-Octylammonium bromide (F8)	14866-33-2	Solid	GSK	2	4	4	4
3-Hydroxy-2-phenyl-4-quinolinecarboxylic acid (F24)	485-89-2	Solid	GSK	0	0	0	0
Sodium hydroxide (F31)	1310-73-2	Liquid	GSK	4	4	4	4
2-Nitro-4-thio-N-propylaniline (F21)	54393-89-4	Solid	GSK	0	0	1	4
2-Nitro-4-propoxyaniline (F23)	NA	Solid	GSK	0	0	1	3
2-Nitro-4-thiocyananiline (F7)	54029-45-7	Solid	GSK	0	0	2	2
Mebrophen hydramine HCl (F5)	13977-28-1	Solid	GSK	2	4	3	4
4,4'-Pyridylpiperidine (F12)	NA	Solid	GSK	4	4	4	3

Substance	CASRN	Form Tested	Testing Lab	Maximum Corneal Opacity		Maximum Fluorescein Uptake	
				Cloudiness	Area	Intensity	Area
2,6-Dichloro-5-fluoro-beta-oxo-3-pyridinepropanoate (F16)	96568-04-6	Solid	GSK	0	0	0	0
6-(Methylamino)-2-pyridine ethanol formate (1:1) (salt) (F17)	NA	Solid	GSK	1	4	0	0
3-((Benzylthio)methyl)-6-chloro-1,1-dioxide (F29)	NA	Solid	GSK	0	0	0	0
4,4'-Sulfonylbisbenzenamine (F25)	NA	Solid	GSK	0	0	0	0
Sulfonyl chloride #18	80-08-0	Solid	GSK	1	2	1	2
Toluene (F40)	108-88-3	Liquid	GSK	0	0	0	0
Trichloroacetic acid (F32)	76-03-9	Liquid	GSK	4	4	4	4

NA = Not Applicable; GSK = GlaxoSmithKline

Substance	Mean Corneal Swelling (Hr)				Corneal Epithelial Observations	In Vitro Irritancy Classification
	1	2	3	4		
Acetanilide (F22)	3.2	1.4	1.5	2.6	Normal	Nonsevere Irritant
Acetone (F33)	19.3	24.5	39.0	49.6	Loosening/roughening of epithelium	Severe Irritant
Acetophenone (F27)	6.1	3.4	2.0	2.5	Residual test material present	Nonsevere Irritant
Dimethyl carbonate (F30)	16.6	22.8	30.7	39.4	Slight pitting	Severe Irritant
Allyl alcohol (F34)	41.0	56.1	68.5	77.2	Pitting, sloughing	Severe Irritant
Ammonium nitrate (F36)	10.5	12.2	NA	15.0	Normal	Nonsevere Irritant
di-Isopropyl aminoethyldiphenyl acetamide (F15)	6.3	6.9	6.6	7.6	Normal	Nonsevere Irritant
3,4-Dimethoxybenzaldehyde (F19)	7.2	13.0	16.5	17.4	Normal	Nonsevere Irritant
5-Chloro-N-[4-methoxy-3-(1-piperazinyl)phenyl]-3-methylbenzo[B]thiophene-2-sulfonamide monohydrochloride (F4)	3.2	4.8	4.0	7.6	Residual test material present	Severe Irritant
2,6-Dichlorobenzenesulfonyl chloride (F1)	21.8	30.4	39.5	45.4	Residual test material present	Severe Irritant
(S)-1-Phenyl-N-propylamine (F13)	20.3	75.4	80.5	98.2	Cloudy, pitted	Severe Irritant
n-Butanol (F35)	54.6	68.3	81.4	91.8	Pitting, loosening of epithelium	Severe Irritant
n-Butyl acetate (F39)	18.5	17.2	21.5	30.1	Normal	Severe Irritant
gamma-(Aminocarbonyl)-N-methyl-N,N-bis(1-methylethyl)-gamma-phenyl-, iodide (F14)	7.3	4.8	5.2	5.9	Normal	Nonsevere Irritant
Cetylpyridium bromide (F37)	49.0	48.8	61.0	31.1+	Loosening of epithelium	Severe Irritant
3,4-Dichloroaniline hydrochloride (F11)	51.4	98.0	112.6	118.2	Mottled, residual test material, smooth cloudy appearance	Severe Irritant
Sodium dicyanamide (F3)	40.7	58.7	64.3	71.0	Sloughing	Severe Irritant
Isopropyl dicyanamide (F9)	31.8	43.6	53.0	62.2	Mottled, sloughing	Severe Irritant
Glycerol (F41)	13.1	15.5	16.5	21.4	Normal	Nonsevere Irritant
1-(3,4-Dichlorophenyl)-5-isopropylbiguanide HCl (F6)	13.2	21.7	27.0	27.7	Sloughing	Severe Irritant

