

3-31-86 PD-603
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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

006191

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAR 31 1986

MEMORANDUM

SUBJECT: EPA File Symbol 50534-ROR
Bravo Plus

FROM: Deloris F. Graham *DjH 3/31/86*
Technical Support Section
Fungicide-Herbicide Branch
Registration Division (TS-767C) *E 3/31/86*

TO: Henry M. Jacoby, PM 21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

Applicant: SDS Biotech Corporation
P.O. Box 348
Painesville, OH 44077

Active Ingredient:

2158 Chlorothalonil.	27.0%
249 Copper Oxychloride.	48.3%
539 Maneb	5.4%
Inert Ingredients	19.3%

Background:

Submitted Acute Oral, Acute Dermal, Eye Irritation,
Primary Dermal Irritation, and Dermal Sensitization Studies.
Studies conducted by SISA Toxicological Laboratories, Inc.
Data under Accession Number 258411. Method of support not
indicated.

Recommendation:

1. FHB/TSS finds these data acceptable to support
conditional registration of this product.

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2. An Acute Inhalation Study was not submitted and one must be submitted or data to support waiver.
3. The appropriate signal word is WARNING.

Label:

1. Precautionary "Statements must precede Directions for Use on label.
2. Precautionary Statements must be revised to include "Causes substantial but temporary eye injury."
3. The statement "Do not apply this product . . . must be vacated by unprotected persons" must be deleted from under the heading "Hazards to Humans" and placed under the heading "Directions for Use."
4. See enclosed copy for appropriate labeling procedures and format.

Review:

- (1) Acute Oral Toxicity Study: SISA Toxicological Labs.; Report No. TEK/0018/P1105/O; March 4, 1985.

Procedure:

Five groups consisting of five male and five female rats each received one of the following doses of the test material: 2500, 3600, 5000, 7100 or 10,000 mg/kg. Doses selected based on a single maximum dose (5000 mg/kg) study. Observations made for 14 days postdosing. Necropsy performed on all animals.

Results:

At 2500 mg/kg, 1/5 M died; at 3600 mg/kg, 2/5 M and 4/5 F died; at 5000 mg/kg, 4/5 M and 5/5 F; at 7100 mg/kg, 5/5 M and 5/5 F died; at 10,000 mg/kg, 4/5 M and 5/5 F died. Toxic signs reported included decreased activity, diarrhea or loose stool, perinasal staining, piloerection, arched back, red secretion and crusting around the eyes. Necropsy report indicated rigor mortis; green staining around anus; stomach and intestines filled with green fluid; mottled lungs; stomach and intestines gaseous; tissues autolyzed; signs of diarrheal and perinasal staining; gastrointestinal tract gaseous and filled with dark green fluid; both adrenals dark reddish brown; green fecal staining around anus; cecum and large intestines filled with

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dark green fluid. LD₅₀ for males reported to be 4100 mg/kg with 95% confidence limits between 2808 and 5986 mg/kg. LD₅₀ for females reported to be in the range of 2500 to 3600 mg/kg. LD₅₀ for males and females combined reported to be 3450 mg/kg with 95% confidence limits between 2738 to 4347 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(2) Acute Dermal Toxicity Study: SISA Toxicology Labs.;
Report No. TEK/0018/P1106/D; February 22, 1985.

Procedure:

Five male and five female rabbits with intact skin sites each received a single 2000 mg/kg dose of the test material under occlusive wrap for 24-hour exposure period. Observations made for 14 days postexposure. Necropsy performed on all animals.

Results:

No mortalities reported. Very slight to moderate erythema and very slight edema noted. Necropsy report indicated stomach and intestines gaseous; pale coloring to both kidneys; mucous material in lower region of large intestines in one animal. LD₅₀ reported to be greater than 2000 mg/kg.

Study Classification: Core Guideline Data.

Toxicity Category: III - CAUTION.

(3) Eye Irritation Study: SISA Toxicological Labs.; Report
No. TEK/0018/P1104/E; February 18, 1985.

Procedure:

Six male and six female rabbits received 100 mg of the test material in one eye each. The treated eyes of six male and 3 female rabbits were washed with 100 ml of distilled water 20 to 30 seconds after treatment. Observations for 28 days posttreatment.

