(2-8-90)

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - I

Antimicrobial Program Branch

IN 12-07-89 OUT 02-06-90

Reviewed By Emily H. Mitchell 2/8/90 Date 02-06-90

EPA Reg. No. or File Symbol 56392-T

EPA Petition or EUP No. None

Date Division Received 01-24-90

Type Product(s) Hospital Disinfectant

Data Accession No.(s) 412691-04-07

Product Mgr. No. PM 32 (Kempter)

Product Name(s) DISPATCH ®

Company Name(s) Caltech Industries, Inc.

Submission Purpose New Submission with efficacy data and proposed label.

Chemical & Formulation Liquid Pump Spray

Active Ingredient(s):	%
Sodium Hypochlorite (5500 ppm NaOCl)	0.55%

EFFICACY EVALUATION AND TECHNICAL MANAGEMENT SECTION
EFFICACY REVIEW - II)

Antimicrobial Program Branch

EPA Reg. No. or File Symbol	56392-T
Date Division Received	01-24-90
Data Accession No.(s)	412691-04-07
Product Manager No.	PM 32 (Kempter)
Product Name	DISPATCH ®
Company Name	Caltech Industries, Inc.

200.0 Introduction

200.1 Uses:

"One step" hospital cleaner/disinfectant for use on hard non-porous surfaces such as stainless steel, plastic, ceramic tile, laminated plastic countertops, vinyl, tile, linoleum, porcelain enamel, fiberglass, chrome, porcelain and grout.

200.2 Background Information:

The submission received 01-24-90, is a new submission with efficacy data and proposed labels provided.

201.0 Data Summary (MRID Nos. 412691-04-07)

201.1 Brief Description of Tests:

a. Reports of Bactericidal Tests by Daniel L. Prince, Ph.D.
Gibraltar Biological Laboratories, Inc.
122 Fairfield Road, Fairfield, N.J. 07006

b. Reports of Virucidal Tests by Gordon W. Rose, Ph.D.
EnviroCon Environmental Consulting Services,
1205 Devonshire, Grosse Pointe Park, MI 48230

c. Reports of Tuberculocidal Tests by Gordon W. Rose, Ph.D.
EnviroCon Environmental Consulting Services,
1205 Devonshire, Grosse Pointe Park, MI 48230

d. Reports of Virucidal (HIV) Tests by
Daniel L. Prince, Ph.D.
Gibraltar Biological Laboratories, Inc.
23 Just Road, Fairfield, N.J. 07006

201.2 Test Summaries:

a. Bactericidal Tests

1. Method: A.O.A.C. Germicidal Spray Test, 14th Edition, 1984.

2. Modifications: 5% calf serum

3. Samples:

Test Bacteria	Sample No.	Date Tested
P. aeruginosa	45747/1	01-13-89
	45747/2	01-24-89
	45747/3	01-24-89

Test Bacteria	Sample No.	Date Tested
S. aureus	45747/1	02-01-89
	45747/2	02-01-89
	45747/3	02-01-89
S. choleraesusis	45747/1	02-06-89
	45747/2	02-06-89
	45747/3	02-06-89

4. Dilution: Undiluted

5. Exposure: 1 minute

6. Subculture Medium/Neutralizer:
0.1% Sodium Thiosulfate

7. Incubation of Subcultures: 48 hours at 30-35°C

8. Test Bacteria:

Test Bacteria	ATTC No.	Phenol Res.
Pseudomonas aeruginosa	15442	Not Listed
Staphylococcus aureus	6538	Not Listed
Salmonella choleraesuis	10708	Not Listed

9. Survival of Inoculum on Control Carriers:

Test Bacteria	Organism/Carrier
P. aeruginosa	3.4×10^6
	2.0×10^6
	2.0×10^6
S. aureus	1.5×10^5
	4.2×10^5
	4.2×10^5
S. choleraesuis	2.3×10^6
	4.1×10^6
	4.1×10^6

10. Test Results:

Test Bacteria	Lot Number	No. Carriers Tested	No. of Carriers Demonstrating Growth
P. aeruginosa	45747/1	60	0/60
	45747/2	60	0/60
	45747/3	60	0/60