Substance	Mean Corneal Swelling (Hr)				Corneal Epithelial Observations	In Vitro Irritancy Classification
	1	2	3	4		
2-(4-Oxopentyl)-1H-isoindole-1,3 (2H)-dione (F26)	5.9	9.8	10.9	14.8	Residual test material present	Nonsevere Irritant
4,4'-Methylenebis-(2,6-di-tert-butylphenol) (F43)	9.4	12.3	12.8	15.1	Normal	Nonsevere Irritant
1H-Indole-2,3-dione (F28)	1.3	0.2	0.4	2.0	Normal	Nonsevere Irritant
Methyl ethyl ketone (F38)	34.8	62.6	85.6	104.7	Loosening of epithelium	Severe Irritant
1-(5-Amino-2-methoxyphenyl)piperazine hydrochloride (F20)	12.4	12.0	19.1	22.4	Mottled Appearance	Severe Irritant
1-(2-Methoxyphenyl)piperazine hydrogen sulfate (F2)	9.3	14.1	15.7	20.0	Normal	Severe Irritant
Polyethylene glycol 400 (F44)	12.7	13.4	16.9	17.8	Normal	Nonsevere Irritant
Propylene glycol (F42)	10.1	10.2	10.8	16.3	Normal	Nonsevere Irritant
Iodine chloride with pyridine (1:1) (F10)	16.6	23.6	28.4	25.4	Normal	Severe Irritant
tetra-N-Octylammonium bromide (F8)	22.2	74.7	83.9	109.9	Pitting/Sloughing	Severe Irritant
3-Hydroxy-2-phenyl-4-quinolinecarboxylic acid (F24)	2.4	3.7	5.0	7.1	Residual test material present	Nonsevere Irritant
Sodium hydroxide (F31)	110.5	NA	NA	NA	Rippling, loosening of epithelium	Severe Irritant
2-Nitro-4-thio-N-propylaniline (F21)	17.6	22.5	28.3	31.5	Normal	Severe Irritant
2-Nitro-4-propoxyaniline (F23)	4.8	5.6	3.4	6.8	Residual test material adhered to cornea	Nonsevere Irritant
2-Nitro-4-thiocyananiline (F7)	6.6	8.1	9.3	7.4	Residual test material adhered to cornea, pitting	Severe Irritant
Mebrophen hydramine HCl (F5)	58.8	79.6	99.2	113.0	Mottled Appearance	Severe Irritant
4,4'-Pyridylpiperidine (F12)	111.5	117.5	83.9	101.1	Sloughing/mottled	Severe Irritant

Substance	Mean Corneal Swelling (Hr)				Corneal Epithelial Observations	In Vitro Irritancy Classification
	1	2	3	4		
2,6-Dichloro-5-fluoro-beta-oxo-3-pyridinepropanoate (F16)	4.6	4.9	4.7	2.7	Normal	Nonsevere Irritant
6-(Methylamino)-2-pyridine ethanol formate (1:1) (salt) (F17)	4.5	4.9	4.3	2.5	Normal	Severe Irritant
3-((Benzylthio)methyl)-6-chloro-1,1-dioxide (F29)	1.5	1.4	1.5	2.0	Normal	Nonsevere Irritant
4,4'-Sulfonylbisbenzenamine (F25)	2.9	2.7	3.2	4.4	Normal	Nonsevere Irritant
Sulfonyl chloride #18	8.6	12.9	14.2	14.9	Residual test material present	Nonsevere Irritant
Toluene (F40)	7.4	9.8	13.4	14.6	Normal	Nonsevere Irritant
Trichloroacetic acid (F32)	12.2	21.1	38.2	54.1	Roughening of epithelium	Severe Irritant

