ANNEX E
(Cytosensor *In Vitro* Data)

E1 IIVS Positive Control Data

SLS MRD-50 DATA FOR CYTOSENSOR PROTOCOL (20 MIN) WITHOUT INSERT

DATE	MRD-50 (mg/ml)	DATE	MRD-50 (mg/ml)
4/14/94	0.0785	5/16/95	0.1230
4/15/94	0.0811	5/16/95	0.0802
5/4/94	0.0821	5/17/95	0.0906
5/4/94	0.0842	5/17/95	0.1620
5/5/94	0.0737	5/17/95	0.1300
5/5/94	0.0749	5/17/95	0.1490
5/26/94	0.0771	5/25/95	0.0863
5/27/94	0.0701	5/26/95	0.0808
1/4/95	0.0794	5/26/95	0.0769
1/10/95	0.0659	6/6/95	0.0838
1/11/95	0.0773	6/6/95	0.0792
1/12/95	0.0613	7/17/95	0.0755
1/17/95	0.0814	7/17/95	0.0427
1/18/95	0.0856	7/18/95	0.0758
1/18/95	0.0871	7/18/95	0.0772
1/24/95	0.0853	7/19/95	0.0842
3/1/95	0.0834	7/20/95	0.0815
3/2/95	0.0741	7/21/95	0.0782
3/3/95	0.0676	7/25/95	0.0764
3/7/95	0.0668	7/26/95	0.0839
3/8/95	0.0916	7/26/95	0.0847
3/9/95	0.0802	8/16/95	0.0798
3/10/95	0.0864	8/17/95	0.0850
3/13/95	0.0782	8/18/95	0.0849
3/21/95	0.0770	8/24/95	0.0840
3/22/95	0.0756	8/31/95	0.0853
3/23/95	0.0812	9/1/95	0.0828
3/29/95	0.0686	9/6/95	0.0866
3/30/95	0.0837	9/21/95	0.0787
3/31/95	0.0855	9/22/95	0.0701
4/4/95	0.0919	9/26/95	0.0780
4/6/95	0.0828	10/4/95	0.0748
4/7/95	0.0817	10/9/95	0.0837
4/12/95	0.0804	10/10/95	0.0815
4/14/95	0.0867	10/10/95	0.0789
4/18/95	0.0817	10/17/95	0.0779
4/19/95	0.0852	10/18/95	0.0743
4/20/95	0.0745	10/20/95	0.0789
4/26/95	0.0861	10/24/95	0.0804
5/3/95	0.0775	10/26/95	0.0736
5/4/95	0.0822	10/27/95	0.0775
5/5/95	0.0797	10/31/95	0.0785
5/16/95	0.0845	10/31/95	0.0784
5/16/95	0.0797	11/2/95	0.0805

DATE	MRD-50 (mg/ml)	DATE	MRD-50 (mg/ml)
11/7/95	0.0545	8/16/96	0.0875
12/13/95	0.0638	8/20/96	0.0859
12/14/95	0.0743	8/21/96	0.0846
12/14/95	0.0723	8/22/96	0.0880
12/20/95	0.0851	12/17/96	0.0850
12/22/95	0.0795	12/18/96	0.0811
12/22/95	0.0772	12/18/96	0.0761
12/27/95	0.0846	2/25/97	0.0819
12/27/95	0.0844	2/26/97	0.0767
1/23/96	0.0806	2/27/97	0.0850
1/25/96	0.0765	2/28/97	0.0685
1/26/96	0.0688	3/3/97	0.0764
1/30/96	0.0810	3/4/97	0.0852
1/31/96	0.0743	3/6/97	0.0816
2/1/96	0.0808	3/7/97	0.0850
2/13/96	0.0851	3/13/97	0.0847
2/27/96	0.0853	3/14/97	0.0765
2/27/96	0.0867	3/14/97	0.0787
2/28/96	0.0838	3/20/97	0.0901
2/28/96	0.0874	3/21/97	0.0871
3/5/96	0.0846	3/25/97	0.0837
3/6/96	0.0816	3/26/97	0.0869
3/7/96	0.0835	3/27/97	0.0845
4/4/96	0.0882	4/04/97	0.0853
4/9/96	0.0841	4/07/97	0.0866
4/10/96	0.0812	4/07/97	0.0872
4/11/96	0.0831	5/29/97	0.0791
4/19/96	0.0842	5/30/97	0.0795
4/25/96	0.0837	5/30/97	0.0669
4/25/96	0.0808	5/30/97	0.0783
4/26/96	0.0825	6/30/97	0.0805
4/29/96	0.0827	6/30/97	0.0643
4/29/96	0.0731	7/01/97	0.0766
4/30/96	0.0807	7/02/97	0.0727
5/1/96	0.0840	7/28/97	0.0791
5/1/96	0.0770	7/27/97	0.0635
5/2/96	0.0807	7/31/97	0.0602
5/2/96	0.0745	8/01/97	0.0706
5/3/96	0.0824	8/05/97	0.0588
6/10/96	0.0829	8/07/97	0.0774
6/11/96	0.0788	8/07/97	0.0773
6/12/96	0.0794	10/30/97	0.0649
7/16/96	0.0771	10/31/97	0.0725
7/17/96	0.0811	10/31/97	0.0694
7/17/96	0.0762	11/20/97	0.0823
8/7/96	0.0835	11/21/97	0.0813
8/8/96	0.0855	12/04/97	0.0785
8/9/96	0.0824	12/05/97	0.0789
8/14/96	0.0840	12/09/97	0.0783
8/15/96	0.0841	12/10/97	0.0804