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Test Bacteria	Lot Number	No. Carriers Tested	No. of Carriers Demonstrating Growth
S. aureus	45747/1	60	0/60
	45747/2	60	0/60
	45747/3	60	0/60
S. choleraesuis	45747/1	60	0/60
	45747/2	60	0/60
	45747/3	60	0/60

11. Conclusions: Results show satisfactory performance of the product against all test bacteria undiluted for 1 minute.

b. Virucidal Tests

1. Method: EPA Test Method (DIS/TSS-7)

2. Modifications: 5% fetal bovine serum

3. Samples:

Sample Number	Completed Date
AJ880506	01-16-89
FJ870122	01-16-89

4. Dilution: Undiluted

5. Exposure: 1 minute at 20°C.

6. Recovery Medium Neutralizer/Diluent: Hanks Balanced Salt Solution with 0.07% Lecithin & 0.5% polysorbate 80 Neutralizer

7. Incubation: 37°C up to 7 days

8. Test Virus Host System:
Herpes Simplex, Type 2-Vero Cells(African Green Monkey Cells)
Poliovirus 1-LLC-MK_2 Cells(Rhesus Monkey Kidney Continous Line)

9. Drying Time and Temperature: 30 minutes at 37°C $\pm$ 1.5°C

10. Assay System for Virus Recovery:
Herpes Simplex, Type 2-Cytopathic Effect
Poliovirus 1-Cytopathic Effect

11. Method For Estimating 50 per cent end point:
Reed Muench Method

12. Test Virus:
Herpes Simplex, Type 2 (MS Strain)
Poliovirus 1 (Mahoney Strain)

13. Test Results:

		ID-50 (-log 10)			
Test Virus	Lot No.	Virus Control	Virus Disin.	Toxicity Control	Virus Inact-vation
Herpes Simpex Type 2	AJ880506	7.0	1.0	1.0	6.0
	FJ870122	7.0	1.5	1.5	5.5
poliovirus 1	AJ880506	4.5	0.5	0.5	4.0
	FJ870122	4.5	1.0	1.0	3.5

14. Conclusions: This product showed satisfactory performance against the test viruses when used undiluted for 1 minutes at 20°C.

c. Tuberculocidal Tests

1. Method: A.O.A.C. Tuberculocidal Test

2. Modifications: 5% fetal bovine serum

3. Samples:

Lot/Batch	Competed Date
AJ880506	02-27-89
FJ870122	02-27-89

4. Dilution: Undiluted

5. Exposure Time: 2 minutes at 20°C

6. Subculture Medium/Neutralizer:
Modified Proskauer-Beck
Middlebrook 7H9 Broth
Kirchner's Medium

7. Incubation of Subcultures: 90 days at 37°C
Each subculture tube was incubated for 60 days and in the absence of growth, an additional 30 days.

8. Test Organism:

Test Organism	ATCC No.	Phenol Res.
Mycobacterium bovis	35743	1:50(no growth) 1:75(growth)

9. Test Results:

	Number of Positive Carriers			
Sample No.	Proskauer Beck Modified	Middlebrook 7H9	Kirchner	No. of pos. Carriers
AJ880506	0/10	0/10	0/10	0/10
FJ870122	0/10	0/10	0/10	0/10

10. Conclusions: Results show satisfactory performance of product against Mycobacterium bovis (BCG) undiluted for 2 minutes at 20°C.

d. Virucidal Tests (HIV-virus)

1. Method: "EPA Efficacy Data Requirements: Virucides" (DIS/TSS-7) and GBL HIV test protocol accepted by EETMS (Efficacy), APB, RD, on 12-03-87.

2. Test Virus: Human immunodeficiency virus, Type 1 (HIV-1)

3. Virus Inoculum: Supernatant from HIV-infected H-9 cells was obtained by centrifugation and frozen at -70°C until used. The virus pool was suspended in RPMI -1640 containing 10% heat-inactivated fetal calf serum (as determined by ethanol precipitate test).

4. Test Procedure: 0.3 ml of virus inoculum, containing 10% heat inactivated fetal calf serum as an organic soil, was spread over the surface of 60-mm (diameter) glass petri dishes ($28cm^2$ area) and allowed to dry for 45 minutes at 35-37°C. The product was diluted beyond its use dilution by mixing 1 gram with 9.2ml of deionized water. After drying, 3ml of disinfectant was spread over the virus film (10^{-1} dilution of virus). After 1 minute contact at 20-25°C, the virus disinfectant mixture was removed by pipette and 10-fold serial diluitons were made in trypticase soy broth containing 20% fetal calf serum as a neutralizer. Decimal dilutions were then inoculated into H-9 cells in suspension for 21 days at 37±1°C. The virus-disinfectant mixture represents 10^{-1} virus in the presence of use dilution of test agent.

