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

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NOV 15 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Naled - PP#5E3179, Revised Section F (Submitted June 28, 1985) proposing a tolerance for residues in/on boysenberries at 0.5 ppm (IR-4). EPA Registration No. 239-1633. Caswell 586

FROM: Irving Mauer, Ph.D. 11/06/85
Toxicology Branch
Hazard Evaluation Division (TS-769C)

TO: Hoyt Jamerson, Product Manager (43)
Registration Support and Emergency Response Branch
Registration Division (TS-767C)

THRU: Jane E. Harris, Ph.D., Head 11/7/85 11/14/85
Section VI
Toxicology Branch
Hazard Evaluation Division (TS-769C)

Petitioner: IR-4, Cook College, Rutgers, NJ, Agricultural Experiment Station, New Brunswick, on behalf of the IR-4 National Director, Dr. R.H. Kupelian, and the Agricultural Experiment Station of California.

Action Requested:

Evaluate the tolerance proposed for residues of naled (1,2-dibromo-2,2-dichloroethyl dimethyl phosphate) and its conversion product, 2,2-dichlorovinyl dimethyl phosphate (DDVP, aka dichlorvos) expressed as naled, in/on raw agricultural commodity (rac) boysenberries at 0.5 part per million.

TB Recommendation/Conclusion:

Based upon adequate toxicological data recently submitted (detailed below), a PADI (100 for cholinesterase inhibition) of 0.002 mg/kg/day has been calculated. TB has determined

(1)

that the percent of ADI calculated increases from 919.5% to 919.7% with the new tolerance (0.5 ppm) on boysenberries.

Background and Current Toxicology Data Base:

A tolerance of 0.5 ppm had previously been established (42 FR 46304, September 15, 1977) for naled in or on rac's, except (higher in) those otherwise listed in 40 CFR 180.215 (attached), from its use for area pest (mosquito and fly) control. However, neither an ADI or MPI had previously been calculated because an inadequate tox. data base could not generate supportable NOEL's (see Naled Registration Standard, December 15, 1982, esp. p. 25, attached). For example, only the following CORE-SUPPLEMENTARY (pivotal) studies were previously available for defining such provisional "no-effect levels":

(1) Rat 90-Day Subchronic (feed) [Hazleton, February 13, 1959] - NOEL/ChE = 30 ppm (= 1.5 mg/kg/day) - NOEL/Syst = 300 ppm (= 15 mg/kg/day)

(2) Dog 90-Day Subchronic (capsule) [Hazleton, June 12, 1958] - NOEL/ChE = 0.25 mg/kg/day - NOEL/Syst = 7.5 mg/kg/day

In response to a 3(c)(2)(B) DCI Notice (issued June 1983), the following adequate studies (CORE-MINIMUM or better) are currently available.

(1) Rat Teratology [Science Applications, Inc. #SAI-583008, January 18, 1984] - NOEL/Terat > 40 mg/kg/day - NOEL/Fetotox > 40 mg/kg/day - NOEL/Mat = 10 mg/kg/day

(2) Rat 2-Year Chronic (gavage) [Bio-Research Lab. #9394, June 7, 1984] - NOEL/ChE = 0.2 mg/kg/day - NOEL/Syst = 10 mg/kg/day

Hence, based upon the recently promulgated TB Standard Operating Procedure for "Establishing an ADI for Pesticide Chemicals" (#1002, dated September 12, 1985), a provisional acceptable daily intake (PADI) can now be assigned for this chemical, choosing the lowest NOEL available (0.2 mg/kg/day for cholinesterase inhibition in the rat) and a hundredfold SF.

This results in a PADI/ChE (100) of 0.002 mg/kg/day and an MPI (60 kg) of 0.12 mg/day. The existing TMRC = 1.1034 mg/day (1.5 kg) already represents 919.5% of the ADI. If the tolerance for boysenberries (0.5 ppm) was granted (considered a minor use), it would increase the TMRC by approximately 0.03 percent (0.5 ppm x 0.03 FF ÷ 100 x 1.5 kg = 0.00023 mg/day) i.e., 1.1037 mg/day, and increase the percent ADI occupied to 919.7%.

