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Executive Summary of Wex-Cide Reports:

- The EPA has established four toxicity categories for acute hazards of pesticide products based on the LD50 and LC50 values.
- Wex-Cide 128 is a phenolic disinfectant that falls under EPA Category IV, indicating the least toxic potential.
- Dermal irritation caused by Wex-Cide 128 was evaluated in a study on six rabbits using the Draize method, and the results showed that the product is not a primary irritant.
- An ocular study conducted on six rabbits showed that Wex-Cide 128 does not cause any significant ocular irritation.
- Wex-Cide 128 did not induce sensitization in a study on guinea pigs.
- In an acute oral tox study on female rats, all rats survived and gained weight during the study, and the acute oral LD50 of Wex-Cide 128 is greater than 5,000 milligrams per kilogram of body weight.
- All studies in this document were conducted at use dilution.

Introduction to Wex-Cide and Irritation:

The EPA has established four toxicity categories for acute hazards of pesticide products, with Category I being the highest toxicity category[1]. The categories are determined by the LD50 (lethal dose for 50% of tested animals) for acute oral and dermal toxicity, and by the LC50 (lethal concentration for 50% of tested animals) for acute inhalation toxicity[2]. The categories for eye and skin irritation are based on the severity of the observed effects[3].

Wex-Cide 128, a phenolic disinfectant, has been tested for toxicity and falls under EPA Category IV, indicating the least toxic potential. The following pages focus specifically on dermal irritation caused by Wex-Cide 128 and concludes that the product does not cause any dermal irritation.

Dermal Study

This study evaluated the potential skin irritancy of Wex-cide 128 using six rabbits in accordance with EPA health effects guidelines. A dose of 0.5 mL of the test article was applied to each rabbit's skin for four hours, and the degree of irritation was graded using the Draize method. The primary irritation score was calculated to be 0, indicating that Wex-cide 128 is not a primary irritant. Additionally, there was no evidence of systemic pharmacotoxic effects or injury. Based on the EPA toxicity indicator, Wex-cide 128 falls under Category IV, indicating no irritation.

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Ocular Study

A primary eye irritation study was conducted on Wex-Cide 128 as well, where a clear liquid disinfectant prepared at a use dilution of 1 part by weight q.s. to 256 ml in distilled water. The study was conducted on six healthy young adult albino rabbits in accordance with the Health Effects Guidelines proposed by the EPA in August 1982. One eye of each rabbit was dosed with 0.1 ml of the prepared test article, while the other eye remained untreated as a control. The degree of irritation was graded according to a modification of the Draize method. Results showed that one hour after application, slight conjunctival redness was seen in three out of six test eyes, but this was not positive for irritation. At 24 hours, all eyes were normal, and no corrosive or systemic effects were observed at any time during the study. Overall, the study concludes that Wex-Cide 128 does not cause any significant ocular irritation. The EPA toxicity indicator for primary ocular irritation for test article Wex-Cide 128 at a use dilution of 1:256 is best described as Category IV, no corneal involvement or irritation.

Sensitizer Study

In a study on Sensitizer effects of Wex-Cide 128, the disinfectant did not induce sensitization and can be considered a non-sensitizer in the guinea pig.

Acute Oral Toxicity Study

Finally, in an acute oral tox study, all rats survived and gained weight during the study, and while two females showed hypoactivity and/or ano-genital staining after administration, they recovered by Day 2, with no gross abnormalities noted during necropsy; the acute oral LD50 of Wex-Cide 128 in female rats is greater than 5,000 milligrams per kilogram of body weight.

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1. Toxicity category rating - Wikipedia
2. eCFR :: 40 CFR 156.62 – Toxicity Category
3. Series 870 - Health Effects Test Guidelines | US EPA
4. Acute Toxicity | Pesticide Info

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The following tables are from the **EPA Label Review Manual**
Chapter 7: Precautionary Statements (Revised March 2018)