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5. Controls: The untreated virus control consisted of the virus film diluted to 3.0ml with RPMI-1640 9/10, then further diluted and titrated as described above. The cytotoxicity control consisted of disinfectant, without virus, inoculated into the cell cultures.

6. Host Cell Infection & Virus assay: For infectivity determinations, the sample dilutions were inoculated into each of 4 cultures of H-9 T-cells fed with RPMI-1640/serum, supplemented with L-glutamine, penicillin, streptomycin, and amphotericin, and incubated 14-21 days at 37±1°C in 5%±1% CO_2.

   Virus assays were conducted by enzyme-linked immunosorbent sandwich assay (ELISA) of the H-9 cell supernatants. Cultures were also monitored for cytopathic effect (CPE) by phase microscopy; however, the HIV-H9 system employed was reported as not providing marked CPE.

   Cytotoxicity assays were conducted by phase microscopy for gross morphology changes, by phenol red for pH changes, and by trypan blue uptake for membrane changes.

   TCID-50 and TCLD-50 were determined by the Reed-Muench Method.

7. Test Samples: Formulation XC20003.05

   Batch FJ870122
   Batch BJ871215

   Mfg. Dates: FJ870122 (1-22-87) & BJ871215 (12-15-87)
   Assay Date: 02-12-88
   Completed Date: 03-20-88

8. Dilution: Undiluted (Neat)

9. Results: See attached tables.

10. Conclusions: The data met the requirements for demonstrating virucidal performance of the product against HIV-1 in the presence of organic soil (10% blood serum) undiluted for a contact time of 1 minute.

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ATTACHMENT I

202.0 Recommendations

202.1 Efficacy Supported by the Data:

a. The submitted efficacy data appear adequate to support effectiveness of the product as a bactericide against Staphylococcus aureus, Salmonella choleraesuis, and Pseudomonas aeruginosa when used undiluted in the presence of organic soil load for a contact time of 1 minute on non-porous surfaces.

b. The submitted efficacy data appear adequate to support effectiveness of the product as a virucide against Herpes Simplex, Type 2 and Poliovirus 1 undiluted for a contact time of 1 minute at 20°C.

c. The submitted efficacy data appear adequate to support effectiveness of the product as a tuberculocide against Mycobacterium bovis undiluted for a contact time of 2 minutes at 20°C.

d. The submitted efficacy data appear adequate to support effectiveness of the product as a virucide against Human Immunodeficiency Virus (HIV-1) undiluted for a contact time of 1 minute.

203.0 Labeling

a. The unqualified recommendation for the use of an anitmicrobial agent on plastics will no longer be accepted. Since there are several types of plastics used by the healthcare industry, the product label should indicate generically plastics compatability.

b. Contact time and temperature must appear on label for the tuberculocidal disinfection claim.

c. Immediately above the heading "SPECIAL INSTRUCTIONS FOR CLEANING AND DECONTAMINATION . . . " include the statement Kills HIV on pre-cleaned environmental surfaces/objects previously soiled with blood/body fluids in health care settings or other settings in which there is an expected likelihood of soiling of inanimate surfaces/objects with blood or body fluids, and in which the surfaces/objects likely to be soiled with blood or body fluids can be associated with the potential for transmission of human immunodeficiency virus Type 1 (HIV-1) (associated with AIDS).

d. "Cleaning Procedure. . . " should read "Cleaning Procedure: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the disinfectant."

e. "Contact Time . . ." should read "Contact Time: Leave surfaces wet for 1 minute."

THE LABEL

EPA'S SECTION 3 REGULATIONS KEYED FOR BOTH RESTRICTED USE AND GENERAL

PRESENTED BY JERRY A. MOORE, ACTING CHIEF, EPA STANDARDS AND LABELING.

The pesticide label is the final result of the registration and/or reregistration process and reflects the risks and benefits of a given pesticide to the user. The label is not only the primary source of information to the user, it is also the primary tool of pesticide regulation. The label, in a sense, is a legal document. Improvement of pesticide labels benefits both the industry and the public.