DATE	MRD-50 (mg/ml)	DATE	MRD-50 (mg/ml)
12/11/97	0.0771	2/24/99	0.0886
12/12/97	0.0794	2/25/99	0.0804
12/16/97	0.0779	2/26/99	0.0960
12/16/97	0.0757	2/26/99	0.0750
12/23/97	0.0813	3/01/99	0.0848
12/23/97	0.0788	3/02/99	0.0779
12/24/97	0.0811	3/03/99	0.0816
12/24/97	0.0810	3/03/99	0.0821
1/21/98	0.0815	3/04/99	0.0830
1/21/98	0.0825	3/04/99	0.0840
1/21/98	0.0791	3/05/99	0.0827
4/14/98	0.0812	3/09/99	0.0775
4/16/98	0.0798	3/10/99	0.0978
4/17/98	0.0785	3/16/99	0.0768
4/24/98	0.0813	3/18/99	0.0727
4/28/98	0.0795	3/19/99	0.0796
4/28/98	0.0809	3/23/99	0.1410
6/5/98	0.0817	3/24/99	0.0864
6/15/98	0.0870	3/25/99	0.0793
6/15/98	0.0907	3/26/99	0.0711
6/19/98	0.0779	3/30/99	0.0754
6/19/98	0.0837	4/01/99	0.0801
7/28/98	0.0821	4/02/99	0.0758
7/29/98	0.0791	4/06/99	0.0813
7/30/98	0.0834	4/07/99	0.0763
7/31/98	0.0906	4/08/99	0.0801
8/3/98	0.0869	4/09/99	0.0763
9/10/98	0.0780	4/09/99	0.0727
9/11/98	0.0811	4/13/99	0.0612
9/11/98	0.0941	4/14/99	0.0674
10/9/98	0.0858	4/15/99	0.0738
10/13/98	0.0814	4/22/99	0.0752
10/14/98	0.0869	4/23/99	0.0742
10/15/98	0.0859	4/27/99	0.0752
10/16/98	0.0854	4/28/99	0.0710
10/20/98	0.0799	4/30/99	0.0661
10/21/98	0.0813	5/04/99	0.0719
10/22/98	0.0826	5/05/99	0.0723
10/23/98	0.0826	5/07/99	0.0690
11/6/98	0.0840	5/28/99	0.0770
11/9/98	0.0957	5/28/99	0.0770
11/10/98	0.0831	5/28/99	0.0820
11/11/98	0.0922	5/28/99	0.0810
11/13/98	0.0968	5/28/99	0.0730
11/16/98	0.0924	5/28/99	0.0670
1/29/99	0.0831	5/28/99	0.0690
2/1/99	0.0830	6/02/99	0.0789
2/4/99	0.0840	6/03/99	0.0760
2/5/99	0.0916	6/04/99	0.0711
2/23/99	0.0818	8/10/99	0.0785

