

103603
SHAUGHNESSEY NO.

3
REVIEW NO.

EEB BRANCH REVIEW

DATE: IN 7-7-81 OUT 7-31-81

FILE OR REG. NO. 524-332

PETITION OR EXP. PERMIT NO. _____

DATE DIV. SUBMISSION 7-7-81

DATE OF SUBMISSION _____

DATE SUBMISSION ACCEPTED _____

TYPE PRODUCT(S): I, D, (H,) F, N, R, S _____

DATA ACCESSION NO(S). 245326

PRODUCT MANAGER NO. (25) Taylor/Walters

PRODUCT NAME(S) Polado® Plant Growth Regulator

COMPANY NAME Monsanto Company

SUBMISSION PURPOSE Data requested as condition of registration

SHAUGHNESSEY NO.	CHEMICAL, & FORMULATION	% A.I.
<u>103603</u>	<u>Sodium salt N-(phosphonomethyl)</u>	<u>_____</u>
<u>_____</u>	<u>glycine of glyphosate</u>	<u>75%</u>
<u>_____</u>	<u>_____</u>	<u>_____</u>
<u>_____</u>	<u>_____</u>	<u>_____</u>

252

Sodium salt N-(Phosphonomethyl) glycine of glyphosate

100 Pesticide Label Information

100.1 Pesticide Use

Plant growth regulator for sugarcane

100.2 Formulation Information

Sodium salt N-(phosphonomethyl)
glycine of glyphosate-75%
Inert ingredients - 25%

100.3 - 100.5 Application Methods, Directions, Rates

See A. Rosenkranz's review
of 4-24-80.

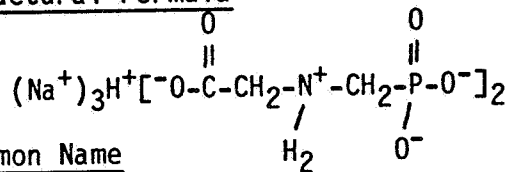
101 Physical and Chemical Properties

101.1 Chemical Name

Sodium salt N-(phosphonomethyl)
glycine of glyphosate

This name was taken from the 4th Ed. of "Acceptable
Common Names and Chemical Names for the Ingredient
Statement on Pesticide Labels," and is found under
1132.5 on page 1133.

101.2 Structural Formula



101.3 Common Name

Trisodium diglyphosate

101.4 Trade Name

MON 8000
Polado

101.5 Vapor Pressure

10-7 mm of Hg range (per. comm. S.Creeger)

253

102 Behavior in the Environment

See A. Rosekranz's review
of 4-24-80

103 Toxicological Properties

See glyphosate reviews McLane (7/13/79)
and 8/10/79) and Urban (7/19/78)

103.2 Avian and Aquatic Studies

<u>Company Data Library Acc#</u>	<u>Organisms</u>	<u>Study</u>	<u>Result</u>	<u>Test Material</u>	<u>Validation Category</u>
245326	bobwhite quail	Acute Oral	LD ₅₀ >2510 mg/kg	MON 8000	Supplemental
"	"	Subacute Dietary	LC ₅₀ >5620 mg/kg	" "	"
"	mallard duck	Subacute Dietary	LC ₅₀ >5620 mg/kg	" "	"
"	bluegill sunfish	Acute 96-h	LC ₅₀ >1000 mg/L	" "	"
"	rainbow trout	Acute 96-h	LC ₅₀ >1000 mg/L	" "	"
"	<u>Daphnia magna</u>	Acute 48-h	LC ₅₀ >1000 mg/L	" "	"
"	sheepshead minnows	Acute 96-h	LC ₅₀ = 620 mg/L	" "	"
"	mysid shrimp	Acute 96-h	LC ₅₀ = 24 mg/L	" "	"
"	eastern oyster	Acute 48-h	EC ₅₀ >20 mg/L	" "	"
"	fiddler crab	Acute 96-h	LC ₅₀ >1000 mg/L	" "	"

254

104 Hazard Assessment

104.1 Discussion

(Rosenkranz's review of 4-24-80)

"Polado® is a foliar applied growth regulator that is to be sprayed onto sugarcane at rates of 0.2 pounds to 0.9 pounds active ingredient per acre depending upon location and ripening conditions. At the maximum application rate the maximum expected residues in the environment are: 215 ppm on vegetation, 20 ppm on the surface, and 0.661 ppm in the top six inches of water."

104.2 Likelihood of Adverse Effects to Non-Target Organisms

The hazard assessment (Rosenkranz, 4-24-80) previously made in connection with this use raised questions concerning the [redacted] since Roundup, another glyphosate formulation, had [redacted] highly toxic to aquatic organisms. In addition, sugarcane is raised near water, such as, Lake Okeechobee in Florida. However, the data evaluated with this action indicates the formulation is slightly toxic to practically non-toxic for aquatic organisms. Therefore, minimal hazard is expected on aquatic organisms is expected.

