Supplement to a Background Review Document of an *In Vitro* Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products

Reliability Analysis Based on Predicted EPA and GHS Hazard Categories

Submitted by the Institute for In Vitro Sciences, Inc. on behalf of the Alternatives Testing Steering Committee

1.0 Cytosensor Reliability

Reliability (relative to EPA and GHS hazard categories) of the CM was determined using the prediction model discussed in Chapter 6 – Test Method Predictive Capacity, of the Background Review Document of an In Vitro Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products. This was the same prediction model proposed in the Cytosensor Microphysiometer Bioassay Background Review Document submitted to ECVAM and is given below:

1) **If the anti-microbial cleaning product has an MRD_{50} score of <2 mg/ml, it is classified as EPA Category I or GHS Category 1.**

2) **If the anti-microbial cleaning product has an MRD_{50} score of ≥2 mg/ml, but < 80 mg/ml, it is classified as EPA Category III. If the anti-microbial cleaning product has an MRD_{50} score of ≥2 mg/ml, but <10 mg/ml, it is classified as GHS Category 2B.**

3) **If the anti-microbial cleaning product has an MRD_{50} score of ≥80 mg/ml, it is classified as EPA Category IV. If the anti-microbial cleaning product has an MRD_{50} score of ≥10 mg/ml, it is classified GHS Category NI.**

All calculations in the following CM sections are based on this prediction model.

1.1 Cytosensor Intralaboratory Repeatability

An analysis of intralaboratory repeatability was conducted as part of the Cytosensor Microphysiometer Bioassay Background Review Document submitted to ECVAM. Since ECVAM has supplied that document to ICCVAM, we will just reproduce the appropriate section here. Table and Figure designations follow those used in the Background Review Document of Existing Methods for Eye Irritation Testing: Silicon Microphysiometer and Cytosensor Microphysiometer.

5.2.2.3 Reproducibility of predicted hazard classifications for the EC/HO study

A comparison of the between laboratories reproducibility of the prediction of hazard classifications is given in this section. Since none of the formal studies of the CM reported on in this BRD had predetermined prediction models for hazard classifications (although several did for Draize scores), the following analyses are based on prediction models derived during the construction of this BRD and presented in Chapter 6 – Predictive Capacity. Specifically these analyses of the EC/HO study are based on the prediction models proposed in Section 6.1.3.1.

Tables 5.2.2.3.a and 5.2.2.3.b. present the predicted EU, GHS and EPA classifications predicted for the surfactant and non-surfactant materials, respectively from the MRD_{50} values produced by each of the four participating laboratories. These

predictions were then consolidated into summary tables which are Tables 5.2.2.3.c and 5.2.2.3.d for the surfactants and non-surfactant materials, respectively.

Table 5.2.2.3.c shows that for the surfactant materials where all four laboratories tested the materials (all but one of the cases) that 6 of the 11 materials were predicted to be the same classification, 3 of the 11 materials were predicted identically by 3 of the 4 labs, and 2 of the materials had similar predictions between less than three of the labs.

Table 5.2.2.3.d shows that for the non-surfactant materials where all four laboratories tested the materials that 9 of 17 materials were predicted the same by all four labs. Five materials had agreement between only 3 of the 4 labs and 3 of the 17 materials had agreement between less than 3 of the labs.

For the two non-surfactant materials where only three of the labs tested the materials three labs agreed on one and only two labs agreed on the other. If only two labs tested the materials, then both agreed for one material and both disagreed for the remaining three materials.

It appears from the above data that as fewer labs decided that a material was not testable under the constraints of the protocol, the reproducibility of the hazard predictions became worse.

Table 5.2.2.3.a Surfactant Materials - EU, GHS, and EPA classifications based on Cytosensor MRD_{50} values from EC/HO study. Cut-off values from Figures 6.1.3.1.a, 6.1.3.1.b, and 6.1.3.1.c were used. The number of replicates for each lab is unknown. N = 12 surfactant materials.

Chemical	Conc. tested	EU				GHS				EPA			
		CM 30	CM 31	CM 32	CM 33	CM 30	CM 31	CM 32	CM 33	CM 30	CM 31	CM 32	CM 33
Benzalkonium chloride	5%	R41	R41	R41	R41	1	1	1	1	I	I	I	I
Benzalkonium chloride	10%	R41	R41	R41	R41	1	1	1	1	I	I	I	I
Benzalkonium chloride [1]/[2]	1%	R36	R36	R36	R36	2A or 2B	2A or 2B	2A or 2B	2A or 2B	II or III	II or III	II or III	II or III
Cetylpyridinium bromide	10%	R41	R41	R36	R41	1	1	2A or 2B	1	I	I	II or III	I
Cetylpyridinium bromide	6%	R41	R41	R41	R41	1	1	1	1	I	I	I	I
Cetylpyridinium bromide	0%	R36	NL	R36	NL	2A or 2B	NL	2A or 2B	NL	II or III	IV	II or III	IV
Polyethylene glycol 400	100%	*	*	*	NL	*	*	*	NL	*	*	*	IV
Sodium lauryl sulfate	15%	R41	R41	R41	R41	1	1	1	1	I	I	I	I
Sodium lauryl sulfate	3%	R36	R36	R36	R36	2A or 2B	2A or 2B	2A or 2B	2A or 2B	II or III	II or III	II or III	II or III
Triton X-100	10%	R41	R41	R41	R36	1	1	1	2A or 2B	I	I	I	II or III
Triton X-100 [1]/[2]	5%	R41	R36	R36	R36	1	2A or 2B	2A or 2B	2A or 2B	I	II or III	II or III	II or III
Tween 20	100%	R41	R36	R36	R41	1	2A or 2B	2A or 2B	1	I	II or III	II or III	I

** = not tested*

Table 5.2.2.3.b Non-surfactant Materials – EU, GHS, and EPA classifications based on Cytosensor MRD_{50} values from EC/HO study. Cut-off values from Figures 6.1.3.1.a, 6.1.3.1.b, and 6.1.3.1.c were used. The number of replicates for each lab is unknown. N = 48 non-surfactant materials.

Chemical	Conc. tested	EU				GHS				EPA			
		CM 30	CM 31	CM 32	CM 33	CM 30	CM 31	CM 32	CM 33	CM 30	CM 31	CM 32	CM 33
1-Naphthalene acetic acid	100%	R36	*	*	*	2A or 2B	*	*	*	II or III	*	*	*
1-Naphthalene acetic acid	100%	*	*	*	*	*	*	*	*	*	*	*	*
2,2-Dimethylbutanoic acid	100%	*	*	*	*	*	*	*	*	*	*	*	*
2,5-Dimethylohexanediol	100%	R36	NL	R36	NL	2A or 2B	NL	2A or 2B	NL	II or III	IV	II or III	IV
2,6-Dichlorobenzoyl chloride	100%	*	*	*	*	*	*	*	*	*	*	*	*
2-Ethyl-1-hexanol	100%	*	*	*	*	*	*	*	*	*	*	*	*
4-Carboxybenzaldehyde	100%	*	*	*	*	*	*	*	*	*	*	*	*
Acetone	100%	NL	NL	NL	NL	NL	NL	NL	NL	IV	IV	IV	IV
Ammonium nitrate	100%	R36	NL	R36	*	2A or 2B	NL	2A or 2B	*	II or III	IV	II or III	*
Benzoyl-L-tartaric acid	100%	R41	*	*	*	1	*	*	*	I	*	*	*
Captan 90 concentrate	100%	*	*	*	*	*	*	*	*	*	*	*	*
Chlorhexidine	100%	*	*	*	*	*	*	*	*	*	*	*	*
Cyclohexanol	100%	R36	*	R41	*	2A or 2B	*	1	*	II or III	*	I	*
Dibenzyl phosphate	100%	R41	*	*	*	1	*	*	*	I	*	*	*
Ethanol	100%	NL	NL	NL	NL	NL	NL	NL	NL	IV	IV	IV	IV
Ethyl acetate	100%	*	R36	*	*	*	2A or 2B	*	*	*	II or III	*	*
Ethyl trimethyl acetate	100%	*	*	*	*	*	*	*	*	*	*	*	*
Ethyl-2-methylacetoacetate	100%	*	*	R41	*	*	*	1	*	*	*	I	*
Fomesafen	100%	*	*	*	*	*	*	*	*	*	*	*	*
Gammabutyrolactone	100%	R36	NL	R41	NL	2A or 2B	NL	1	NL	II or III	IV	I	IV
Glycerol	100%	NL	NL	R36	NL	NL	NL	2A or 2B	NL	IV	IV	II or III	IV
Imidazole	100%	R36	R36	R41	R36	2A or 2B	2A or 2B	1	2A or 2B	II or III	II or III	I	II or III
Isobutanol	100%	R36	R36	R36	R36	2A or 2B	2A or 2B	2A or 2B	2A or 2B	II or III	II or III	II or III	II or III
Isopropanol	100%	NL	NL	NL	NL	NL	NL	NL	NL	IV	IV	IV	IV
L-Aspartic acid	100%	R41	R41	*	*	1	1	*	*	I	I	*	*
Maneb	100%	*	*	*	*	*	*	*	*	*	*	*	*
Methyl acetate	100%	R36	NL	NL	NL	2A or 2B	NL	NL	NL	II or III	IV	IV	IV
Methyl cyanoacetate	100%	R36	*	R41	*	2A or 2B	*	1	*	II or III	*	I	*
Methyl ethyl ketone	100%	R36	R36	R36	R36	2A or 2B	2A or 2B	2A or 2B	2A or 2B	II or III	II or III	II or III	II or III
Methyl isobutyl ketone	100%	*	*	R41	*	*	*	1	*	*	*	I	*
Methylcyclopentane	100%	*	*	*	*	*	*	*	*	*	*	*	*

n-Butyl acetate	*100%*	*	*	*	*	*	*	*	*	*	*	*	*
n-Hexanol	*100%*	*	*	*	*	*	*	*	*	*	*	*	*
n-Octanol	*100%*	*	*	*	*	*	*	*	*	*	*	*	*
Parafluoraniline	*100%*	*	*	*R36*	*	*	*	*2A or 2B*	*	*	*	*II or III*	*
Potassium cyanate	*100%*	*R36*	*R36*	*R36*	*R36*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*II or III*	*II or III*	*II or III*	*II or III*
Promethazine HCl	*100%*	*R41*	*R41*	*R41*	*R41*	*1*	*1*	*1*	*1*	*I*	*I*	*I*	*I*
Pyridine	*100%*	*R41*	*R36*	*R36*	*R36*	*1*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*I*	*II or III*	*II or III*	*II or III*
Quniacrine	*100%*	*	*	*R41*	*	*	*	*1*	*	*	*	*I*	*
Sodium hydroxide	*10%*	*R36*	*R41*	*R36*	*R36*	*2A or 2B*	*1*	*2A or 2B*	*2A or 2B*	*II or III*	*I*	*II or III*	*II or III*
Sodium hydroxide	*1%*	*R36*	*R36*	*R36*	*R36*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*II or III*	*II or III*	*II or III*	*II or III*
Sodium oxalate	*100%*	*	*	*	*	*	*	*	*	*	*	*	*
Sodium perborate, 4H20	*100%*	*R41*	*	*	*R36*	*1*	*	*	*2A or 2B*	*I*	*	*	*II or III*
Tetraaminopyrimidine sulfate	*100%*	*R41*	*	*	*	*1*	*	*	*	*I*	*	*	*
Thiourea	*100%*	*R36*	*R36*	*	*R36*	*2A or 2B*	*2A or 2B*	*	*2A or 2B*	*II or III*	*II or III*	*	*II or III*
Toluene	*100%*	*	*	*	*	*	*	*	*	*	*	*	*
Trichloroacetic acid	*30%*	*R41*	*R36*	*R41*	*R36*	*1*	*2A or 2B*	*1*	*2A or 2B*	*I*	*II or III*	*I*	*II or III*
Trichloroacetic acid	*3%*	*R36*	*R36*	*R36*	*R36*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*2A or 2B*	*II or III*	*II or III*	*II or III*	*II or III*

** = not tested*

Table 5.2.2.3.c Surfactant Materials – Agreement table for EU, GHS, and EPA classifications based on Cytosensor MRD_{50} values for the EC/HO study.