Results:

At 24 hours, 1/6 animals of the washed group had corneal opacity (1/6 = 5); 1/6 of the washed group could not be scored

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for opacity due to cream color discharge and severe chemosis; 3/6 of the washed group and 6/6 of the unwashed group had iris irritation (3/6 = 5) (1/6 = 5, 5/6 = 10); 6/6 washed and 6/6 unwashed had conjunctive redness (1/6 = 2, 5/6 = 3) (6/6 = 3), chemosis (1/6 = 3, 5/6 = 4) (2/6 = 3, 4/6 = 4) and discharge (6/6 = 3) (6/6 = 3).

At 7 days, 4/6 unwashed animals had corneal opacity (3/6 = 10, 1/6 = 45); 2/6 unwashed had iris irritation (1/6 = 5, 1/6 = 10); 1/6 washed and 6/6 unwashed had redness (1/6 = 1) (3/6 = 1, 3/6 = 2); 1/6 washed and 4/6 unwashed had chemosis (1/6 = 1) (2/6 = 1, 2/6 = 2); 1/6 discharge (1/6 = 1).

At day 16 one male animal of washed group found dead and at day 17 one female animal of the unwashed group found dead. Deaths reported to be due to mucoid enteropathy, a common enteric disease in rabbits.

At day 21, 1/6 animals of unwashed group had corneal opacity (1/6 = 10) and redness (1/6 = 1). Opacity and redness in this animal still present at 28 days posttreatment.

Study Classification: Core Guideline

Toxicity Category: WARNING.

(4) Primary Dermal Sensitization Study: SISA Toxicological Labs.; Report No. TEK/0018/P1103/S; December 20, 1984.

Procedure:

Six rabbits with one intact and one abraded skin site each received 0.5 g of the test material under occlusive wrap for 4-hour exposure period. Observations made for 7 days post-treatment.

Results:

Five out of six animals had slight edema (5/6 = 1) at abraded sites at 1 hour posttreatment. At 24 hours, 4/6 had slight edema (4/6 = 1) at abraded skin sites. At 72 hours, 2/6 slight edema (2/6 = 1) at abraded skin sites. Edema had cleared by day 4.

Study Classification: Core Guideline Data.

Toxicity Category: IV - CAUTION.

(5) Dermal Sensitization Study: SISA Toxicological Labs.; Report No. TEK/0018/P1121/BEUH; April 10, 1985.

Procedure:

Two groups consisting of ten guinea pigs each received nine (three per week) applications of one of the following materials: test material or dinitrochlorobenzene (DNCB), positive control, during the induction phase. The test group received 0.18 g of test material moistened with 0.2 ml of 0.9% saline and the DNCB group received 0.2 ml of 0.5% DNCB in 80% ethanol. Seventeen days after ninth induction phase application, a challenge dose was applied to the test group and DNCB group, also a third untreated group was challenged with test group at one site and DNCB at another. Observations made at 24 and 48 hours after each application.

Results:

Very slight to slight erythema and edema reported in most animals during induction phase of test group with very slight erythema reported in one animal at challenge. Necrosis also noted in a few animals. These results indicate that no dermal sensitization reaction was produced.

Very slight to slight erythema and edema reported in most animals of DNCB group during induction phase and five of the ten animals had moderate to severe erythema at challenge dose, which indicated that a dermal sensitization reaction occurred. Necrosis noted in most animals.

Study Classification: Core Guideline Data.

Toxicity Category: Nonsensitizing.

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PROPOSED LABEL

Net Contents

Logo

BRAVO^R Plus

Agricultural Fungicide/ Bactericide

Active Ingredients:

Chlorothalonil (tetrachloroisophthalonitrile) . .	27.0%
Copper Oxychloride*	48.3%
Maneb (manganese ethylene bisdithiocarbamate) . .	5.4%

Inert Ingredients:	<u>19.3%</u>
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Total	100.0%
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*Metallic copper equivalent 27.0%

KEEP OUT OF REACH OF CHILDREN

WARNING - AVISO

See side panel for additional precautionary statements

Only for Sale to, Use, and Storage by
Agricultural Personnel or Commercial Applicators

Precaucion al Usuario:

Si usted no lee ingles, no use este producto
hasta que la etiqueta haya sido explicado ampliamente.