Table 1. Acute Toxicity Categories

Study	**Category I**	**Category II**	**Category III**	**Category IV**
Acute Oral	LD_{50} ≤50 mg/kg	LD_{50} >50 –500 mg/kg	LD_{50} >500 – 5,000 mg/kg	LD_{50} >5,000 mg/kg
Acute Dermal	LD_{50} ≤200 mg/kg	LD_{50} >200 – 2,000 mg/kg	LD_{50} >2,000 – 5,000 mg/kg	LD_{50} >5,000 mg/kg
Acute Inhalation	LC_{50} ≤0.05 mg/l	LC_{50} >0.05 – 0.5 mg/l	LC_{50} >0.5 –2mg/l	LC_{50} >2 mg/l
Eye Irritation	Corrosive (irreversible destruction of ocular tissue) or corneal involvement or irritation persisting for more than 21 days	Corneal involvement or other eye irritation clearing in 8-21 days	Corneal involvement or other eye irritation clearing in 7 days or less	Minimal effects clearing in less than 24 hours
Skin Irritation	Corrosive (tissue destruction into the dermis and/or scarring)	Severe irritation at 72 hours (severe erythema or edema)	Moderate irritation at 72 hours (moderate erythema)	Mild or slight irritation at 72 hours (no irritation or slight erythema)
Dermal Sensitization	**Positive**		**Negative**	
	Product is a sensitizer or is positive for sensitization		Product is not a sensitizer or is negative for sensitization	

Toxicity Category I	**DANGER**
Toxicity Category II	**WARNING**
Toxicity Category III	**CAUTION**
Toxicity Category IV	None required (or **CAUTION** as optional)

Wex-Cide 128 after dilution at one ounce per gallon Is EPA category IV: no precautionary statements or signal word required.

Below are the results of toxicity testing. Some of the tests were performed on the concentrated product before dilution but had Category IV results. These tests were not repeated on the use-solution, because they were already at the least toxic level.

Product	Test	Results *	EPA Toxicity Category
128 Use Solution	Primary Skin Irritation	No irritation	IV
256 Use Solution	Primary Eye Irritation	No corneal involvement or irritation	IV
256 Concentrate	Dermal Sensitization	Non-sensitizer	IV
128 Concentrate	Acute Oral Toxicity	LD50 >5,000 mg/kg	IV
128 Concentrate	Acute Dermal Toxicity	LD50 >5,000 mg/kg	IV
256 Concentrate	Acute Inhalation Toxicity	LC50 >3.23 mg/l - maximum attainable concentration (LC50 >2 mg/l)	IV

*Test result summaries attached

Test Article: Wexcide

C.S.E #S1688-11

Primary Dermal Irritation Study in Rabbits

Data Requirement: Guideline Para 158.135, 81-5

Author: Geoffrey R. Robbins, M.R.C.V.S.
Diplomate, American Board of Toxicology

Study Director: Gerald Rosenfeld

Study Completed on: 9 April 1988

Performing Laboratory: Cosmopolitan Safety Evaluation, Inc.

(C.S.E.)

P.O. Box 71
Lafayette, New Jersey 07848
Telephone: (201) 383-6253

Laboratory Project I.D. Study #E1844

Primary Dermal Irritation Study in Rabbits Dosed with Wexcide

Summary: The test article, Wexcide, a clear liquid prepared at the use dilution of 1 part by weight q.s. to 256 ml in distilled water, was tested in conformity with the Health Effects Guidelines proposed by the EPA in August 1982.

A dose of 0.5 ml of the prepared test article was applied per application site for 4 hours on each of six rabbits. The degree of irritation was graded by the method of Draize and a primary irritation score was calculated (maximum possible 4.0).

There was no immediate sign of discomfort. Approximately 45 minutes after patch removal there was there was no evidence of any irritation and all test sites remained normal for the 72 hour study duration.

There was no systemic pharmacotoxic effect and no evidence of any injury in depth.

The primary irritation score for Wexcide at a use dilution of 1:256 was 0 and the test article is not a primary irritant. The EPA toxicity indicator is best described as Category IV, no irritation.

SEPTEMBER 14, 1990

READY TO USE WEX-CIDE
GERMICIDAL DETERGENT
EPA FILE SYMBOL 34810-21

PRIMARY EYE IRRITANCY STUDY IN RABBITS
(Use Dilution)

Data Requirement
Guieline Para. 158.135, 81-4

Study Completed on April 8, 1988

COSMOPOLITAN SAFETY EVALUATION, INC.
P. O. BOX 71
LAFAYETTE, NEW JERSEY 07848

LABORATORY PROJECT I.D. - STUDY #D1844

Submitted By
SAID I. RAZIQ
Director of Research

WEXFORD LABS, INC.
325 Leffingwell Avenue
Kirkwood, Missouri 63122

Primary Eye Irritation Study in Rabbits Dosed with Wexcide

Summary: The test article, Wexcide, a clear liquid prepared at the use dilution of 1 part by weight q.s. to 256 ml in distilled water, was tested in conformity with the Health Effects Guidelines proposed by the EPA in August 1982.