DATE	MRD-50 (mg/ml)	DATE	MRD-50 (mg/ml)
8/11/99	0.0779	07/25/00	0.0731
8/12/99	0.0782	07/27/00	0.0761
8/13/99	0.0801	07/28/00	0.0721
8/17/99	0.0815	08/02/00	0.0811
8/18/99	0.0794	08/10/00	0.0772
9/16/99	0.0781	08/11/00	0.0740
9/17/99	0.0805	08/11/00	0.0731
9/17/99	0.0801	08/25/00	0.0847
10/07/99	0.0745	08/25/00	0.0730
10/13/99	0.0824	10/04/00	0.0750
10/14/99	0.0816	10/06/00	0.0777
10/15/99	0.0796	10/11/00	0.0815
10/19/99	0.0833	11/27/00	0.0727
10/21/99	0.0861	11/28/00	0.0742
10/22/99	0.0812	11/29/00	0.0786
11/22/99	0.0793	12/12/00	0.0788
11/23/99	0.0804	12/13/00	0.0699
11/24/99	0.0786	12/14/00	0.0765
12/13/99	0.0820	12/28/00	0.0816
12/14/99	0.0732	12/29/00	0.0729
12/15/99	0.0847	12/29/00	0.0809
12/16/99	0.0788	2/5/01	0.0887
12/17/99	0.0756	2/6/01	0.0753
12/20/99	0.0823	2/9/01	0.0734
12/21/99	0.0783	2/12/01	0.0773
12/23/99	0.0968	3/5/01	0.0751
01/25/00	0.0832	3/6/01	0.0759
01/25/00	0.0824	3/14/01	0.0782
01/26/00	0.0761	3/20/01	0.0798
01/26/00	0.0768	3/21/01	0.0666
01/27/00	0.0787	3/22/01	0.0687
01/28/00	0.0788	3/23/01	0.0769
02/01/00	0.0840	3/27/01	0.0783
02/02/00	0.0749	**6/27/01**	**0.1247**
02/03/00	0.0772	6/28/01	0.0790
02/04/00	0.0794	7/2/01	0.0811
04/14/00	0.0764	7/3/01	0.0767
04/17/00	0.0780	7/6/01	0.0765
04/18/00	0.0740	7/11/01	0.0753
04/19/00	0.0723	7/12/01	0.0738
04/24/00	0.0810	7/13/01	0.0917
04/25/00	0.0824	7/17/01	0.0793
06/13/00	0.0813	7/18/01	0.0834
06/13/00	0.0753	7/19/01	0.0817
06/13/00	0.0802	7/20/01	0.0768
07/13/00	0.0841	8/22/01	0.0740
07/14/00	0.0729	8/23/01	0.0765
07/17/00	0.0762	8/24/01	0.0769
07/24/00	0.0800	**8/28/01**	**0.0227**
07/25/00	0.0758	8/29/01	0.0698

DATE	MRD-50 (mg/ml)	DATE		MRD-50 (mg/ml)
9/5/01	0.0790	05/30/02		0.0848
9/6/01	0.0748	08/02/02		0.0713
9/6/01	0.0752	08/08/02		0.0748
9/7/01	0.0694	08/09/02		0.0743
9/12/01	0.0795	**08/15/02**		**0.1137**
9/13/01	0.0681	08/15/02		0.0782
9/13/01	0.0702	09/06/02		0.0871
10/02/01	0.0813	09/10/02		0.0808
10/03/01	0.0817	09/11/02		0.0760
10/03/01	0.0812	09/12/02		0.0791
10/17/01	0.0832	09/17/02		0.0857
11/06/01	0.0802	09/19/02		0.0703
11/07/01	0.0754	09/25/02		0.0849
11/08/01	0.0786	09/26/02		0.0718
11/09/01	0.0803	09/26/02		0.0850
11/13/01	0.0749	**02/07/03**	*	**0.2325**
11/14/01	0.0740	02/11/03		0.0818
11/15/01	0.0754	02/13/03		0.0790
11/16/01	0.0975	02/21/03		0.0732
11/27/01	0.0753	02/21/03		0.0832
11/28/01	0.0796	04/24/03		0.0846
11/29/01	0.0696	04/24/03		0.0831
11/30/01	0.0735	04/29/03		0.0810
11/30/01	0.0798	04/29/03		**0.1734**
12/04/01	**0.1630**	04/30/03		0.0780
12/05/01	0.0704	05/07/03		0.0867
12/05/01	0.0782	05/08/03		0.0836
12/12/01	0.0711	05/09/03		0.0860
12/13/01	0.0723	05/14/03		0.0827
12/14/01	0.0755	05/15/03		0.0833
12/18/01	0.0693	05/16/03		0.0864
01/23/02	0.0722	07/22/03		0.0763
01/24/02	0.0722	07/23/03		0.0675
01/31/02	0.0799	07/24/03		0.0778
01/31/02	0.0772	07/25/03		0.0812
02/01/02	0.0763	07/30/03		0.0851
02/05/02	0.0742	07/31/03		**> 0.03**
02/08/02	0.0719	08/01/03		0.0803
02/12/02	0.0739	08/05/03		0.0838
03/19/02	0.0928	08/06/03		0.0790
03/20/02	0.0756	08/07/03		0.0805
03/21/02	0.0849	08/08/03		0.0773
03/22/02	0.0760	08/13/03		0.0849
05/08/02	0.0848	08/14/03		0.0741
05/09/02	0.0747	08/15/03		0.0685
05/10/02	0.0848	08/19/03		0.0840
05/15/02	0.0661	08/20/03		0.0821
05/17/02	0.0792	08/21/03		0.0812
05/28/02	0.0766	08/22/03		0.0820
05/29/02	0.0766	08/26/03		0.0826