The reregistration process provides for overall improvement in labels. Certain of the changes in label are requirements, other changes are recommendations. The charts that follow will clearly indicate what is required and what is preferred. It is hoped that avoidance of all-inclusive requirements will allow flexibility in those labels which may not fit the more standard situations.

The Section 3 Regulations require that certain statements must appear at certain locations on the label. The designation of specific areas of the label for specific information is known as **format labeling.** This is not a new concept, i.e., signal words have been required to appear on the front panel. The application of the concept to the entire label is new. If pesticide users know to look at the same locations on labels for certain kinds of information, we should be able to better train and educate people, thus improving the understanding of the proper use of pesticides. We ask your cooperation in making the format label a viable concept. We recognize the potential conflict between marketing concepts of product identity and the standardization which results from format labeling. However, the primary purpose of the pesticide label is a means of use communication and regulation. Marketing is a secondary purpose, although a very real purpose. Leeway for product individuality is provided in format labels, but only with the recognition that the label is a legal document to instruct the user on use and safety. As you might expect, there is less leeway in the case of RESTRICTED use labels since these products are not for use by the general public.

The tables on the following pages outline the basic elements of the pesticides label and are keyed to the sample labels which are found on the front and back covers of this magazine. These sample labels represents a typical three panel label for a RESTRICTED USE product of highest toxicity and a three panel label for a GENERAL Classification product. In the tables, Column 2 identified each label element. Column 3 outlines the applicability of the requirement. Columns 4 and 5 describe the location of the element on the label and indicate what is required and what is recommended. Column 6 contains any additional comments or information on format.

Type Size Requirements

The table below will serve as a guide for the type size requirements on various sized labels:

Size of label on front panel in square inches	Signal Word as Required Minimum Type Size All Capitals	"Keep Out of Reach of Children" as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

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LABELING REQUIREMENTS OF THE FIFRA, AS AMENDE (refer to the sample labels following)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
1	Product Name	All Products	Front Panel	Center front panel	
2	Company Name and Address	All Products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for***" "Distributed by***", etc.
3	Net Contents	All Products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units
4	EPA Reg. No.	All Products	None	Front Panel	Must be in similar type size and run parallel to other type
5	EPA Est. No.	All Products	None	Front panel, immediately before or following Reg. No.	May appear on the container instead of the label
6a	Ingredients Statement	All Products	Front Panel	Immediately following product name	Text must run parallel with other text on the panel
6b	Pounds/Gallon Statement	Liquid products where dosage given as lbs ai/unit area	Front Panel	Directly below the main ingredients statement	
7	FRONT PANEL PRECAUTIONARY STATEMENTS	All Products	Front Panel		All front panel precautionary statements must be grouped together; preferably blocked
7a	Keep Out of Reach of Children (Child Hazard Warning)	All Products	Front Panel	Above signal word	Note type size requirements
7b	Signal Word	All Products	Front Panel	Immediately below Child Hazard Warning	Note type size requirements
●	Skull & Crossbones and word "POISON" (in red)	All products which are Category I based on oral, dermal or inhalation toxicity	Front Panel	Both in close proximity to signal word	
7d	Statement of Practical Treatment	All products in Categories I, II, and III	*Category I*: Front panel unless referral statement is used. *Others*: Grouped with side panel precautionary statements	Front panel for all	
7e	Referral Statement	All products where precautionary labeling appears on other than front panel	Front Panel		
8	SIDE/BACK PANEL PRECAUTIONARY STATEMENTS	All Products	None	Top or side of back panel preceding Directions for Use	Must be grouped under the headings given in 8a, 8b, and 8c; Preferably blocked
8a	Hazards to Humans and Domestic Animals	All Products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word
8b	Environmental Hazards	All Products	None	Same as above	Environmental hazards include the bee caution where applicable