Avian data was also submitted with this action (see section 103). Verify the low toxicity of previous data on technical glyphosate. Therefore, minimal hazard is expected to avian species.

It should be mentioned that Polado® would be expected to act as a herbicide on more sensitive plants. Sugarcane is a grass. They are generally more tolerant of pesticides than other plants. Hence, there is a concern for non-target plants, particularly, the tropical plants, such as, papaya, passion fruit, taro, and pineapple, which may be grown near sugarcane in Hawaii.

104.3 Endangered Species Considerations

The toxicity data for mammals, birds, and aquatic organisms indicates glyphosate is of very low toxicity. The most sensitive is eastern oysters. The LC₁₀ for this species is 12 mg/L which would not be expected to occur at these application rates.

A review of the agricultural statistics indicates that the counties growing sugarcane do not have any endangered plants except the island of Hawaii. They are the following:

1. Stenogyne angustifolia var. angustifolia

2. Haplostachys haplostachya
var. angustifolia
3. Lipochaeta venasa
4. Vicia menziesii
or Hawaiian wild
broad-bean

Fortunately, the closest of these is 10 or more miles from the nearest sugarcane field. Hence, endangered plants would not be expected to be adversely affected. During periods of high winds or high temperatures (>35°C) glyphosate may volatilize from the fields and be carried to nontarget areas. However, these periods should not cause any undue concern, though data on the phytotoxicity of glyphosate to tropical crops will help substantiate this.

104.4 Adequacy of Toxicity Data

The data evaluated in connection with this review was performed with the formulated product as required by Rosenkranz in her review of 4-24-80.

The data were scientifically sound and are adequate for hazard assessment.

104.5 Additional Data Required

No additional zoological toxicity data will be required at this time.*

Note to the PM: Due to our concern for tropical plants, this is a request for any phytotoxicity data on these types of plants the company may have available.)

Dennis J. McLane
Biologist
Ecological Effects Branch/HED

Dennis McLane

Raymond Matheny
Head, Review Section 1
Ecological Effects Branch/HED

Raymond Matheny

8/7/81

Clayton Bushong
Branch Chief
Ecological Effects Branch /HED

Clayton Bushong

8/7/81

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (Formulated product)
2. FORMULATION: Trisodium diglyphosate - 75% [REDACTED]
3. CITATION: Beavers, J.B. 1981. Acute oral LD50 - bobwhite quail MON 8000 FINAL REPORT Wildlife International Ltd. Project No. 139-192, Submitted by Monsanto Co. EPA Reg. No. 524-332, CDL 245326 on 6-25-81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 16, 1981
6. TEST TYPE: Acute oral LD50 - Bobwhite Quail
7. REPORTED RESULTS: The acute LD50 of MON 8000 in bobwhite quail is estimated to be greater than 2810 ppm.
8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and indicates Polado® is practically non-toxic to bobwhite quail.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

257

9. MATERIALS AND METHODS

A. Test Procedures

The following testing regime was used:

<u>Treatment</u>	<u>Pens</u>	<u>Birds/Pen</u>	<u>Dietary Conc. (ppm)</u>
Control	1	10	Distilled water only
Experimental	5	10	398, 631, 1000, 1590, and 2510

B. Statistical Analysis

The study cited D.J. Finney's
"Probit Analysis".

C. Discussion/Results

Controls - There were no mortalities in the control group during the course of the study. All birds were normal in appearance and behavior throughout the test period.

Experimental Material - There were no mortalities in the 398 mg/kg dosage level. One cock was noted isolated in a corner on Day 3, and exhibited lethargy, a ruffled appearance with some depression, and wing droop through Day 8. The symptoms observed may have been the result of or augmented by aggressive activity toward this bird by other cocks in this level. At the 631 mg/kg dosage level one hen was found dead on Day 2, and another on Day 4. Neither bird had exhibited prior symptoms of toxicity and all other birds at this dosage level appeared normal throughout the test period.

At the 1000 mg/kg dosage level one male was noted as lethargic on Day 2, and continued to exhibit lethargy, with some depression, reduced reaction to external stimuli (sound and movement), a ruffled appearance and wing droop until found dead on Day 7. One hen was noted with a ruffled appearance on Day 4, and a cock and a hen were noted as lethargic on Day 5. The hen which was found dead on Day 6 had extensive lesions on her head and neck indicative of head picking. At the 1590 mg/kg dosage level one cock was noted as lethargic on Day 2, and one hen on Day 3. Two hens were found dead on Day 4. A few birds were noted as lethargic on Day 5, and a few birds were noted as possibly lethargic on Day 8. The bird found dead on Day 9, had extensive lesions of toe and hock picking.