DATE		MRD-50 (mg/ml)
08/27/03		0.0785
09/04/03		0.0818
09/05/03		0.0797
09/09/03		0.0850
09/10/03		0.0815
09/11/03		0.0843
09/24/03		0.0833
09/25/03		0.0802
09/26/03		0.0814
10/01/03		0.0813
10/02/03		0.0832
10/03/03		0.0841
10/30/03		0.0823
10/31/03		0.0825
11/05/03		0.0778
11/06/03		0.0810
11/07/03		0.0804
11/11/03		0.0839
11/12/03		0.0748
11/13/03		0.0781
12/03/03		0.0873
12/04/03		0.0810
12/05/03		0.0795
12/10/03		0.0829
12/11/03		0.0842
12/12/03		0.0820
12/16/03		0.0835
12/17/03	#	0.0812
12/18/03		0.0832
12/19/03		0.0837
12/23/03		0.0745
12/30/03		0.0755
12/31/03		0.0856
12/31/03		0.0784
01/14/04		0.0821
01/15/04		0.0797
01/16/04		0.0790
01/20/04		0.0808
01/21/04		0.0783
01/22/04		0.0803
01/23/04		0.0797
01/27/04		0.0839
01/28/04		0.0807
01/29/04		0.0800
01/30/04		0.0801
02/11/04		0.0840
02/12/04		0.0805
02/12/04		0.0758
02/24/04		0.0830
02/26/04		0.0859

DATE		MRD-50 (mg/ml)
03/02/04		0.0838
03/11/04		0.0826
03/18/04		0.0820
03/18/04		0.0837
03/31/04		0.0808
04/01/04		**0.1602**
04/02/04		0.0771
04/08/04		0.0799
04/21/04	*	0.0430
04/22/04		0.0684
04/23/04		0.0781
04/27/04		0.0812
04/28/04		0.0830
04/29/04		0.0803
05/05/04		0.0809
05/06/04		0.0703
05/07/04		0.0809
05/12/04		0.0758
05/13/04		0.0828
05/14/04		0.0795
05/19/04		0.0811
05/20/04		0.0793
05/21/04		0.0805
05/26/04		0.0828
06/30/04		0.0842
07/01/04		0.0778
07/07/04		0.0759
07/08/04		0.0809
07/15/04		0.0721
08/04/04		0.0810
08/05/04		0.0785
08/05/04		0.0775
08/24/04		0.0799
08/25/04		0.0797
08/26/04		0.0792
09/01/04		0.0834
09/02/04		0.0756
09/02/04		0.0582
10/06/04		0.0782
10/07/04		0.0769
10/12/04		0.0757
11/23/04		0.0821
11/24/04		0.0833
11/30/04		0.0767
12/07/04		0.0781
12/08/04		0.0750
12/09/04		0.0751
01/11/05		0.0782
01/12/05		0.0771
01/12/05		0.0775

DATE	MRD-50 (mg/ml)
05/03/05	**0.0529**
05/04/05	0.0704
05/05/05	0.0745
05/10/05	0.0787
05/11/05	**0.0221**
05/12/05	**0.0219**
05/17/05	0.0801
05/18/05	0.0742
05/18/05	0.0755
06/07/05	0.0836
06/08/05	0.0786
06/09/05	0.0784
06/29/05	0.0836
06/30/05	0.0702
07/06/05	0.0841
07/07/05	0.0746
07/13/05	0.0821
08/24/05	0.0780
08/25/05	0.0622
08/31/05	0.0801
09/20/05	0.0817
09/21/05	0.0714
09/22/05	**0.1097**
09/23/05	0.0802
09/29/05	**0.0208**
09/30/05	0.0793
10/06/05	0.0799
10/13/05	0.0837
11/16/05	0.0880
11/17/05	0.0810
11/22/05	0.0842
11/30/05	0.0855
12/01/05	0.0795
12/02/05	0.0790
03/08/06	0.0774
03/09/06	0.0730
03/10/06	0.0765
03/16/06	0.0711
05/03/06	0.0675
05/09/06	0.0800
05/10/06	0.0769
05/12/06	0.0743
06/28/06	0.0855
06/29/06	0.0789
06/30/06	0.0783
Average (mg/mL)	0.0799
ST DV	0.011
CV (%)	14.3

* - Not included in the historical calculation since it was tested on a defective channel.
# - Not included in the historical calculation since cell seeding density may have been inaccurate.
Numbers in bold indicate failed assays. Value is used to calculate the average.