Six healthy young adult albino rabbits were used. One eye of each rabbit was dosed with 0.1 ml of the prepared test article, the other eye remaining untreated as a control. All eyes were examined before testing and then at 1, 24, 48 and 72 hours after dosing. The degree of irritation was graded according to a modification of the Draize method.

One hour after application slight conjunctival redness (Grade 1, not positive for irritation) was seen in three (3/6) test eyes. At 24 hours all eyes were normal and remained apparently normal until termination.

At no time was there any corrosive effect on the eye and no evidence of any systemic effect was observed.

Summary (continued)

The EPA toxicity indicator for primary ocular irritation for test article Wexcide at a use dilution of 1:256 is best described as Category IV, no corneal involvement or irritation.

TABLE 1
(continued)
OCULAR IRRITATION

SCORE CHART for Period 72 HOURS

Animal #	8099 M	8100 M	8101 F	8102 F	8103 F	8104 M
Test Eye	R	R	R	R	R	R
Cornea Opacity	0	0	0	0	0	0
Iris	0	0	0	0	0	0
Conjunctivae:						
Redness	0	0	0	0	0	0
Chemosis	0	0	0	0	0	0
Opaque Area	None	None	None	None	None	None
Dye Retention	None	None	None	None	None	None
Response:						
Test Eye	Negative	Negative	Negative	Negative	Negative	Negative
Control	Negative	Negative	Negative	Negative	Negative	Negative

Note: P = Pannus V = Neovascularization (Minimal granulation)
Cornea scored for most severely affected area.
(Blank or absent diagrams indicate no opacity or dye retention at this time.)

Study carried out for:

WEXFORD LABS, INC.

Test Substance: WEX-C103
C.S.R. #31666-16

Dermal Sensitization (Buehler)
on Guinea Pigs

.....A technical report

Data Requirement: Guideline Para 81-6

Author: Geoffrey R. Robbins, M.R.C.V.S.
Diplomate, American Board of Toxicology

Study Director: Anita J. Buss, B.S.

Experimental Initiation: 25 June 1998

Experimental Termination: 26 July 1998

Performing Laboratory: Cosmopolitan Safety Evaluation, Inc.

P.O. Box 71
Lafayette, New Jersey 07848
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FAX: (973) 383-0383

Laboratory Project I.D.: Study #F3556

Scores Following Induction and Challenge and on Naive Controls

Principle Reader:

	Response	24 Hours 1st Ind	2nd Ind	3rd Ind	V.Chl	Rep	48 Hours V.Chl	Rep	72 Hours V.Chl	Rep
Test Substance	0	0/10	0/10	0/10	7/10	N/A	7/10	N/A	9/10	N/A
	±	0	0	0	3		3		1	
	1	10	10	7						
	2			3						
Naive Control	0	N/A	N/A	N/A	4/5	N/A	5/5	N/A	5/5	N/A
	±				1					

Ind = Induction V.Chl = Challenge Rep = Repeat (2nd) Challenge

CONCLUSION

WEX-CIDE did not induce sensitization and can be considered a non-sensitizer in the guinea pig.

[Note: Appendix IV. By contrast, a positive control group concurrently induced with a 25% $^{w}/_{w}$ concentration of 1,4-phenylenediamine dihydrochloride in distilled water applied topically showed a strong positive sensitizing response on challenge (10% $^{w}/_{w}$) in all pigs tested. Reference Notebook #F0014, 7 August 1998.]

eurofins | Product Safety Laboratories

PRODUCT

Wex-Cide 128

STUDY TITLE

Acute Oral Toxicity Up And Down Procedure In Rats

DATA REQUIREMENT

U.S. EPA Health Effects Test Guidelines, OPPTS 870.1100 (2002)

AUTHOR

S. Dana Oley, B.A.

STUDY COMPLETED ON

November 14, 2008

PERFORMING LABORATORY

Eurofins | Product Safety Laboratories

LABORATORY STUDY NUMBER

26095

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7. QUALITY ASSURANCE

The final report was audited for agreement with the raw data records and for compliance with the protocol, Eurofins | Product Safety Laboratories Standard Operating Procedures and appropriate Good Laboratory Practice Standards. Dates of inspections and audits performed during the study and the dates of reporting of the inspection and audit findings to the Study Director and Facility Management are presented in the Quality Assurance Statement.