Where 4 labs tested the material			
Agreement	**EU**	**GHS**	**EPA**
4 labs	6	6	6
3 labs	3	3	3
<3 labs	2	2	2

Table 5.2.2.3.d Non-Surfactant Materials – Agreement table for EU, GHS, and EPA classifications based on Cytosensor MRD_{50} values for the EC/HO study.

Where 4 labs tested the material			
Agreement	**EU**	**GHS**	**EPA**
4 labs	9	9	9
3 labs	5	5	5
<3 labs	3	3	3
Where 3 labs tested the material			
Agreement	**EU**	**GHS**	**EPA**
3 labs	1	1	1
2 labs	1	1	1
<2 labs	0	0	0
Where 2 labs tested the material			
Agreement	**EU**	**GHS**	**EPA**
Both agree	1	1	1
Both disagree	3	3	3

1.2 Cytosensor Interlaboratory Reproducibility

As stated in our submitted BRD, there were no examples of interlaboratory reproducibility for studies conducted specifically for developing the anti-microbial cleaning products testing strategy. As far as can be determined, only one laboratory (IIVS) conducted the anti-microbial cleaning product studies. However, two existing studies did provide data for this type of comparison. The first was the EC/HO study which had four CM laboratories participating, and the second was the COLIPA validation study which had two CM laboratories.

1.2.1 EC/HO Study

Reproducibility analyses of EPA hazard classifications for the EC/HO study are given in Tables 1-1 and 1-2 for surfactant materials and non-surfactant materials, respectively. Four laboratories participated in the study, and for the surfactants (Table 1-1), there was 100% agreement among laboratories for 6 of the 11 materials (55%), 75% agreement for 3 of the 11 materials (27%) and 50% agreement for 2 of the 11 materials (18%). For a twelfth material only one laboratory determined that it was compatible with the test system. For four of the materials, the disagreement between laboratories appeared to be large, e.g. a two category difference (I and III). However, this was due to the fact that only three EPA hazard categories (I, III and IV) are part of the CM prediction model, so the difference between a Category I and a Category III could be a very small difference in ET_{50} value.

For the non-surfactants in the EC/HO study (Table 1-2), the reproducibility analysis was based only on the materials which two or more laboratories found to be compatible with the test system (23 of 48 total test materials). There was 100% agreement among laboratories for 11 of 23 materials (48%), 75% agreement for 5 of 23 materials (22%), 67% agreement for 1 of 23 test materials (4%), 50% agreement for 3 of 23 materials (13%), and 0% agreement for 3 of 23 test materials (13%). For twenty-five materials only one laboratory, or none of the laboratories, determined that it was compatible with the test system. For some of the materials the disagreement between laboratories appeared to be large, e.g. a two category difference (I and III). However, this was due to the fact that only three EPA hazard categories (I, III and IV) are part of the CM prediction model, so the difference between a Category I and a Category III could be a very small difference in ET_{50} value.

Table 1-1 modified from BRD Table 7-13 Surfactant materials – Between laboratories reproducibility of CM results from the EC/HO study. Analysis by EPA hazard categories.

Chemical	Formulation Type	Conc. tested	EPA Category CM 30	CM 31	CM 32	CM 33	Percent Agreement	Concordance
Cetylpyridinium bromide	SU	10%	I	I	III	I	75%	100% Agreement
Cetylpyridinium bromide	SU	6%	I	I	I	I	100%	for 6 of 11 (55%)
Benzalkonium chloride	SU	5%	I	I	I	I	100%	
Benzalkonium chloride	SU	10%	I	I	I	I	100%	75% Agreement
Triton X-100	SU	10%	I	I	I	III	75%	for 3 of 11 (27%)
Sodium lauryl sulfate	SU	15%	I	I	I	I	100%	
Benzalkonium chloride [1]/[2]	SU	1%	III	III	III	III	100%	50% Agreement
Triton X-100 [1]/[2]	SU	5%	I	III	III	III	75%	for 2 of 11 (18%)
Sodium lauryl sulfate	SU	3%	III	III	III	III	100%	
Tween 20	SU	100%	I	III	III	I	50%	
Cetylpyridinium bromide	SU	0.10%	III	IV	III	IV	50%	
Polyethylene glycol 400	SU	100%	*	*	*	IV	*	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-2 modified from BRD Table 7-14 Non-surfactant materials – Between laboratories reproducibility of CM results from the EC/HO study. Analysis by EPA hazard categories.

Chemical	Formulation Type	Conc. tested	EPA Category CM 30	CM 31	CM 32	CM 33	Percent Agreement	Concordance
Sodium hydroxide	AL	10%	III	I	III	III	75%	100% Agreement for 11 of 23 (48%)
Trichloroacetic acid	AC	30%	I	III	I	III	50%	
Captan 90 concentrate		100%	*	*	*	*	*	
Chlorhexidine		100%	*	*	*	*	*	75% Agreement for 5 of 23 (22%)
Cyclohexanol	SO	100%	III	*	I	*	0%	
Quinacrine		100%	*	*	I	*	*	
Promethazine HCl		100%	I	I	I	I	100%	67% Agreement for 1 of 23 (4%)
Parafluoraniline		100%	*	*	III	*	*	
Acetone	SO	100%	IV	IV	IV	IV	100%	
n-Hexanol	SO	100%	*	*	*	*	*	50% Agreement for 3 of 23 (13%)
1-Naphthalene acetic acid		100%	III	*	*	*	*	
Sodium oxalate		100%	*	*	*	*	*	
Isobutanol	SO	100%	III	III	III	III	100%	0% Agreement for 3 of 23 (13%)
Imidazole	SU	100%	III	III	I	III	75%	
2-Ethyl-1-hexanol	SO	100%	*	*	*	*	*	
4-Carboxybenzaldehyde		100%	*	*	*	*	*	
Methyl ethyl ketone	SO	100%	III	III	III	III	100%	
Pyridine		100%	I	III	III	III	75%	
1-Naphthalene acetic acid		100%	*	*	*	*	*	
2,2-Dimethylbutanoic acid	AC	100%	*	*	*	*	*	
Gammabutyrolactone		100%	III	IV	I	IV	50%	
Thiourea		100%	III	III	*	III	100%	
n-Octanol	SO	100%	*	*	*	*	*	
Methyl acetate	SO	100%	III	IV	IV	IV	75%	
L-Aspartic acid	AC	100%	I	I	*	*	100%	
Benzoyl-L-tartaric acid		100%	I	*	*	*	*	
Potassium cyanate		100%	III	III	III	III	100%	
Isopropanol	SO	100%	IV	IV	IV	IV	100%	
Sodium perborate, $4H_20$		100%	I	*	*	III	0%	
Dibenzyl phosphate	AC	100%	I	*	*	*	*	
2,5-Dimethylohexanediol	SO	100%	III	IV	III	IV	50%	
Methyl cyanoacetate		100%	III	*	I	*	0%	
Sodium hydroxide	AL	1%	III	III	III	III	100%	
Ethanol	SO	100%	IV	IV	IV	IV	100%	
2,6-Dichlorobenzoyl chloride		100%	*	*	*	*	*	
Ammonium nitrate		100%	III	IV	III	*	67%	
Ethyl-2-methylacetoacetate		100%	*	*	I	*	*	
Ethyl acetate	SO	100%	*	III	*	*	*	
Maneb		100%	*	*	*	*	*	
Fomesafen		100%	*	*	*	*	*	
Tetraaminopyrimidine sulfate		100%	I	*	*	*	*	
Toluene		100%	*	*	*	*	*	
n-Butyl acetate		100%	*	*	*	*	*	
Trichloroacetic acid	AC	3%	III	III	III	III	100%	
Methyl isobutyl ketone		100%	*	*	I	*	*	

Ethyl trimethyl acetate		100%	*	*	*	*	*	
Methylcyclopentane		100%	*	*	*	*	*	
Glycerol	AL	100%	IV	IV	III	IV	75%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Reproducibility analyses of GHS hazard classifications for the EC/HO study are given in Tables 1-3 and 1-4 for surfactant materials and non-surfactant materials, respectively. Four laboratories participated in the study, and for the surfactants (Table 1-3), there was 100% agreement among laboratories for 6 of the 11 materials (55%), 75% agreement for 4 of the 11 materials (36%) and 50% agreement for 1 of the 11 materials (9%). For a twelfth material only one laboratory determined that it was compatible with the test system. For four of the materials the disagreement between laboratories appeared to be large, e.g. a two category difference (1 and 2B). However, this was due to the fact that only three GHS hazard categories (1, 2B and NI) are part of the CM prediction model, so the difference between a Category 1 and a Category 2B could be a very small difference in ET_{50} value.

For the non-surfactants in the EC/HO study (Table 1-4), the reproducibility analysis was based only on the materials which two or more laboratories found to be compatible with the test system (23 of 48 total test materials). There was 100% agreement among laboratories for 12 of 23 materials (52%), 75% agreement for 7 of 23 materials (30%), 50% agreement for 1 of 23 materials (4%), and 0% agreement for 3 of 23 test materials (13%). For twenty-five materials only one laboratory, or none of the laboratories, determined that it was compatible with the test system. For some of the materials the disagreement between laboratories appeared to be large, e.g. a two category difference (1 and 2B). However, this was due to the fact that only three GHS hazard categories (1, 2B and NI) are part of the CM prediction model, so the difference between a Category 1 and a Category 2B could be a very small difference in ET_{50} value.

Table 1-3 modified from BRD Table 7-13 Surfactant materials – Between laboratories reproducibility of CM results from the EC/HO study. Analysis by GHS hazard categories.

Chemical	Formulation Type	Conc. tested	GHS Category CM 30	CM 31	CM 32	CM 33	Percent Agreement	Concordance
Cetylpyridinium bromide	SU	10%	1	1	2B	1	75%	100% Agreement
Cetylpyridinium bromide	SU	6%	1	1	1	1	100%	for 6 of 11 (55%)
Benzalkonium chloride	SU	5%	1	1	1	1	100%	
Benzalkonium chloride	SU	10%	1	1	1	1	100%	75% Agreement
Triton X-100	SU	10%	1	1	1	2B	75%	for 4 of 11 (36%)
Sodium lauryl sulfate	SU	15%	1	1	1	1	100%	
Benzalkonium chloride [1]/[2]	SU	1%	2B	2B	2B	2B	100%	50% Agreement
Triton X-100 [1]/[2]	SU	5%	1	2B	2B	2B	75%	for 1 of 11 (9%)
Sodium lauryl sulfate	SU	3%	2B	2B	2B	2B	100%	
Tween 20	SU	100%	1	2B	2B	1	50%	
Cetylpyridinium bromide	SU	0.10%	NI	NI	2B	NI	75%	
Polyethylene glycol 400	SU	100%	*	*	*	NI	*	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-4 modified from BRD Table 7-14 Non-surfactant materials – Between laboratories reproducibility of CM results from the EC/HO study. Analysis by GHS hazard categories.

