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

JUL 15 2003

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: BPPD Evaluation of Oak Ridge National Laboratory's Scientific Review of **TRIAD** (EPA Reg. Symbol 69493-EUP-R).

FROM: Carol E. Frazer, Ph.D., Toxicologist Carol
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

THROUGH: Roger Gardner, Senior Scientist Roger Gardner 7/31/03
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511C)

Submission Contents:

- Product chemistry (MRIDs 455524-01 and -02), acute toxicity studies (MRIDs 455524-03 and -06), primary irritation studies (MRIDs 455524-04 and -05), hypersensitivity incidents (455524-07), non-target plant studies (455524-08), efficacy (MRID 455524-09) and supporting safety data (MRID 455564-01) from **TRIAD** (EPA File Symbol 69493-EUP-R), Chemical #072604; Case No. 071723; Submission #S609855; DP Barcode D283572.

- Product contents – 2.41% sodium metasilicate and 97.59% other ingredients

Action Requested

Dr. W.L. Biehn, Interregional Research Project No. 4 submitted an exemption from the requirement of a tolerance petition (2E6381) pursuant to Section 408(e) of the Federal Food, Drug and Cosmetic Act, as amended, for the biochemical pesticide sodium metasilicate, including supporting studies (MRIDs 455524-01 through -09 and 455564-01) (EPA File Symbol 69493-EUP-R).

(1)

Conclusions:

1. Of the required Tier I toxicity studies, waivers for the acute dermal toxicity study, the genotoxicity studies and the immune response study were submitted, but they were not sufficient. Using the status of the compound as "generally accepted as safe" (GRAS), is not appropriate. GRAS is limited by the FDA as "appropriate for the applied use," and the pesticidal use was not specified by the FDA. Please provide the concentrations of metasilicate used for the purposes approved by FDA.

2. CSF:
   a. The CAS No. for [redacted] which is not a CAS No.
   b. The PC codes for [redacted] need to be provided.
   c. The Supplier's Name and address for the [redacted] needs to be provided
   d. The lower limit for the a.i. is out of the approved limits, and no justification provided.

3. The Table of Contents in MRID 45552401 states that Appendix III in the report contains active ingredient information, but the MSDS is actually for [redacted] and the MSDS for the a.i. is in MRID 45552402.

4. No details are given for the [redacted] by which the a.i. is created. The units of the ingredients [redacted] sodium metasilicate, [redacted] are not given on the CSF and are assumed to be grams. No details of experimental conditions (e.g. temperatures) in (ii).

5. The registrant states that since the active ingredient sodium metasilicate is a GRAS substance, the form of unintentional ingredients is not relevant and there is no evidence that the a.i. breaks down in solution or reacts with any inerts. Since the TGAI is not a registered a.i. and a reaction occurred to make the a.i, it should be discussed if there are unreacted beginning material or side reactions.

6. The study report indicates that "determination of silicon dioxide in detergent formulations by ion chromatography" is the test to verify certified limits of the active ingredient. Details of the ion chromatography are included to determine silicon dioxide in detergent. No references are made to the product Triad. Preliminary analysis was not conducted and no explanation was provided.

7. A one-year storage study test needs to be performed, and explanation given for oxidation/reduction characteristics, explodability, and dielectric breakdown voltage which were not addressed

If these are corrected, EPA will re-evaluate the submission for acceptance.

TOXICITY PROFILE OF **TRIAD**
2.41% Sodium metasilicate

Acute oral toxicity	IV	Acceptable	MRID 455524-03
Acute dermal toxicity			Waiver requested
Acute inhalation toxicity	IV	Acceptable	MRID 455524-06
Primary eye irritation	I	Acceptable	MRID 455524-05
Primary dermal irritation	III	Acceptable	MRID 455524-04
Hypersensitivity incidents	No	Acceptable	MRID 455524-07

LABELING: No labeling will be considered until all the required data is provided.

PRODUCT CHEMISTRY OF **TRIAD** (69493-EUP)

Guideline §151-10: Product identity and disclosure of ingredients (MRID 455524-01)

The following table summarizes information submitted by the registrant regarding the active ingredient.

Chemical Name:	sodium metasilicate
CAS Registry Nos.:	6834-92-0
Synonym(s):	silicic acid, disodium salt; sodium silicate, meta anhydrous; Dry S-25
Chemical Family:	Metal oxide
Source of Biochemical:	Not a biochemical
Mode of Action:	Desiccant
Molecular Formula:	Na_2O - SiO_2

A confidential statement of formula was submitted by the registrant.

BPB's Comment: Data submitted on the product identity satisfy the requirements of 40 CFR 158.155.

Guideline §§151-11: Manufacturing process (MRID 455524-01)

In Confidential Appendix

Guideline §151-12: Discussion on the formation of unintentional ingredients (MRID 455524-01)

In Confidential Appendix

Guideline §151-13: Analysis of samples (MRID 455524-02)

(3)

In Confidential Appendix

Guideline §151-15: Certification of ingredient limits (MRID 455524-02)

In Confidential Appendix

Guideline §151-16: Analytical methods for certified limits (MRID 455524-02)

In Confidential Appendix

Guideline §151-17: Physical and Chemical Characteristics

The registrant submitted information on the physical and chemical characteristics of **TRIAD** which are summarized below:

STUDY TYPE	CHARACTERISTIC	SOURCE
Color	Brown	MRID 455524-02
Physical State	Liquid	"
Odor	Mild organic	"
pH	12.3	"
Melting point	N/A	"
Boiling point	N/A	"
Density	1.08	"
Flammability	Non-flammable	"
Solubility	N/A	"
Storage stability	Based on observations of no chemical change during blending and qualitative results from field trials over time, all indications are the formula is stable for a period greater than one year.	"
Corrosion characteristics	Non-corrosive	"
Miscibility	Readily miscible in water (requires agitation)	"

Viscosity	65/75 SUS (Saybolt Universal Seconds) @ 100 °F, 10.8/13.6 CST (centistokes) @ 40 °C	"
Vapor pressure	N/A	"

BPB's Comment: Data submitted on the physical and chemical characteristics of TRIAD does not satisfy the requirements of 40 CFR 158.190. The package is upgradable if information is provided on a one year storage stability study. Oxidation/reduction characteristics, explodability, and dielectric breakdown voltage are not addressed.

(5)

PRODUCT TOXICOLOGY FOR **TRIAD**

Acute Oral Toxicity Study (OPPTS 870.1100) (MRID 455524-03)

The oral LD_{50} for males, females, and combined was > 5,000 mg/kg. This places Triad in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE**.