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[illegible] 180.215 [illegible] 1[illegible]/25/85

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ACCEPTABLE DAILY INTAKE D[illegible] **DRAFT**

NOEL change not recorded. [illegible]

FAT, other food mg/kg	ppm	S.F.	ADI mg/kg/day	ADI mg/day (60KG)
0.200	4.00	100	0.0020	0.1200

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Published Tolerances

CROP	Tolerance	Food Factor	mg/day(1.5kg)
Celery(2[illegible])	3.[illegible]00	0.2[illegible]	0.[illegible]1288
Collards(37)	3.000	0.08	0.00368
Grapefruit(65)	3.[illegible]	[illegible].99	0.[illegible]4461
Kale(75)	3.000	0.03	0.[illegible]0135
Lemons([illegible]2)	3.[illegible]00	0.17	0.00782
Oranges(106)	3.000	[illegible].17	0.[illegible]750
Swiss Chard(155)	3.[illegible]	[illegible]3	0.00135
Tangerines(160)	3.000	0.03	0.00135
Broccoli(15)	1.000	0.10	0.00153
Brussel Sprouts(20)	1.000	0.03	0.00045
Cabbage, sauerkraut(22)	1.000	0.74	0.[illegible]1104
Cauliflower(27)	1.000	0.07	0.00107
Lettuce(84)	1.000	1.31	0.[illegible]1962
Strawberries(152)	1.000	0.18	0.00276
Beans(9)	0.500	2.[illegible]4	0.[illegible]1530
Cottonseed (oil)(41)	0.500	0.15	0.[illegible]112
Eggplant(53)	0.5[illegible]	0.[illegible]3	0.[illegible]023
Grapes, inc raisins([illegible])	0.500	0.49	0.[illegible]0368
Hops(73)	0.500	0.03	0.[illegible]0023
Melons(92)	0.[illegible]	[illegible].00	0.[illegible]1502
Mushrooms(97)	0.500	0.[illegible]3	0.00023
Peaches(114)	0.500	[illegible].90	0.[illegible]0675
Peas(117)	0.500	0.69	0.00521
Peppers(120)	0.500	0.12	0.00092
Pumpkin, inc squash(1[illegible]1)	0.[illegible]	0.11	0.00084
Rice(137)	0.500	0.55	0.[illegible]0414
Safflower(141)	0.[illegible]00	[illegible]3	0.[illegible]0023
Sugar, cane&beet(154)	0.500	3.64	[illegible].[illegible]2725
Summer squash(155)	0.500	0.03	0.[illegible]23
Tomatoes(163)	0.[illegible]0	[illegible].[illegible]7	0.[illegible]196
[illegible]lnuts(167)	0[illegible]00	[illegible]3	[illegible].[illegible]0023
Alm[illegible]s(1)	0.[illegible]	0.[illegible]3	0.[illegible]02
Eggs(54)	0.[illegible]50	[illegible].77	0.[illegible]
Cattle(26)	0.[illegible]	7.1[illegible]	0.00535
[illegible]([illegible])	0.[illegible]	0.[illegible]3	0.[illegible]002
[illegible]	[illegible].050	3.43	0.00258
[illegible](20[illegible])	0.[illegible]	0.[illegible]3	0.[illegible]
Milk, dairy products([illegible]3)	0.[illegible]50	[illegible].[illegible]2	0.0214[illegible]
Poultry([illegible])	0.[illegible]	2.[illegible]4	0.[illegible]221
[illegible](145)	[illegible]	[illegible]	0.[illegible]015
Winter squash(171)	0.5[illegible]	[illegible]	0.[illegible]23
Spinach(1[illegible])	3.0[illegible]	[illegible]	0.[illegible]
Cucumbers, inc pickl(4[illegible])	0.50[illegible]	[illegible].73	0.[illegible]54[illegible]
[illegible] Foods(1[illegible]7)	[illegible]	1.[illegible]	[illegible]
Turnip greens([illegible])	3.[illegible]	[illegible]3	0.[illegible]135

[illegible] [illegible] [illegible]

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/day(60kg)   1.1037 mg/day(1.5kg)   919.82

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Drift Rating 0.3179

Crop	Tolerance	Food Factor	mg/day(1.5kg)
Boysenberries(17)	0.00	0.05	0.00023

UPI %	EEC	% ADI
0.1200 mg/day(60kg)	1.1037 mg/day(1.5kg)	919.71

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Commodity	Parts per million
Poultry, fat	0.1
Poultry, meat	0.1
Poultry (mbyp)	0.1
Rice	0.1
Rice, straw	0.5

(Sec. 408(e), 68 Stat. 514; (21 U.S.C. 346a(e)))

[45 FR 86492, Dec. 31, 1980]

§ 180.215 Naled; tolerances for residues.

