Rev. 4/14/82 (Toxicology Branch/HED Review (

10-4-82

Caswell No(s).: 589

To: Hoyt Jamerson PM43 RD TS-767

Registration No(s).:

Pesticide Petition No(s).: 2E2760

Chemical(s): 1-Naphtalene acetic acid (NAA)

Requested Action(s): Tolerance Sweet Cherries 0.1 ppm

Recommendation: Approval

Inert(s) cleared 180.1001: Yes

% of ADI occupied: Existing: 1.53 Resulting: 1.53

Resulting % increase in TMRC: 0.4

Data considered in setting the ADI: 6-m oral (capsule) dog NOEL 50 mg/kg/day SF=1000

Attached (?): ADI printout: (YES)/NO ; TOX "one-liner": (YES)/NO ; DER: YES/(NO)

Existing regulatory actions against registration: None

RPAR status: None

New Data: None

Data gaps: 2nd Teratology Study

Comments: BEST AVAILABLE COPY

Reviewer: ZENDZIAN Date: 9/29/82

OCT 4 1982

Tox Chem No. 589 File Last Updated 7/20/82 Current Date

Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD_{50}, LC_{50}, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Acute dermal LD_{50} - rabbit Williamette Lab.	Indole-3-butyric acid 1.0% 1-Naphthaleneaetic acid 0.5%		LD_{50} > 2 g/kg (male and female; single dose tested; cutaneous ulcero and subcutaneous abscess)	III	Minimum 000455

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Study/Lab/Study #/Date	Material	EPA Accession No.	Results: LD_{50}, LC_{50}, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Acute oral LD_{50} - rat Williamete Lab.	Indole-3-Butyric acid . 1.0% 1-Naphthalenacetic acid 0.5%		LD_{50} > 5 g/kg (male and female; single dose tested)	IV	Minimum 000462
Primary eye irritation - rabbit Williamete Lab.	Indole-3-Butyric acid . 1.0% 1-Naphthalenacetic acid 0.5%		Corneal opacity at day 1, 2 animals one clear by day 2 and the other by 4. Iris and conjunctive irritation which had cleared by day 10.	III	Guideline 000462
Primary dermal irritation - rabbit Williamete Lab.	Indole-3-Butyric acid . 1.0% 1-Naphthalenacetic acid 0.5%		No evidence of inflammation.	IV	Minimum 000462
Sensitization - guinea pig Leberco Lab.#4772 06/03/80	Indole-3-Butyric acid . 1.0% 1-Naphthalenacetic acid 0.5%		Very slight erythema and edema at 24 and 48 hours. Test material was not acting as a sensitizing agent.		Guideline 000462

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Study/Lab/Study #/Date	Material	EPA Accession No.	Results/LD50, LC50, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
Mutagenic (yeast)	Tech (1-NAA)	099029	Negative		Acceptable
Mutagenic (yeast)	Tech (1-NAA)	099029	Negative		Acceptable
Mutagenic (yeast)	Tech (1-NAA)	099029	Negative		Acceptable
Mutagenic (Escherichia)	Tech (1-NAA)	099029	Negative		Acceptable
Mutagenic (Ames)	Tech (1-NAA)	099029	Negative		Acceptable
Micronucleus test	Tech (1-NAA)	099029	Negative		Acceptable
Mutagenic-dominant lethal, rats	Tech (1-NAA)	099029	Negative at 500 mg/kg (highest dose tested)		Acceptable
Teratology, rats Huntingdon Res. Center #R42k6 - 46k-350 1/14/77	Tech (1-NAA)	099029	NOEL = > 250 mg/kg/day (teratology) (highest level fed) NEL = 50 mg/kg/day (maternal toxicity) Maternal LEL = 250 mg/kg (decreased body weight)		Minimum
Tumorigenicity, mice	Tech (1-NAA)	099030	Negative at 517 ppm		Minimum
90-day feeding, rat	Tech NAA	099030	NOEL = 150 mg/kg/day LEL = 500 mg/kg/day (decreased body weight in both sexes and liver enlargement in females		Minimum
Acute inhalation LC50, rat	Tech. (ethyl ester of NAA)	099029	LC50 = >206.5 mg/L	IV	Minimum
Acute dermal LD50, rat	Tech. (ethyl ester of NAA)	099029	LD50 = >5000 mg/kg	IV	Minimum
Acute oral LD50, rat	Tech (ethyl ester of NAA)	099029	LD50 = 3580 mg/kg	III	Minimum
Primary eye irritation, rabbit	Tech (ethyl ester of NAA)	099029	PSI = 0.0/110	IV	Minimum

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Study/Lab/Study #/Date	Material	EPA Accession No.	Results/LD50, LC50, PIS, NOEL, LEL	TOX Category	CORE Grade/ Doc. No.
3-generation reproduction, mouse	Methyl ester of 1-NAA		NOEL = 86 ppm (highest level fed)		
2-year feeding, rat	Methyl ester of 1-NAA		Cannot be found as of 3/18/82		
Gavage, rat	NAA	099030	No effect level established (range finding)		Minimum
6-month oral, dog	NAA	099035	NOEL < 50 mg/kg/day		
Acute dermal LD50, rabbit	AMCHEM-72-A112 E.C. 79068 (15.1% A.I.) EPA#264-GGA	099029	LD50 = >5000 mg/kg	III	Minimum
Primary eye irritation, rabbit	AMCHEM-72-A112 E.C. 79068 (15.1% A.I.) EPA#264-GGA	099029	Corneal opacity at days 7 and 14 PIS = 57/110	I	Minimum
Acute inhalation, rat	AMCHEM-72-A112 E.C. 79068 (15.1% A.I.) EPA#264-GGA	099029	LC50 = >217.1 mg/L	IV	Minimum
Acute oral LD50, rat	AMCHEM-72-A112 E.C. 79068 (15.1% A.I.) EPA#264-GGA	099029	LD50 = 5585 mg/kg	IV	Minimum

CFR 180.155 Naphtnaleneacetic acid 9/29/82

File last updated 9/29/82

ACCEPTABLE DAILY INTAKE DATA

Dog mg/kg	NOEL ppm	S.F.	ADI mg/kg/day	MPI mg/day/60kg
50.000	2000.00	1000	0.0500	3.0000

Published Tolerances

CROP	Tolerance	Food Factor	mg/day/1.5kg
Apples(2)	1.000	2.53	0.03795
Pears(116)	1.000	0.26	0.00383
Quinces(132)	1.000	0.03	0.00045
Olives(104)	0.100	0.06	0.00009
Pineapple(123)	0.050	0.30	0.00022

MPI	TMRC	% ADI
3.0000 mg/day/60kg	0.0425 mg/day/1.5kg	1.42

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Unpublished,Tox Approved 7E1956

CROP	Tolerance	Food Factor	mg/day/1.5kg
Oranges(108)	0.100	2.17	0.00325
Tangerines(160)	0.100	0.03	0.00005

MPI	TMRC	% ADI
3.0000 mg/day/60kg	0.0458 mg/day/1.5kg	1.53

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Current Action 2E2760

CROP	Tolerance	Food Factor	mg/day/1.5kg
Cherries(30)	0.100	0.10	0.00015

MPI	TMRC	% ADI
3.0000 mg/day/60kg	0.0460 mg/day/1.5kg	1.53

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