Acute Inhalation Toxicity Test (OPPTS 870.1300) (MRID 455524-06)

The inhalation LC_{50} for males, females, and combined was > 2.12 mg/L. This places Triad in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

Primary Eye Irritation Test (OPPTS 870.2400) (MRID 455524-05)

Based on the presented/submitted data, corneal opacity was noted on 0/6, 6/6, 6/6, 4/6, 2/6, 2/6, 2/6, 2/6, 2/6, and 2/6 rabbits 1, 24, 48, 72 hours, and 4, 7, 10, 14, 17, and 21 days after test material instillation, respectively. Iritis was noted on 2/6, 6/6, 5/6, 2/6, and 1/6 rabbits 1, 24, 48, 72 hours and 4 days after test material instillation, respectively, with resolution by day 7. . Positive conjunctival irritation (score 2) was noted on all rabbits 24 hours after test material instillation with resolution by day 4. The maximum average score was 31.3 at 24 hours after test material instillation. Triad was severely irritating and is in TOXICITY CATEGORY I. The packet classification is **ACCEPTABLE.**

Primary Dermal Irritation Test (OPPTS 870.2500) (MRID 455524-04)

Very slight erythema with very slight edema was noted on all rabbits one hour after patch removal with clearance by day 7. The primary irritation index was 1.6. Triad was slightly irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

Skin Sensitization (OPPTS 870.2600) (MRID 455524-07)

Sodium metasilicate is classified as a GRAS substance and is cleared as a direct food ingredient. The registrant indicated that Triad did not cause any hypersensitivity or adverse effects among workers using Triad.

Target Area Phytotoxicity (OPPTS 850.4025) (MRID 455524-08)

Three field studies were conducted on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes. As part of these efficacy studies, phytotoxicity of Triad formulations to non-target plants was evaluated. The Triad 7 formulation applied at rates of 2 and 3 oz./gal. exhibited the least amount of phytotoxicity. Higher concentrations (4 and 6 oz./gal.) of Triad 7 and other formulations (Triad 9 and 12) expressed phytotoxicity and adversely impacted grape quality at harvest. When applied at 7 and 14 day

intervals, Triad 7 @ 2 oz./gal. controlled powdery mildew as well as Botrytis and Measles without indications of phytotoxicity. **Unacceptable**, but upgradable when a.i. concentrations are provided for the Triad formulations tested.

Product Performance/Efficacy (OPPTS 810.3000) (MRID 455524-09)

Three field studies on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes were conducted. Study one indicated the best treatment for controlling adult leafhoppers and nymphs consisted of the Triad 7 formulation @ 3.0 oz./gal. and Triad 7 (75%) @ 2.0 and 3.0 oz./gal. application rate. The Triad 7 formulation and application rates of 2 and 3 oz./gal. exhibited the least amount of phytotoxicity. Results for the Triad 7 formulation compared favorably with the commercial standard (dimethoate) in reducing numbers of leafhoppers and reducing feeding damage. The second study tested for Triad formulations for control of powdery mildew. Triad 7 @ 2 oz./gal. provided disease control and limited phytotoxicity. Higher concentrations of Triad 7 and other formulations expressed phytotoxicity and adversely impacted grape quality at harvest. The third study investigated various application timings of Triad 7 @ 2 oz./gal. to achieve optimum control of powdery mildew. When applied at 7 and 14-day intervals, Triad 7 @ 2 oz./gal. controlled powdery mildew as well as Botrytis and Measles without indications of phytotoxicity. **Unacceptable**, but upgradable when a.i. concentrations are provided for the Triad formulations tested.

BPB's Comment: Of the required Tier I studies for acceptance, the acute dermal toxicity study, the genotoxicity studies and the immune response study were not submitted, and the waiver requests for those studies are insufficient.

DATA EVALUATION RECORD

Reviewed by: Susan Chang, M.S., H. Tim Borges, M.Y. (A.S.C.P.), Ph.D., D.A.B.T.,Robert H. Ross, M.S.

Secondary Reviewers: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE: .....Acute Oral Toxicity - Rats (OPPTS 870.1100)
MRID NO: 45552403
TEST MATERIAL: .....Triad (EPA Reg. No. 69493-R)
PROJECT NO: 4776
SPONSOR: .....Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY: .....Product Safety Labs, East Brunswick, NJ
TITLE OF REPORT: .....Acute Oral Toxicity Limit Test
AUTHOR: .....Gary Wnorowski, B.A.
STUDY COMPLETED: .....December 2, 1996
GOOD LABORATORY PRACTICE: .....GLP Compliant
CONCLUSION: The oral LD_{50} for males, females, and combined was greater than 5000 mg/kg.
CLASSIFICATION: .....**ACCEPTABLE** -- TOXICITY CATEGORY IV

I. **STUDY DESIGN:**

1. **Test Material**: Triad

2. **Test Animals:** Five male and five female Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA and weighed 224-245 g (males) and 167-188 g (females) on the day of dosing. The young adult animals were housed individually in suspended stainless steel cages with mesh floors. Purina Rodent Chow No. 5012 was available *ad libitum* except for approximately 18 hours before dosing. Filtered tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 66-71°F and photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rats were ear-tagged (males: 5593-5597 and females: 5598-5602). The rats were quarantined for 7 days and fasted overnight prior to dosing. The test material (5000 mg/kg body weight) was dosed as received by oral gavage. Body weights were recorded prior to dosing and on days 7 and 14. The test animals were observed for clinical signs of toxicity 1 and 3 hours after dosing and at least once daily thereafter for 14 days. All animals were necropsied.

II. **RESULTS:**

1. **Mortality**: No animals died during the study.

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2. **Body Weights**: All animals had normal body weight gains.

3. **Clinical Observations:** All animals were active and healthy.

4. **Gross Necropsy:** No test material-related abnormalities were noted.

III. **DISCUSSION:** The oral LD_{50} for males, females, and combined was > 5000 mg/kg. This places Triad in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

Reviewed by: Susan Chang, M.S., H. Tim Borges, M.T. (A.S.C.P.), Ph.D., D.A.B.T., Robert H. Ross, M.S.

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE: Acute Inhalation Toxicity - Rats (OPPTS 870.1300)
MRID NO: 45552406
TEST MATERIAL: Triad (EPA Reg. No. 69493-R)
PROJECT NO: 4779
SPONSOR: Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY: Product Safety Labs, East Brunswick, NJ
TITLE OF REPORT: Acute Inhalation Toxicity Limit Test
AUTHOR: Gary Wnorowski, B.A.
STUDY COMPLETED: December 2, 1996
GOOD LABORATORY PRACTICE: GLP Compliant
CONCLUSION: The inhalation LC_{50} for males, females, and combined was > 2.12 mg/L.
CLASSIFICATION: **ACCEPTABLE** -- TOXICITY CATEGORY IV

I. **STUDY DESIGN**:

Test Material: Triad

1. **Test Animals**: Five male and five female albino Sprague-Dawley rats were received from Ace Animals, Inc., Boyertown, PA and were weighed 246-267 g (males) and 209-221 g (females) on the day of dosing. The young adult animals were housed individually in suspended stainless steel cages with mesh floors. Purina Rodent Chow No. 5012 was available and tap water was available *ad libitum*. The environmental conditions of the animal room were as follows: temperature, 69-71°F and photoperiod, 12 hour light/dark cycle.