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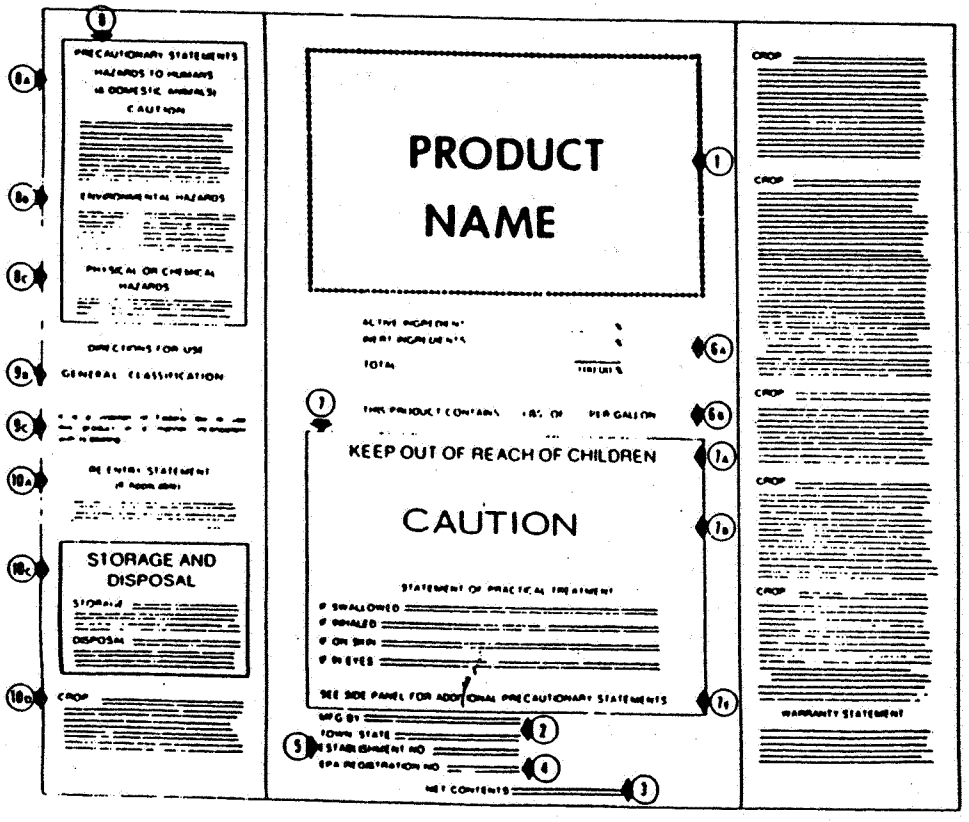
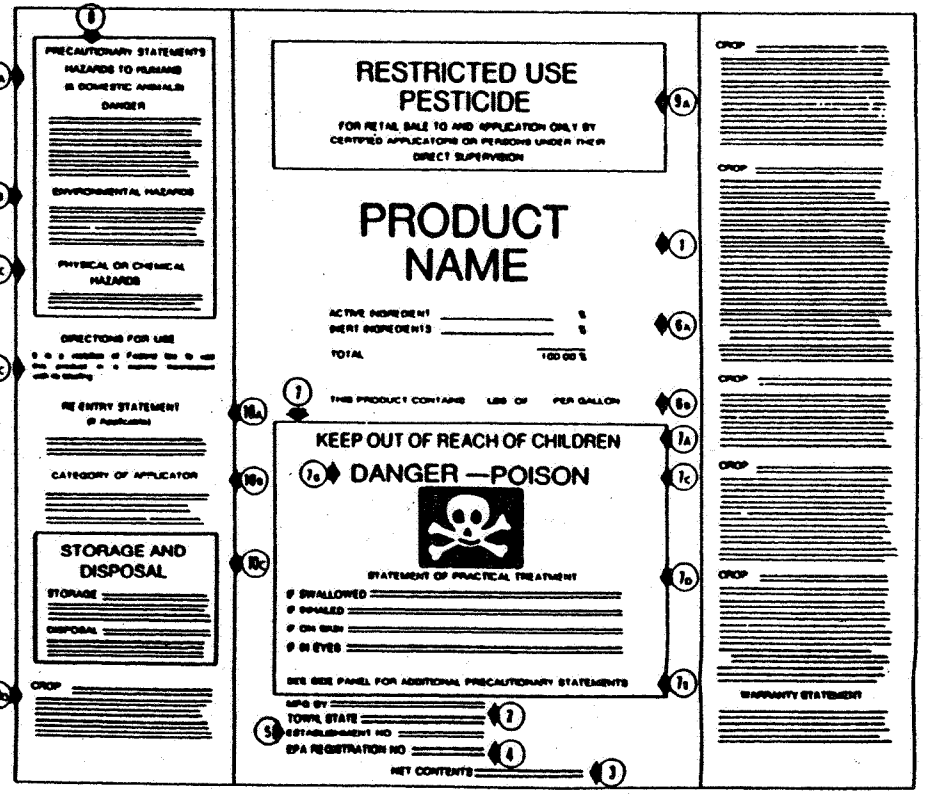
	Hazards	~~For pressurized products;~~ others with flash points under 150°F	None	Same as above	
~~9a~~	Restricted Block	All RESTRICTED products	Top center of	Preferably blocked front panel	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be the same type size as signal word.
9b	Statement of Classification	All products classified GENERAL	Immediately following heading of Directions for Use		
9c	Misuse Statement	All products	Immediately following Statement of Classification or head of Directions for Use		
~~10a~~	Re-entry Statement	All cholinesterase inhibitors	In the Directions for Use	Immediately after Misuse Statement	
~~10b~~	Category of Applicator	All RESTRICTED products	In the Directions for Use	Immediately after Re-entry Statement (when used)	
10c	Storage and Disposal Block	All products	In the Directions for Use	Immediately before specific directions for use or at the end of directions for use	Must be grouped together, and preferably blocked. Heading must be same type size as Child Hazard Warning
10d	Directions for Use	All products	None	None	May be in metric units as well as U.S. units.