Chemical	Formulation Type	Conc. tested	GHS Category CM 30	CM 31	CM 32	CM 33	Percent Agreement	Concordance
Sodium hydroxide	AL	10%	2B	1	2B	2B	75%	100% Agreement for 12 of 23 (52%)
Trichloroacetic acid	AC	30%	1	2B	1	2B	50%	
Captan 90 concentrate		100%	*	*	*	*	*	
Chlorhexidine		100%	*	*	*	*	*	
Cyclohexanol	SO	100%	NI	*	1	*	0%	75% Agreement for 7 of 23 (30%)
Quinacrine		100%	*	*	1	*	*	
Promethazine HCl		100%	1	1	1	1	100%	
Parafluoraniline		100%	*	*	2B	*	*	
Acetone	SO	100%	NI	NI	NI	NI	100%	50% Agreement for 1 of 23 (4%)
n-Hexanol	SO	100%	*	*	*	*	*	
1-Naphthalene acetic acid		100%	NI	*	*	*	*	
Sodium oxalate		100%	*	*	*	*	*	
Isobutanol	SO	100%	NI	NI	NI	NI	100%	0% Agreement for 3 of 23 (13%)
Imidazole	SU	100%	NI	NI	1	NI	75%	
2-Ethyl-1-hexanol	SO	100%	*	*	*	*	*	
4-Carboxybenzaldehyde		100%	*	*	*	*	*	
Methyl ethyl ketone	SO	100%	NI	NI	NI	NI	100%	
Pyridine		100%	1	NI	NI	NI	75%	
1-Naphthalene acetic acid		100%	*	*	*	*	*	
2,2-Dimethylbutanoic acid	AC	100%	*	*	*	*	*	
Gammabutyrolactone		100%	NI	NI	1	NI	75%	
Thiourea		100%	NI	NI	*	NI	100%	
n-Octanol	SO	100%	*	*	*	*	*	
Methyl acetate	SO	100%	NI	NI	NI	NI	100%	
L-Aspartic acid	AC	100%	1	1	*	*	100%	
Benzoyl-L-tartaric acid		100%	1	*	*	*	*	
Potassium cyanate		100%	NI	NI	2B	NI	75%	
Isopropanol	SO	100%	NI	NI	NI	NI	100%	
Sodium perborate, $4H_20$		100%	1	*	*	2B	0%	
Dibenzyl phosphate	AC	100%	1	*	*	*	*	
2,5-Dimethylohexanediol	SO	100%	NI	NI	2B	NI	75%	
Methyl cyanoacetate		100%	NI	*	1	*	0%	
Sodium hydroxide	AL	1%	NI	NI	NI	NI	100%	
Ethanol	SO	100%	NI	NI	NI	NI	100%	
2,6-Dichlorobenzoyl chloride		100%	*	*	*	*	*	
Ammonium nitrate		100%	NI	NI	NI	*	100%	
Ethyl-2-methylacetoacetate		100%	*	*	1	*	*	
Ethyl acetate	SO	100%	*	NI	*	*	*	
Maneb		100%	*	*	*	*	*	
Fomesafen		100%	*	*	*	*	*	
Tetraaminopyrimidine sulfate		100%	1	*	*	*	*	
Toluene		100%	*	*	*	*	*	
n-Butyl acetate		100%	*	*	*	*	*	
Trichloroacetic acid	AC	3%	NI	NI	NI	NI	100%	
Methyl isobutyl ketone		100%	*	*	1	*	*	
Ethyl trimethyl acetate		100%	*	*	*	*	*	

Methylcyclopentane		100%	*	*	*	*	*	
Glycerol	AL	100%	NI	NI	2B	NI	75%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

1.2.2 COLIPA Study

Interlaboratory reproducibility for the CM during the COLIPA study as estimated by predicted EPA hazard categories is given in Tables 1-5 to 1-7 for surfactant materials, surfactant-based formulations and mixtures, and non-surfactants, ingredients and mixtures, respectively. For surfactant materials there was 100% agreement between the two participating laboratories for nine of ten materials (90%). For surfactant-based formulations and mixtures there was100% agreement for seven of seven materials (100%). For non-surfactants, ingredients and mixtures there was 100% agreement for seven of nine materials (78%).

Table 1-5 modified from BRD Table 7-16 Surfactant Materials - Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by EPA hazard categories.

Chemical	Formulation Tested	Conc. tested	EPA Category MA	EPA Category CT AB	Percent Agreement	Concordance
Triton X-100 1%	SU	1%	III	III	100%	100% Agreement for 9 of 10 (90%)
Tween 20	SU	100%	III	III	100%	
SLS 3%	SU	3%	III	III	100%	
Triton X-100 5%	SU	5%	III	III	100%	
Benzalkonium chloride 1%	SU	5%	III	III	100%	
SLS 15%	SU	1%	I	I	100%	0% Agreement for 1 of 10 (10%)
SLS 30%	SU	100%	I	*	*	
Triton X-100 10%	SU	15%	III	I	0%	
Benzalkonium chloride 5%	SU	30%	I	I	100%	
Benzalkonium chloride 10%	SU	10%	I	I	100%	
Cetylpyridinium bromide 6%	SU	100%	I	*	*	
Cetylpyridinium bromide 10%	SU	100%	*	*	*	
Polyethylene glycol 400	SU	100%	IV	IV	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-6 modified from BRD Table 7-17 Surfactant based formulations and mixtures - Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by EPA hazard categories.

Chemical	Formulation Tested	Conc. tested	EPA Category MA	EPA Category CT AB	Percent Agreement	Concordance
Perfumed skin lotion	SU	100%	*	*		100% Agreement for 7 of 7 (100%)
Eye make-up remover	SU	100%	IV	IV	100%	
Hair dye base F#1	SU	100%	*	*		
Pump Deodorant	SU	5%	III	III	100%	
Emulsion antiperspirant	SU	100%	*	*		
Gel cleaner	SU	100%	III	III	100%	
Sunscreen SPF 15	SU	100%	*	*		
Hydrophilic ointment	SU	100%	*	*		
Hair conditioner	SU	100%	*	*		

Moisturiser with sunscreen	SU	100%	*	*		
Hair dye base form #3	SU	100%	*	*		
Polishing scrub	SU	100%	*	*		
Shampoo #1 normal	SU	100%	I	I	100%	
Hand cleaner	SU	100%	*	*		
Hand soap	SU	100%	*	*		
Shampoo - baby	SU	100%	III	III	100%	
Liquid soap #1	SU	100%	I	I	100%	
Shampoo antidandruff	SU	100%	*	*		
Shampoo 2-in-1	SU	100%	*	*		
Cleansing foam III	SU	100%	*	*		
Shower gel	SU	100%	*	*		
Skin cleaner	SU	100%	I	I	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-7 modified from BRD Table 7-18 Non-Surfactants, ingredients, and mixtures – Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by EPA hazard categories.

Chemical	Formulation Tested	Conc. tested	EPA Category		Percent Agreement	Concordance
			MA	CT AB		
Blush		100%	*	*		100% Agreement for 7 of 9 (78%)
Eye liner		100%	*	*		
n-Butyl acetate		100%	*	*		
Imidazole		100%	III	III	100%	
Propylene glycol		100%	IV	IV	100%	0% Agreement for 2 of 9 (22%)
Glycerol	SO	100%	IV	IV	100%	
Ethyl acetate		100%	*	*		
Sodium hydroxide 1%	AL	1%	III	III	100%	
Isopropanol	SO	100%	III	IV	0%	
Methyl ethyl ketone		1%	III	*	*	
Sunscreen lotion		10%	*	*		
Cologne		100%	*	*		
Eye shadow		100%	*	*		
Mascara		100%	*	*		
Hair styling lotion		100%	IV	IV	100%	
Mouthwash		100%	III	III	100%	
Toothpaste		100%	*	*		
Hair dye base form #2		100%	*	*		
Sodium hydroxide 10%	AL	6%	III	I	0%	
Trichloroacetic acid 30%	AC	30%	I	I	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Interlaboratory reproducibility for the CM during the COLIPA study as estimated by predicted GHS hazard categories is given in Tables 1-8 to 1-10 for surfactant materials, surfactant-based formulations and mixtures, and non-surfactants, ingredients and mixtures, respectively. For surfactant materials there was 100% agreement between the two participating laboratories for nine of ten materials (90%). For surfactant-based formulations and mixtures there was 100% agreement for seven of seven materials (100%). For non-surfactants, ingredients and mixtures there was 100% agreement for seven of nine materials (78%).

Table 1-8 modified from BRD Table 7-16 Surfactant Materials - Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by GHS hazard categories.

Chemical	Formulation Tested	Conc. tested	GHS Category MA	GHS Category CT AB	Percent Agreement	Concordance
Triton X-100 1%	SU	1%	NI	NI	100%	100% Agreement for 9 of 10 (90%)
Tween 20	SU	100%	2B	2B	100%	
SLS 3%	SU	3%	2B	2B	100%	
Triton X-100 5%	SU	5%	2B	2B	100%	
Benzalkonium chloride 1%	SU	5%	2B	2B	100%	0% Agreement for 1 of 10 (10%)
SLS 15%	SU	1%	1	1	100%	
SLS 30%	SU	100%	1	*		
Triton X-100 10%	SU	15%	2B	1	0%	
Benzalkonium chloride 5%	SU	30%	1	1	100%	
Benzalkonium chloride 10%	SU	10%	1	1	100%	
Cetylpyridinium bromide 6%	SU	100%	1	*		
Cetylpyridinium bromide 10%	SU	100%	*	*		
Polyethylene glycol 400	SU	100%	NI	NI	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-9 modified from BRD Table 7-17 Surfactant based formulations and mixtures - Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by GHS hazard categories.

Chemical	Formulation Tested	Conc. tested	GHS Category MA	GHS Category CT AB	Percent Agreement	Concordance
Perfumed skin lotion	SU	100%	*	*		100% Agreement for 7 of 7 (100%)
Eye make-up remover	SU	100%	NI	NI	100%	
Hair dye base F#1	SU	100%	*	*		
Pump Deodorant	SU	5%	NI	NI	100%	
Emulsion antiperspirant	SU	100%	*	*		
Gel cleaner	SU	100%	2B	2B	100%	
Sunscreen SPF 15	SU	100%	*	*		
Hydrophilic ointment	SU	100%	*	*		
Hair conditioner	SU	100%	*	*		
Moisturiser with sunscreen	SU	100%	*	*		
Hair dye base form #3	SU	100%	*	*		
Polishing scrub	SU	100%	*	*		
Shampoo #1 normal	SU	100%	1	1	100%	
Hand cleaner	SU	100%	*	*		
Hand soap	SU	100%	*	*		
Shampoo - baby	SU	100%	2B	2B	100%	
Liquid soap #1	SU	100%	1	1	100%	
Shampoo antidandruff	SU	100%	*	*		
Shampoo 2-in-1	SU	100%	*	*		
Cleansing foam III	SU	100%	*	*		
Shower gel	SU	100%	*	*		
Skin cleaner	SU	100%	1	1	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

Table 1-10 modified from BRD Table 7-18 Non-Surfactants, ingredients, and mixtures – Between-laboratories reproducibility of Cytosensor Microphysiometer results from COLIPA study. Analysis by GHS hazard categories.

Chemical	Formulation Tested	Conc. tested	GHS Category		Percent Agreement	Concordance
			MA	CT AB		
Blush		100%	*	*		100% Agreement for 7 of 9 (78%)
Eye liner		100%	*	*		
n-Butyl acetate		100%	*	*		
Imidazole		100%	NI	NI	100%	
Propylene glycol		100%	NI	NI	100%	0% Agreement for 2 of 9 (22%)
Glycerol	SO	100%	NI	NI	100%	
Ethyl acetate		100%	*	*		
Sodium hydroxide 1%	AL	1%	2B	NI	0%	
Isopropanol	SO	100%	NI	NI	100%	
Methyl ethyl ketone		1%	NI	*	*	
Sunscreen lotion		10%	*	*		
Cologne		100%	*	*		
Eye shadow		100%	*	*		
Mascara		100%	*	*		
Hair styling lotion		100%	NI	NI	100%	
Mouthwash		100%	NI	NI	100%	
Toothpaste		100%	*	*		
Hair dye base form #2		100%	*	*		
Sodium hydroxide 10%	AL	6%	2B	1	0%	
Trichloroacetic acid 30%	AC	30%	1	1	100%	

*** Participating laboratory did not test the chemical because it determined that the chemical was not compatible with the test system.**

2.0 EpiOcular Reliability

Reliability (relative to EPA and GHS hazard categories) of the EO assay was determined using the prediction model discussed in Chapter 6 – Test Method Predictive Capacity, of the Background Review Document of an In Vitro Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products. That prediction model is:

1) **If the anti-microbial cleaning product has an ET_{50} score of <4 minutes, it is classified as EPA Category I or GHS Category 1.**

2) **If the anti-microbial cleaning product has an ET_{50} score of ≥4 minutes, but <70 minutes, it is classified as EPA Category III or GHS Category 2B.**

3) **If the anti-microbial cleaning product has an ET_{50} score of ≥70 minutes, it is classified as EPA Category IV or GHS Category NI.**

2.1 EpiOcular Intralaboratory repeatability for antimicrobial cleaning products

Between experiments reproducibility for a single laboratory can be estimated for several of the anti-microbial cleaning products that were tested more than once by IIVS. Table 2-1 shows the EPA hazard category predictions for the only three materials which were tested more than once. Results from multiple runs showed 100% agreement for all three materials.

Table 2-1 modified from BRD Table 7-20 EpiOcular intralaboratory repeatability both within run and between experiments. Analysis only of between experiments by EPA categories.