2. **Methods**: Rats were ear-tagged (males: 5623-5627 and females: 5628-5632). The rats were quarantined for 10 days prior to exposure. Animals were assigned to the test groups noted in Table 1. The rats were exposed whole body in a perspex dynamic flow inhalation chamber for four hours and 15 minutes at a slightly negative pressure. They were observed every 30 minutes during exposure, upon removal from the chamber, and at least once daily thereafter for 14 days. They were weighed prior to test material exposure and on days 7 and 14. All rats were sacrificed and necropsied.

TABLE 1. Concentrations, exposure conditions, mortality/animals treated

Nominal Conc. (mg/L)	Grav. Conc. (mg/L)	MMAD (um)	GSD (um)	Particles ≤3.3 µm
24.08	2.12	3.8	1.67	68

(%)Temp(°F)	Humidity (%)
69-71	44-100

Mortality

Male	Female	Combined
0/5	0/5	0/10

(Data taken from pp. 9, 11, and 15-17, MRID 45552406.)

3. **Generation of the test atmosphere and description of the chamber**: The exposure atmosphere was generated by a pressure Spraying System air atomizer (1/4 inch JCO), FC4 fluid cap, and AC1502 air cap. The test material was metered to the atomization nozzle through Tygon tubing and a pump and filtered air was supplied by a compressor to the spray atomization nozzle. Filtered conditioned room air was supplied as diluent air. The average total airflow was 45.6 liters/min and the exposure chamber volume was 150 L. Oxygen content of chamber air and the number of chamber air changes were not reported. Time to equilibrium was 15 minutes.

4. **Test atmosphere concentration**: Gravimetric samples were collected with glass fiber filters at six intervals from the breathing zone of the animals. The filter papers were weighed before and after collection to determine the mass collected. The chamber concentration was determined by this value divided by the total volume of air sampled. The average results are in Table 1 above.

5. **Particle size determination**: Particle size was determined using an eight-stage Andersen cascade impactor. Samples were withdrawn from the breathing zone of the animals at two intervals. The mass collected upon each stage was determined by weight difference of the filter paper before and after sampling. The aerodynamic mass median diameter and geometric standard deviation were determined graphically using two-cycle logarithmic probit axes. Results are in Table 1 above.

II. **RESULTS**:

1. **Mortality**: No rats died during the study (Table 1).

2. **Body Weights**: All rats gained weight during the study.

3 **Clinical Observation**: During exposure, the animals showed hunched posture and hypoactivity. Upon removal from the chamber, the test material was noted on the fur. The animals were active and healthy throughout the remainder of the study.

4. **Gross Necropsy**: No test material-related abnormalities were noted from any rat.

III. **DISCUSSION**: The inhalation LC_{50} for males, females, and combined was > 2.12 mg/L. This places Triad in TOXICITY CATEGORY IV. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

Reviewed by: Susan Chang, M.S., H. Tim Borges, M.T. (A.S.C.P.), Ph.D., D.A.B.T., Robert H. Ross, M.S.

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:	Acute Eye Irritation - Rabbits (OPPTS 870.2400)
MRID NO:	45552405
TEST MATERIAL:	Triad (EPA Reg. No. 69493-R)
PROJECT NO:	4777
SPONSOR:	Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY:	Product Safety Labs, East Brunswick, NJ
TITLE OF REPORT:	Primary Eye Irritation
AUTHOR:	Gary Wnorowski, B.A.
STUDY COMPLETED:	35400
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Corneal opacity was noted on 0/6, 6/6, 6/6, 4/6, 2/6, 2/6, 2/6, 2/6, 2/6, and 2/6 rabbits 1, 24, 48, 72 hours, and 4, 7, 10, 14, 17, and 21 days after test material instillation, respectively. Iritis was noted on 2/6, 6/6, 5/6, 2/6, and 1/6 rabbits 1, 24, 48, 72 hours and 4 days after test material instillation, respectively, with resolution by day 7. Positive conjunctival irritation was noted on all rabbits 24 hours after test material instillation with resolution by day 4. The maximum average score was 31.3 at 24 hours after test material instillation. Triad was severely irritating.
CLASSIFICATION:	ACCEPTABLE -- TOXICITY CATEGORY I

I. **STUDY DESIGN:**

1. **Test Material:** Triad

2. **Test Animals:** Three male and three female New Zealand White rabbits were received from Davidson's Mill Farm, South Brunswick, NJ. The adult animals were housed individually in suspended stainless steel cages with mesh floors. Pelleted Purina Rabbit chow No. 5326 and filtered tap water (*ad libitum*) were available. The environmental conditions of the animal room were as follows: temperature, 67-71°F and photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rabbits were ear-tagged: 0738 to 0743 (males and females). The rabbits were quarantined for 13 days. The test material (0.1 mL/eye/animal) was applied in the conjunctival sac of the right eye, and the eye held closed for one second. The contralateral eye served as control. The eyes were examined and scored 1, 24, 48 and 72 hours and 4, 7, 10, 14, 17, and 21 days after test material instillation.

II. RESULTS:

1. **Mortality:** No animals died during the study.

2. **Ocular Lesions:** Corneal opacity was noted on all rabbits 24 hours after test material instillation with resolution on two rabbits (Nos. 0739 and 0740) by 72 hours and on two rabbits (Nos. 0742 and 0743) by day 4, but persisted on two rabbits (Nos. 0738 and 0741) through the end of the study (Table 1). Iritis was noted on 2/6, 6/6, 5/6, 2/6, and 1/6 rabbits 1, 24, 48, 72 hours and 4 days after test material instillation, respectively, with resolution by day 7 (Table 2). Positive conjunctival irritation (score 2) was noted on all rabbits 24 hours after test material instillation with resolution by day 4. The maximum average score was 31.3 at 24 hours after test material instillation (Table 3).