At the 2510 mg/kg dosage level two birds were noted as lethargic on Day 2, and lethargy continued to be exhibited by some birds at this dosage level through Day 7. One hen was noted as slightly lethargic on Day 12. The cock found dead at this dosage level on Day 14 was noted with extensive head lesions.

All other birds at all dosage levels appeared normal throughout the test period, and no effect was noted on body weight gain or feed consumption.

10. REVIEWER'S EVALUATION

A. Test Procedures

The study failed to report the temperature, humidity and the necropsy results.

B. Statistical Analysis

The mortality which occurred was explained in the study and this type of behavior as typical for birds in this type of situation. The control deaths was very similar to those under treatment indicating that the herbicide was probably not the cause of the behavior which caused the deaths. The distribution of the deaths across the various treatment levels indicates that they were not dose related response.

C. Discussion/Results

The study is scientifically sound and acceptable to determine the effect of the formulated product.

D. Conclusions

1. Category - Supplemental
2. Rational - There are no guideline requirements for studies of the formulated product.
3. Repairability - the study can not be repaired since it is on the formulated product.

RESULTS CALCULATED USING THE PROBIT METHOD

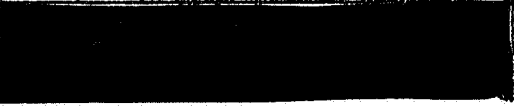
ITERATIONS	G	H	GOODNESS OF FIT PROBABILITY
6	2.067834	1	0.5138658

SLOPE + 1.046857
95 PERCENT CONFIDENCE LIMITS = -0.4585195 AND 2.552233

LC50 = 8205.143
95 PERCENT CONFIDENCE LIMITS = 2209.578 AND +INFINITY

LC10 = 502.2627
95 PERCENT CONFIDENCE LIMITS = 0 AND 1263.194

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (Formulated product)
2. FORMULATION: Trisodium diglyphosate - 75% 
3. CITATION: Beavers, J.B. 1981. Eight-day dietary LC₅₀ - bobwhite quail
MON 8000 FINAL REPORT (WL-80-361) Wildlife International Ltd.
Project No. 139-190, Submitted by Monsanto Co. EPA Reg. No.
524-332, CDL 245326 on 6-25-81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 27, 1981
6. TEST TYPE: Eight - Day Dietary LC₅₀ - Bobwhite Quail
7. REPORTED RESULTS: The subacute LC₅₀ of MON8000 in bobwhite
quail is estimated to be greater than 5620
ppm.
8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and indicates
Polado® is practically non-toxic to bobwhite
quail.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

261

9. MATERIALS AND METHODS

A. Test Procedures

The following testing regime was used:

<u>Treatment</u>	<u>Pens</u>	<u>Birds/Pen</u>	<u>Dietary Conc. (ppm)</u>
Control	5	10	Basal Diet only
Lab Standard	5	10	15.9, 25.1, 39.8, 63.1, and 100
Experimental	5	10	562, 1000, 1780, 3160, and 5620

B. Statistical Analysis

The study cited D.J. Finney's "Probit Analysis".

C. Discussion/Results

Controls - In the first negative control group one bird was found dead with lesions of toe picking on Day 7, and an additional bird was found dead with evidence of toe picking on Day 8. In the third negative control group one bird was noted with slight lesions of toe picking on Day 5. In the fourth negative control group one bird was found dead with lesions of toe picking on Day 6, and one additional bird was noted with lesions from this form of cannibalism. Subsequently, four additional birds were found dead at this level with extensive lesions of toe picking. All other birds in the negative control groups were normal in appearance and behavior throughout the test period. The negative social interaction associated with cannibalism may have contributed to a slight reduction in feed consumption noted at the first and fourth negative control levels.

Experimental Material - At the 562 ppm concentration level, nostril picking was first observed on Day 2, and the three birds subsequently found dead at this concentration level all exhibited lesions pathognomonic of this form of cannibalism. At the 1000 ppm concentration level, one bird was found dead on Day 2 with external lesions of toe picking.

At the 1780 ppm concentration level, one bird was found dead on Day 3. The bird was light in weight, but autolysis precluded a precise determination of the cause of death. One additional bird at this concentration level was found dead on Day 5 with extensive lesions of both toe and nostril picking. At the 3160 ppm concentration level, the bird found dead on Day 2 exhibited lesions

pathognomonic of toe picking. At the 5620 ppm concentration level, one bird was found dead on Day 2. No external lesions were noted during gross necropsy, but some bruising was evident on the breast muscles, and the bird's gastro-intestinal tract was empty except for fluid and gas, possibly the result of autolysis.