on Front Panel in Square Inches	Minimum Type Size All Capitals	of Children as Required
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

●

-BODONI BOLD 18 & 12 Pt.-

.POISON . DANGER . WARNING . CAUTION.

KEEP OUT OF REACH OF CHILDREN

Keep Out of Reach of Children

●

-BODONI BOLD 14 & 10 Pt.-

.POISON . DANGER . WARNING . CAUTION.

KEEP OUT OF REACH OF CHILDREN

Keep Out of Reach of Children

●

-BODONI BOLD 12 & 8 Pt.-

.POISON . DANGER . WARNING . CAUTION.

KEEP OUT OF REACH OF CHILDREN

Keep Out of Reach of Children

●

-BODONI BOLD 10 & 6 Pt.-

.POISON . DANGER . WARNING . CAUTION.

KEEP OUT OF REACH OF CHILDREN

Keep Out of Reach of Children

●

-BODONI BOLD 6 Pt.-

.POISON . DANGER . WARNING . CAUTION.

KEEP OUT OF REACH OF CHILDREN

Keep Out of Reach of Children

A-79 ENCLOSURE

Final printed labeling is defined as that labeling which will accompany the pesticide product to market, and includes not only the container label, but also all accompanying technical information, brochures, etc.

Final printed labeling for the Agency's files should be of a size that can be stored conveniently in 8 1/2 x 11 inch files. Labels may be mounted or photoreduced to meet the size requirements provided the printing is legible and is of microfilm reproduction quality. Should photoreduction make any of the text illegible, the text must be typed out on an accompanying sheet of paper.

PASTE-ON LABELING: This should be submitted as it, unless it requires photoreduction.

SCREEN PRINTED LABELING: These labels should be printed by taping paper on the container as it goes through the printing process. The actual container should not be submitted.

EMBOSSED LABELING: These labels should be photocopied.

UNUSUAL SIZE LABELING: Large bags or boxes must be photoreduced. Either the entire label on one reduction or in sections so that each section is 8 1/2 x 11 inches.

SAMPLE

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STATEMENT OF PRACTICAL TREATMENT

If Swallowed: Drink promptly a large quantity of water. Do not induce vomiting. Avoid alcohol. Get medical attention.

If In Eyes: Flush with plenty of water for 15 minutes. Get medical attention.

If On Skin: Wash with plenty of soap and water. Get medical attention if irritation persists.

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Page _____ is not included in this copy.

Pages 16 through 20 are not included in this copy.

The material not included contains the following type of information:

_____ Identity of product inert ingredients.

_____ Identity of product impurities.

_____ Description of the product manufacturing process.

_____ Description of quality control procedures.

_____ Identity of the source of product ingredients.

_____ Sales or other commercial/financial information.

_____ A draft product label.

_____ The product confidential statement of formula.

_____ Information about a pending registration action.

✓ FIFRA registration data.

_____ The document is a duplicate of page(s) _____.

_____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.