Code	Class	Assay Date	EPA Cat.	GHS Cat.	Conc.	ET_{50} (min)	Predicted EPA Category	Percent Agreement	Concordance
H	AL	12/7/2005	II	2A	Neat	9.4	**III**	100%	100% Agreement for 3 of 3
		4/5/2006	II	2A	Neat	9.8	**III**		
		4/5/2006	II	2A	Neat	9.1	**III**		
P	AL	12/7/2005	IV	NI	Neat	125.8	**IV**	100%	
		4/5/2006	IV	NI	Neat	74	**IV**		
W	SU	12/7/2005	IV	NI	Neat	39.6	**III**	100%	
		4/5/2006	IV	NI	Neat	43.3	**III**		

Table 2-2 shows the GHS hazard category predictions for the only three materials which were tested more than once. Results from multiple runs showed 100% agreement for all three materials.

Table 2-2 modified from BRD Table 7-20 EpiOcular intralaboratory repeatability both within run and between experiments. Analysis only of between experiments by GHS categories.

Code	Class	Assay Date	EPA Cat.	GHS Cat.	Conc.	ET_{50} (min)	Predicted GHS Category	Percent Agreement	Concordance
H	AL	12/7/2005	II	2A	Neat	9.4	**2B**	100%	100% Agreement for 3 of 3
		4/5/2006	II	2A	Neat	9.8	**2B**		
		4/5/2006	II	2A	Neat	9.1	**2B**		
P	AL	12/7/2005	IV	NI	Neat	125.8	**2B**	100%	
		4/5/2006	IV	NI	Neat	74	**2B**		
W	SU	12/7/2005	IV	NI	Neat	39.6	**NI**	100%	
		4/25/2006	IV	NI	Neat	43.3	**NI**		

2.2 EpiOcular Interlaboratory reproducibility

Between laboratories reproducibility in predicted hazard categories cannot be estimated for any of the anti-microbial cleaning products tested for this BRD because only one laboratory conducted this testing. However, the EO model has been used by many laboratories worldwide, and it is possible to estimate the interlaboratory reproducibility from the results of two phases of a validation study sponsored by Colgate-Palmolive for surfactants and surfactant-containing products. Although the protocol used in these studies differed slightly from those in this BRD (e.g. in the validation study surfactants were diluted to 20% before testing), the vast majority of the manipulations were identical. Table 2-3 and 2-4 show the results for Phase II of the validation study. For EPA hazard categories, there was 100% agreement for 14 of 19 of the materials (74%), 75% agreement for 2 of 19 materials (11%), and 50% agreement for 3 of 19 materials (16%). For GHS hazard categories the results were identical.

Table 2-3 modified from BRD Table 7-24 Interlaboratory reproducibility of four laboratories in the Colgate-Palmolive Phase II validation study. Analysis of experiments by EPA hazard categories.

Test Material	Formulation Type	EPA Category Lab 1	Lab 2	Lab 3	Lab 4	Percent Agreement	Concordance
Shampoo #1 (2 in 1)	SU	III	III	III	III	100%	100% Agreement for 14 of 19 (74%)
Shampoo #2 (Regular)	SU	III	III	III	III	100%	
Shampoo #3 (Regular)	SU	III	III	III	III	100%	
Dishwashing Liquid	SU	IV	III	III	IV	50%	
All purpose cleaner	SU	III	III	III	III	100%	75% Agreement for 2 of 19 (11%)
Disinfectant cleaner	SU	III	III	III	III	100%	
Sodium linear alkylbenzene sulfonate	SU	III	III	III	III	100%	
30% Dimethyltetradecylamine oxide	SU	III	IV	IV	III	50%	50% Agreement for 3 of 19 (16%)
1.5% branched alkyldimethylamine	SU	III	III	III	III	100%	
PPG-5 Ceteth-20	SU	I	I	III	I	75%	
C9-11 Alcohol ethoxylate EO6:1	SU	III	III	III	III	100%	
C12-14 Alcohol ethoxylate 2EO	SU	III	III	III	III	100%	
C12-16 Alcohol ethoxylate 3EO	SU	III	III	III	III	100%	
2.46% Lauryl hydroxysultaine	SU	III	III	III	III	100%	
10% Polyoxyethylene (10) oleyl ether	SU	I	I	I	III	75%	
3.2% Benzalkonium chloride	SU	IV	III	IV	III	50%	
36% Sodium methyl 2-sulfonate & disodium 2-sulfolaurate	SU	III	III	III	III	100%	
2.4% Imidazolium compound	SU	I	I	I	I	100%	
C12-15 Alcohol ethoxylate EO7:1	SU	III	III	III	III	100%	

Table 2-4 modified from BRD Table 7-24 Interlaboratory reproducibility of four laboratories in the Colgate-Palmolive Phase II validation study. Analysis of experiments by GHS hazard categories

Test Material	Formulation Type	GHS Category				Percent Agreement	Concordance
		Lab 1	Lab 2	Lab 3	Lab 4		
Shampoo #1 (2 in 1)	SU	2B	2B	2B	2B	100%	100% Agreement for 14 of 19 (74%)
Shampoo #2 (Regular)	SU	2B	2B	2B	2B	100%	
Shampoo #3 (Regular)	SU	2B	2B	2B	2B	100%	
Dishwashing Liquid	SU	NL	2B	2B	NL	50%	
All purpose cleaner	SU	2B	2B	2B	2B	100%	
Disinfectant cleaner	SU	2B	2B	2B	2B	100%	75% Agreement for 2 of 19 (11%)
Sodium linear alkylbenzene sulfonate	SU	2B	2B	2B	2B	100%	
30% Dimethyltetradecylamine oxide	SU	2B	NL	NL	2B	50%	
1.5% branched alkyldimethylamine	SU	2B	2B	2B	2B	100%	
PPG-5 Ceteth-20	SU	1	1	2B	1	75%	
C9-11 Alcohol ethoxylate EO6:1	SU	2B	2B	2B	2B	100%	50% Agreement for 3 of 19 (16%)
C12-14 Alcohol ethoxylate 2EO	SU	2B	2B	2B	2B	100%	
C12-16 Alcohol ethoxylate 3EO	SU	2B	2B	2B	2B	100%	
2.46% Lauryl hydroxysultaine	SU	2B	2B	2B	2B	100%	
10% Polyoxyethylene (10) oleyl ether	SU	1	1	1	2B	75%	
3.2% Benzalkonium chloride	SU	NL	2B	NL	2B	50%	
36% Sodium methyl 2-sulfonate & disodium 2-sulfolaurate	SU	2B	2B	2B	2B	100%	
2.4% Imidazolium compound	SU	1	1	1	1	100%	
C12-15 Alcohol ethoxylate EO7:1	SU	2B	2B	2B	2B	100%	

Table 2-5 and 2-6 show the results for Phase III of the validation study. For both the EPA (Table 2-5) and GHS (Table 2-6) hazard categories, there was 100% agreement for 51 of 54 of the materials (94%) and 0% agreement for 3 of 54 materials (6%).

Table 2-5 modified from BRD Table 7-25 Interlaboratory reproducibility of two laboratories in the Colgate-Palmolive Phase III validation study. Analysis of experiments by EPA hazard categories.

Test Material	Formulation Type	Concentration Tested	EPA Category Raw data		Percent Agreement	Concordance
			Lab 1	Lab 2		
1-decanaminium, N-decyl-N,N-dimethyl, Cl-	SU	50%	I	I	100%	100% Agreement for 51 of 54 (94%)
20% Myristalkonium chloride/ 20% Quaternium-14	SU	100%	I	I	100%	
Alkyldimethyl benzyl ammonium Cl-	SU	5%	I	I	100%	
Ammonium lauryl sulfate	SU	12%	III	III	100%	0% Agreement for 3 of 54 (6%)
Ammonium lauryl sulfate	SU	28%	III	III	100%	
Ammonium nonoxyl-4 sulfate	SU	10%	III	III	100%	
Behentrimonium methosulfate & cetearyl alcohol	SU	100%	IV	IV	100%	
Benzalkonium chloride	SU	0.10%	IV	IV	100%	
Benzalkonium chloride	SU	0.50%	III	III	100%	
Benzalkonium chloride	SU	1%	III	III	100%	
Benzalkonium chloride	SU	2.50%	I	I	100%	
Benzalkonium chloride	SU	5%	I	I	100%	
Benzalkonium chloride	SU	10%	I	1	100%	
Benzethonium chloride	SU	3.20%	III	1	0%	

Benzethonium chloride	SU	1.00%	III	III	100%	
Branched alkyldimethylamine	SU	1.50%	III	III	100%	
Branched alkyldimethylamine	SU	30%	I	I	100%	
C10-12 Alcohol ethoxylate (PO)	SU	100%	I	I	100%	
Ceteareth-12	SU	100%	IV	IV	100%	
Cetrimonium chloride	SU	2.50%	III	III	100%	
Cetyl alcohol	SU	100%	IV	IV	100%	
Cetylpyridinium bromide	SU	10%	III	III	100%	
Cetylpyridinium bromide	SU	0.10%	IV	IV	100%	
Cetylpyridinium bromide	SU	1%	III	III	100%	
Cocamidopropyl betaine	SU	10%	III	III	100%	
Cocamidopropyl betaine	SU	30%	III	III	100%	
Decyl glucoside	SU	10%	III	I	0%	
Didecyldimethyl ammonium chloride (DDAC)	SU	1%	III	III	100%	
Didecyldimethyl ammonium chloride (DDAC)	SU	3.20%	I	I	100%	
Didecyldimethyl ammonium chloride (DDAC)	SU	5%	III	III	100%	
Lauryl glucoside	SU	12%	IV	IV	100%	
Myristalkonium chloride/Quaternium-14/Ethanol	SU	3%	III	I	0%	
Myristalkonium chloride/Quaternium-14/Ethanol	SU	20%	I	I	100%	
PPG-5-Ceteth 20	SU	100%	IV	IV	100%	
Quaternium-18	SU	100%	IV	IV	100%	
Shampoo #4	SU	10%	III	III	100%	
Sodium C14-16 olefin sulfonate	SU	10%	III	III	100%	
Sodium ether sulfate 3EO	SU	30%	III	III	100%	
Sodium laureth sulfate	SU	12%	III	III	100%	
Sodium laureth sulfate	SU	25%	III	III	100%	
Sodium lauroyl sarcosinate	SU	10%	III	III	100%	
Sodium lauroyl sarcosinate	SU	30%	III	III	100%	
Sodium lauryl sulfate	SU	3%	III	III	100%	
Sodium lauryl sulfate	SU	10%	III	III	100%	
Sodium lauryl sulfate	SU	15%	III	III	100%	
Sodium lauryl sulfate	SU	20%	III	III	100%	
Sodium lauryl sulfate	SU	30%	III	III	100%	
Sodium methyl 2-sulfonate & disodium 2-sulfolaurate	SU	39%	III	III	100%	
TEA-lauryl sulfate	SU	20%	III	III	100%	
Triton X-100	SU	1%	III	III	100%	
Triton X-100	SU	2.50%	III	III	100%	
Triton X-100	SU	5%	III	III	100%	
Triton X-100	SU	10%	I	I	100%	
Triton X-100	SU	20%	I	I	100%	

Table 2-6 modified from BRD Table 7-25 Interlaboratory reproducibility of two laboratories in the Colgate-Palmolive Phase III validation study. Analysis of experiments by GHS hazard categories.

