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Monsanto Company
800 N. Lindbergh Boulevard
St. Louis, Missouri 63167
Phone: (314) 694-1000

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November 25, 1992

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Attention: Section 8(e) Coordinator (CAP Agreement)

This submission is pursuant to the TSCA Section 8(e) Compliance Audit Program and CAP Agreement #8ECAP-0036. This information was inadvertently overlooked as we were assembling our final submission under CAP. This study has been added to the Monsanto final report for the CAP.

The information included is characterized as follows:

Chemical Identity: Santoflex 13: N-(1,3-dimethylbutyl)-N'-phenyl-1,4-benzenediamine
Chemical CAS No.: 793248

Information/Study Type: (II,B,2,b)/Acute, Environmental

Title: Acute Toxicity of Santoflex 13 to Daphnia magna
Study Identification #: MO-92-9043

Summary of reportable adverse effects: Submitted due to a high order of toxicity in an aquatic organism.

It should be noted that environmental effects were previously reported for this material under the CAP, as shown on Appendix A.

It should be noted that this summary may not highlight all adverse effects that EPA may judge to meet TSCA 8(e) reportability.

No information in this submission is trade secret or confidential business information.

Sincerely,

J.R. Condray
Director, Regulatory Management
(314) 694-8883

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APPENDIX A

Previous environmental effect submissions under #8ECAP-0036 for Santoflex 13, CAS #793248

Acute Toxicity of Santoflex 13 to Daphnia (AB780121A)
Dynamic Toxicity of Santoflex 13 to Fatheads (AB780121B)
Acute Toxicity of Santoflex 13 to Selenastrum (BN780362)

MO 92-9043

REPORT NO.: ES-81-SS-36

JOB/PROJECT NO.: 24-000-760.32-4101444

DATE: December 30, 1981

TITLE: ACUTE TOXICITY OF SANTOFLEX® 13 TO DAPHNIA MAGNA

AUTHORS: C. Calvert, W. J. Renaudette, and W. J. Adams

ABSTRACT: The acute toxicity of Santoflex® 13 to Daphnia magna was assessed at the MIC aquatic laboratory, during two 48-hour static tests. The 48-hour EC50 value for Santoflex 13 without food is 0.77 mg/L and with food is 1.3 mg/L.

DISTRIBUTION: W. J. Adams - N1B*
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W. J. Renaudette - N1B
J. A. Ruder - B2SE
M. W. Stevens - G2WD*

*Raw Data attached

AUTHORS: C. Calvert, W. J. Renaudette, and W. J. Adams
TITLE: ACUTE TOXICITY OF SANTOFLEX® 13 TO DAPHNIA MAGNA

REPT. NO.: ES-81-SS-36
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temperature. Temperature of the control beakers was monitored at the beginning of the study. Test solutions were not aerated during the test. Ten daphnids (≤ 24 hours old) were randomly assigned to each test vessel within 30 minutes after the compound was added for a total of 30 daphnids per concentration.

Two tests were conducted. One test was performed according to standard acute testing procedures (Grueber and Adams, 1980). The other test was identical except each test vessel contained 20 mg/L of PR-11 Daphnia food. Tests were conducted with and without food to assess the effects of suspended food particles on the toxicity of Santoflex 13 to Daphnia. This information is needed prior to conducting a Daphnia Chronic study. The Daphnia food consists of a commercial trout chow (PR-11) blended and mixed with well water.

During these tests, the dissolved oxygen concentration, pH, alkalinity, and hardness, of test solutions were monitored at the initiation (control and high concentration only) and termination of the toxicity test in the high, middle, low and control test concentrations. DO was measured by the Winkler titration method (SOP #EAS-80-SOP-006). The pH was measured with a Beckman pH meter (SOP #EAS-80-SOP-007). The total hardness and alkalinity determinations were conducted according to "Standard Methods for the Examination of Water and Wastewater" (1971) (SOPs #EAS-80-SOP-008 and #EAS-80-SOP-009). A complete analysis of the well water is presented in Table 1 taken from Adams et al. (1978).

Test concentrations and corresponding percent immobilization data derived from definitive tests were used to calculate the 48-hour median effect concentrations (EC50) and 95% confidence intervals. The EC50 values were calculated using a LC50 computer program developed by Stephen et al. (1978). The EC50 is defined as the calculated nominal concentration of the test compound in dilution water which causes 50% immobilization in the test animal population at the stated exposure interval.

RESULTS

During the 48-hour toxicity tests with Santoflex 13, the pH and dissolved oxygen ranged from 7.9 to 8.40 and 5.4 mg/L to 9.0 mg/L, respectively. The average temperature was 21°C and the alkalinity and hardness ranged from 254 to 316 mg/L and 248 to 376 mg/L, (Tables 2 and 3). The water quality measurements made during these studies are considered to be normal and adequate for satisfactory static acute tests.