TABLE 1. Individual Male (M) and Female (F) Eye Scores w/ Time: Cornea (A=Density of Opacity, B=Area of Opacity)

Animal No.	1 hour		24 hours		48 hours		72 hours		4 days		7 days		10 days		14 days		17 days		21 days	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B
0738	0	4	1	4	1	4	1	2	1	2	1	2	1	2	1	2	1	1	1	1
0739	0	4	1	2	1	1	0	4	0	4	0	4	0	4	0	4	0	4	0	4
0740	0	4	1	2	1	1	0	4	0	4	0	4	0	4	0	4	0	4	0	4
0741	0	4	1	4	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1
0742	0	4	1	2	1	2	1	1	0	4	0	4	0	4	0	4	0	4	0	4
0743	0	4	1	2	1	2	1	1	0	4	0	4	0	4	0	4	0	4	0	4

TABLE 2. Summary of Eye Irritation Scores with Time: Conjunctiva and Iris										
Score Conditions	1 hour	24 hours	48 hours	72 hours	4 days	7 days	10 days	14 days	17 days	21 days
Conjunctiva										
Hyperemia	37257	37289	37257	0	0	0	0	0	0	0
Chemosis	37257	37257	37257	0	0	0	0	0	0	0
Discharge	37289	37258	0	0	0	0	0	0	0	0
Iris	2	6	5	2	1	0	0	0	0	0

Irritation score is based on Draize Method

Scale for Scoring Ocular Lesions

Cornea

A. **Opacity-degree of density (area most dense taken for reading)**
   - No Opacity 0
   - Scattered or diffuse area, details of iris clearly visible
   - Easily discernible translucent areas, details of iris slightly obscured 2
   - Opalescent areas, no details of iris visible, size of pupil barely discernible 3
   - Opaque, iris invisible 4

B. **Area of cornea involved**
   - One quarter (or less) but not zero 1
   - Greater than one quarter, but less than half 2
   - Greater than half, but less than three quarters 3
   - Greater than three quarters, up to whole area 4

Score = A x B x 5 **Total Maximum Score = 80**

Iris

A. **Values**
   - Normal 0
   - Folds above normal, congestion, swelling, circumcorneal injection (any or all of these or combination of any thereof), iris still reacting to light (sluggish reaction is positive) 1
   - No reaction to light, hemorrhage, gross destruction (any or all of these) 2

Score = A x 5 **Total Maximum Score = 10**

Conjunctivae

A. **Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)**
   - Vessels normal 0
   - Vessels definitely injected above normal 1
   - More diffuse, deeper crimson red, individual vessels not easily discernible 2
   - Diffuse beefy red 3

B. **Chemosis**
   - No swelling 0
   - Any swelling above normal (includes nictitating membrane) 1
   - Obvious swelling with partial eversion of lids 2
   - Swelling with lids about half closed 3
   - Swelling with lids about half closed to completely closed 4

C. **Discharge**

No discharge 0

Any amount different from normal (does not include small amounts observed in inner canthus of normal animals) 1

Discharge with moistening of the lids and hairs just adjacent to lids 2

Discharge with moistening of the lids and hairs, and considerable area around the eye 3

Score = (A + B + C) x 2 **Total Maximum Score = 20**

TABLE 3. *Summary of Total[a] and Primary Eye Irritation Scores with Time*

Animal #	1 h	24 h	48 h	72 h	4 d	7 d	10 d	14 d	17 d	10 d
738	17	39	39	27	21	10	10	10	5	5
739	14	27	11	2	0	0	0	0	0	0
740	8	25	14	2	0	0	0	0	0	0
741	15	37	34	18	7	5	5	5	5	5
742	8	29	25	11	0	0	0	0	0	0
743	10	31	29	13	2	0	0	0	0	0
[b]Total	12	31.3	25.3	12.2	5	2.5	2.5	2.5	1.7	1.7

[a]Formula: Total Irritation Score = I + II + III, where,

I = Corneal Score = [Density (A) x Area (B)] x 5

II = Iris Score = Severity x 5

III = Conjunctival Score = [Hyperemia (A) + Chemosis (B) + Discharge (C)] x 2

[b]Primary Irritation = Sum of Total Irritation Scores ÷ 6

III. **DISCUSSION:** Based on the presented/submitted data, corneal opacity was noted on 0/6, 6/6, 6/6, 4/6, 2/6, 2/6, 2/6, 2/6, 2/6, and 2/6 rabbits 1, 24, 48, 72 hours, and 4, 7, 10, 14, 17, and 21 days after test material instillation, respectively. Iritis was noted on 2/6, 6/6, 5/6, 2/6, and 1/6 rabbits 1, 24, 48, 72 hours and 4 days after test material instillation, respectively, with resolution by day 7. Positive conjunctival irritation (score 2) was noted on all rabbits 24 hours after test material instillation with resolution by day 4. The maximum average score was 31.3 at 24 hours after test material instillation. Triad was severely irritating and is in TOXICITY CATEGORY I. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

Reviewed by: Susan Chang, M.S., H. Tim Borges, M.T. (A.S.C.P.), Ph.D., D.A.B.T., Robert H. Ross, M.S.

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:	Primary Dermal Irritation - Rabbits (OPPTS 870.2500)
MRID NO:	45552404
TEST MATERIAL:	Triad (EPA Reg. No. 69493-R)
PROJECT NO:	4778
SPONSOR:	Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY:	Product Safety Labs, East Brunswick, NJ
TITLE OF REPORT:	Primary Skin Irritation
AUTHOR:	Gary Wnorowski, B.A.
STUDY COMPLETED:	35400
GOOD LABORATORY PRACTICE:	GLP Compliant
CONCLUSION:	Very slight to well defined erythema with very slight edema was noted on all rabbits one hour after patch removal with clearance by day 7. The primary irritation index was 1.6. Triad was slightly irritating.
CLASSIFICATION:	**ACCEPTABLE** -- TOXICITY CATEGORY III

I. STUDY DESIGN:

1. Test Material: Triad

2. **Test Animals:** Two male and four female New Zealand White rabbits were received from Davidson's Mill Farm, South Brunswick, NJ. The adult animals were housed individually in suspended stainless steel cages with mesh floors. Pelleted Purina Rabbit chow No. 5326 and filtered tap water (*ad libitum*) were available. The environmental conditions of the animal room were as follows: temperature, 68-74°F and photoperiod, 12 hour light/dark cycle.

3. **Methods:** Rabbits were ear-tagged: 0687 and 0691 (males) and 0686 and 0688 to 0690 (females). The rabbits were quarantined for 22 or 28 days. On the day before treatment, the fur was clipped on the dorsal area and the trunk of each rabbit. The rabbits were given a single 0.5 mL dose of test material applied to a 6 cm^2 clipped area that was covered with gauze pad. The pad and the trunk were wrapped with semi-occlusive tape. Elizabethan collars were placed on each rabbit. The covering and the collar were removed 4 hours later and the site wiped with water and a towel to remove any residual test material. Dermal examination was recorded at 1, 24, 48, and 72 hours and on day 7 after removal of the patch.

II. RESULTS:

1. **Mortality:** All rabbits survived the study.