No overt symptoms of toxicity were noted at any concentration level tested, and all those birds not subjected to cannibalistic attacks appeared normal throughout the test period. There may have been a very slight reduction in body weight gain of surviving birds at the 5620 ppm concentration level.

10. REVIEWER'S EVALUATION

A. Test Procedures

The study failed to report the temperature, and humidity.

B. Statistical Analysis

The mortality which occurred was explained in the study and this type of behavior is typical for birds in this type of situation. The control deaths was very similar to those under treatment indicating that the herbicide was probably not the cause of the behavior which caused the deaths. The distribution of the deaths across the various treatment levels indicates that they were not dose related response.

C. Discussion/Results

The study is scientifically sound and acceptable to determine the effect of the formulated product.

D. Conclusions

1. Category - Supplemental
2. Rational - There are no guideline requirements for studies on the formulated product.
3. Repairability - the study can-not be given a higher category because the formulated product was tested.

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (Formulated product)
2. FORMULATION: Trisodium diglyphosate - 75% [REDACTED]
3. CITATION: Beavers, J.B. 1980. Eight-day dietary LC₅₀-mallard duck MON 8000 WL-80-360. Final report Wildlife International Ltd. Project No. 139-191, Submitted by Monsanto Co. EPA Reg No. 524-332, CDL 245326 on 6-25-81.
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: 7-27-81
6. TEST TYPE: Eight-day dietary LC₅₀-mallard duck
7. REPORTED RESULTS: The subacute LC₅₀ of MON 8000 in the mallard duck is estimated to be greater than 5620 ppm.
8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and indicates Polado® is practically non-toxic to mallard ducks.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

264

9. MATERIALS AND METHODS

A. Test Procedures

The following testing regime was used:

<u>Treatment</u>	<u>Pens</u>	<u>Birds/Pen</u>	<u>Dietary Conc (ppm)</u>
Control	5	10	Basal Diet Only
Experimental	5	10	562, 1000, 1780 3160, and 5620

B. Statistical Analysis

The study cited D.J. Finney's "Probit Analysis".

C. Discussion/Results

1. Controls - There were no mortalities in any negative control group.

All birds were normal in both appearance and behavior throughout the test period.

2. Experimental Material - There were no mortalities at any concentration level tested, and all birds appeared normal throughout the test period. There was a reduction in body weight gain noted at the 1000 ppm concentration level, and a slight reduction in feed consumption at all concentration levels.

10. REVIEWER'S EVALUATION

A. Test Procedures

The study did not report the humidity during the test. Also the temperature was 75°F is 20°F below the recommended temperature.

B. Statistical Analysis

No deaths occurred at any of concentration tested, hence, statistical analysis was not necessary.

C. Discussion/Results

The lack of adequate temperature would stress the birds and be more likely to produce ill effects. Since the observed effects were slight, the results of the study are considered valid.

265

D. Conclusions

1. Category - Supplemental
2. Rationale - There are no guideline requirements for studies on the formulated product.
3. Repairability - This would be a care study if the technical grade chemical was used.

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate-75%, [REDACTED]
3. CITATION: Thompson, C.M., Griffen, J., McKee, M., and Boudreau, P. 1980, Acute toxicity of MON 8000 (Lot No. QUSS-0501) (AB-80-497) to bluegill sunfish (Lepomis macrochirus), Analytical Bio Chemistry Laboratories, Inc., Columbia, MO. submitted by Monsanto Chemical Co., St. Louis, Missouri, CDL 245326, EPA Reg. No. 534-332 on 6/25/81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 10, 1981
6. TEST TYPE: Ninety-six Hour LC50-Bluegill Sunfish
7. REPORTED RESULTS: TABLE 2

The Acute Toxicity of MON 8000 (Lot No. QUSS-0501) and Antimycin A to Bluegill Sunfish (Lepomis macrochirus)

<u>Compound</u>	<u>LC50 in milligrams/liter (ppm)</u>		
	<u>24 hours</u>	<u>48 hours</u>	<u>96 hours</u>
MON 8000	> 1000	> 1000	> 1000
(Lot No. QUSS-501)	0.000060	0.000060	0.000056
Antimycin A	6.000042-0.000075	(0.000042-0.000075)	(0.000042-0.000075)

8. REVIEWER'S CONCLUSIONS:

The study is scientifically sound and indicates Polado® is practically non-toxic to bluegill sunfish.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

267

9. MATERIALS AND METHODS

A. Test Procedure

Five concentrations, 100, 180, 320, 560, and 1000 mg/l, were tested, in addition, to the control.

B. Statistical Analysis

The study cited:

Stephan, C.E., K.A. Busch, R. Smith, J. Burke and R.W. Andrew. 1978. A computer program for calculating an LC50. U.S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August 1978.