The 48-hour EC50 value for Santoflex 13 without food is 0.77 mg/L and with food is 1.3 mg/L (Table 4). The no effect level was 0.4 mg/L in both tests. The no effect level is the highest concentration that causes 10 percent or less immobilization. The percent immobilization which occurred at each test concentration is shown in Tables 5 and 5.

QUALITY ASSURANCE

All aspects of this study meet the recommended criteria for an acceptable test as specified in Grueber and Adams (1980). Both a control and solvent control were used in this study. No mortality was observed in either of the control sets. Results of the water quality measurements indicate all parameters measured were within the accepted guidelines for testing Daphnia magna (ASTM, 1980).

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ACUTE TOXICITY OF SANTOFLEX® 13 TO DAPHNIA MAGNA

INTRODUCTION

The purpose of this study is to determine the acute toxicity of Santoflex® 13 tested with and without food, to a common aquatic invertebrate, Daphnia magna. The use of Daphnia magna as a representative aquatic species is viewed by the scientific community (Cairns et al., 1979) as a valid means of obtaining an estimate of the toxicity of a chemical to aquatic organisms. Toxicological information together with an estimate of environmental exposure concentration can be used to evaluate the potential environmental hazard of a chemical resulting from manufacture, use and disposal. Acute Daphnia toxicity tests conducted both in the presence and absence of Daphnia food are useful in interpreting the effect of suspended solids on toxicity and identifying appropriate test concentrations for a chronic test.

SUMMARY

The acute toxicity of Santoflex 13 to Daphnia magna was assessed at the MIC aquatic laboratory in the presence and absence of food, during two 48-hour static tests. The 48-hour EC50 values are 0.77 mg/L, without food, and 1.3 mg/L with food.

MATERIALS AND METHODS

Procedures used in the acute toxicity tests closely followed those described in the MIC Environmental Assessment Method for Conducting Acute Toxicity tests with Daphnia magna (Grueber and Adams, 1980), and Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians (U.S. EPA, 1975). The Daphnia magna used in this test were cultured at the MIC aquatic laboratory and came from adults which were fed algae (Selenastrum capricornutum) daily. Daphnids known to be less than 24 hours old were separated from the adults and used for this test. Nominal concentrations were reported as milligrams of test compound per liter of dilution water (mg/L). The chemical used in these tests was obtained from P.R. Graham, Rubber Chemicals Division, Monsanto, St. Louis, Missouri. The test chemical, Santoflex 13 was received in good condition (on 4/10/80) in a glass bottle (Lot #KD 03017, NBP 1384316, P.R. Graham). The sample was labeled and logged on Notebook page 1803033. It is stored in the Environmental Assessment Group chemical storage cabinet. The tests started on 7/7/81 and was completed on 7/9/81. All raw data for this study can be found on notebook pages 2033435 and 2033436.

The static toxicity tests were conducted in 250 milliliter (mL) beakers which contained 200 mL of test solution. The dilution water used in this study was well water from St. Peters, Missouri. For each test concentration, the appropriate amount of the test compound dissolved in acetone, was pipetted into 1000 mL of dilution water, and shaken vigorously for 1 minute. This solution was then divided into three 200 mL aliquots in triplicate beakers to provide appropriate replication. The remaining 400 mL were used for 0-hour DO, pH, alkalinity and hardness determinations. A control, consisting of the same dilution water and conditions but with no test compound, was established. A solvent control was also used which contained dilution water and the same amount of acetone was used in the highest test concentration. The maximum amount of acetone used was 0.5 mL/L. All test vessels were maintained at room

TABLE 1. Average water quality characteristics of the dilution (well) water.

Characteristic	Well Water Measurement
Alkalinity (mg/l CaCO ₃)	303
Hardness (mg/l CaCO ₃)	297
pH (median)	8.10
Aluminum (mg/l Al)	0.014
Ammonia-total (mg/l N)	0.35
Ammonia-unionized (mg/l NH ₄)	0.001
Antimony (mg/l Sb)	0.006
Barium (mg/l B)	<0.035
Beryllium (mg/l Be)	0.001
Cadmium (mg/l Cd)	<0.001
Calcium (mg/l Ca)	67.0
Chloride (mg/l Cl ⁻)	54.5
Chromium (mg/l Cr)	<0.009
Cobalt (mg/l Co)	0.002
Copper (mg/l Cu)	0.005
Fluoride (mg/l F ⁻)	1.90
Iron (mg/l Fe)	0.013
Lead (mg/l Pb)	0.01
Magnesium (mg/l Mg)	2.79
Manganese (mg/l Mn)	0.001
Molybdenum (mg/l Mo)	0.005

TABLE 1. cont'd.