NA = Not Applicable; GSK = (

Appendix C3

Gettings et al. (1996) Data Sorted by Substance

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Substance	CASRN	Form Tested	Testing Lab	REET 1 Corneal Thickness Measurement	REET 2 Corneal Thickness Score (1-4)	Overall In Vitro Irritancy Classification
HZA-1	NA	Liquid formulation	Unilever	32.1	2.3	Severe irritant
HZB-1	NA	Liquid formulation	Unilever	24.8	1.7	Nonsevere irritant
HZC-1	NA	Liquid formulation	Unilever	21.2	1.0	Nonsevere irritant
HZD-1	NA	Liquid formulation	Unilever	20.3	1.0	Nonsevere irritant
HZE-1	NA	Liquid formulation	Unilever	6.4	0.0	Nonsevere irritant
HZF-1	NA	Liquid formulation	Unilever	14.3	1.0	Nonsevere irritant
HZG-1	NA	Liquid formulation	Unilever	29.5	2.0	Severe irritant
HZH-1	NA	Liquid formulation	Unilever	7.7	0.0	Nonsevere irritant
HZI-1	NA	Liquid formulation	Unilever	28.6	1.7	Severe irritant
HZJ-1	NA	Liquid formulation	Unilever	16.3	1.0	Nonsevere irritant
HZK-1	NA	Liquid formulation	Unilever	36.4	2.7	Severe irritant
HZL-1	NA	Liquid formulation	Unilever	36.2	2.7	Severe irritant

Substance	CASRN	Form Tested	Testing Lab	REET I Corneal Thickness Measurement	REET 2 Corneal Thickness Score (1-4)	Overall In Vitro Irritancy Classification
HZM-1	NA	Liquid formulation	Unilever	26.0	1.7	Severe irritant
HZN-1	NA	Liquid formulation	Unilever	37.7	2.7	Severe irritant
HZP-1	NA	Liquid formulation	Unilever	25.0	1.7	Severe irritant
HZQ-1	NA	Liquid formulation	Unilever	7.5	0.3	Nonsevere irritant
HZR-1	NA	Liquid formulation	Unilever	13.4	1.0	Nonsevere irritant
HZS-1	NA	Liquid formulation	Unilever	33.3	2.3	Severe irritant
HZT-1	NA	Liquid formulation	Unilever	2.5	0.0	Nonsevere irritant
HZU-1	NA	Liquid formulation	Unilever	36.7	3.0	Severe irritant
HZV-1	NA	Liquid formulation	Unilever	25.6	1.3	Severe irritant
HZW-1	NA	Liquid formulation	Unilever	23.9	1.7	Nonsevere irritant
HZX-1	NA	Liquid formulation	Unilever	20.9	1.3	Nonsevere irritant
HZY-1	NA	Liquid formulation	Unilever	18.6	1.0	Nonsevere irritant

Substance	CASRN	Form Tested	Testing Lab	REET I Corneal Thickness Measurement	REET 2 Corneal Thickness Score (1-4)	Overall In Vitro Irritancy Classification
HZZ-1	NA	Liquid formulation	Unilever	2.8	0.0	Nonsevere irritant

NA = Not Applicable; REET = Rabbit Enucleated Eye Test

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Appendix C4

CEC (1991) Data Sorted by Substance

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CEC (1991) Data Sorted By Substance