C. Discussion/Results

The authors did not describe any symptoms or reaction other than the raw mortality values.

10. REVIEWER'S EVALUATION

A. Test Procedures

The study had the following problems:

1. Toxic symptoms were not discussed.
2. The prophylactic and therapeutic treatment of nitrofurazone exceed the 3-5 mg/l concentration. The raw data indicates 1 hour each day for three days of the test, 12/10, 12/11, and 12/12. A treatment of 10 ppm was applied.
3. The fish had an average weight of 0.21g. which is below the recommended range of 0.5-5g.
4. Oil globules were observed on the surface of all test concentrations after 72 hours of testing. However, the actual concentration was not measured.
5. The control mortality death was not described or explained.

B. Statistical Analysis

The Stephan program used did not include Abbots formula which would adjust the LC50 to compensate for the 1 death in the controls.

C. Discussion/Results

The items mentioned under Test Procedures should be discussed or explained. These items would tend to increase the toxic effect of the chemical. Hence, the study LC50 of >1000 mg/l which indicates a practically non-toxic chemical would be expected to be correct. Basis on the available information, the study is scientifically sound.

D. Conclusion

1. Category - Supplemental
2. Rationale - The items mentioned under Test Procedures should be explained.
3. Repairability - No, there are no guideline requirements for studies on the formulated product.

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate-75.0% [REDACTED]
3. CITATION: Thompson, C.M., 1980, Acute toxicity of MON 8000 (Lot No. Quss-0501) (AB-80-496) to rainbow trout (Salmo gairdneri), Analytical Bio Chemistry Laboratories, Inc., Columbia, MO. submitted by Monsanto Chemical Co. St. Louis, Missouri, CDL 245326, EPA Reg. No. 524-332 on 6/25/81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 10, 1981
6. TEST TYPE: Ninety-six Hour LC50-Rainbow Trout
7. REPORTED RESULTS:

TABLE 2
The Acute Toxicity of MON 8000 (Lot No. QUSS-0501) and Antimycin A to Rainbow Trout (Salmo gairdneri)

<u>Compound</u>	<u>24 hours</u>	<u>48 hours</u>	<u>96 hours</u>
MON 8000 (Lot No. QUSS-0501)	> 1000	> 1000	> 1000
Antimycin A**	0,00019	0.000050 (0.000040-0.000064)**	0.000020 (0.000014- 0.000042)

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound, and indicates that this formulation is practically non-toxic to rainbow trout.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

270

9. MATERIALS AND METHODS

A. Test Procedures

Five concentrations, 100, 180, 320, 560, and 1000 mg/l, were tested, in addition, to the control.

B. Statistical Methods

The study cited:

Stephan, C.E., K.A. Busch, R. Smith, J. Burke and R.W. Andrew. 1978. A computer program for calculating on LC50. U.S. Environmental Protection Agency, Duluth, Minnesota, prepublication manuscript, August, 1978.

C. Discussion/Results

The authors did not describe any symptoms or reaction other than the raw mortality values.

10. REVIEWER'S EVALUATION

A. Test Procedures

The failure of the study to indicate the condition of the fish at the end of the test limits its value in assessing the toxicity of the chemical. Also, the fish had an average weight of 0.13g which is below the recommend range of 0.5-5g.

B. Statistical Analysis

Statistical analysis was not necessary. Only, the highest concentration tested cause mortality.

C. Discussion/Results

The study is scientifically sound and indicates that Polado is practically non-toxic to the rainbow trout. There are no guidelines for testing formulated products.

D. Conclusion/Category

Supplemental

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate-75%, [REDACTED]
3. CITATION: Forbis, A.D., Boudreau, P., and Thompson, C.M. 1980, Acute toxicity of MON 8000 (AB-80-498) to Daphnia magna, Analytical Bio Chemistry Laboratories, Inc., Columbia, MO. submitted by Monsanto Chemical Co., St Louis, Missouri; CDL 245326, EPA Reg. No. 534-332
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 13, 1981
6. TEST TYPE: Forty-eight hour LC50 Daphnia magna
7. REPORTED RESULTS:

TABLE 2
The Acute Toxicity of MON 8000
to Daphnia magna

	<u>LC50 (mg/l)</u>	
<u>Compound</u>	<u>24 hours</u>	<u>48 hours</u>
MON 8000	- - -	> 1,000 mg/l

8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound and indicates that Polado® is practically non-toxic to Daphnia magna.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

9. MATERIALS AND METHODS

A. Test Procedures

Five concentrations in duplicate of the test compound with ten Daphnia (first instar less than 24 hours old) per beaker were selected for their respective bioassay. These concentrations were a logarithmic series ranging from 100 to 1,000 mg/l.