2. **Dermal responses.:** Very slight to well defined erythema was noted on all rabbits one hour after patch removal that persisted or reduced to very slight on all rabbits through 24 hours (Table 1). By 72 hours, four rabbits (Nos. 0686, 0688 to 0690) had very slight erythema. Very slight edema was noted on all rabbits one hour after patch removal that persisted on two rabbits (Nos. 0687 and 0689) through 24 hours, on two rabbits (Nos. 0686 and 0688) through 48 hours, and on one rabbit (No. 0690) through 72 hours. The dermal irritation cleared by day 7. The primary irritation index was 1.6.

3. **Irritation Scores:**

TABLE 1. Summary of individual rabbit's dermal irritation scores with time

		Hours				Days
Animal No.		1	24	48	72	7
F	686	2/1 [a]	37256	37256	37255	0
M	687	36891	37256	0	0	0
F	688	37287	37287	37256	37255	0
F	689	37256	36891	37255	37255	0
F	690	37256	37256	37256	37256	0
M	691	37256	37255	37255	0	0

Data taken from Table 1, p. 12, MRID 45552404.
[a]Erythema/Edema

Description of rating method:

Evaluation of Skin Reaction

Erythema formation:	Score
No erythema	0

Very slight erythema (barely perceptible) 1
Well-defined erythema
Moderate to severe erythema 2
Severe erythema (beet redness) to slight eschar formation (injuries in depth) 3
. 4

Edema Formation

No edema 0
Very slight edema (barely perceptible) 1
Slight edema (edges of area well-defined by definite raising) 2
Moderate edema (raised approximately 1 mm) 3
Severe edema (raised by more than 1 mm extending beyond the area of exposure) 4

III. DISCUSSION:

Very slight erythema with very slight edema was noted on all rabbits one hour after patch removal with clearance by day 7. The primary irritation index was 1.6. Triad was slightly irritating and is in TOXICITY CATEGORY III. The packet classification is **ACCEPTABLE.**

DATA EVALUATION RECORD

Reviewed by: Susan Chang, M.S., H. Tim Borges, M.T. (A.S.C.P.), Ph.D., D.A.B.T., Robert H. Ross, M.S.

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE: ..... Skin Sensitization (OPPTS 870.2600)
MRID NO: 45552407
TEST MATERIAL: ..... Triad (EPA Reg. No. 69493-R)
PROJECT NO: ..... IR-4 PR No. 88B
SPONSOR: ..... Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY: ..... Environmentally Safe Systems, Inc., Solvang, CA
TITLE OF REPORT: ..... Sodium metasilicate (Triad), Hypersensitivity Incidents
AUTHOR: ..... Erik DeWeese Black
STUDY COMPLETED: ..... August 23, 2001
GOOD LABORATORY PRACTICE: ..... Not GLP Compliant
CONCLUSION:

Sodium metasilicate is classified as a GRAS substance and is cleared as a direct food ingredient. The registrant indicated that Triad did not cause any hypersensitivity or adverse effects among workers using Triad.

CLASSIFICATION: ..... N/A

I. **STUDY DESIGN:**

Test Material: Triad

Test Animals: Not applicable

Methods: Not applicable

4.—**RESULTS:**

Mortality: Not applicable

Body Weights: Not applicable

Skin Effects: Not applicable

III. **DISCUSSION:** Sodium metasilicate is classified as a GRAS substance and is cleared as a direct food ingredient. The registrant indicated that Triad did not cause any hypersensitivity or adverse effects among workers using Triad.

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DATA EVALUATION RECORD

Reviewed by: Anthony Q. Armstrong, M.S., Eric B. Lewis, M.S., Robert H. Ross, M.S.

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:	Target Area Phytotoxicity (OPPTS 850.4025)
MRID NO:	45552408
TEST MATERIAL:	Triad
PROJECT NO:	IR-4 PR No. 88B
SPONSOR:	Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY:	Environmentally Safe Systems, Inc., Solvang, CA
TITLE OF REPORT:	Sodium Metasilicate Plant Studies
AUTHOR:	Erik DeWeese Black
STUDY COMPLETED:	November 12, 2001
GOOD LABORATORY PRACTICE:	Not GLP Compliant
CONCLUSION:	Three field studies were conducted on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes. As part of these efficacy studies, phytotoxicity of Triad formulations to non-target plants was evaluated. The Triad 7 formulation applied at rates of 2 and 3 oz./gal. exhibited the least amount of phytotoxicity. Higher concentrations (4 and 6 oz./gal.) of Triad 7 and other formulations (Triad 9 and 12) expressed phytotoxicity and adversely impacted grape quality at harvest. When applied at 7 and 14 day intervals, Triad 7 @ 2 oz./gal. controlled powdery mildew as well as Botrytis and Measles without indications of phytotoxicity.
CLASSIFICATION:	Unacceptable, but upgradable when a.i. concentrations are provided for the Triad formulations tested.

TEST MATERIAL: Triad 1, 7, 9 and 12 (sodium metasilicate, a.i.)

METHODS and RESULTS: Three field studies on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes were conducted in California. In addition, data on phytotoxicity to plants was collected during these efficacy studies. The data presented in this study report (MRID # 45552408) is identical to data presented in MRID # 4552409. Only data related to phytotoxicity results will be described below.

Efficacy Field Study of Triad Formulations for Leafhoppers

Field study one was a dose/response study which consisted of commercial applications of Triad 1, Triad 7 and Triad 7 (75%) @ 1, 2 and 3 oz./gal. application rates. These formulations were applied to replicates of three vines (16ft x 12ft) in a vineyard where grapes were produced for Chardonnay wine. Each formulation and concentration was applied to four plots. Treatments were applied every 14 days until study termination after the third treatment. Untreated control and positive control (dimethoate treated) plots were also maintained. The vines were evaluated for insect presence, feeding damage and phytotoxicity. Leafhopper nymphs and adult counts were determined by inspecting 25 leaves per plot. Feeding damage was assessed by inspecting 25 leaves from the center vine of each plot. Phytotoxicity was rated based on appearance of leaves or grapes when compared to the untreated control. Statistical analyses of results were performed using Duncan's multiple range test.

Triad phytotoxicity to leaves and grapes was not evident in this field trial due to the low application rates (1, 2 and 3 oz./gal.) and the formulations tested. Previously conducted preliminary field studies indicated phytotoxicity at application rates greater than 4 oz./gal. and with different Triad formulations.

Efficacy Field Study of Triad for Powdery Mildew

Field study two was a dose/response study which consisted of commercial applications of Triad 1, Triad 7, Triad 9 and Triad 12 at various application rates for the control of powdery mildew. These formulations were applied to replicates of three vines (24ft x 12ft) in a vineyard where grapes were produced for Chardonnay wine. Each formulation and concentration was applied to four plots. Treatments were applied when shoots were 6 and 18 inches, pre-bloom, bloom, bloom+14 days, bloom +28 days, bunch closure and veraison. Untreated control and positive control (growers standard of Rally, Rubigan, Abound and Thiolux treated) plots were also maintained. Powdery mildew presence and disease severity were determined by inspecting 25 leaves per plot. A disease severity scale was established based on the size of the diseased area of the plant. Phytotoxicity was rated based on appearance of leaves or grapes when compared to the untreated control. Observations for phytotoxicity effects and preharvest evaluation of % marketable grapes were conducted. Statistical analyses of results were performed using Duncan's multiple range test.