Substance	CASRN	Form Tested	Testing Lab	Mean Corneal Swelling (%) - Minutes				
				30	75	120	180	240
Acetic acid	64-19-7	Liquid	TNO-CIVO	2	8	16	22	27
Acetic acid	64-19-7	Liquid	I.H.E.	16	23	31	40	50
Acetic acid	64-19-7	Liquid	SHELL	-	31	34	42	45
Brij 35	9002-92-0	Solution	TNO-CIVO	7	11	12	13	15
Brij 35	9002-92-0	Solution	I.H.E.	2	6	9	11	9
Brij 35	9002-92-0	Solution	SHELL	-	6	11	14	13
Benzalkonium chloride	8001-54-5	Solution	TNO-CIVO	14	26	37	51	52
Benzalkonium chloride	8001-54-5	Solution	I.H.E.	28	50	65	75	81
Benzalkonium chloride	8001-54-5	Solution	SHELL	-	45	83	107	115
Dimethyl sulfoxide	67-68-5	Solution	TNO-CIVO	11	14	16	17.0	20.0
Dimethyl sulfoxide	67-68-5	Solution	I.H.E.	4	6	6	3.0	-1.0
Dimethyl sulfoxide	67-68-5	Solution	SHELL	-	4	11	15.0	16.0
Sodium fluorescein	518-47-8	Solution	TNO-CIVO	1	0	0	-1	-1
Sodium fluorescein	518-47-8	Solution	I.H.E.	-1	1	3	3	1
Sodium fluorescein	518-47-8	Solution	SHELL	-	6	9	11	14
Glycerol	56-81-5	Solution	TNO-CIVO	6	6	5	5	4
Glycerol	56-81-5	Solution	I.H.E.	2	4	6	6	4
Glycerol	56-81-5	Solution	SHELL	-	0	1	4	8
Triacetin	102-76-1	Solution	TNO-CIVO	3	2	1	0	0
Triacetin	102-76-1	Solution	I.H.E.	4	4	5	5	0
Triacetin	102-76-1	Solution	SHELL	-	1	1	2	3
Mercury chloride	7546-30-7	Solution	TNO-CIVO	7	23	38	52	57
Mercury chloride	7546-30-7	Solution	I.H.E.	5	15	35	65	95
Mercury chloride	7546-30-7	Solution	SHELL	-	-	NT	NT	NT
Silver nitrate	7761-88-8	Solution	TNO-CIVO	15	13	8	9	9
Silver nitrate	7761-88-8	Solution	I.H.E.	9	14	18	21	20
Silver nitrate	7761-88-8	Solution	SHELL	-	15	17	20	21
Sodium hydroxide	1310-73-2	Solution	TNO-CIVO	27	34	35	44	52
Sodium hydroxide	1310-73-2	Solution	I.H.E.	37	47	64	69	81
Sodium hydroxide	1310-73-2	Solution	SHELL	-	35	49	60	69
Toluene	108-88-3	Liquid	TNO-CIVO	3	11	13	13	13
Toluene	108-88-3	Liquid	I.H.E.	4	7	8	9	7
Toluene	108-88-3	Liquid	SHELL	-	9	11	11	12
Triethanolamine	102-71-6	Solution	TNO-CIVO	1	0	0	1	1
Triethanolamine	102-71-6	Solution	I.H.E.	4	9	12	14	13
Triethanolamine	102-71-6	Solution	SHELL	-	1	2	4	5