B. Statistical Analysis

The study cited Stephan's LC50 computerized program:

Stephan, C.E., K.A. Busch, R. Smith, J. Burke and R.W. Andrews. 1978. A computer program for calculating an LC50. U.S. Environmental Protection Agency, Duluth, Minnesota, pre-publication manuscript, August, 1978.

C. Discussion/Results

Toxic symptoms were not described.

10. REVIEWER'S EVALUATION

A. Test Procedure

The study failed to described the behavior and physical condition of the daphnids at anytime during the study.

B. Statistical Analysis

Statistical analysis was not necessary. Only, the highest concentration tested cause mortality.

C. Discussion/Results

The study is scientifically sound and indicates the toxicity of Polado® is practically non-toxic to the rainbow trout. There are no guidelines for testing formulated products.

D. Conclusion/Category

Supplemental

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate-75% [REDACTED]
3. CITATION: Ward, S.G., 1981. Acute toxicity of technical MON-8000 to sheepshead minnows (Cyprinodon variegatus), EG&G Bionomics, Project Number L95, Report Number BP-81-5-76 Submitted by Monsanto Co., CDL 245326, EPA Reg. No. 524-322 on 6/25/81

4. REVIEWED BY:

Dennis J. McLane
Biologist
EEB/HED

5. DATE REVIEWED: July 13, 1981
6. TEST TYPE: Ninety - six hour LC50 - Sheepshead Minnow
7. REPORTED RESULTS: 96-hour LC50: 620 mg/l
95% confidence limits: 480-800 mg/l
No-observed-effect concentration: 480 mg/l.
8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound and indicates that Polado® is practically non-toxic to the sheepshead minnow.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

274

9. MATERIALS AND METHODS

A. Test Procedure

Five fish were tested per container and treatments were duplicated. The following concentrations were used: 100, 170, 290, 480, and 800 mg/l.

B. Statistical Analysis

The study cited the following article by Stephan:

Stephan, C.E. 1977. Methods for calculating an LC50. ASTM, Aquatic Toxicology and Hazard Evaluation, ASTM STP 634, F.L. Mayer and J.L. Hamelink, eds. pp. 65-84.

C. Discussion/Results

After 96 hours of exposure to technical MON-8000, mortality was 100% in the 800 ppm concentration and 0% in all the remaining concentrations. There was no mortality in the control.

10. REVIEWER'S EVALUATION

A. Test Procedure

Two items were not addressed in the discussion of the study:

1. Pretest fast for 96 hours
2. Whether or not any symptoms occurred other than death.

B. Statistical Analysis

The Stephan program available to EEB on the Waterside Mall minicomputer verified the results presented in the study. Neither the moving average or the probit were applicable. Hence, the binomial provided the LC50 value.

C. Discussion/Results

The study is scientifically sound and indicates that Polado® is practically non-toxic to the sheepshead minnow.

There are no guidelines for testing formulated products.

D. Conclusion

Supplemental

275

ENTER YOUR NAME.

? MCLANE

ENTER THE TRADE NAME OF THE CHEMICAL.

? POLADO

ENTER THE TEST TYPE. (I.E. QUAIL. ACUTE ORAL LD50)

? FISH

ENTER THE NUMBER OF CONTROL ANIMALS USED.

IF UNKNOWN, ENTER 0.

? 10

ENTER THE NUMBER OF CONTROL ANIMALS THAT DIED.

? 0

ENTER THE NUMBER OF TREATMENT LEVELS,
EXCLUDING CONTROLS.

? 5

ON THE NEXT 5 LINES, ENTER (IN DESCENDING ORDER)
THE CONCENTRATIONS TO WHICH EACH GROUP WAS EXPOSED.
ENTER ONE CONCENTRATION PER LINE.

? 800

? 480

? 290

? 170

? 100

ON THE NEXT 5 LINES, ENTER THE NUMBER OF
ANIMALS EXPOSED AT EACH TREATMENT LEVEL. USE SAME ORDER.

? 10

? 10

? 10

? 10

? 10

ON THE NEXT 5 LINES, ENTER THE NUMBER OF
ANIMALS AT EACH TREATMENT LEVEL THAT WERE DEAD
AT THE CONCLUSION OF THE TEST. USE SAME ORDER.

? 10

? 0

? 0

? 0

? 0

CONC.	NUMBER EXPOSED	NUMBER DEAD	PERCENT DEAD	BINOMIAL PROB. (PERCENT)
800	10	10	100	0.09765625
480	10	0	0	0.09765625
290	10	0	0	0.09765625
170	10	0	0	0.09765625
100	10	0	0	0.09765625

THE BINOMIAL TEST SHOWS THAT 480 AND 800 CAN BE
USED AS STATISTICALLY SOUND CONSERVATIVE 95 PERCENT
CONFIDENCE LIMITS, BECAUSE THE ACTUAL CONFIDENCE LEVEL
ASSOCIATED WITH THESE LIMITS IS GREATER THAN 95 PERCENT.