Results indicate that after the second application (applied when shoots were 18 inches) of Triad 1 @ 2, 4 and 6 oz./gal. undesirable phytotoxicity of the plants was observed. More severe signs

of phytotoxicity were observed at higher application rates (4 and 6 oz./gal.). The young leaf tips were stunted and burned and application at the 6 oz./gal. rate was discontinued. For the remainder of this field study, only Triad application rates of less than 2 oz./gal. did not exhibit phytotoxic effects.

Efficacy Field Study of Triad for Powdery Mildew - Timing Evaluation

Field study three consisted of a commercial application of Triad 1 @ 2 oz./gal. applied in single doses at either 7, 14 or 21 day intervals to control powdery mildew. These formulations were applied to replicates of four vines (24ft x 12ft) in a vineyard where grapes were produced for Chardonnay wine. Each formulation and concentration was applied to four plots. Untreated control and positive control (growers standard of Rally, Rubigan, Abound and Thiolux treated) plots were also maintained. Powdery mildew presence and disease severity were determined by inspecting 30 clusters and 50 leaves per plot. Disease incidence was determined by calculating the number of leaves or clusters with powdery mildew out of the 30 or 50 examined. A disease severity scale was established based on the size of the diseased area of the plant. Statistical analyses of results were performed using Duncan's multiple range test.

Results indicate that Triad 1 @ 2 oz./gal. applied at 7 and 14 day intervals performed well during the entire trial up until harvest, ending at veraison. Applications at 21-day intervals showed no effect on powdery mildew until after the second scheduled application at which time disease tapered off and remained absent until harvest. No signs of phytotoxicity were observed in applications of Triad 1 @ 2 oz./gal. tested at various timing regimes.

DISCUSSION: The field studies of Triad demonstrate adverse toxic effects to grape vines when applied at rates of 4 oz./gal. or greater. Phytotoxic effects were not observed at application rates of 2 or less oz./gal. Additional testing of Triad 1 and 7 to optimize application rates and application timing may enhance effectiveness and reduce phytotoxicity. One deficiency noted is that the concentration of the a.i. (sodium metasilicate) was not provided in the study report for the different Triad formulations (Triad 1,7,9, and 12). This information is required.

The packet classification is **UNACCEPTABLE** but upgradable provided concentrations of the a.i. in the Triad formulations is provided.

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DATA EVALUATION RECORD

Reviewed by: Anthony Q. Armstrong, M.S., Eric B. Lewis, M.W., Robert H. Ross, M.S.
Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:	Product Performance/Efficacy (OPPTS 810.3000)
MRID NO:	45552409
TEST MATERIAL:	Triad (EPA Reg No. 69493-R)
PROJECT NO:	IR-4 PR No. 88B
SPONSOR:	Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY:	Environmentally Safe Systems, Inc., Solvang, CA
TITLE OF REPORT:	Sodium metasilicate (TRIAD) Performance Data
AUTHOR:	Erik DeWeese Black
STUDY COMPLETED:	November 12, 2001
GOOD LABORATORY PRACTICE:	Not GLP Compliant

CONCLUSION: Three field studies on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes were conducted. Study one indicated the best treatment for controlling adult leafhoppers and nymphs consisted of the Triad 7 formulation @ 3.0 oz./gal. and Triad 7 (75%) @ 2.0 and 3.0 oz./gal. application rate. The Triad 7 formulation and application rates of 2 and 3 oz./gal. exhibited the least amount of phytotoxicity. Results for the Triad 7 formulation compared favorably with the commercial standard (dimethoate) in reducing numbers of leafhoppers and reducing feeding damage. The second study tested for Triad formulations for control of powdery mildew. Triad 7 @ 2 oz./gal. provided disease control and limited phytotoxicity. Higher concentrations of Triad 7 and other formulations expressed phytotoxicity and adversely impacted grape quality at harvest. The third study investigated various application timings of Triad 7 @ 2 oz./gal. to achieve optimum control of powdery mildew. When applied at 7 and 14-day intervals, Triad 7 @ 2 oz./gal. controlled powdery mildew as well as Botrytis and Measles without indications of phytotoxicity.

CLASSIFICATION: Unacceptable, but upgradable when a.i. concentrations are provided for the Triad formulations tested.

TEST MATERIAL: Triad 1, 7, 9 and 12 (sodium metasilicate, a.i.)

METHODS and RESULTS: Three field studies on the efficacy of Triad to control leafhoppers and powdery mildew on Chardonnay grape vines and grapes were conducted in California. Each study will be described below.

Efficacy Field Study of Triad Formulations for Leafhoppers

Field study one was a dose/response study which consisted of commercial applications of Triad 1, Triad 7 and Triad 7 (75%) @ 1, 2 and 3 oz./gal. application rates. These formulations were applied to replicates of three vines (16ft x 12ft) in a vineyard where grapes were produced for Chardonnay wine. Each formulation and concentration was applied to four plots. Treatments were applied every 14 days until study termination after the third treatment. Untreated control and positive control (dimethoate treated) plots were also maintained. The vines were evaluated for insect presence, feeding damage and phytotoxicity. Leafhopper nymphs and adult counts were determined by inspecting 25 leaves per plot. Feeding damage was assessed by inspecting 25 leaves from the center vine of each plot. Phytotoxicity was rated based on appearance of leaves or grapes when compared to the untreated control. Statistical analyses of results were performed using Duncan's multiple range test.

Observations seven days after the initial application indicated significant reductions in feeding damage with the Triad 7 @ 2.0 and 3.0 oz./gal. treatments and all rates of the Triad 7 (75%) formulation. Within seven days after application #2, increasing numbers of leafhopper nymphs appeared in the treated and untreated plots. The 3 oz./gal. rates of all Triad formulations were significantly superior to the untreated control and similar to the positive control in controlling feeding damage. The best treatments for reducing feeding damage were all three application rates of Triad 7 (75%). Within two days of application #3, the nymph population declined while the adult population remained steady. Control of nymphs and adults by all three Triad formulations @ 3.0 oz./gal. was significantly better than the untreated control and equal to the positive control (dimethoate). Triad 7 and 7 (75%) @ 3 oz./gal. and the positive control provided the best reduction of feeding damage. The seven day evaluation after application #3 indicated no changes in the level of control when compared to data after application #2. Overall, all three Triad formulations @ 3.0 oz./gal. and Triad 7 (75%) @ 2.0 oz./gal. compared favorably to the positive control.