SDS BIOTECH CORPORATION
Agricultural Chemicals Business
7528 Auburn Road
Concord Township
P.O. Box 348
Painesville, OH 44077

(EPA Reg. No. 50534-)

EPA Est. No. 50534-TX-01

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A BROAD SPECTRUM AGRICULTURAL FUNGICIDE/ BACTERICIDE

Read entire label carefully and use only as directed.

GENERAL INFORMATION

BRAVO Plus contains chlorothalonil which is an excellent fungicide when used according to label directions for control of a broad spectrum of diseases of tomatoes, peaches and nectarines. In addition, **BRAVO Plus** contains copper oxychloride plus maneb to provide control of bacterial spot and bacterial speck of tomatoes and bacterial canker, bud blast and bacterial spot of peaches and nectarines when applied as indicated in the following use directions.

BRAVO Plus is a broad spectrum protectant fungicide/ bactericide which is most effective when applied in dilute sprays. Applications should be started early before infection and continued as indicated in the Directions for Use. Application should be made at the recommended label rate and timing starting at the first sign of disease, first report of disease in the area, or when environmental conditions become favorable for disease development. Thorough, uniform coverage is essential for effective disease control.

DO NOT combine **BRAVO Plus** in the spray tank with surfactants, fertilizers or other pesticides unless your prior use has shown the combination physically compatible, effective and non-injurious under your conditions of use.

DO NOT combine **BRAVO Plus** with Dipel 4L or Triton AG-98 as phytotoxicity may result from the combination when applied to the crops on this label.

Dipel is a registered trademark of Abbott Laboratories;
Triton AG-98 is a trademark of Rohm and Haas Company.

The required amount of **BRAVO Plus** should be added slowly into the spray tank during filling. Keep agitator running when filling spray tank and during spray operations. DO NOT use on greenhouse-grown tomatoes.

PRECAUTIONARY STATEMENTS

Hazard to Humans and Domestic Animals

WARNING

Causes eye irritation.

Do not get in eyes. Wear goggles or face shield when handling this product.

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Avoid prolonged contact with skin.

Do not take internally.

Avoid breathing spray mist.

Do not apply this product in such a manner as to directly, or through drift, expose workers or other persons. The area being treated must be vacated by unprotected persons.

FIRST AID

Note to User: Wash exposed areas of skin with soap and warm water after handling or using.

In case of contact with eyes, flush eyes with plenty of water and continue for 15 minutes. Seek medical attention for eyes immediately.

Note to User: BRAVO Plus may produce temporary allergic side effects characterized by redness of the eyes, mild bronchial irritation and redness or rash on exposed skin areas. Persons having allergic reaction should contact a physician.

Note to physician: Persons having a temporary allergic reaction respond to treatment with antihistamines or steroid creams and/or systemic steroids.

ENVIRONMENTAL HAZARD

This product is toxic to fish, aquatic invertebrates, and marine/estuarine organisms. Runoff from treated areas may be hazardous to aquatic organisms in neighboring areas. Do not apply directly to water. Do not apply when weather conditions favor drift from treated areas.

Apply only to crops specified on label.

DIRECTIONS FOR USE

Only for Sale to, Use, and Storage by Agricultural Personnel or Commercial Applicators.

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Note to User: This product may produce temporary allergic side effects characterized by redness of eyes, mild bronchial irritation and redness or rash on exposed skin areas. Persons having allergic reaction should contact a physician.

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Note to User: Wear long sleeve shirt, long pants, and gloves while mixing, loading and applying this product.