E2 COLIPA Raw Data from CellTox AB

CellTox AB

Date/Datum

Our/Vår ref.

950627

Anders Peterson

Dr David Lovell
COLIPA Data Coordinator
BIBRA Toxicology International
Crashalton
Surrey, SM5 4DS
United Kingdom

Below and in the revised protocols are my answers to the" BIBRA Quality Assurance Audits" comments to Laboratory 28.

b (i). Entries under the column "Physical appearance" are wrong due to a missunderstanding. Entries are changed in the revised protocol.

b(ii). NST (not suitable for testing) is changed to "Unsuitable for testing" and placed in the MRD50 columns.

b(iii). Changed in accordance with your comments.

b(iv).. For sample 2479 n.f. means "not found", This is taken from the Excel spreadsheet analysis since no MRD50 value was obtained. Since I runned out of test sample no additional testing was performed.

b(v). The formula in the original protocoll shall be changed, wich had been reported from the leading laboratory.
The correct formula shall be:

$A / 1 + e^{(B * (\log MRD50 - G))}$

b(vi). Sample number 3825 MRD50 found to be higher than 316.2 mg/ml.
b(vii) Compliance with GLP. Corrected for.
I hope you will find changes and comments made satisfactory.

Most Sincerely

Address
S. Långebergsgatan 30
S-421 32 Västra Frölunda
Sweden

Telephone
+46 31 68 04 99

Telefax
+46 31 68 07 17

Appendix 2
Data Report Form
COLIPA In Vitro Eye Irritation Validation Programme
PHASE 2

CORE DATA Cytosensor Microphysiometer								SUPPLIMENTAL DATA
Sample ID	Physical Appearance	Log (MRD_{50}) (MRD_{50} in ug/ml)				Predicted MMAS*	95% Confidence*	
		Trial 1	Trial 2	Trial 3	Average			
2003	Pink clear liquid	4.879	4.686	4.279	4.679	2.060	-27.6 / 31.5	
2136	colourless liquid	3.433	3.441	3.456	3.444	17.310	-12.6 / 46.8	
2146	White gel	Unsuitable for testing						
2201	Colourless liquid	4.994	4.995	5.002	4.997	1.158	-28.3 / 30.7	
2254	Colourless liquid	5.469	5.455	5.472	5.466	0.500	-28.9 / 30.0	
2263	Red powder	Unsuitable for testing						
2283	White gel	Unsuitable for testing.						
2292	White gel	Unsuitable for testing.						
2300	White gel	Unsuitable for testing.						
2331	White gel	Unsuitable for testing.						
2386	Clear yellow vis	2.826	2.771	2.892	2.833	42.358	11.6 / 71.2	
2405	White gel	Unsuitable for testing.						
2459	Clear liq.w.pre.	Unsuitable for testing.						
2475	White gel	Unsuitable for testing.						
2479	Clear visc.liq.	n.f	5.315	5.324	5.320	0.651	-28.8 / 30.2	

* Values to be determined by parties directed by the management team.

Performing Laboratory Code No.: 28

n.f = not found
visc. = viscous
liq. = liquid

Study Director for Performing Laboratory: Dr. Anders Peterson
(print)

(signature) 950628
(date)

Assays Supervised by: Peter Sandberg
(print)

(signature) 950628
(date)

Please return this form to:
Dr. David Lovell, COLIPA Data Coordinator, BIBRA Toxicology International Woodmansterne Road, Crashalton, SURREY, SM5 4DS, UK (Fax: 44-(0)81-661 7029)

Appendix 2
Data Report Form
COLIPA In Vitro Eye Irritation Validation Programme
PHASE 2