Characteristic	Well Water Measurement
Nickel (mg/l Ni)	0.025
Phosphorus (mg/l P)	0.006
Silicon (mg/l Si)	4.3
Silver (mg/l Ag)	<0.001
Sodium (mg/l Na)	83.2
Sulfate (mg/l SO ₄ ⁻)	175.4
Strontium (mg/l Sr)	1.30
Tin (mg/l Sn)	0.006
Titanium (mg/l Ti)	0.001
Total Organochlorine (ug/l)	<0.5
Total Organophosphorus (ug/l)	<0.05
Vanadium (mg/l V)	0.14
Zinc (mg/l Zn)	0.006

Table 2. Temperature, Dissolved Oxygen Concentrations, pH, Alkalinity, and Hardness Measurements Taken During the 48-Hour Acute Test With Santoflex® 13 Without Food.

Measurement	Conc. (mg/L)	0-Hour	48-Hour
Temperature (°C)	Control	21.5	-
D.O. (mg/L)	Control	8.7	6.4
	0.2	7.8	6.3
	0.8	8.5	5.4
	6.4	7.8	6.2
pH	Control	7.9	8.4
	0.2	8.0	8.4
	0.8	8.1	8.3
	6.4	8.1	8.4
Alkalinity (mg/L)	Control	302	272
	0.2	308	300
	0.8	258	254
	6.4	316	306
Hardness (mg/L)	Control	324	272
	0.2	320	308
	0.8	248	298
	6.4	280	330

Table 3. Temperature, Dissolved Oxygen Concentrations, pH, Alkalinity, and Hardness Measurements Taken During the 48-Hour Acute Test With Santoflex® 13 With Food.

Measurement	Conc. (mg/L)	0-Hour	48-Hour
Temperature (°C)	Control	21.5	-
D.O. (mg/L)	Control	7.9	8.6
	0.2	7.4	9.0
	0.8	8.6	8.3
	6.4	7.2	8.1
pH	Control	8.0	8.2
	0.2	8.0	8.3
	0.8	8.0	8.4
	6.4	8.1	8.4
Alkalinity (mg/L)	Control	254	326
	0.2	300	294
	0.8	282	270
	6.4	276	304
Hardness (mg/L)	Control	310	324
	0.2	312	290
	0.8	304	318
	6.4	312	376

TABLE 4. Acute toxicity of Santoflex® 13 to Daphnia magna in the absence and presence of food.

Product	24 Hours	48 Hours	No Effect Concentration at 48 Hours (mg/L)
Santoflex 13 (without food)	1.6 (1.3-2.1)	0.79 (0.70-0.91)	0.4
Santoflex 13 (with food)	1.8 (1.5-2.1)	1.3 (1.1-1.6)	0.4

TABLE 5. Concentrations tested and corresponding percent immobilization of Daphnia magna exposed to Santoflex® 13 without food.

Nominal Concentration (mg/L)	Percent Immobilization for Combined Replicates	
	24 Hours	48 Hours
Control	0	0
Solvent Control	0	0
0.2	0	3.3
0.4	0	6.7
0.8	27	40
1.6	53	100
3.2	73	100
6.4	100	100

TABLE 6. Concentrations tested and corresponding percent immobilization of Daphnia magna exposed to Santoflex® 13 with food.

Nominal Concentration (mg/L)	Percent Immobilization for Combined Replicates	
	24 Hours	48 Hours
Control	0	0
Solvent Control	0	0
0.2	0	0
0.4	0	10
0.8	10	13.3
1.6	33.3	56.7
3.2	86.7	96.7
6.4	100	100

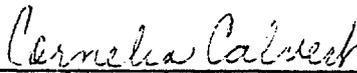
LITERATURE CITED

- Adams, W.J., W. J. Renaudette, and W.E. Gledhill, 1978. Water Quality Characteristics of the Water Supplies Used in the N-Building Environmental Laboratory Part II. Environmental Sciences Report No. ES-78-SS-22.
- American Society for Testing Materials. 1980. Standard Practice for Conducting Acute Toxicity Tests With Fishes, Macroinvertebrates, and Amphibians. ASTM Standard Practice Designation: E729-80.
- Cairns, J. Jr., K. L. Dickson and A. W. Maki, 1978. Estimating the Hazard of Chemical Substances to Aquatic Life. American Society for Testing Materials. STP 657.
- Grueber, D.J. and W. J. Adams. 1980. MIC Environmental Assessment Method for Conducting Acute Tests with Daphnia magna. Environmental Sciences Report ES-80-M-6.
- Standard Methods for the Examination of Water and Wastewater. 1971. 13th Edition, New York, 874.
- Standard Operating Procedure MIC Environmental Sciences. Dissolved Oxygen Determination - Winkler Method. 1980. Document number EAS-80-SOP-006.
- Standard Operating Procedure MIC Environmental Sciences. pH Determination 1980. Document number EAS-80-SOP-007.
- Standard Operating Procedure MIC Environmental Sciences. Alkalinity Measurement. 1980. Document number EAS-80-SOP-008.
- Standard Operating Procedure MIC Environmental Sciences. Hardness Determination in Test and Culture Water. 1980. Document number EAS-80-SOP-009.
- Stephan, C.E., K. A. Busch, R. Smith, J. Burke, and R. W. Andrews. 1978. A Computer Program for Calculating an LC50. U.S. EPA, Duluth, Minnesota, prepublication manuscript, August 1978.
- U. S. EPA. 1975. Methods for Acute Toxicity Tests with Fish, Macroinvertebrates and Amphibians. Ecological Research Series, EPA 660/3-75-009, 61 pp.