Efficacy Field Study of Triad for Powdery Mildew

Field study two was a dose/response study which consisted of commercial applications of Triad 1, Triad 7, Triad 9 and Triad 12 at various application rates for the control of powdery mildew. These formulations were applied to replicates of three vines (24ft x 12ft) in a vineyard where grapes were produced for Chardonnay wine. Each formulation and concentration was applied to four plots. Treatments were applied when shoots were 6 and 18 inches, pre-bloom, bloom, bloom+14 days, bloom +28 days, bunch closure and veraison. Untreated control and positive control (growers standard of Rally, Rubigan, Abound and Thiolux treated) plots were also maintained. Powdery mildew presence and disease severity were determined by inspecting 25 leaves per plot. A disease severity scale was established based on the size of the diseased area of the plant. Phytotoxicity was rated based on appearance of leaves or grapes when compared to the untreated control. Observations for phytotoxicity and preharvest evaluation of % marketable grapes were conducted. Statistical analyses of results were performed using Duncan's multiple range test.

Results indicate that Triad 1 @ 2 oz./gal. provided the most consistent and safest control of powdery mildew when compared to other formulations of Triad and the positive control. Triad 1 @ 4 oz./gal. provided good control but exhibited adverse effects at harvest when compared to grapes from the 2 oz./gal. treatment group. Triad 7 @ 4 oz./gal. indicated plant development problems such as stunting. Triad 7 @ 2 oz./gal. provided adequate control of powdery mildew and no adverse phytotoxicity when compared to other Triad treatments and the positive control. Further testing of Triad 1 and 7 formulations to refine dosage and application timing may enhance efficacy and limit phytotoxicity.

Efficacy Field Study of Triad for Powdery Mildew - Timing Evaluation

Field study three consisted of a commercial application of Triad 1 @ 2 oz./gal. applied in single doses at either 7, 14 or 21 day intervals to control powdery mildew. These formulations were applied to replicates of four vines (24ft x 12ft) in a vineyard where grapes were produced for

Chardonnay wine. Each formulation and concentration was applied to four plots. Untreated control and positive control (growers standard of Rally, Rubigan, Abound and Thiolux treated) plots were also maintained. Powdery mildew presence and disease severity were determined by inspecting 30 clusters and 50 leaves per plot. Disease incidence was determined by calculating the number of leaves or clusters with powdery mildew out of the 30 or 50 examined. A disease severity scale was established based on the size of the diseased area of the plant. Statistical analyses of results were performed using Duncan's multiple range test.

Results indicate that Triad 1 @ 2 oz./gal. applied at 7 and 14 day intervals performed well during the entire trial up until harvest, ending at veraison. Triad 1 applications at 21-day intervals showed no effect on powdery mildew until after the second scheduled application at which time disease tapered off and remained absent until harvest. Powdery mildew, Botrytis and Measles symptoms were not observed at harvest in any of the Triad-1 treatments or positive control. All Triad 1 treatments and the positive control controlled powdery mildew equally well up to harvest.

DISCUSSION: The field studies of Triad demonstrate effectiveness in controlling leafhoppers and powdery mildew in grape vines. Additional testing of Triad 1 and 7 to optimize application rates and application timing may enhance effectiveness and reduce phytotoxicity. One deficiency noted is that the concentration of the a.i. (sodium metasilicate) was not provided in the study report for the different Triad formulations (Triad 1,7,9, and 12). This information is required.

The packet classification is **UNACCEPTABLE** but upgradable provided concentrations of the a.i. in the Triad formulations is provided.

[illegible] NOT INCLUDED

DATA EVALUATION RECORD

Reviewed by: Toxicology and Hazard Assessment Group, Life Sciences Division, Oak Ridge National Laboratory

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:
Product Identity and Composition (OPPTS 830.1550)
Description of Beginning Materials (OPPTS 830.1600)
Description of Formulation Process (OPPTS 830.1650)
Discussion of Formation of Impurities (OPPTS 830.1670)
MRID NO: 45552401
TEST MATERIAL: Triad (EPA Reg No. 69493-R; 2.41% by weight sodium metasilicate,a.i.)
PROJECT NO: IR-4 PR No. 88B
SPONSOR: Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY: Environmentally Safe Systems, Inc., Solvang, CA
TITLE OF REPORT: Sodium metasilicate (TRIAD). Product Identity and Disclosure of Ingredients, Manufacturing Process and Discussion on the Formation of Unintentional Ingredients
AUTHOR: Erik DeWeese Black
STUDY COMPLETED: August 23, 2001
GOOD LABORATORY PRACTICE: Not GLP Compliant
CONCLUSION: ESF-1 (Triad, a proposed trade name, EPA Reg. No. 69493-R) is an end-use product (EP) and a biological pesticide. The product is for experimental use only. The active ingredient is 2.41% by weight sodium metasilicate and the inerts are [redacted]

CLASSIFICATION: UNACCEPTABLE, but upgradable upon providing additional details of the manufacturing process and the PC codes for all inerts and correct CAS No. for [redacted] In addition, impurity formation needs to be discussed adequately.

Test Material: Triad (2.41% by weight sodium metasilicate, a.i.)

I. **PRODUCT IDENTITY AND COMPOSITION:** ESF-1 (Triad, a proposed trade name, EPA Reg. No. 69493-R) is an end-use product (EP) and used as a foliar spray to control or suppress leafhoppers and to suppress powdery mildew for almonds, apricots, broccoli, brussel sprouts, cabbage, cauliflower, celery, citrus, lettuce, grapes, nectarines, peaches, plums, spinach, and ornamentals. The product is for experimental use only. The active ingredient is 2.41% by weight sodium metasilicate (CAS No. 6834-92-0, PC code 072604).

[redacted]

Deficiencies: The CSF listed the CAS No. for [redacted] as 1-20-93 which is not a CAS No. The PC codes for [redacted] The Supplier's Name and address for the [redacted] also needs to be provided

II. **DESCRIPTION OF BEGINNING MATERIALS:** The beginning materials used to produce the product as indicated in the study report are [redacted]. The MSDSs of the inerts are included in the study report (MRID 45552401), but the MSDS of the a.i. is included in MRID 45552402.

Deficiencies: The Table of Contents in MRID 45552401 states that Appendix III in the report contains active ingredient information, but the MSDS is actually for [redacted] for the a.i. is in MRID 45552402.

II. **DESCRIPTION OF FORMULATION PROCESS**

[redacted]

[redacted]

IV. DISCUSSION OF FORMATION OF IMPURITIES: The registrant states that since the active ingredient sodium metasilicate is a GRAS substance, the form of unintentional ingredients is not relevant and there is no evidence that the a.i. breaks down in solution or reacts with any inerts. Since the TGAI is not a registered a.i. and a reaction occurred to make the a.i, it should be discussed if there are unreacted beginning material or side reactions.