Test Material	Formulation Type	Concentration Tested	GHS Category Raw Data		Percent Agreement	Concordance
			Lab 1	Lab 2		
1-decanaminium, N-decyl-N,N-dimethyl, Cl-	SU	50%	1	1	100%	100% Agreement for 51 of 54 (94%)
20% Myristalkonium chloride/ 20% Quaternium-14	SU	100%	1	1	100%	
Alkyldimethyl benzyl ammonium Cl-	SU	5%	1	1	100%	
Ammonium lauryl sulfate	SU	12%	2B	2B	100%	0% Agreement for 3 of 54 (6%)
Ammonium lauryl sulfate	SU	28%	2B	2B	100%	
Ammonium nonoxyl-4 sulfate	SU	10%	2B	2B	100%	
Behentrimonium methosulfate & cetearyl alcohol	SU	100%	NI	NI	100%	
Benzalkonium chloride	SU	0.10%	NI	NI	100%	
Benzalkonium chloride	SU	0.50%	2B	2B	100%	
Benzalkonium chloride	SU	1%	2B	2B	100%	
Benzalkonium chloride	SU	2.50%	1	1	100%	
Benzalkonium chloride	SU	5%	1	1	100%	
Benzalkonium chloride	SU	10%	1	1	100%	
Benzethonium chloride	SU	3.20%	2B	1	0%	
Benzethonium chloride	SU	1.00%	2B	2B	100%	
Branched alkyldimethylamine	SU	1.50%	2B	2B	100%	
Branched alkyldimethylamine	SU	30%	1	1	100%	
C10-12 Alcohol ethoxylate (PO)	SU	100%	1	1	100%	
Ceteareth-12	SU	100%	NI	NI	100%	
Cetrimonium chloride	SU	2.50%	2B	2B	100%	
Cetyl alcohol	SU	100%	NI	NI	100%	
Cetylpyridinium bromide	SU	10%	2B	2B	100%	
Cetylpyridinium bromide	SU	0.10%	NI	NI	100%	
Cetylpyridinium bromide	SU	1%	2B	2B	100%	
Cocamidopropyl betaine	SU	10%	2B	2B	100%	
Cocamidopropyl betaine	SU	30%	2B	2B	100%	
Decyl glucoside	SU	10%	2B	1	0%	
Didecyldimethyl ammonium chloride (DDAC)	SU	1%	2B	2B	100%	
Didecyldimethyl ammonium chloride (DDAC)	SU	3.20%	1	1	100%	
Didecyldimethyl ammonium chloride (DDAC)	SU	5%	2B	2B	100%	
Lauryl glucoside	SU	12%	NI	NI	100%	
Myristalkonium chloride/Quaternium-14/Ethanol	SU	3%	2B	1	0%	
Myristalkonium chloride/Quaternium-14/Ethanol	SU	20%	1	1	100%	
PPG-5-Ceteth 20	SU	100%	NI	NI	100%	
Quaternium-18	SU	100%	NI	NI	100%	
Shampoo #4	SU	10%	2B	2B	100%	
Sodium C14-16 olefin sulfonate	SU	10%	2B	2B	100%	
Sodium ether sulfate 3EO	SU	30%	2B	2B	100%	
Sodium laureth sulfate	SU	12%	2B	2B	100%	

Sodium laureth sulfate	SU	25%	2B	2B	100%	
Sodium lauroyl sarcosinate	SU	10%	2B	2B	100%	
Sodium lauroyl sarcosinate	SU	30%	2B	2B	100%	
Sodium lauryl sulfate	SU	3%	2B	2B	100%	
Sodium lauryl sulfate	SU	10%	2B	2B	100%	
Sodium lauryl sulfate	SU	15%	2B	2B	100%	
Sodium lauryl sulfate	SU	20%	2B	2B	100%	
Sodium lauryl sulfate	SU	30%	2B	2B	100%	
Sodium methyl 2-sulfonate & disodium 2-sulfolaurate	SU	39%	2B	2B	100%	
TEA-lauryl sulfate	SU	20%	2B	2B	100%	
Triton X-100	SU	1%	2B	2B	100%	
Triton X-100	SU	2.50%	2B	2B	100%	
Triton X-100	SU	5%	2B	2B	100%	
Triton X-100	SU	10%	1	1	100%	
Triton X-100	SU	20%	1	1	100%	

3.0 BCOP Reliability

Reliability (relative to EPA and GHS hazard categories) of the BCOP was determined using the prediction model discussed in Chapter 6 – Test Method Predictive Capacity, of the Background Review Document of an In Vitro Approach for EPA Toxicity Labeling of Anti-Microbial Cleaning Products. That prediction model is:

1) **All anti-microbial cleaning products having an *In Vitro* Score ≥75 should be classified as an EPA Category I or a GHS Category 1. No histopathology needs to be conducted.**

2) **Anti-microbial cleaning products having an *In Vitro* Score <75 and ≥ 25 are given a preliminary classification of EPA Category II or GHS Category 2A. They should be further assessed with a histopathological evaluation and given the final categorization of whichever determination (in vitro score or histological evaluation) is more severe.**

3) **Anti-microbial cleaning products having an *In Vitro* Score <25 are given a preliminary classification of EPA Category III or GHS Category 2B. They should be further assessed with a histopathological evaluation and given the final categorization of whichever determination (in vitro score or histological evaluation) is more severe.**

However, since the vast majority of the test materials considered in the following sections (3.1 – 3.3), did not have histopathology conducted on the corneas, that part of the prediction model is not being considered. Only the hazard categories as determined by the above mentioned cut-off values will be used to evaluated reproducibility of the EPA or GHS hazard categories.

3.1 BCOP within-run reproducibility

Sufficient data are available from the testing of anti-microbial cleaning products during this current program that it is possible to estimate the within-run reproducibility of the BCOP assay. Since the final BCOP *In Vitro* Score is generally determined by the average of 3 to 5 replicate corneas, the predicted EPA or GHS hazard category can be estimated for each cornea.

An analysis of the within-run reproducibility by EPA hazard categories is given in Table 3-1. It can be seen that there was 100% agreement between the 3-5 corneas for 63 of the75 test materials (84%), 67% agreement for 11 of 75 test materials (15%), and 60% agreement for 1 of 75 test materials (1.3%). In none of the 12 cases where there was less than full agreement, did the hazard classifications differ by more than a single class.

Of the 12 divergent cases, seven had reactive chemistry. Of the others, two were alkaline, two were surfactants and one was acidic. For the non-reactive chemistry materials, the numerical differences in *In Vitro* Score among the replicate corneas were generally small, e.g. 69.5, 75.2 and 70.8 (material EG) where the cut-off was 75; or 27.8, 26.7 and 15.0 (material BR) where the cut-off was 25. However, for the reactive materials the numerical differences were sometimes very large, e.g. 413.0, 53.4 and 56.8 (material F). This was generally due to increases in corneal opacity which correlated with the presence of numerous stromal vacuoles that were easily observed histopathologically.

Table 3-1 modified from BRD Table 7-27 BCOP within run reproducibility for anti-microbial cleaning products. Analysis by EPA hazard categories.

Test Material Code	Formulation Type	Cornea Number	EPA Category	Concordance
H	AL	43	III	100% Agreement for 63 of 75 (84%)
		44	III	
		45	III	
		avg	III	
		Percent Agreement	100%	
I	SU	34	III	67% Agreement for 11 of 75 (15%)
		35	III	
		36	III	
		avg	III	
		Percent Agreement	100%	
J	SU	23	III	60% Agreement for 1 of 75 (1.3%)
		24	III	
		25	III	
		avg	III	
		Percent Agreement	100%	
K	RC	21	III	
		22	III	
		24	III	
		avg	III	
		Percent Agreement	100%	
L	SU	17	III	
		18	III	
		19	III	
		avg	III	
		Percent Agreement	100%	
O	SU	14	III	
		15	III	
		16	III	
		avg	III	
		Percent Agreement	100%	
P	AL	29	III	
		30	III	
		31	III	
		avg	III	
		Percent Agreement	100%	
R	SU	35	III	
		36	III	
		46	III	
		avg	III	
		Percent Agreement	100%	
T	AC	27	III	
		28	III	
		29	III	
		avg	III	
		Percent Agreement	100%	

U	SU	26	III	
		27	III	
		28	III	
		avg	III	
		Percent Agreement	100%	
W	SU	45	III	
		47	III	
		48	III	
		avg	III	
		Percent Agreement	100%	
AF	AC	34	III	
		37	III	
		38	III	
		avg	III	
		Percent Agreement	100%	
BB	SO	25	III	
		26	III	
		28	III	
		avg	III	
		Percent Agreement	100%	
BK	SO	29	III	
		30	III	
		31	III	
		avg	III	
		Percent Agreement	100%	
BL	SO	14	III	
		16	III	
		17	III	
		avg	III	
		Percent Agreement	100%	
CG	AL	12	III	
		13	III	
		14	III	
		avg	III	
		Percent Agreement	100%	
H	AL	15	III	
		17	III	
		18	III	
		avg	III	
		Percent Agreement	100%	
H	AL	48	III	
		49	III	
		50	III	
		avg	III	
		Percent Agreement	100%	
H	AL	37	III	
		38	III	
		40	III	
		avg	III	
		Percent Agreement	100%	

H	AL	50	III	
		51	III	
		52	III	
		avg	III	
		Percent Agreement	100%	
H	AL	29	III	
		32	III	
		33	II	
		avg	III	
		Percent Agreement	67%	
Q	SU	42	III	
		43	III	
		44	III	
		avg	III	
		Percent Agreement	100%	
V	SU	19	III	
		20	III	
		21	III	
		avg	III	
		Percent Agreement	100%	
X	RC	19	I	
		21	I	
		22	I	
		avg	I	
		Percent Agreement	100%	
Z	SO	39	II	
		41	II	
		43	II	
		avg	II	
		Percent Agreement	100%	
AQ	RC	11	I	
		12	I	
		13	I	
		avg	I	
		Percent Agreement	100%	
AS	RC	27	I	
		28	I	
		29	II	
		avg	I	
		Percent Agreement	67%	
AT	RC	34	I	
		35	I	
		36	I	
		avg	I	
		Percent Agreement	100%	
AW	RC	29	II	
		30	II	
		34	I	
		avg	II	
		Percent Agreement	67%	

BD	SO	16	III	
		17	III	
		18	III	
		avg	III	
		Percent Agreement	100%	
BP	SO	11	III	
		12	III	
		13	III	
		avg	III	
		Percent Agreement	100%	
A	SU	25	I	
		26	I	
		28	I	
		avg	I	
		Percent Agreement	100%	
B	SU	11	I	
		12	I	
		13	I	
		avg	I	
		Percent Agreement	100%	
C	RC	47	III	
		48	II	
		49	II	
		avg	II	
		Percent Agreement	67%	
D	AC	15	I	
		16	I	
		18	I	
		avg	I	
		Percent Agreement	100%	
E	SU	15	I	
		16	I	
		19	I	
		avg	I	
		Percent Agreement	100%	
F	RC	32^	II	
		35	I	
		37	I	
		avg	I	
		Percent Agreement	67%	
F	RC	22	I	
		24	II	
		26	II	
		avg	I	
		Percent Agreement	67%	
G	SU	12	I	
		13	I	
		14	I	
		avg	I	
		Percent Agreement	100%	

M	SU	32	II	
		35	II	
		37	II	
		avg	II	
		Percent Agreement	100%	
N	RC	15	III	
		16	III	
		17	I	
		avg	I	
		Percent Agreement	67%	
S	AC	22	III	
		23	III	
		24	III	
		avg	III	
		Percent Agreement	100%	
Y	RC	28	II	
		29	I	
		33	II	
		avg	II	
		Percent Agreement	67%	
AB	SU	27	I	
		28	I	
		29	I	
		avg	I	
		Percent Agreement	100%	
AC	AC	25	I	
		26	I	
		27	I	
		avg	I	
		Percent Agreement	100%	
AD	SU	18	I	
		19	I	
		20	I	
		avg	I	
		Percent Agreement	100%	
AE	AL	17	II	
		18	II	
		20	II	
		avg	II	
		Percent Agreement	100%	
AG	AL	6	I	
		7	I	
		8	I	
		9	I	
		10	I	
		avg	I	
		Percent Agreement	100%	

AH	AL	6	I	
		7	I	
		8	I	
		9	I	
		10	I	
		avg	I	
		Percent Agreement	100%	
AI	AL	6	I	
		7	I	
		8	I	
		9	I	
		10	I	
		avg	I	
		Percent Agreement	100%	
AJ	AL	1	I	
		2	I	
		3	I	
		4	I	
		5	I	
		avg	I	
		Percent Agreement	100%	
AK	AL	16	I	
		17	I	
		18	I	
		19	I	
		20	I	
		avg	I	
		Percent Agreement	100%	
AL	AL	6	I	
		7	I	
		8	I	
		9	I	
		21	I	
		avg	I	
		Percent Agreement	100%	
AM	SO	1	I	
		2	I	
		3	I	
		4	I	
		5	I	
		avg	I	
		Percent Agreement	100%	
AN	AL	1	I	
		2	I	
		3	I	
		4	I	
		5	I	
		avg	I	
		Percent Agreement	100%	

