

US EPA ARCHIVE DOCUMENT

ACUTE ORAL TOXICITY STUDY SYNOPSIS AND TOXICITY CATEGORY RECOMMENDATION

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL: (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.1100

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product description as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION: (Product dilution used in testing, include dilution instructions)

ACUTE DERMAL IRRITATION STUDY SYNOPSIS AND TOXICITY CATEGORY RECOMMENDATION

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL: (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.2500

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product use-pattern, as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION/PREPARATION: (Product dilution used in testing, include dilution instructions and diluent)

7.4 WEIGHT/VOLUME ADMINISTERED: (Amount of product applied)

ACUTE EYE IRRITATION STUDY SYNOPSIS AND TOXICITY CATEGORY RECOMMENDATION

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.2400

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product description as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION: (Product dilution used in testing, include dilution instructions)

7.4 WEIGHT/VOLUME ADMINISTERED (Amount instilled into the eye)

8.0 TEST RESULTS:

Species _____

Number of Males tested _____

Number of Females tested _____

Time Post Instillation	Incidence of Positive Irritation Findings*		
	Corneal Opacity	Iritis	Conjunctivitis**
1 hour			
24 hours			
48 hours			
72 hours			
Day 4			
Day 7			
Day 14			
Day 21			

* Readings are presented as Number of Positive Findings/ Total Number of Animals Tested
** Readings of 1 are not considered a positive finding for conjunctival irritation

9.0 TEST CONCLUSIONS:

Time to resolution of all positive readings _____

10.0 NOTES:

11.0 EPA ACUTE EYE IRRITATION CATEGORY (I-IV) _____

12.0 PREPARER'S SIGNATURE _____

Acute Eye Irritation

(Typed name)

Date

**ACUTE INHALATION TOXICITY STUDY SYNOPSIS
AND TOXICITY CATEGORY RECOMMENDATION**

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.1300

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product description as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION: (Product dilution used in testing, vehicle if used, including dilution instructions)

8.0 TEST CONDITIONS:

8.1 AIR CHANGES/HR: (Measured air changes/hr)

8.2 NOSE ONLY/WHOLE BODY: (Choose type of exposure)

8.3 DURATION OF EXPOSURE: (Time animals were exposed; ex. 1 hr, 4 hr)

9.0 TEST RESULTS:

Species _____

Nominal Conc.	Analytical/Gravimetric Conc.*	MMAD ± SD	Incidence of Mortality - Males	Incidence of Mortality - Females

*Concentration measured _____ Analytically _____ Gravimetrically

9.0 TEST CONCLUSIONS:

	Males	Females	Combined
LC ₅₀			

10.0 BRIEF DESCRIPTION OF AEROSOL GENERATING SYSTEM:

11.0 NOTES:

12.0 EPA ACUTE INHALATION TOXICITY CATEGORY (I-IV) _____

13.0 PREPARER'S SIGNATURE _____
 (Typed name) Date

ACUTE DERMAL IRRITATION STUDY SYNOPSIS AND TOXICITY CATEGORY RECOMMENDATION

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL: (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.2500

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product use-pattern, as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION/PREPARATION: (Product dilution used in testing, include dilution instructions and diluent)

7.4 WEIGHT/VOLUME ADMINISTERED: (Amount of product applied)

8.0 TEST RESULTS:

Species _____
Time of Exposure: _____
Number of Males Tested: _____
Number of Females Tested: _____
Primary Irritation Index: _____
Time to Resolution of all Positive Readings: _____

9.0 NOTES:

10.0 EPA ACUTE DERMAL IRRITATION CATEGORY (I-IV) _____

11.0 PREPARER'S SIGNATURE _____
(Typed name) Date

SKIN SENSITIZATION (BUEHLER) STUDY SYNOPSIS AND CATEGORY RECOMMENDATION

PRODUCT NAME: (EPA file name)

EPA REG. NO./FILE SYMBOL: (EPA Reg. No., registrant's number and product number if already registered, otherwise leave blank)

REGISTRANT: (Name and address as on file with EPA)

1.0 STUDY TITLE: (Title of study performed including test method name)

2.0 GUIDELINE: OPPTS 870.2600

3.0 LABORATORY PROJECT NO.: (Lab identification number assigned to study.)

4.0 TESTING FACILITY: (Name and address of testing laboratory)

5.0 STUDY DATES:

5.1 STUDY INITIATION DATE: (Date protocol is signed by study director)

5.2 EXPERIMENTAL START DATE: (Date first animal is dosed)

5.3 EXPERIMENTAL END DATE: (Date last animal sacrificed/dies)

5.4 STUDY COMPLETION DATE: (Date final report is signed by study director)

6.0 GLP COMPLIANCE: (Description of compliance with 40CFR§160)

7.0 TEST SUBSTANCE:

7.1 DESCRIPTION: (Product use-pattern, as per label and form)

7.2 % ACTIVE INGREDIENT: (Ingredient(s) name and percent claimed on label)

7.3 DILUTION/PREPARATION: (Product dilution used in testing, include dilution instructions and diluent)

7.4 WEIGHT/VOLUME ADMINISTERED: (Amount of product applied)

Skin Sensitization (Buehler Method)

8.0 TEST RESULTS:

Species _____

Rangefinder Readings

Dose/Conc	Total Number of Animals with a Reading of Grade*:					
	0	±	1	2	3	4

Induction Readings

Week	Dose/Conc	Total Number of Animals with a Reading of Grade*:					
		0	±	1	2	3	4
1							
2							
3							

Challenge Readings

Group	Dose/Conc	Total Number of Animals with a Reading of Grade*:						Mean Score
		0	±	1	2	3	4	
Control								
Treated								

Rechallenge Readings

Group	Dose/Conc	Total Number of Animals with a Reading of Grade*:						Mean Score
		0	±	1	2	3	4	
Control								
Treated								

* Readings are listed as the number of animals with a particular grade at 24 hr /48 hour (ex. 2/4 in the ± column means at 24 hrs there were 2 animals with a ± and by 48 hr there were 4 animals with a ± reading).

9.0 NOTES:

10.0 EPA SKIN SENSITIZER CLASSIFICATION YES NO

11.0 PREPARER'S SIGNATURE _____
(Typed name) Date _____