TOMATO: BRAVO Plus is a specially designed product which controls bacterial and fungal diseases of tomato. The following diseases can be controlled through proper use of BRAVO Plus:

Bacterial Spot (*Xanthomonas*)
 Bacterial Speck (*Pseudomonas*)
 Early Blight
 Late Blight (*Phytophthora infestans*)
 Gray Leaf Mold (*Cladosporium*)
 Gray Leaf Spot (*Stemphylium*)
 Septoria Leafspot
 Alternaria Fruit Rot (Black Mold)
 Gray Mold (*Botrytis*)
 Rhizoctonia Fruit Rot
 Anthracnose

Apply in sufficient water to obtain complete coverage of canopy, generally 50 to 125 gallons per acre. On upright staked tomatoes use application equipment capable of thoroughly covering the crop canopy, generally over-row sprayers with vertical boom orientation. On bush tomatoes, use nozzle placement that will insure thorough coverage of the canopy. Begin applications when dew or rain occur and disease threatens. Repeat applications on a weekly or semi-weekly (every 3-4 days) schedule, using the rates listed below:

<u>SCHEDULE</u>	<u>APPLICATION RATE</u> (Per 100 Gal)	<u>RECOMMENDED SPRAY</u> <u>VOLUME (GAL/A)</u>	
		<u>Pre-Bloom</u>	<u>Bloom-Harvest</u>
Weekly	4 - 6 lbs	50 - 75	75 - 125
Semi-weekly	2 - 3 lbs	50 - 75	75 - 125

When conditions favor severe disease, use the highest rate listed for the application schedule selected. DO NOT apply more than 7.5 lbs/A of BRAVO Plus per application. DO NOT apply BRAVO Plus within 5 days of harvest.

PEACH, NECTARINE: The following diseases can be controlled through proper use of BRAVO Plus:

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Leaf curl
Coryneum blight (shothole)
Bacterial canker, Bud blast (dead bud)
Bacterial spot

Apply BRAVO Plus in sufficient water and with proper calibration to obtain uniform coverage of the tree canopy, generally 50-200 gallons/A. Application with ground equipment is preferable because ground applications generally give better coverage. When treating non-bearing or immature trees, the lower rate of BRAVO Plus may be used.

For best control of Leaf curl and Coryneum blight and bacterial diseases, apply at leaf fall in late autumn. When conditions favor high disease levels, and for best control of bacterial diseases, use the high rate of application and apply once more in mid to late winter before budswell. If the late fall application is not practical, applications of BRAVO Plus for control of Leaf curl may be made prior to budswell the following spring. When Coryneum blight (shothole) and Bacterial spot occur, also apply at budbreak.

<u>DISEASES</u>	RECOMMENDED	SPRAY VOLUME
	APPLICATION RATE/ ACRE	(GAL/A)
=====	=====	=====
Leaf curl, Coryneum blight, Bacterial canker, Bud blast (dead bud), Bacterial spot	6 - 10 lbs	50 - 200

Note to User: Do not rotate to crops other than those listed on labels within 12 months of the last treatment. After 12 months from the last application, leafy vegetables (i.e. spinach, lettuce, kale, etc.) may also be rotated.

REENTRY

Note to User: Do not enter treated area to perform hand labor within 24 hours of application unless protective clothing is worn.

Because certain states may require more restrictive reentry intervals for various crops treated with this product, consult your State Department of Agriculture for further information.

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Written or oral warnings must be given to workers who are expected to be in a treated area or in an area about to be treated with this product. When oral warnings are given, warnings shall be given in a language customarily understood by workers. Oral warnings must be given if there is reason to believe that written warnings cannot be understood by workers. Oral and written warnings must include the following information: "WARNING. Area treated with BRAVO Plus on (date of application). Do not enter without appropriate protective clothing until the sprays have dried. In case of accidental exposure, wash exposed area with plenty of water and get medical attention. For further information see 'Precautionary Statements' on the label".

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal. Open dumping is prohibited.

Storage: Store in a cool place. Protect from excessive heat.

Pesticide Disposal: Pesticide wastes are toxic. Improper disposal of excess pesticide, pesticide spray or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance.

Container Disposal: Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.

WARRANTY AND LIMITATION OF DAMAGES

Seller warrants that this material conforms to its chemical description and is reasonably fit for the purposes stated on the label when used in accordance with directions under normal conditions of use and Buyer assumes the risk of any use contrary to such directions. Seller makes no other express or implied warranty, including any other express or implied warranty of Fitness or of Merchantability. In no event shall Seller's liability for any breach of warranty exceed the purchase price of the material as to which a claim is made.

SDS BIOTECH CORPORATION
Agricultural Chemicals Business
7528 Auburn Road
Concord Township
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Painesville, Ohio 44077

EPA Reg. No. 50534-

EPA Est. No. 50534-TX-01

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