Submitted by:

Monsanto Industrial Chemicals Company
Environmental Sciences Section - N1B
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

Prepared by:

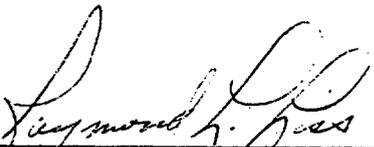


Cornelia Calvert
Research Technician



Wilfred J. Renaudette
Research Technician III

Reviewed for
Compliance With GLP:



Raymond L. Liss
Environmental Assessment Manager

Approved by:



William J. Adams
Research Group Leader



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

J. R. Condray
Director, Regulatory Management
Monsanto Agricultural Company
800 North Lindbergh Boulevard
St. Louis, Missouri 63167

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FEB 27 1995

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EPA looks forward to continued cooperation with your organization in its ongoing efforts to evaluate and manage potential risks posed by chemicals to health and the environment.

Sincerely,

Terry R. O'Bryan
Terry R. O'Bryan
Risk Analysis Branch

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 0502 INFO REQUESTED (TECU)
 0503 INFO REQUESTED (VOL ACTIONS)
 0504 INFO REQUESTED (REPORTING RATIONALE)
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CHEMICAL NAME: SantaFlex 13 CASE 793-24-8

INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C	INFORMATION TYPE:	P F C
0201 ONCO (HUMAN)	01 02 04	0216 EPICLIN	01 02 04	0241 IMMUNO (ANIMAL)	01 02 04
0202 ONCO (ANIMAL)	01 02 04	0217 HUMAN EXPOS (PROD CONTAM)	01 02 04	0242 IMMUNO (HUMAN)	01 02 04
0203 CELL TRANS (IN VITRO)	01 02 04	0218 HUMAN EXPOS (ACCIDENTAL)	01 02 04	0243 CHEM/PHYS PROP	01 02 04
0204 MUTA (IN VITRO)	01 02 04	0219 HUMAN EXPOS (MONITORING)	01 02 04	0244 CLASTO (IN VITRO)	01 02 04
0205 MUTA (IN VIVO)	01 02 04	0220 ECOAQUA TOX	01 02 04	0245 CLASTO (ANIMAL)	01 02 04
0206 REPRO/TERATO (HUMAN)	01 02 04	0221 ENV. OCCURENCE/FATE	01 02 04	0246 DNA DAM/REPAIR	01 02 04
0207 REPRO/TERATO (ANIMAL)	01 02 04	0222 EMER INCI OF ENV CONTAM	01 02 04	0247 DNA DAM/REPAIR	01 02 04
0208 NEURO (HUMAN)	01 02 04	0223 RESPONSE REQUEST DELAY	01 02 04	0248 PRODUCE/PROC	01 02 04
0209 NEURO (ANIMAL)	01 02 04	0224 PROD/CON/PROC ID	01 02 04	0251 MSDS	01 02 04
0210 ACUTE TOX. (HUMAN)	01 02 04	0225 REPORTING RATIONALE	01 02 04	0299 OTHER	01 02 04
0211 CHR. TOX. (HUMAN)	01 02 04	0226 CONFIDENTIAL	01 02 04		
0212 ACUTE TOX. (ANIMAL)	01 02 04	0227 ALLERG (HUMAN)	01 02 04		
0213 SUB CHRONIC TOX (ANIMAL)	01 02 04	0228 ALLERG (ANIMAL)	01 02 04		
0214 SUB CHRONIC TOX (ANIMAL)	01 02 04	0229 METAB/PHARMACO (ANIMAL)	01 02 04		
0215 CHRONIC TOX (ANIMAL)	01 02 04	0240 METAB/PHARMACO (HUMAN)	01 02 04		

TRIAL/DATA: NON-CBL INVENTORY **ONGOING REVIEW:** YES (DROPPED/REBER) **SPECIES:** Daphnia Magna **TOXICOLOGICAL CONCERN:** LOW

CAS SR: NO **NO (CONTINUE):** NO **MED:** HIGH

USE: _____ **PRODUCTION:** _____

1-25-92