AN APPROXIMATE LC50 FOR THIS SET OF DATA IS 619.6774

WHEN THERE ARE LESS THAN TWO CONCENTRATIONS AT WHICH THE
PERCENT DEAD IS BETWEEN 0 AND 100, NEITHER THE MOVING AVERAGE NOR THE
PROBIT METHOD CAN GIVE ANY STATISTICALLY SOUND RESULTS.

276

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate-75% [REDACTED]
3. CITATION: Hollister, T.A. 1981. Acute toxicity of technical MON-8000 to mysid shrimp (Mysidopsis bahia); EG&G Bionomics, Project Number L 95, Report Number BP-81-5-78, Submitted by Monsanto Co., CDL 245326, EPA Reg. No. 524-322 on 6/25/81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 14, 1981
6. TEST TYPE: Ninety - six LC50 - Mysid shrimp
7. REPORTED RESULTS: 96-hour LC50: 24 mg/l
95% confidence limits: 17-35 mg/l
No-observed-effect concentration: 3 mg/l
8. REVIEWER'S CONCLUSIONS:

This study is scientifically sound and indicates that Polado is slightly toxic to 8-day old mysid shrimp which did not molt during test.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

9. MATERIALS AND METHODS

A. Test Procedure

Ten shrimp per concentration for the following six levels:
2, 3, 6, 12, 25, and 50 mg/l.

B. Statistical Analysis

The study cited the following article by Stephan:

Stephan, C.E. 1977. Methods for calculating an LC50.
ASTM, Aquatic Toxicology and Hazard Evaluation, ASTM
STP 634, F.L. Mayer and J.L. Hamelink, eds. pp. 65-84.

C. Discussion/Results

The sample of technical MON-8000 was toxic to mysid shrimp in nominal test concentrations ≥ 6 ppm. After 96 hours, mortality was from 10% in 6 ppm and 12 ppm to 100% in 50 ppm; there was no mortality in the control.

10. REVIEWER'S EVALUATION

A. Test Procedure

The test used mysids 8-days old it is very unlikely shrimp this age would molt during the 96-hour test period. Hence, the most sensitive period of exposure has been avoided

B. Statistical Analysis

The Stephan's program gave a probit LC50 of 24.13681 with confidence limits, of 16.90954 and 37.18842. These values are very similar to the study's reported results indicating their method was sufficient.

C. Discussion/Results

The study is scientifically sound, although, it was not designed to test the most sensitive stage of the mysid life cycle.

D. Conclusion

1. Category - Supplemental
2. Rational - The study is scientifically sound and tests a formulated product for which there are no guidelines.
3. Repairability - Studies on the formulated product can not meet guideline requirements.

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate - 75%, [REDACTED]
3. CITATION: Hollister, T.A. 1981. Acute toxicity of MON-8000 to embryos - larvae of eastern oysters (*Crassostrea virginica*), EG & G Bionomics, Project Number L 95, Report Number BP-81-5-86, Submitted by Monsanto Co, CDL 245326, EPA Reg. No. 524-322 on 6/25/81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: July 14, 1981
6. TEST TYPE: Forty-eight hour EC₅₀ - Eastern oyster
7. REPORTED RESULTS: Effect criterion: Normal development to straight-hinged veliger stage
48-hour EC₅₀: 20 mg/l
95% confidence limits: 13-29 mg/L.
8. REVIEWER'S CONCLUSIONS:

The study is scientifically sound and fulfills requirements for an acute aquatic toxicity study for estuarine molluscan embryo-larvae.

9. MATERIALS AND METHODS

A. Test Procedure

The methods for the 48-hour oyster embryo-larval test were based on the BMRL Test Protocol for Bivalve Mollusc Larvae, February 1980, Embryos were obtained by combining eggs and sperm excised from gonads of sexually mature adult oysters. Fertilization was confirmed microscopically and was estimated to be > 90%. Density of the embryos was determined by a Sedgwick-Rafter count of a 1:15 dilution (1 ml embryo suspension; 14 ml of seawater) from the spawning chamber,

Five test concentrations of Polado, ranging from 6 to 100 ppm, and a control were triplicated. Test containers were 1-L glass beakers, each of which contained 900 ml of filtered, natural seawater.

Each test container was inoculated with an estimated 24,100 embryos within 1 hour after fertilization and then placed into a temperature - controlled water bath. After 48 hours of exposure the larvae from each container were collected into a bottle with 24 ml of filtered sea water and preserved with 1 ml of neutralized formalin.