Substance	CASRN	Form Tested	Testing Lab	Mean Corneal Swelling (%) - Minutes				
				30	75	120	180	240
n-Hexane	110-54-3	Liquid	TNO-CIVO	2	2	2	0	0
n-Hexane	110-54-3	Liquid	I.H.E.	9	10	14	17	15
n-Hexane	110-54-3	Liquid	SHELL	-	0	1	3	6
Chloroform	67-66-3	Liquid	TNO-CIVO	14	19	22	29	29
Chloroform	67-66-3	Liquid	I.H.E.	16	26	34	30	46
Chloroform	67-66-3	Liquid	SHELL	-	6	10	13	17
2-Methoxyethanol	109-86-4	Liquid	TNO-CIVO	8	15	21	32	42
2-Methoxyethanol	109-86-4	Liquid	I.H.E.	15	25	30	39	46
2-Methoxyethanol	109-86-4	Liquid	SHELL	-	18	30	34	40
Butanol	71-36-3	Liquid	TNO-CIVO	22	29	35	44	49
Butanol	71-36-3	Liquid	I.H.E.	23	32	46	59	67
Butanol	71-36-3	Liquid	SHELL	-	33	42	53	65
Acetaldehyde	75-07-0	Liquid	TNO-CIVO	12	15	17	18	27
Acetaldehyde	75-07-0	Liquid	I.H.E.	7	10	17	29	36
Acetaldehyde	75-07-0	Liquid	SHELL	-	12	31	36	41
2-Butoxyethyl acetate	112-07-2	Liquid	TNO-CIVO	7	8	10	12	12
2-Butoxyethyl acetate	112-07-2	Liquid	I.H.E.	6	10	13	14	16
2-Butoxyethyl acetate	112-07-2	Liquid	SHELL	-	12	31	36	41
Sodium dodecyl sulfate	151-21-3	Solution	TNO-CIVO	8	13	17	19	21
Sodium dodecyl sulfate	151-21-3	Solution	I.H.E.	8	10	12	12	11
Sodium dodecyl sulfate	151-21-3	Solution	SHELL	-	24	31	34	40
Dibutyltin	683-18-1	Solution	TNO-CIVO	NT	NT	NT	NT	NT
Dibutyltin	683-18-1	Solution	I.H.E.	6	13	20	31	38
Dibutyltin	683-18-1	Solution	SHELL	-	9	11	10	21
Tributyltin	688-73-3	Solution	TNO-CIVO	7	10	16	43	58
Tributyltin	688-73-3	Solution	I.H.E.	4	17	29	57	109
Tributyltin	688-73-3	Solution	SHELL	32	40	75	95	124

Abbreviations: CASRN = Chemical Abstracts Service Registry Number; NT = Not Tested; TNO = Institute CIVO-Toxicology and Nutrition; I.H.E. = Institute for Hygiene and Epidemiology; Shell = Shell Oil Company

Substance	Mean Corneal Opacity - Minutes					Mean Corneal Swelling (%) - Minutes			
	30	75	120	180	240	30	75	120	180
Acetic acid	1.8	2.0	2.0	2.0	2.0	2.0	2.0	Severe	Severe
Acetic acid	1.6	-	-	-	1.4	1.6	3.0	Severe	
Acetic acid	-	-	-	-	-	-	2.0	Severe	
Brij 35	1.0	1.0	1.0	1.0	1.0	1.0	1.0	Nonsevere	Nonsevere
Brij 35	0.0	-	-	-	0.0	3.0	1.6	Severe	
Brij 35	-	-	-	-	-	-	0.0	Nonsevere	
Benzalkonium chloride	3.0	3.0	3.0	3.0	3.0	3.0	3.0	Severe	Severe
Benzalkonium chloride	1.2	-	-	-	3.0	3.0	3.0	Severe	
Benzalkonium chloride	-	-	-	-	-	-	2.0	Severe	
Dimethyl sulfoxide	1.0	1.0	1.0	1.0	1.0	2.0	2.0	Nonsevere	Nonsevere
Dimethyl sulfoxide	0.0	-	-	-	0.0	0.0	0.0	Nonsevere	
Dimethyl sulfoxide	-	-	-	-	-	-	2.0	Nonsevere	
Sodium fluorescein	0.0	0.0	0.0	0.0	0.0	0.0	0.0	Nonsevere	Nonsevere
Sodium fluorescein	0.0	-	-	-	0.0	0.0	0.0	Nonsevere	
Sodium fluorescein	-	-	-	-	-	-	1.0	Nonsevere	
Glycerol	0.8	0.8	0.8	0.8	0.8	1.0	1.0	Nonsevere	Nonsevere
Glycerol	0.0	-	-	-	0.0	0.0	0.0	Nonsevere	
Glycerol	-	-	-	-	-	-	0.0	Nonsevere	
Triacetin	0.0	0.0	0.0	0.0	0.0	0.0	0.0	Nonsevere	Nonsevere
Triacetin	0.0	-	-	-	0.0	0.0	0.0	Nonsevere	
Triacetin	-	-	-	-	-	-	0.0	Nonsevere	
Mercury chloride	NM	3.0	3.0	2.7	2.0	NM	3.0	Severe	Severe
Mercury chloride	3.0	-	-	-	2.8	1.0	2.0	Severe	
Mercury chloride	NT	NT	NT	NT	NT	NT	NT	NT	
Silver nitrate	1.0	1.0	1.0	1.5	1.5	1.0	1.0	Nonsevere	Nonsevere
Silver nitrate	2.0	-	-	-	2.0	0.0	0.0	Nonsevere	
Silver nitrate	-	-	-	-	-	-	2.0	Nonsevere	
Sodium hydroxide	3.0	3.0	3.0	3.0	3.0	2.0	3.0	Severe	Severe
Sodium hydroxide	3.0	-	-	-	3.0	3.0	3.0	Severe	
Sodium hydroxide	-	-	-	-	-	-	3.0	Severe	
Toluene	1.2	1.2	1.2	1.2	1.2	2.0	2.2	Nonsevere	Nonsevere
Toluene	0.0	-	-	-	0.0	1.8	2.0	Nonsevere	
Toluene	-	-	-	-	-	-	1.0	Nonsevere	
Triethanolamine	0.0	0.0	0.0	0.0	0.0	0.2	0.2	Nonsevere	Nonsevere
Triethanolamine	0.0	-	-	-	0.0	0.0	0.0	Nonsevere	
Triethanolamine	-	-	-	-	-	-	0.0	Nonsevere	