V. DISCUSSION The product identity and composition, description of beginning materials, description of production process, and discussion of formation of impurities of the EP ESF-1 (Triad, a proposed trade name, EPA Reg No. 69493-R) are addressed in MRID 45552401, the product label, and the CSF. The product is for experimental use only. The active ingredient is 2.41% by weight sodium metasilicate and the inerts are [redacted]

The manufacturing process as given in the study report inadequately describes the production of the a.i. or the formulation of a.i. and inerts to make the EP. Impurity formation is not adequately discussed.

The packet classification is **UNACCEPTABLE,** but upgradable upon providing additional details of the manufacturing process and the PC codes for all inerts and correct CAS No. for [redacted] The Supplier of the [redacted] used for formulation of the product must be identified more completely and an address provided. In addition, impurity formation needs to be discussed adequately.

DATA EVALUATION REPORT

Reviewed by: **Toxicology and Hazard Assessment Group, Life Sciences Division. Oak Ridge National Laboratory**

Secondary Reviewer: Carol E. Frazer, Ph.D., Roger Gardner

STUDY TYPE:
Preliminary Analysis (OPPTS 830.1700)
Certified Limits (OPPTS 830.1750)
Enforcement Analytical Method (OPPTS 830.1800)
Physical/Chemical Characteristics (OPPTS 830.6302-830.7950)
MRID NO: 45552402
TEST MATERIAL: Triad (EPA Reg No. 69493-R; 2.41% by weight sodium metasilicate, a.i.)
PROJECT NO: IR-4 PR No. 88B
SPONSOR: Environmentally Safe Systems, Inc., Solvang, CA
TESTING FACILITY: Environmentally Safe Systems, Inc., Solvang, CA
TITLE OF REPORT: Sodium metasilicate (TRIAD). Analysis of Samples, Certification of Ingredient Limits and Analytical Methods for Certified Limits and Physical and Chemical Properties
AUTHOR: Erik DeWeese Black
STUDY COMPLETED: August 23, 2001
GOOD LABORATORY PRACTICE: Not GLP Compliant
CONCLUSION: For the EP Triad (2.41% sodium metasilicate, a.i.), the upper certified limit is within guidelines proposed in OPPTS 830.1750 and 40 CFR 158.175, but the lower certified limit is slightly wider (-6%). The upper and lower certified limits for the inerts are within guidelines proposed in OPPTS 830.1750. Details of the ion chromatography method to determine silicon dioxide in detergent are included, but no references are made to the product Triad. Preliminary analysis was not conducted and no explanation was provided. The physical/chemical characteristics of Triad are adequately addressed with the exception of oxidation/reduction characteristics, explodability, dielectric breakdown voltage, and one year storage stability, but the methods were not reported.
CLASSIFICATION: UNACCEPTABLE, but upgradable upon providing explanation of the wider lower certified limit of the active ingredient, the enforcement analytical method, preliminary analysis of five batches, and a one year storage stability study. In addition, oxidation/reduction characteristics, explodability, and dielectric breakdown voltage are not addressed.

Test Material: Triad (2.41% by weight sodium metasilicate, a.i.)

I. **PRELIMINARY ANALYSIS:** Preliminary analysis was not conducted and no explanation was provided.

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II. **CERTIFIED LIMITS:** Table 1 lists the nominal concentrations and the upper and lower limits for the ingredients as given on the CSF. The lower and upper certified limits of the active ingredient are 2.27% and 2.48% by weight, respectively. The upper certified limit is within guidelines proposed in OPPTS 830.1750, but the lower certified limit is slightly wider (-6%). The upper and lower certified limits for the inerts are within guidelines proposed in OPPTS 830.1750.

Table 1. Nominal concentrations and the upper and lower limits for the ingredients

Ingredients	Nominal	Upper Limit	Lower Limit
Active ingredient			
Sodium metasilicate[a]	2.41%	2.48%	2.27%
Inert ingredients			
[redacted]			
Total	100.00%		

[a]Exemption for food use; exempted from the requirement of a tolerance under 40 CFR 180 of 1999, *40 CFR 180.1001 (c).*

III. **ENFORCEMENT ANALYTICAL METHOD**: The study report indicates that "determination of silicon dioxide in detergent formulations by ion chromatography" is the test to verify certified limits of the active ingredient. Details of the ion chromatography are included to determine silicon dioxide in detergent. No references are made to the product Triad.

IV. **PHYSICAL AND CHEMICAL CHARACTERISTICS**:

1. **Methods and Results:** Physical/Chemical Properties are as follows (Table 1):

Table 1. Physical and chemical properties of Triad

Parameters	Results
Color	Brown
Physical State	Liquid
Odor	Mild organic
Melting Point	Not applicable
Boiling Point	Not applicable
Density/Specific Gravity	1.08
Solubility	Not applicable
Vapor Pressure	Not applicable
pH	12.3
Stability	Not applicable
Flammability	Non-flammable
Storage Stability	Stable for greater than one year; based on no chemical change during blending and qualitative results from field trials over time
Viscosity	65/75 SUS @100°F 10.8/13.6 Centistoke@40°C
Miscibility	Readily miscible in water with agitation
Corrosion Characteristics	Non-corrosive

2. **Deficiencies**: Methods are not provided in the study. Oxidation/reduction characteristics, explodability, dielectric breakdown voltage, and a one year storage stability study are needed.

III. **DISCUSSION:** The lower and upper certified limits of the active ingredient sodium metasilicate are 2.27% and 2.48% by weight, respectively. The upper certified limit is within guidelines proposed in OPPTS 830.1750, but the lower certified limit is slightly wider (-6%). The upper and lower certified limits for the inerts are within guidelines proposed in OPPTS 830.1750.

The study report indicates that "determination of silicon dioxide in detergent formulations by ion chromatography" is the test to verify certified limits of the active ingredient. Details of the ion chromatography are included to determine silicon dioxide in detergent. No references are made to the product Triad. Preliminary analysis was not conducted and no explanation was provided.

The color, physical state, odor, melting point, boiling point, density/specific gravity, solubility, vapor pressure, pH, stability, flammability, viscosity, miscibility, and

corrosion characteristics of Triad are adequately addressed in MRID 45552402. In addition, oxidation/reduction characteristics, explodability, and dielectric breakdown voltage need to be addressed and a one year storage stability study is needed.

The packet classification is **UNACCEPTABLE**, but upgradable upon providing explanation of the wider lower certified limit of the active ingredient, the enforcement analytical method, preliminary analysis, and a one year storage stability study. Oxidation/reduction characteristics, explodability, and dielectric breakdown voltage are not addressed.