8. DEVIATIONS FROM FINAL PROTOCOL

None.

9. FINAL REPORT AND RECORDS TO BE MAINTAINED

The original, signed final report will be forwarded to the Sponsor. A copy of this signed report, together with the protocol and all raw data generated at Eurofins | Product Safety Laboratories, is maintained in the Eurofins | Product Safety Laboratories Archives. EPSL will maintain these records for a period of at least five years. After this time, the Sponsor will be offered the opportunity to take possession of the records or may request continued archiving by EPSL.

10. RESULTS

Individual body weights and doses are presented in Table 1. Individual cage-side and necropsy observations are presented in Tables 2 and 3, respectively.

All animals survived exposure to the test substance and gained body weight during the study. Following administration, two females were hypoactive and/or exhibited ano-genital staining. However, the animals recovered by Day 2, and along with the other animal, appeared active and healthy for the remainder of the 14-day observation period. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

11. CONCLUSION

Under the conditions of this study, the acute oral LD_{50} of Wex-Cide 128 is greater than 5,000 milligrams per kilogram of body weight in female rats.

PRODUCT

Wex-Cide 128

STUDY TITLE

Acute Dermal Toxicity Study in Rats

DATA REQUIREMENT

U.S. EPA Health Effects Test Guidelines, OPPTS 870.1200 (1998)

AUTHOR

S. Dana Oley, B.A.

STUDY COMPLETED ON

March 17, 2009

PERFORMING LABORATORY

Eurofins | Product Safety Laboratories

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10. RESULTS

Individual body weights and doses are presented in Table 1. Individual cage-side and necropsy observations are presented in Tables 2 and 3, respectively.

All animals survived exposure to the test substance. Although one female lost weight by Day 7, all animals gained body weight over the 14-day observation period. Other than the dermal irritation noted for all dose sites between Days 1 and 14, there were no other adverse clinical findings recorded for any animal over the course of the study. No gross abnormalities were noted for any of the animals when necropsied at the conclusion of the 14-day observation period.

11. CONCLUSION

Under the conditions of this study, the single dose acute dermal LD_{50} of Wex-Cide 128 is greater than 5,000 mg/kg of body weight in male and female rats.

STUDY IDENTIFICATION

STUDY TITLE:	Acute Inhalation Toxicity of WEX-CIDE in Rats
STUDY NUMBER:	C3549
TEST SUBSTANCE:	WEX-CIDE Lot/Batch No.: 040182 EPA Reg. No.: 34810-8
STUDY DIRECTOR:	Anita J. Buss, B.S. Cosmopolitan Safety Evaluation, Inc. P.O. Box 71 Lafayette, New Jersey 07848
SPONSOR:	Said I. Raziq Wexford Labs, Inc. 325 Leffingwell Avenue Kirkwood, Missouri 63122 Telephone: (314) 966-4134
TESTING FACILITY:	Cosmopolitan Safety Evaluation, Inc. 33a, Broad Street, Branchville
Postal Address:	P.O. Box 71 Lafayette, New Jersey 07848 Telephone: (973) 383-6253
STUDY INITIATION DATE:	24 April 1998
EXPERIMENTAL START:	5 May 1998
EXPERIMENTAL TERMINATION:	19 May 1998
COMPLETION DATE:	29 May 1998
INITIAL LOCATION OF RAW DATA/SPECIMEN RETENTION:	Cosmopolitan Safety Evaluation, Inc. Statesville Quarry Road P.O. Box 71 Lafayette, New Jersey 07848

Acute Inhalation in Rats. Study #C3549

Reported Mortality

Exposure Concentration mg/ℓ	(NUMBER KILLED/NUMBER TESTED) Males	Females	Combined
3.23	0/5	0/5	0/10

mg/ℓ Nom Conc	Grav Conc	Analyt Conc	MMAD	GSD	Temp[C]	Hum%	Air Flow [l/m]
6.4	3.23	----	0.8	3.2	21-22	81-91	10.0

EVALUATION

The LC_{50} was >3.23 mg/ℓ, the maximum attainable concentration of aerodynamic particles, for the four hour exposure. The EPA toxicity indicator for test substance WEX-CIDE is best described as Category IV, no mortality at >2.0 mg/ℓ.