CORE DATA Cytosensor Microphysiometer								SUPPLEMENTAL DATA
Sample ID	Physical Appearance	Log (MRD_{50}) (MRD_{50} in ug/ml)				Predicted MMAS*	95% Confidence*	
		Trial 1	Trial 2	Trial 3	Average			
2563	Colourless liquid	4.561	4.730	4.703	4.671	2.090	-27.4 / 31.7	
2638	White gel	Unsuitable for testing.						
2673	Opalescent white	Unsuitable for testing.						
2764	Colourless two-ph	Unsuitable for testing.						
2811	Colourless liquid	3.093	3.155	3.167	3.140	27.660	-2.5 / 56.9	
2845	Colourless liquid	Unsuitable for testing.						
2901	Colourless liquid	2.556	2.477	2.415	2.491	63.220	32.5 / 92.7	
3067	Clear yellow liq.	Unsuitable for testing.						
3177	Colourless liquid	Unsuitable for testing.						
3191	Colourless liquid	2.724	2.699	2.699	2.708	49.530	20 / 71.9	
3207	Colourless liquid	4.245	4.221	4.208	4.225	4.610	-25.2 / 34.8	
3232	Black gel	Unsuitable for testing.						
3306	Colourless liqui	3.121	3.425	3.394	3.332	20.660	-8.0 / 51.4	
3328	Colburless vis.li	2.886	2.903	2.851	2.881	39.785	14.3 / 74.0	
3337	White crystals	4.424	4.396	4.426	4.415	3.296	-26.2 / 33.0	

* Values to be determined by parties directed by the management team.

n.f = not found
visc. = viscous liq. = liquid

Performing Laboratory Code No.: 28

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Appendix 2
Data Report Form
COLIPA In Vitro Eye Irritation Validation Programme
PHASE 2

CORE DATA Cytosensor Microphysiometer								SUPPLIMENTAL DATA
Sample ID	Physical Appearance	Log (MRD_{50}) (MRD_{50} in ng/ml)				Predicted MMAS*	95% Confidence*	
		Trial 1	Trial 2	Trial 3	Average			
3355	White vis.liquid	Unsuitable for testing.						
3357	Colourless liquid	4.290	4.026	4.028	4.133	5.416	-24.4 / 34.9	
3392	White gel	Unsuitable for testing.						
3415	White viscous liq.	Unsuitable for testing.						
3434	Colourless liquid	2.771	2.785	2.785	2.785	45.040	14.34 / 74.0	
3440	Colourless liquid	2.833	2.898	2.845	2.863	40.740	11.6 / 71.2	
3470	White-yellow gel	Unsuitable for testing.						
3488	Colourless liquid	Unsuitable for testing.						
3500	Colourless liquid	3.394	3.371	3.387	3.386	18.984	-11.2 / 48.3	
3517	Colourless liquid	3.480	3.667	3.727	3.636	12.657	-17.3 / 42.0	
3556	Colourless liquid	5.357	5.329	5.334	5.340	0.628	-29.0 / 30.1	
3561	Slightly yell liq.	3.622	3.476	3.519	3.543	14.751	-15.2 / 44.3	
3677	Green clear vis	3.691	3.836	3.668	3.739	10.657	-19.2 / 40.1	
3720	Colourless liquid	3.127	3.164	2.963	3.093	29.970	-2.5 / 56.9	
3724	Colourless liquid with crystal precipitation					Unsuitable for testing.		

* Values to be determined by parties directed by the management team.

Performing Laboratory Code No.: 28

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liq. = liquid

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Appendix 2
Data Report Form
COLIPA In Vitro Eye Irritation Validation Programme
PHASE 2

CORE DATA Cytosensor Microphysiometer								SUPPLEMENTAL DATA
Sample ID	Physical Appearance	Log (MRD_{50}) (MRD_{50} in ug/ml)				Predicted MMAS[a]	95% Confidence[a]	
		Trial 1	Trial 2	Trial 3	Average			
3731	Orange powder	Unsuitable for testing						
3746	Black gel	Unsuitable for testing						
3764	White gel	Unsuitable for testing						
3789	Colourless liquid	4.980	5.135	5.151	5.095	0.983	28.6 / 30.5	
3825	Colourless liquid	>5.5	>5.5			<0.330		
3837	White gel	Unsuitable for testing						
3864	Colourless liquid	3.114	3.090	3.079	3.093	29.630	0.4 / 59.0	
3881	White gel	Unsuitable for testing						
3906	White gel	Unsuitable for testing						
3918	White powder	Unsuitable for testing						

Values to be determined by parties directed by the management team.

n.f = not found
visc. = viscous liq. = liquid

Performing Laboratory Code No.: 28

Study Director for Performing Laboratory: Dr. Anders Peterson
(print)

(signature) 950628 (date)

Assays Supervised by: Peter Sandberg
(print)

(signature) 950628 (date)

Please return this form to:
Dr. David Lovell, COLIPA Data Coordinator, BIBRA Toxicology International Woodmansterne Road, Carshalton, SURREY, SM5 4DS, UK (Fax 44-(0)81-661 7029)

E3 COLIPA Raw Data from Microbiological Associates, Inc.