AO	AL	11	I	
		12	I	
		13	I	
		14	I	
		15	I	
		avg	I	
		Percent Agreement	100%	
AP	AL	16	I	
		17	I	
		18	I	
		19	I	
		20	I	
		avg	I	
		Percent Agreement	100%	
AR	RC	18	I	
		19	I	
		20	I	
		avg	I	
		Percent Agreement	100%	
AU	RC	40	I	
		42	I	
		44	I	
		avg	I	
		Percent Agreement	100%	
AV	RC	48	I	
		49	I	
		51	I	
		avg	I	
		Percent Agreement	100%	
AV	RC	19	I	
		20	I	
		22	I	
		avg	I	
		Percent Agreement	100%	
AX	SO	11	I	
		12	I	
		13	I	
		14	I	
		15	I	
		avg	I	
		Percent Agreement	100%	
AX	SO	1	I	
		2	I	
		3	I	
		4	I	
		5	I	
		avg	I	
		Percent Agreement	100%	

AY	RC	41	I	
		42	I	
		43	I	
		avg	I	
		Percent Agreement	100%	
BE	AC	1	III	
		2	III	
		3	III	
		4	III	
		5	III	
		avg	III	
		Percent Agreement	100%	
BF	SO	35	II	
		36	II	
		37	II	
		avg	II	
		Percent Agreement	100%	
BJ	AL	11	I	
		12	I	
		13	II	
		14	II	
		15	I	
		avg	I	
		Percent Agreement	60%	
BJ	AL	7	I	
		8	I	
		9	I	
		avg	I	
		Percent Agreement	100%	
BM	SO	32	III	
		36	III	
		37	II	
		avg	II	
		Percent Agreement	67%	
BN	SU	1	III	
		2	III	
		3	III	
		4	III	
		5	III	
		avg	III	
		Percent Agreement	100%	
BQ	SO	20	II	
		22	II	
		23	II	
		avg	II	
		Percent Agreement	100%	

BR	SU	43	II	
		46	II	
		47	III	
		avg	III	
		Percent Agreement	67%	
BS	RC	10	I	
		11	I	
		12	I	
		avg	I	
		Percent Agreement	100%	
EF	RC	40	I	
		41	I	
		42	I	
		avg	I	
		Percent Agreement	100%	
EG	AC	26	II	
		27	I	
		32	II	
		avg	II	
		Percent Agreement	67%	

An analysis of the within-run reproducibility by GHS hazard categories is given in Table 3-2. As with the EPA analysis, there was 100% agreement between the 3-5 corneas for 63 of the 75 test materials (84%), 67% agreement for 11 of 75 test materials (15%), and 60% agreement for 1 of 75 test materials (1.3%). In none of the 12 cases where there was less than full agreement, did the hazard classifications differ by more than a single class.

The observations concerning the reactive chemistry materials were the same as for the EPA hazard category analysis.

Table 3-2 modified from BRD Table 7-27 BCOP within run reproducibility for anti-microbial cleaning porducts. Analysis by GHS hazard categories.

Test Material Code	Formulation Type	Cornea Number	GHS Category	Concordance
H	AL	43	2B	100% Agreement for 63 of 75 (84%)
		44	2B	
		45	2B	
		avg	2B	
		Percent Agreement	100%	
I	SU	34	2B	67% Agreement for 11 of 75 (15%)
		35	2B	
		36	2B	
		avg	2B	
		Percent Agreement	100%	
J	SU	23	2B	60% Agreement for 1 of 75 (1.3%)
		24	2B	
		25	2B	
		avg	2B	
		Percent Agreement	100%	

K	RC	21	2B	
		22	2B	
		24	2B	
		avg	2B	
		Percent Agreement	100%	
L	SU	17	2B	
		18	2B	
		19	2B	
		avg	2B	
		Percent Agreement	100%	
O	SU	14	2B	
		15	2B	
		16	2B	
		avg	2B	
		Percent Agreement	100%	
P	AL	29	2B	
		30	2B	
		31	2B	
		avg	2B	
		Percent Agreement	100%	
R	SU	35	2B	
		36	2B	
		46	2B	
		avg	2B	
		Percent Agreement	100%	
T	AC	27	2B	
		28	2B	
		29	2B	
		avg	2B	
		Percent Agreement	100%	
U	SU	26	2B	
		27	2B	
		28	2B	
		avg	2B	
		Percent Agreement	100%	
W	SU	45	2B	
		47	2B	
		48	2B	
		avg	2B	
		Percent Agreement	100%	
AF	AC	34	2B	
		37	2B	
		38	2B	
		avg	2B	
		Percent Agreement	100%	
BB	SO	25	2B	
		26	2B	
		28	2B	
		avg	2B	
		Percent Agreement	100%	

BK	SO	29	2B	
		30	2B	
		31	2B	
		avg	2B	
		Percent Agreement	100%	
BL	SO	14	2B	
		16	2B	
		17	2B	
		avg	2B	
		Percent Agreement	100%	
CG	AL	12	2B	
		13	2B	
		14	2B	
		avg	2B	
		Percent Agreement	100%	
H	AL	15	2B	
		17	2B	
		18	2B	
		avg	2B	
		Percent Agreement	100%	
H	AL	48	2B	
		49	2B	
		50	2B	
		avg	2B	
		Percent Agreement	100%	
H	AL	37	2B	
		38	2B	
		40	2B	
		avg	2B	
		Percent Agreement	100%	
H	AL	50	2B	
		51	2B	
		52	2B	
		avg	2B	
		Percent Agreement	100%	
H	AL	29	2B	
		32	2B	
		33	2A	
		avg	2B	
		Percent Agreement	67%	
Q	SU	42	2B	
		43	2B	
		44	2B	
		avg	2B	
		Percent Agreement	100%	
V	SU	19	2B	
		20	2B	
		21	2B	
		avg	2B	
		Percent Agreement	100%	

X	RC	19	1	
		21	1	
		22	1	
		avg	1	
		Percent Agreement	100%	
Z	SO	39	2A	
		41	2A	
		43	2A	
		avg	2A	
		Percent Agreement	100%	
AQ	RC	11	1	
		12	1	
		13	1	
		avg	1	
		Percent Agreement	100%	
AS	RC	27	1	
		28	1	
		29	2A	
		avg	1	
		Percent Agreement	67%	
AT	RC	34	1	
		35	1	
		36	1	
		avg	1	
		Percent Agreement	100%	
AW	RC	29	2A	
		30	2A	
		34	1	
		avg	2A	
		Percent Agreement	67%	
BD	SO	16	2B	
		17	2B	
		18	2B	
		avg	2B	
		Percent Agreement	100%	
BP	SO	11	2B	
		12	2B	
		13	2B	
		avg	2B	
		Percent Agreement	100%	
A	SU	25	1	
		26	1	
		28	1	
		avg	1	
		Percent Agreement	100%	
B	SU	11	1	
		12	1	
		13	1	
		avg	1	
		Percent Agreement	100%	

C	RC	47	2B	
		48	2A	
		49	2A	
		avg	2A	
		Percent Agreement	67%	
D	AC	15	1	
		16	1	
		18	1	
		avg	1	
		Percent Agreement	100%	
E	SU	15	1	
		16	1	
		19	1	
		avg	1	
		Percent Agreement	100%	
F	RC	32^	2A	
		35	1	
		37	1	
		avg	1	
		Percent Agreement	67%	
F	RC	22	1	
		24	2A	
		26	2A	
		avg	1	
		Percent Agreement	67%	
G	SU	12	1	
		13	1	
		14	1	
		avg	1	
		Percent Agreement	100%	
M	SU	32	2A	
		35	2A	
		37	2A	
		avg	2A	
		Percent Agreement	100%	
N	RC	15	2B	
		16	2B	
		17	1	
		avg	1	
		Percent Agreement	67%	
S	AC	22	2B	
		23	2B	
		24	2B	
		avg	2B	
		Percent Agreement	100%	
Y	RC	28	2A	
		29	1	
		33	2A	
		avg	2A	
		Percent Agreement	67%	

AB	SU	27	1	
		28	1	
		29	1	
		avg	1	
		Percent Agreement	100%	
AC	AC	25	1	
		26	1	
		27	1	
		avg	1	
		Percent Agreement	100%	
AD	SU	18	1	
		19	1	
		20	1	
		avg	1	
		Percent Agreement	100%	
AE	AL	17	2A	
		18	2A	
		20	2A	
		avg	2A	
		Percent Agreement	100%	
AG	AL	6	1	
		7	1	
		8	1	
		9	1	
		10	1	
		avg	1	
		Percent Agreement	100%	
AH	AL	6	1	
		7	1	
		8	1	
		9	1	
		10	1	
		avg	1	
		Percent Agreement	100%	
AI	AL	6	1	
		7	1	
		8	1	
		9	1	
		10	1	
		avg	1	
		Percent Agreement	100%	
AJ	AL	1	1	
		2	1	
		3	1	
		4	1	
		5	1	
		avg	1	
		Percent Agreement	100%	

AK	AL	16	1	
		17	1	
		18	1	
		19	1	
		20	1	
		avg	1	
		Percent Agreement	100%	
AL	AL	6	1	
		7	1	
		8	1	
		9	1	
		21	1	
		avg	1	
		Percent Agreement	100%	
AM	SO	1	1	
		2	1	
		3	1	
		4	1	
		5	1	
		avg	1	
		Percent Agreement	100%	
AN	AL	1	1	
		2	1	
		3	1	
		4	1	
		5	1	
		avg	1	
		Percent Agreement	100%	
AO	AL	11	1	
		12	1	
		13	1	
		14	1	
		15	1	
		avg	1	
		Percent Agreement	100%	
AP	AL	16	1	
		17	1	
		18	1	
		19	1	
		20	1	
		avg	1	
		Percent Agreement	100%	
AR	RC	18	1	
		19	1	
		20	1	
		avg	1	
		Percent Agreement	100%	

AU	RC	40	1	
		42	1	
		44	1	
		avg	1	
	Percent Agreement		100%	
AV	RC	48	1	
		49	1	
		51	1	
		avg	1	
	Percent Agreement		100%	
AV	RC	19	1	
		20	1	
		22	1	
		avg	1	
	Percent Agreement		100%	
AX	SO	11	1	
		12	1	
		13	1	
		14	1	
		15	1	
		avg	1	
	Percent Agreement		100%	
AX	SO	1	1	
		2	1	
		3	1	
		4	1	
		5	1	
		avg	1	
	Percent Agreement		100%	
AY	RC	41	1	
		42	1	
		43	1	
		avg	1	
	Percent Agreement		100%	
BE	AC	1	2B	
		2	2B	
		3	2B	
		4	2B	
		5	2B	
		avg	2B	
	Percent Agreement		100%	
BF	SO	35	2A	
		36	2A	
		37	2A	
		avg	2A	
	Percent Agreement		100%	

BJ	AL	11	1	
		12	1	
		13	2A	
		14	2A	
		15	1	
		avg	1	
		Percent Agreement	60%	
BJ	AL	7	1	
		8	1	
		9	1	
		avg	1	
		Percent Agreement	100%	
BM	SO	32	2B	
		36	2B	
		37	2A	
		avg	2A	
		Percent Agreement	67%	
BN	SU	1	2B	
		2	2B	
		3	2B	
		4	2B	
		5	2B	
		avg	2B	
		Percent Agreement	100%	
BQ	SO	20	2A	
		22	2A	
		23	2A	
		avg	2A	
		Percent Agreement	100%	
BR	SU	43	2A	
		46	2A	
		47	2B	
		avg	2B	
		Percent Agreement	67%	
BS	RC	10	1	
		11	1	
		12	1	
		avg	1	
		Percent Agreement	100%	
EF	RC	40	1	
		41	1	
		42	1	
		avg	1	
		Percent Agreement	100%	
EG	AC	26	2A	
		27	1	
		32	2A	
		avg	2A	
		Percent Agreement	67%	

3.2 BCOP Intralaboratory Reproducibility

There were five anti-microbial cleaning products tested more than once in the BCOP assay. Table 3-3 shows the EPA and GHS hazard categories assigned during each of the runs. There was 100% agreement among repeat runs for all 5 of the materials.

Table 1-19 modified from BRD Table 7-29 Intralaboratory reproducibility for 5 antimicrobial cleaning products. Analysis by EPA and GHS hazard categories.