Substance	Mean Corneal Opacity - Minutes					Mean Corneal Swelling (%) - Minutes			
	30	75	120	180	240	30	75	120	180
n-Hexane	0.0	0.0	0.0	0.0	0.0	0.0	0.0	Nonsevere	Nonsevere
n-Hexane	0.0	-	-	-	0.0	2.0	1.0	Nonsevere	
n-Hexane	-	-	-	-	-	-	0.0	Nonsevere	
Chloroform	1.5	2.0	2.0	2.0	2.0	3.0	3.0	Severe	Severe
Chloroform	0.0	-	-	-	1.4	2.8	3.0	Severe	
Chloroform	-	-	-	-	-	-	3.0	Severe	
2-Methoxyethanol	1.0	1.5	2.0	2.0	2.0	3.0	3.0	Severe	Severe
2-Methoxyethanol	0.0	-	-	-	2.8	2.0	2.0	Severe	
2-Methoxyethanol	-	-	-	-	-	-	3.0	Severe	
Butanol	3.0	3.0	3.0	3.0	3.0	3.0	3.0	Severe	Severe
Butanol	1.0	-	-	-	2.0	2.4	3.0	Severe	
Butanol	-	-	-	-	-	-	3.0	Severe	
Acetaldehyde	1.4	1.5	1.5	1.5	1.5	2.8	2.8	Severe	Severe
Acetaldehyde	2.0	-	-	-	2.0	3.0	3.0	Severe	
Acetaldehyde	-	-	-	-	-	-	3.0	Severe	
2-Butoxyethyl acetate	0.5	0.9	0.9	0.9	0.9	2.0	2.0	Nonsevere	Nonsevere
2-Butoxyethyl acetate	1.0	-	-	-	1.0	2.0	0.0	Nonsevere	
2-Butoxyethyl acetate	-	-	-	-	-	-	2.0	Severe	
Sodium dodecyl sulfate	0.8	1.0	1.8	1.8	1.8	3.0	3.0	Severe	Severe
Sodium dodecyl sulfate	0.0	-	-	-	1.0	0.0	0.2	Nonsevere	
Sodium dodecyl sulfate	-	-	-	-	-	-	3.0	Severe	
Dibutyltin	NT	NT	NT	NT	NT	NT	NT	NT	Severe
Dibutyltin	1.0	-	-	-	1.0	1.0	2.0	Severe	
Dibutyltin	-	-	-	-	-	-	2.0	Nonsevere	
Tributyltin	2.0	2.0	2.0	2.5	2.0	3.0	3.0	Severe	Severe
Tributyltin	1.0	-	-	-	2.2	2.0	2.6	Severe	
Tributyltin	-	-	-	-	-	-	2.0	Severe	