Appendix 2
Data Report Form
COLIPA In Vitro Eye Irritation Validation Programme:
PHASE 2

CORE DATA Cytosensor Microphysiometer								SUPPLE-MENTAL DATA
Sample ID	Physical Appearance	Log (MRD_{50}) (MRD_{50} in ug/ml)				Predicted MMAS*	95% Confidence* (Lower/Upper)	
		Trial 1	Trial 2	Trial 3	Average			
2056	White flakes	4.40	4.22	4.17	4.26	4.31	-25.2/34.0	
2079	Clear colorless liquid	2.47	2.49	2.52	2.49	63.1	32.5/92.7	
2089	Clear colorless liquid	3.45	3.46	3.60	3.50	15.7	-13.9/45.5	
2092	Clear colorless liquid	2.71	2.97	2.90	2.86	40.9	11.6/71.2	
2115	Clear colorless liquid	5.20	5.24	5.21	5.22	0.783	-28.7/30.3	
2171	Clear pale yellow liquid	3.98	4.17	3.62	3.92	7.79	-21.6/37.8	
2174	Clear colorless liquid	2.46	2.60	2.44	2.50	62.8	32.5/92.7	
2337	Clear colorless liquid	4.94	4.94	4.95	4.95	1.28	-28.3/30.8	
2356	Clear colorless liquid	4.86	4.63	4.63	4.71	1.96	-27.6/31.5	
2365	Clear colorless liquid	Unsuitable for testing						
2392	Opaque viscous liquid	Unsuitable for testing						
2429	Clear colorless liquid	4.44	3.96	4.33	4.24	4.47	-25.2/34.0	
2551	Opaque viscous liquid	Unsuitable for testing						
2575	White paste	Unsuitable for testing						
2639	White cream	Unsuitable for testing						
2652	White cream	Unsuitable for testing						
2713	White cream	Unsuitable for testing						
2721	Clear colorless liquid	2.71	2.73	2.70	2.71	49.2	20.1/79.9	
2774	Red powder	Unsuitable for testing						
2827	White cream	Unsuitable for testing						
2887	Pale yellow opaque cream	Unsuitable for testing						
2906	Black cream	Unsuitable for testing						
2947	White cream	Unsuitable for testing						
2993	White cream	Unsuitable for testing						
3099	White suspension	Unsuitable for testing						
3105	Clear colorless liquid	3.50	3.47	3.15	3.38	19.3	-11.2/48.3	

3148	Clear colorless liquid	3.11	2.88	3.12	3.04	32.0	1.79/61.2	
3166	Black cream	Unsuitable for testing						
3169	Orange powder	Unsuitable for testing						
3213	Clear colorless liquid	2.79	2.87	2.73	2.79	44.5	14.3/74.0	
3244	Clear colorless liquid	3.46	3.26	3.43	3.38	19.2	-11.2/48.3	
3343	Clear yellow liquid	2.95	2.93	2.96	2.95	36.3	6.48/66.0	
3399	Clear colorless liquid	3.67	3.66	3.49	3.61	13.3	-16.3/43.2	
3453	Clear colorless liquid	5.27	5.35	5.37	5.33	0.635	-28.9/30.1	
3458	White cream	Unsuitable for testing						
3507	White cream	Unsuitable for testing						
3524	Clear colorless liquid	3.98	3.99	3.90	3.96	7.35	-22.3/37.1	
3525	Clear pink liquid	4.53	4.59	4.61	4.58	2.47	-27.2/31.9	
3533	White cream	Unsuitable for testing						
3568	Clear colorless liquid	Unsuitable for testing						
3584	White cream	Unsuitable for testing						
3589	Clear colorless liquid	> 5.50	> 5.50	5.41	> 5.41	< 0.553	>-29.0/<30.1	
3631	Clear colorless liquid	3.65	3.62	3.64	3.64	12.6	-17.4/42.1	2.92
3645	Clear blue liquid	3.70	3.57	3.92	3.73	10.8	-19.3/40.2	
3651	Clear amber liquid	Unsuitable for testing						
3704	White cream	Unsuitable for testing						
3740	Clear colorless liquid	4.41	4.31	4.24	4.32	3.91	-25.6/33.7	
3770	Clear colorless liquid	2.94	2.94	2.84	2.91	38.4	9.00/68.5	
3806	Clear colorless liquid	3.65	3.63	3.72	3.67	12.0	-17.4/42.1	> 3.00
3855	Pale yellow cream	Unsuitable for testing						
3870	Clear colorless liquid	4.73	4.76	4.71	4.73	1.87	-27.7/31.4	
3872	Clear colorless liquid	5.42	5.43	5.42	5.42	0.538	-28.9/30.1	
3883	White cream	Unsuitable for testing						
3886	White flaky suspension	3.10	3.09	3.20	3.13	28.1	-2.46/56.9	
3908	Opaque liquid	Unsuitable for testing						

* Values to be determined by parties directed by the management team.