Substance	Formulation Type	EPA Hazard Category	GHS Hazard Category
F	RC	I	1
		I	1
H	AL	IV	2B
		IV	2B
		IV	2B
		IV	2B
		IV	2B
		IV	2B
AV	RC	I	1
		I	1
AX	SO	I	1
		I	1
BJ	AL	I	1
		I	1

3.3 BCOP Interlaboratory Reproducibility

Interlaboratory reproducibility for the anti-microbial cleaning products cannot be directly assessed because only one laboratory conducted the BCOP studies for these materials. However, the BCOP assay is commonly used by many laboratories internationally, and it's between laboratory reproducibility was evaluated by NICEATM during their preparation of a BRD for *in vitro* test methods for corrosive or severe eye irritants. Their review of reproducibility for hazard categories was based on a cut-off value of 55.1 for severe or corrosive materials. The cut-off proposed in this BRD is similar, but is slightly higher at 75 for defining an EPA Category I or GHS Category 1 material. Thus the data from three of the international studies evaluated by NICEATM are reanalyzed here based on the new cut-off value.

Tables 3-4 and 3-5 present the reproducibility among the 12 laboratories in the Gautheron *et al.* (1994) validation study for EPA and GHS hazard categories, respectively. For both analyses there was ≥90% agreement for 37 of 51 test materials (72.5%), and there was ≥75% agreement for 42 of 51 test materials (82.4%).

Table 3-4 modified from BRD Table 7-31 Coefficient of Variation Analysis of the Interlaboratory Variability of the BCOP Test Method for Gautheron *et al.* (1994). Analysis by EPA hazard categories.

Substance	Formulation Type	Lab Number												Percent Agreement	Concordance
		1	2	3	4	5	6	7	8	9	10	11	12		
2-Ethoxyethanol	SO	I	I	I	I	I	I	I	I	I	I	I	I	100%	100% Agreement for 27 of 51 (53%)
2,4-Pentanedione	SO	II	I	I	II	II	II	II	II	II	II	II	I	75%	
Allyl alcohol	SO	I	I	I	I	I	I	I	I	I	I	I	I	100%	
Imidazole		I	II	I	I	I	II	I	I	II	I	I	II	67%	
Furan		II	II	II	II	II	II	I	II	II	II	II	II	92%	
Benzethonium chloride	SU	I	I	I	I	I	I	I	I	I	*	I	I	100%	92% Agreement for 5 of 51 (9.8%)
Butyrolactone		II	II	II	II	II	II	I	II	II	II	II	II	92%	
Cyclohexanone	SO	I	I	I	I	I	I	I	I	I	*	I	I	100%	
2-Methoxyethanol	SO	II	II	II	II	II	II	II	II	II	*	II	I	91%	91% Agreement for 5 of 51 (9.8%)
Laurylsulfobetaine	SU	I	I	I	I	I	II	I	II	I	*	I	II	73%	
Ethyl acetoacetate		II	II	II	II	III	II	II	II	II	*	II	II	91%	
Gluconolactone		II	I	I	II	I	II	I	II	I	*	I	II	55%	
Methylisobutyl ketone	SO	III	II	II	III	III	III	III	III	III	*	III	III	82%	
Pyridine	SO	I	I	I	I	I	I	I	I	I	*	I	I	100%	82% Agreement for 3 of 51 (5.9%)
Ethanol	SO	II	II	II	II	II	II	II	II	II	*	I	II	91%	
3-Glycidoxypropyltrimethoxysilane		III	III	II	III	III	III	III	III	III	III	III	III	92%	
N-Lauroylsarcosine, sodium salt	SU	II	II	II	II	II	II	II	II	II	*	I	II	91%	
Octanol	SO	II	II	II	II	II	II	II	II	II	*	II	II	100%	75% Agreement for 2 of 51 (3.9%)
Deoxycholic acid, sodium salt	SU	I	II	I	II	I	I	I	II	I	II	I	II	58%	
2-Aminophenol		III	III	III	III	III	III	III	III	III	III	III	III	100%	
Hexadecyltrimethylammonium bromide		I	II	II	II	I	II	I	I	II	*	II	I	55%	73% Agreement for 2 of 51 (3.9%)
1-Phenyl-3-pyrazolidone		III	III	III	III	II	III	III	III	III	III	III	III	92%	
Dibenzoyl-L-tartaric acid		I	I	I	I	I	II	I	I	I	*	I	I	91%	
Dimethyl sulfoxide	SO	III	III	III	III	III	III	III	III	III	*	III	III	100%	
1-Nitropropane	SO	III	III	III	III	III	III	III	III	III	III	III	III	100%	67% Agreement for 2 of 51 (3.9%)
1 ,2,4-Trimethylbenzene		II	III	II	III	II	III	III	III	III	III	III	III	75%	
Propyl-4-hydroxybenzoate		III	III	III	III	III	III	III	III	III	*	III	III	100%	
Promethazine hydrochloride		I	I	I	I	I	I	I	II	I	*	I	III	82%	
1 ,2,3-Trichloropropane	SO	II	II	I	II	II	II	II	III	I	*	II	II	73%	64% Agreement for 1 of 51 (1.9%)
Diacetone alcohol	SO	II	II	I	II	II	II	II	II	I	*	II	II	82%	
Methanol	SO	I	I	II	II	I	I	II	III	I	*	I	I	64%	
2,4-Dichloro-5-sulfamoylbenzoic acid		III	III	III	II	III	II	III	II	III	III	II	III	67%	
Sodium oxalate		III	III	III	III	III	III	III	III	III	III	III	III	100%	58% Agreement for 1 of 51 (1.9%)
Quinacrine		III	II	III	II	II	III	III	III	II	*	III	II	55%	
Petroleum ether	SO	III	III	III	III	III	III	III	III	III	III	III	III	100%	
Dimethylbiguanide		III	III	III	III	III	III	III	III	III	*	III	III	100%	
Magnesium carbonate		III	III	III	III	III	III	III	III	III	*	III	III	100%	55% Agreement for 3 of 51 (5.9%)
Triethanolamine	SO	III	III	III	III	III	III	III	III	III	*	III	III	100%	
Aluminum hydroxide		III	III	III	III	III	II	III	III	III	III	III	III	92%	
Tetraaminopyrimidine sulfate		III	III	III	III	III	III	III	III	III	*	III	III	100%	
Hexane	SO	III	III	III	III	III	III	III	III	III	III	III	III	100%	
Iminodibenzyl		III	III	III	III	III	III	III	III	III	*	III	III	100%	

2-Mercaptopyrimidine		III	III	III	III	III	III	III	III	III	III	III	III	100%	
Triton X-155	SU	III	III	III	III	III	III	III	III	III	*	III	III	100%	
DL-Glutamic acid		III	III	III	III	III	III	III	III	III	III	III	III	100%	
Anthracene		III	III	III	III	III	III	III	III	III	III	III	III	100%	
Betaine monohydrate		III	III	III	III	III	III	III	III	III	III	III	III	100%	
MYRJ-45	SU	III	III	III	III	III	III	III	III	III	*	III	III	100%	
EDTA di-potassium salt		III	III	III	III	III	III	III	III	III	III	III	III	100%	
BRIJ-35	SU	III	III	III	III	III	III	III	III	III	*	III	III	100%	
Phenylbutazone		III	III	III	III	III	III	III	III	III	III	III	III	100%	

Table 3-5 modified from BRD Table 7-31 Coefficient of Variation Analysis of the Interlaboratory Variability of the BCOP Test Method for Gautheron *et al.* (1994). Analysis by GHS hazard categories.

Substance	Formulation Type	Lab Number												Percent Agreement	Concordance
		1	2	3	4	5	6	7	8	9	10	11	12		
2-Ethoxyethanol	SO	1	1	1	1	1	1	1	1	1	1	1	1	100%	100% Agreement for 27 of 51 (53%)
2,4-Pentanedione	SO	2A	1	1	2A	2A	2A	2A	2A	2A	2A	2A	1	75%	
Allyl alcohol	SO	1	1	1	1	1	1	1	1	1	1	1	1	100%	
Imidazole		1	2A	1	1	1	2A	1	1	2A	1	1	2A	67%	92% Agreement for 5 of 51 (9.8%)
Furan		2A	2A	2A	2A	2A	2A	1	2A	2A	2A	2A	2A	92%	
Benzethonium chloride	SU	1	1	1	1	1	1	1	1	1	*	1	1	100%	
Butyrolactone		2A	2A	2A	2A	2A	2A	1	2A	2A	2A	2A	2A	92%	91% Agreement for 5 of 51 (9.8%)
Cyclohexanone	SO	1	1	1	1	1	1	1	1	1	*	1	1	100%	
2-Methoxyethanol	SO	2A	2A	2A	2A	2A	2A	2A	2A	2A	*	2A	1	91%	
Laurylsulfobetaine	SU	1	1	1	1	1	2A	1	2A	1	*	1	2A	73%	82% Agreement for 3 of 51 (5.9%)
Ethyl acetoacetate		2A	2A	2A	2A	2B	2A	2A	2A	2A	*	2A	2A	91%	
Gluconolactone		2A	1	1	2A	1	2A	1	2A	1	*	1	2A	55%	
Methylisobutyl ketone	SO	2B	2A	2A	2B	2B	2B	2B	2B	2B	*	2B	2B	82%	
Pyridine	SO	1	1	1	1	1	1	1	1	1	*	1	1	100%	
Ethanol	SO	2A	2A	2A	2A	2A	2A	2A	2A	2A	*	1	2A	91%	
3-Glycidoxypropyltrimethoxysilane		2B	2B	2A	2B	2B	2B	2B	2B	2B	2B	2B	2B	92%	75% Agreement for 2 of 51 (3.9%)
N-Lauroylsarcosine, sodium salt	SU	2A	2A	2A	2A	2A	2A	2A	2A	2A	*	1	2A	91%	
Octanol	SO	2A	2A	2A	2A	2A	2A	2A	2A	2A	*	2A	2A	100%	
Deoxycholic acid, sodium salt	SU	1	2A	1	2A	1	1	1	2A	1	2A	1	2A	58%	73% Agreement for 2 of 51 (3.9%)
2-Aminophenol		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Hexadecyltrimethylammonium bromide		1	2A	2A	2A	1	2A	1	1	2A	*	2A	1	55%	
1-Phenyl-3-pyrazolidone		2B	2B	2B	2B	2A	2B	2B	2B	2B	2B	2B	2B	92%	67% Agreement for 2 of 51 (3.9%)
Dibenzoyl-L-tartaric acid		1	1	1	1	1	2A	1	1	1	*	1	1	91%	
Dimethyl sulfoxide	SO	2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
1-Nitropropane	SO	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	64% Agreement for 1 of 51 (1.9%)
1 ,2,4-Trimethylbenzene		2A	2B	2A	2B	2A	2B	2B	2B	2B	2B	2B	2B	75%	
Propyl-4-hydroxybenzoate		2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Promethazine hydrochloride		1	1	1	1	1	1	1	2A	1	*	1	2B	82%	58% Agreement for 1 of 51 (1.9%)
1 ,2,3-Trichloropropane	SO	2A	2A	1	2A	2A	2A	2A	2B	1	*	2A	2A	73%	
Diacetone alcohol	SO	2A	2A	1	2A	2A	2A	2A	2A	1	*	2A	2A	82%	
Methanol	SO	1	1	2A	2A	1	1	2A	2B	1	*	1	1	64%	
2,4-Dichloro-5-sulfamoylbenzoic acid		2B	2B	2B	2A	2B	2A	2B	2A	2B	2B	2A	2B	67%	55% Agreement for 3 of 51 (5.9%)
Sodium oxalate		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Quinacrine		2B	2A	2B	2A	2A	2B	2B	2B	2A	*	2B	2A	55%	
Petroleum ether	SO	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Dimethylbiguanide		2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Magnesium carbonate		2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Triethanolamine	SO	2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Aluminum hydroxide		2B	2B	2B	2B	2B	2A	2B	2B	2B	2B	2B	2B	92%	
Tetraaminopyrimidine sulfate		2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Hexane	SO	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Iminodibenzyl		2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
2-Mercaptopyrimidine		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Triton X-155	SU	2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
DL-Glutamic acid		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Anthracene		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
Betaine monohydrate		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
MYRJ-45	SU	2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
EDTA di-potassium salt		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	
BRIJ-35	SU	2B	2B	2B	2B	2B	2B	2B	2B	2B	*	2B	2B	100%	
Phenylbutazone		2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	2B	100%	

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Tables 3-6 and 3-7 present the reproducibility among 5 laboratories in the EC/HO validation study for EPA and GHS hazard categories, respectively. For both analyses there was 100% agreement for 30 of 59 test materials (50.8%), and there was ≥80% agreement (4 out of 5 laboratories) for 44 of 51 test materials (86.3%).