Tolerances are established for residues of the insecticide naled (1,2-dibromo-2,2-dichloro-ethyl dimethyl phosphate) and its conversion product 2,2-dichlorovinyl dimethyl phosphate, expressed as naled, resulting from the application of the pesticide to growing crops or from direct application to livestock and poultry, in or on the following raw agricultural commodities:

Commodity	Parts per million
Almonds (hulls)	0.5
Almonds (nuts)	0.5
Beans (dry)	0.5
Beans (succulent)	0.5
Beets, sugar, roots	0.5
Beets, sugar, tops	0.5
Broccoli	1
Brussels sprouts	1
Cabbage	1
Cattle, fat	0.05
Cattle, mbyp	0.05
Cattle, meat	0.05
Cauliflower	1
Celery	3
Collards	3
Cottonseed	0.5
Cucumbers	0.5
Eggplant	0.5
Eggs	0.05
Goats, fat	0.05
Goats, mbyp	0.05
Goats, meat	0.05
Grapefruit	3
Grapes	0.5
Grasses, forage	10
Hogs, fat	0.05
Hogs, mbyp	0.05
Hogs, meat	0.05
Hops	0.5
Horses, fat	0.05
Horses, mbyp	0.05
Horses, meat	0.05
Kale	3
Legumes, forage	10
Lemons	3
Lettuce	1
Melons	0.5
Milk	0.05
Mushrooms	0.5
Oranges	3
Peaches	0.5
Pears (succulent)	0.5
Peppers	0.5
Poultry, fat	0.05
Poultry, mbyp	0.05
Poultry, meat	0.05
Pumpkins	0.5
Rice	0.5
Safflower, seed	0.5
Sheep, fat	0.05
Sheep, mbyp	0.05
Sheep, meat	0.05
Spinach	3
Squash, summer	0.5
Squash, winter	0.5
Strawberries	1
Swiss chard	3
Tangerines	3
Tomatoes	0.5
Turnips, tops	3
Walnuts	0.5

A tolerance of 0.5 part per million is established for the pesticide naled in or on all raw agricultural commodities, except those otherwise listed in this section, from use of the pesticide for area pest (mosquito and fly) control.

[42 FR 46304, Sept. 15, 1977]

§ 180.216 Chloroxuron; tolerances for residues.

Tolerances for combined negligible residues of the herbicide chloroxuron (3-[*p*-(*p*-chlorophenoxy) phenyl]-1,1-dimethylurea) and its metabolites containing the *p*-(*p*-chlorophenoxy) aniline moiety calculated as chloroxuron in or on raw agricultural commodities are established as follows:

(a) 0.15 part per million in or on soybeans and soybean forage.

(b) 0.1 part per million in or on carrots, celery, onions (dry bulb), and strawberries.

[37 FR 2839, Feb. 8, 1972]

§ 180.217 Ammoniates for [ethylenebis-(dithiocarbamato)] zinc and ethylenebis [dithiocarbamic acid] bimolecular and trimolecular cyclic anhydrosulfides and disulfides; tolerances for residues.

Tolerances for residues of a fungicide that is a mixture of 5.2 parts by weight of ammoniates of [ethylenebis (dithiocarbamato)] zinc with 1 part by weight ethylenebis [dithiocarbamic acid] bimolecular and trimolecular

RS 12/15/82, as amended 6/15/83

houses. No changes were noted in the pre- and post-exposure levels of DMP and DMPT in the urine from 100 people outside of the spray area. Levels of DMP and DMPT in the urine from mosquito control workers and the aircraft pilot were similar to the post-exposure levels of DMP and DMPT in urine from people who were outside during the spray period. In addition to DMP and DMPT; the analyses of urine specimens revealed the (unexplained) presence of four other organophosphate metabolites: 0,0-Diethyl phosphate, 0,0-diethyl phosphorothionate, 0,0-dimethyl phosphorodithioate, and 0,0-diethyl phosphorodithioate.

E. Tolerances

Based on disciplinary studies summarized elsewhere in this Standard (Residue Chemisty, Environmental Fate Exposure and Analysis, Usage Patterns, etc.), as well as validated animal toxicological studies considered here, tolerances on raw agricultural commodities (rac) and in processed foods have been published (CFR 180.215). They range between 0.05 ppm (e.g., for eggs, meats and meat byproducts, milk and dairy products) and 3.00 ppm (e.g., for citrus fruits, and certain green vegetables). The TMRC has been calculated as 1.1034 mg/day (based on a 1.5 kg daily diet). Since no NOEL's have been established, ADI and MPI cannot be calculated.

IV. Summary and Recommendations

In terms of human toxicity, products containing naled appear to present only slight to moderate risk to agricultural workers, manufacturing personnel, applicators and household users. ~~(Toxicity Category III or IV)~~. When used with appropriate protection against excessive dermal and/or inhalational exposure according to label directions, little hazard with acute exposures is to be expected, as clinical reporting over the past 15 years has attested. However, there is the possibility of sensitization (and cross-sensitization to other pesticides) with chronic exposures. Palliative treatment exists for the occasional overexposure leading to clinical consequences of cholinesterase inhibition. No fatalities associated with naled use have been reported.

There also appears to be little if any risk to the general public associated with the chronic ingestion of residues on rac or in processed foods. Such residues as have been found have been far below the tolerance levels established. Even if absorbed over an extended period of time, metabolic considerations (such as degradation to innocuous substances and rapid excretion, by a number of biochemical pathways) presumes a risk much lower than with many other OP compounds.

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