Performing Laboratory Code No.: 27

Study Director for
Performing Laboratory: John W. Harbell, Ph.D.
(print)

J. W. Harbell
(signature)

May 12, 1995
(date)

Assays Supervised by: Hans A. Raabe, M.S.
(print)

Hans Raabe
(signature)

May 15, 1995
(date)

Please return this form to:
Dr. David Lovell, COLIPA Data Coordinator, BIBRA Toxicology International Woodmansterne Road, Crashalton, SURREY, SM5 4DS, UK (Fax: 44-(0)81-661 7029)

E4 COLIPA Decoded Samples for Microbiological Associates, Inc.

FAX FROM

BIBRA International
Woodmansterne Road, Carshalton, Surrey SM5 4DS, Great Britain
Telephone: 0181-652 1000 Fax: 0181-661 7029

TO: Dr John Harbell COMPANY: Microbiological Associates, Inc.

FAX NO: 001 301 738 1036

DATE: 29 April 1996

FROM: Mrs Pat Aspin on behalf of Dr Paul G Brantom, Head of Division Customer & Information Services

NO. PAGES (including cover sheet) 3
If you do not receive all pages or quality is poor, please phone 0181-652 1000

Laboratory no: 27
Assay: Silicon Microphysiometer

Dear Dr Harbell

The COLIPA study to assess the validity of *in vitro* alternatives to the Draize eye irritation test

We have been requested by the Management Team to release to your laboratory the decodes for each of the samples tested in the above study. Please find this list attached.

Should you have any queries please do not hesitate to contact me.

Yours sincerely

Pat Aspin

COLIPA study to assess the validity of *in vitro* alternatives to the Draize eye irritation test

Laboratory no. 27		Assay: Silicon Microphysiometer
Code used for statistical analyses	Sample	Code supplied to laboratories
1	Blush	2774
2	Eye liner	2906
3	Perfumed skin lotion	3507
4	Polishing scrub	2713
5	Shampoo no.1 - normal	2042
6	Eye make-up remover	2337
7	Hand cleanser	3458
8	Hair dye base formulation no. 1	3883
9	n-Butyl acetate	2365
10	Imidazole	2056
11	Polyethylene glycol 400	3509
12	Propylene glycol	3872
13	Triton X-100 1%	3740
14	Glycerol	3453
15	Tween 20	2171
16	Ethyl acetate	3568
17	Sodium lauryl sulphate 3%	2089
18	Sodium hydroxide 1%	3524
19	Isopropanol	2356
20	Triton X-100 5%	3806
21	Benzalkonium chloride 1%	3309
22	Methyl ethyl ketone	3870
23	Sodium lauryl sulphate 15%	2721
24	Sodium lauryl sulphate 30%	2079
25	Triton X-100 10%	3244
26	Benzalkonium chloride 5%	3770
27	Benzalkonium chloride 10%	2174

continued/...

COLIPA study to assess the validity of *in vitro* alternatives to the Draize eye irritation test

Laboratory no.	27	Assay: Silicon Microphysiometer
Code used for statistical analyses	Sample	Code supplied to laboratories
28	Pump deodorant / antiperspirant	2429
29	Sunscreen lotion	3584
30	Cologne	3651
31	Eye shadow	3169
32	Mascara	3166
33	Emulsion antiperspirant	3533
34	Gel cleanser	3645
35	Hand soap	2887
36	Shampoo - baby	3105
37	Sunscreen SPF 15	2993
38	Hair styling lotion	2115
39	Liquid soap no. 1	3343
40	Shampoo - antidandruff	3908
41	Shampoo - 2-in-1	2575
42	Hydrophilic ointment	2551
43	Mouthwash	3525
44	Toothpaste	2652
45	Cleansing foam III	3704
46	Hair conditioner	3855
47	Moisturiser with sunscreen	2639
48	Shower gel	2827
49	Skin cleanser	3213
50	Hair dye base formulation no. 9	2302
51	Hair dye base formulation no. 8	2947
52	Cetylpyridinium bromide 6%	3886
53	Cetylpyridinium bromide 10%	3039
54	Sodium hydroxide 10%	3031
55	Trichloroacetic acid 30%	3148