Table 3-6 modified from BRD Table 7-33 Interlaboratory Variability of the BCOP Test Methods for Balls *et al.* (1996) Analysis by EPA hazard categories.

Substance	Formulation Type	Lab Number					Percent Agreement	Concordance
		1	2	3	4	5		
1 -Naphthalene acetic acid, Na salt		I	I	I	I	I	100%	100% Agreement for 30 of 59 (51%)
Benzalkonium chloride (10%)	SU	I	I	I	I	I	100%	
Sodium hydroxide (1%)	AL	I	I	I	I	I	100%	
Cetylpyridinium bromide (6%)	SU	II	I	II	II	II	80%	
Acetone	SO	I	I	I	I	I	100%	80% Agreement for 14 of 59 (24%)
Imidazole		I	I	I	I	I	100%	
Benzalkonium chloride (5%)	SU	I	I	I	I	I	100%	
Methyl acetate	SO	II	II	II	II	II	100%	
Sodium hydroxide (10%)	AL	I	I	I	I	I	100%	60% Agreement for 14 of 59 (24%)
Toluene	SO	II	II	II	II	II	100%	
Chlorhexidine		I	I	I	I	I	100%	
Trichloroacetic acid (30%)	AC	I	I	I	I	I	100%	40% Agreement for 1 of 59 (1.7%)
Dibenzyl phosphate	SO	I	I	I	I	I	100%	
2,2-Dimethylbutanoic acid	AC	I	I	I	I	I	100%	
Pyridine	SO	I	I	I	I	I	100%	
Promethazine hydrochloride		I	I	I	I	I	100%	
Trichloroacetic acid (3%)	AC	I	II	I	I	I	80%	
Benzalkonium chloride (1 %)	SU	I	I	I	II	I	80%	
Parafluoraniline		II	II	II	II	III	80%	
Methyl ethyl ketone	SO	I	II	II	I	II	60%	
4-Carboxybenzaldehyde		I	I	II	II	II	60%	
Ethanol	SO	II	II	II	I	II	80%	
Cetylpyridinium bromide (10%)	SU	II	I	I	II	I	60%	
Triton X-100 (5 %)	SU	II	I	I	I	II	60%	
Triton X-100 (10 %)	SU	I	I	I	II	II	60%	
Isobutanol	SO	II	II	II	II	II	100%	
n-Hexanol	SO	II	I	II	II	II	80%	
Sodium lauryl sulfate (15 %)	SU	II	I	II	II	II	80%	
Cyclohexanol	SO	I	II	II	II	II	80%	
2,6-Dichlorobenzoyl chloride		III	III	III	III	III	100%	
Sodium lauryl sulfate (3 %)	SU	II	II	II	II	III	80%	
Isopropanol	SO	II	II	II	I	II	80%	
Sodium perborate		I	I	I	II	II	60%	
Methyl isobutyl ketone	SO	III	III	III	III	III	100%	
1-Naphthalene acetic acid		I	II	II	I	II	60%	
Butyl acetate	SO	II	II	II	III	III	60%	
Methyl cyanoacetate		III	III	III	III	III	100%	

Ethyl acetate	SO	III	II	II	II	III	60%	
Potassium cyanate		III	III	III	III	III	100%	
2,5-Dimethylhexanediol	SO	III	II	III	II	III	60%	
Benzoyl-L-tartaric acid		I	I	I	I	I	100%	
gamma-Butyrolactone	SO	I	II	II	I	II	60%	
Tetraaminopyrimidine sulfate		III	III	III	III	III	100%	
Methylcyclopentane	SO	III	III	III	III	III	100%	
2-Ethyl-1-hexanol	SO	II	II	II	II	III	80%	
Cetylpyridinium bromide (0.1%)	SU	III	III	III	III	III	100%	
Maneb		II	III	III	II	II	60%	
n-Octanol	SO	II	I	II	III	II	60%	
Ethyl-2-methylacetoacetate		II	III	III	III	III	80%	
Ethyl trimethyl acetate	SO	II	II	III	III	III	60%	
Ammonium nitrate		III	III	III	III	III	100%	
L-Aspartic acid		III	III	III	III	III	100%	
Captan 90 concentrate		II	II	II	I	II	80%	
Quinacrine		III	III	III	III	III	100%	
Fomesafen		II	I	II	III	III	40%	
Sodium oxalate		III	III	III	II	III	80%	
Polyethylene glycol 400	SU	III	III	III	III	III	100%	
Glycerol	SO	III	III	III	III	III	100%	
Tween 20	SU	III	III	III	III	III	100%	

Table 3-7 modified from BRD Table 7-33 Interlaboratory Variability of the BCOP Test Method for Balls *et al.* (1996) Analysis by GHS hazard categories.

Substance	Formulation Type	Lab Number					Percent Agreement	Concordance
		1	2	3	4	5		
1 -Naphthalene acetic acid, Na salt		1	1	1	1	1	100%	100% Agreement for 30 of 59 (51%)
Benzalkonium chloride (10%)	SU	1	1	1	1	1	100%	
Sodium hydroxide (1%)	AL	1	1	1	1	1	100%	
Cetylpyridinium bromide (6%)	SU	2A	1	2A	2A	2A	80%	80% Agreement for 14 of 59 (24%)
Acetone	SO	1	1	1	1	1	100%	
Imidazole		1	1	1	1	1	100%	
Benzalkonium chloride (5%)	SU	1	1	1	1	1	100%	
Methyl acetate	SO	2A	2A	2A	2A	2A	100%	
Sodium hydroxide (10%)	AL	1	1	1	1	1	100%	60% Agreement for 14 of 59 (24%)
Toluene	SO	2A	2A	2A	2A	2A	100%	
Chlorhexidine		1	1	1	1	1	100%	
Trichloroacetic acid (30%)	AC	1	1	1	1	1	100%	40% Agreement for 1 of 59 (1.7%)
Dibenzyl phosphate	SO	1	1	1	1	1	100%	
2,2-Dimethylbutanoic acid	AC	1	1	1	1	1	100%	
Pyridine	SO	1	1	1	1	1	100%	
Promethazine hydrochloride		1	1	1	1	1	100%	
Trichloroacetic acid (3%)	AC	1	2A	1	1	1	80%	
Benzalkonium chloride (1 %)	SU	1	1	1	2A	1	80%	
Parafluoraniline		2A	2A	2A	2A	2B	80%	
Methyl ethyl ketone	SO	1	2A	2A	1	2A	60%	

4-Carboxybenzaldehyde		1	1	2A	2A	2A	60%	
Ethanol	SO	2A	2A	2A	1	2A	80%	
Cetylpyridinium bromide (10%)	SU	2A	1	1	2A	1	60%	
Triton X-100 (5 %)	SU	2A	1	1	1	2A	60%	
Triton X-100 (10 %)	SU	1	1	1	2A	2A	60%	
Isobutanol	SO	2A	2A	2A	2A	2A	100%	
n-Hexanol	SO	2A	1	2A	2A	2A	80%	
Sodium lauryl sulfate (15 %)	SU	2A	1	2A	2A	2A	80%	
Cyclohexanol	SO	1	2A	2A	2A	2A	80%	
2,6-Dichlorobenzoyl chloride		2B	2B	2B	2B	2B	100%	
Sodium lauryl sulfate (3 %)	SU	2A	2A	2A	2A	2B	80%	
Isopropanol	SO	2A	2A	2A	1	2A	80%	
Sodium perborate		1	1	1	2A	2A	60%	
Methyl isobutyl ketone	SO	2B	2B	2B	2B	2B	100%	
1-Naphthalene acetic acid		1	2A	2A	1	2A	60%	
Butyl acetate	SO	2A	2A	2A	2B	2B	60%	
Methyl cyanoacetate		2B	2B	2B	2B	2B	100%	
Ethyl acetate	SO	2B	2A	2A	2A	2B	60%	
Potassium cyanate		2B	2B	2B	2B	2B	100%	
2,5-Dimethylhexanediol	SO	2B	2A	2B	2A	2B	60%	
Benzoyl-L-tartaric acid		1	1	1	1	1	100%	
gamma-Butyrolactone	SO	1	2A	2A	1	2A	60%	
Tetraaminopyrimidine sulfate		2B	2B	2B	2B	2B	100%	
Methylcyclopentane	SO	2B	2B	2B	2B	2B	100%	
2-Ethyl-1-hexanol	SO	2A	2A	2A	2A	2B	80%	
Cetylpyridinium bromide (0.1%)	SU	2B	2B	2B	2B	2B	100%	
Maneb		2A	2B	2B	2A	2A	60%	
n-Octanol	SO	2A	1	2A	2B	2A	60%	
Ethyl-2-methylacetoacetate		2A	2B	2B	2B	2B	80%	
Ethyl trimethyl acetate	SO	2A	2A	2B	2B	2B	60%	
Ammonium nitrate		2B	2B	2B	2B	2B	100%	
L-Aspartic acid		2B	2B	2B	2B	2B	100%	
Captan 90 concentrate		2A	2A	2A	1	2A	80%	
Quinacrine		2B	2B	2B	2B	2B	100%	
Fomesafen		2A	1	2A	2B	2B	40%	
Sodium oxalate		2B	2B	2B	2A	2B	80%	
Polyethylene glycol 400	SU	2B	2B	2B	2B	2B	100%	
Glycerol	SO	2B	2B	2B	2B	2B	100%	
Tween 20	SU	2B	2B	2B	2B	2B	100%	

Tables 3-8 and 3-9 present the reproducibility among 3 laboratories in the prevalidation study of Southee (1998) for EPA and GHS hazard categories, respectively. For both analyses there was 100% agreement for 13 of 16 test materials (81%).

Table 3-8 modified from BRD Table 7-35 Interlaboratory Variability of the BCOP Test Method for Southee (1998) Analysis by EPA hazard categories.

Substance	Formulation Type	Lab Number 1 (Avg)	Lab Number 2 (Avg)	Lab Number 3 (Avg)	Percent Agreement	Concordance
Butyl cellosolve	SO	I	I	I	100%	100% Agreement for 13 of 16 (81%)
Benzalkonium chloride	SU	I	I	I	100%	
NaOH (10%)	AL	I	I	I	100%	
Imidazole		I	I	I	100%	
4-Carboxybenzaldehyde		II	II	II	100%	
Parafluoroaniline		II	II	II	100%	
Methyl ethyl ketone	SO	II	I	II	67%	
Ethanol	SO	II	II	II	100%	
Ammonium nitrate		III	III	III	100%	67% Agreement for 3 of 16 (19%)
Hexadecyltrimethylammonium bromide (10%)		III	II	II	67%	
Glycerol	SO	III	III	III	100%	
Propyl-4-hydroxybenzoate		II	III	III	67%	
Triton X-100 (5%)	SU	III	III	III	100%	
Sodium lauryl sulfate (15%)	SU	III	III	III	100%	
Tween 20	SU	III	III	III	100%	
Sodium oxalate		III	III	III	100%	

Table 3-9 modified from BRD Table 7-35 Interlaboratory Variability of the BCOP Test Method for Southee (1998) Analysis by GHS hazard categories.

Substance	Formulation Type	Lab Number 1 (Avg)	Lab Number 2 (Avg)	Lab Number 3 (Avg)	Percent Agreement	Concordance
Butyl cellosolve	SO	1	1	1	100%	100% Agreement for 13 of 16 (81%)
Benzalkonium chloride	SU	1	1	1	100%	
NaOH (10%)	AL	1	1	1	100%	
Imidazole		1	1	1	100%	
4-Carboxybenzaldehyde		2A	2A	2A	100%	
Parafluoroaniline		2A	2A	2A	100%	
Methyl ethyl ketone	SO	2A	1	2A	67%	
Ethanol	SO	2A	2A	2A	100%	
Ammonium nitrate		2B	2B	2B	100%	67% Agreement for 3 of 16 (19%)
Hexadecyltrimethylammonium bromide (10%)		2B	2A	2A	67%	
Glycerol	SO	2B	2B	2B	100%	
Propyl-4-hydroxybenzoate		2A	2B	2B	67%	
Triton X-100 (5%)	SU	2B	2B	2B	100%	
Sodium lauryl sulfate (15%)	SU	2B	2B	2B	100%	
Tween 20	SU	2B	2B	2B	100%	
Sodium oxalate		2B	2B	2B	100%	