B. Statistical Analysis

Percentage reduction of normal embryos was determined as follows:

$$\% \text{ Reduction} = \frac{\text{No. of normal 48-hr control larvae} - \text{No. of normal 48-hr larvae in each test conc.}}{\text{No. of normal 48-hr control larvae}} \times 100$$

Each test concentration was converted to a logarithm and the corresponding percentage reduction of normal larvae was converted to a probit (Finney, 1971). The 48-hour EC₅₀ and the 95% confidence limits were then calculated by linear regression.

C. Discussion/Results

The calculated 48-hour EC₅₀ for embryos-larvae of eastern oysters exposed to technical MON-8000 in static, unaerated seawater was 20 ppm with 95% confidence limits of 13-29 ppm. There appeared to be no significant reduction of embryos-larvae which developed normally to the straight-hinged veliger stage in 6 ppm or 12 ppm, but a significant reduction of normal larvae did appear to occur in concentrations \geq 25 ppm.

280

Measured concentrations of dissolved oxygen remained > 78% of saturation and the pH was from 7.5 - 7.8 in all treatments and the control after 48 hours of exposure.

10. REVIEWER'S EVALUATION

A. Test Procedure

The report does not contain the raw mortality data, only the number of normal larvae mean, standard deviation, and reduction of normal 48-hour larvae in percent.

B. Statistical Analysis

Due to the lack of sufficient data the EC₅₀ was not verified.


C. Discussion/Results

The study is scientifically sound. However, the raw mortality was not provided with the study.

D. Conclusion

1. Category - Supplemental
2. Rational - There are no guideline requirements for studies on the formulated product and the study did not provide the raw mortality data.
3. Repairability - The study can not be given a higher category because the formulated product was tested.

DATA EVALUATION RECORD

1. CHEMICAL: Polado® (formulated product)
2. FORMULATION: Trisodium diglyphosate - 75% 
3. CITATION: Ward, G.S. 1981. Acute toxicity of technical MON-8000 to fiddler crabs (Uca pugilator), EG&G Bionomics, Project Number L95, Report Number BP-81-5-77, Submitted by Monsanto Co. EPA Reg. No. 524-332, CDL 245326, on 6-25-81
4. REVIEWED BY: Dennis J. McLane
Biologist
EEB/HED
5. DATE REVIEWED: 7-15-81
6. TEST TYPE: Ninety-six hour LC50-Fiddler crab
7. REPORTED RESULTS: Effect criterion: Mortality
96-hour LC50: Not determined
95% confidence limits: Not determined
No-observed-effect concentration: 1000 mg/l
8. REVIEWER'S CONCLUSIONS: This study is scientifically sound and indicates that Polado® is practically non-toxic to crabs.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

9. MATERIALS AND METHODS

A. Test Procedure

The test was conducted in 19-L uncovered glass jars, each of which contained a final volume of 15 L. Three crabs were tested per jar and treatments were quadruplicated. There was no aeration. Animal loading was approximately 0.24g of crab tissue per L of test solution. Crabs were not fed during the test. Three tests were run, one range-finding and 2 definitive. The concentrations used for the range-finding were 1, 10, 100, and 1000 mg/l ; for the first definitive study they were 0, 130, 220, 360, 600, and 1000 mg/l and for the second they were 0, and 1000 mg/l.

Survival of crabs in the control and the test concentration was recorded at 24-hour intervals. After approximately 24, 48, 72, and 96 hours of testing, the DO concentration was measured in each test container. The pH was measured in Replicate A of each treatment at 0, 24, 48, 72, and 96 hours of testing. The salinity and temperature were measured daily in Replicate A of the control.

B. Statistical Analysis

Statistical procedures for calculating the LC50 were not discussed since the only mortality occurred at the highest level was 8%.

C. Discussion/Results

Two definitive studies were performed the first did not maintain sufficient DO concentrations. Hence a second test was run but with only at one level, 1000 mg/L. One fatality occurred after 24-hours, at this level.

10. REVIEWER'S EVALUATION

A. Test Procedure

The study failed to report the following items:

1. The length of the pre-test period.
2. The length of time the crabs were fasted before the test.
3. The second definitive test failed to retest all concentrations.

B. Statistical Analysis

Statistical procedures could not be applied to last definitive test since on one concentration was use.

C. Discussion/Results

The preferred procedure would be to rerun the complete test and not just the 1000 mg/L level. However, the study is scientifically sound.

D. Conclusion

1. Category - Supplemental
2. Rational -
 - a. No guideline requirements have been established for studies on the formulated product
 - b. This test should have been repeated completely not just the 1000 mg/l concentration.
3. Repairability - No, the technical was not tested.