DATE: January 13, 1981

SUBJECT: EPA Registration Symbol: 8568-RR
Dip' n Grow: Caswell #_____

FROM: Deloris F. Graham DFG 1/21/81
FHB/TSS
E 1/21/81

TO: Robert Taylor
Product Manager (25)

Applicant: C-R Chemical Research Company
11040 S.E. Mill Court
Portland, Oregon 97216

Active Ingredient:
Indole-3-butyric acid.....1.0%
1-Naphthaleneactic acid.....0.5%
Inert Ingredients.....98.5%

Background: Submitted Acute Dermal Toxicity data as requested in the original review.

Recommendations:

(1) FHB/TSS finds this data acceptable to support the conditional registration of this product.

(2) In an Acute Dermal Toxicity study a 2g/kg dose must be used and in a Primary Dermal Study 0.5g/kg must be used. Since no toxic or pharmacologic signs were evident at a 2g/kg dose, ~~therefore it is~~ TSS of the scientific opinion that data gained in a study using 0.5g/kg would show no additional hazard.

(3) Please see enclosed copy of "Proposed Guidelines" section 163.81-1 thru 5 for correct testing and reporting procedures.

(4) The appropriate signal word is CAUTION.

Label:

(1) No additional labeling comments.

Review:

(1) Acute Dermal Toxicity: Willamette Laboratories

Procedure: 5M and 5F rabbits received a 2g/kg dose at abraded skin site. Treated skin sites were placed under occlusive wrap for 24-hour exposure. Observations made daily for 14 days.

Results: 3/10 animals exhibited cutaneous ulcers and subcutaneous abscess. The skin of the remaining seven animals was intact with no evidence of inflammation. The abdomen showed evidence of recent shaving but no abrasions were noted at the time of autopsy. No visible abnormalities noted at autopsy, other than cutaneous ulcers present in 3 animals. One animal sacrificed on the 11th day.

Study Classification: Core Minimium Data

Toxicity Category: III - CAUTION

DIRECTIONS FOR USE:

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

DO NOT USE ON FOOD CROPS OR FRUIT TREES. WEAR RUBBER GLOVES, LONG-SLEEVED SHIRT AND OTHER APPROPRIATE CLOTHING WHEN HANDLING DIP'N GROW OR TREATED CUTTINGS.

Mix only for immediate use.

Hardwood Cuttings — mix 1 part DIP'N GROW with 5 parts water.

Medium Hardwood Cuttings — mix 1 part DIP'N GROW with 10 parts water.

Softwood Cuttings and Succulents — mix 1 part DIP'N GROW with 20 parts of water.

Dip cuttings, individually or in bunches. Following dipping, immediately place cuttings into planting media.

NET CONTENTS: 16 Liquid Oz.

Dip'n Grow®

ROOT INDUCING SUBSTANCE

ACTIVE INGREDIENTS

Indole-3-butyric acid	1.0%
1-Naphthaleneacetic acid	0.5%
Inert Ingredients	98.5%
	100 %

Manufactured by:

C-R CHEMICAL RESEARCH CO.

PORTLAND, OREGON 97216

EPA SLN No. WA-790035
EPA Est. 8568-OR-01
EPA SLN NO. OR-780047

For distribution and use only within Oregon and Washington for Greenhouse use only by commercial propagators. Store container at or below 70 degrees F. Keep out of direct sunlight. Do not reuse container. Triple rinse and destroy container when empty.

24(c) Registrant

CAUTION:
KEEP OUT OF REACH OF CHILDREN

May cause irritation. Combustible liquid. Harmful if swallowed. Avoid contact with skin and eyes. If contact occurs, rinse with large amounts of water, immediately. Keep away from heat and open flame.

submitted in quintuplicate and specify the provisions of the regulation deemed to be objectionable and the grounds for the objections. If a hearing is requested, the objections must state the issues for the hearing. If a hearing is granted, the objections must be legally sufficient to justify the relief sought.

Under Executive Order 12044, EPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. EPA labels these other regulations "specialized." This rule has been reviewed, and it has been determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044.

Effective date: November 26, 1980.

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

Dated: November 19, 1980.

Edwin L. Johnson,

Deputy Assistant Administrator for Pesticide Programs.

Therefore, Subpart C of 40 CFR Part 180 is amended by revising the introductory text under § 180.155 to read as follows:

§ 180.155 1-Naphthaleneacetic acid; tolerances for residues.

Tolerances are established for residues of the plant growth regulator 1-naphthaleneacetic acid in or on the raw agricultural commodities apples and pears at 1.0 ppm and olives at 0.1 ppm resulting from the application of 1-naphthaleneacetic acid or the ethyl ester of 1-naphthaleneacetic acid.

* * * * *

[FR Doc. 80-38681 Filed 11-25-80; 8:45 am]

BILLING CODE 6560-32-M

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40 CFR Part 180

[PH-FRL 1683-1; PP OF2277/R276]

Tolerances and Exemptions From Tolerances for Pesticide Chemicals in or on Raw Agricultural Commodities; 1-Naphthaleneacetic Acid

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the plant growth regulator 1-naphthaleneacetic acid to permit application of either 1-naphthaleneacetic acid or the ethyl ester of 1-naphthaleneacetic acid in or on the raw agricultural commodities apples and pears at 1.0 ppm and olives at 0.1 ppm. Tolerances have previously been established for 1-naphthaleneacetic acid on apples and pears at 1.0 ppm and olives at 0.1 ppm. This regulation was requested by Union Carbide Co. This regulation will permit the use of the ethyl ester of 1-naphthaleneacetic acid in or on apples, pears, and olives.

EFFECTIVE DATE: Effective on November 26, 1980.

ADDRESSES: Written objections may be submitted to the: Hearing Clerk, Environmental Protection Agency, Rm. 3708 (A-110), 401 M St. SW., Washington, D.C. 20460.

FOR FURTHER INFORMATION CONTACT: Robert J. Taylor, Product Manager (PM) 25, Registration Division (TS-767), Office of Pesticide Programs, Environmental Protection Agency, Rm. E-359, 401 M St. SW., Washington, D.C. 20460 (202-755-2196).

SUPPLEMENTARY INFORMATION: EPA issued a notice that was published in the Federal Register of December 4, 1979 (44 FR 69726) that Union Carbide Co., Inc., 300 Brookside Avenue, Amber, PA 19002, had filed a pesticide petition (OF2277) with the EPA. The petition proposed the establishment of tolerances for residues of the plant regulator 1-naphthaleneacetic acid in or on the raw agricultural commodities apples and pears at 1.0 ppm, and olives at 0.1 ppm resulting from the application of 1-naphthaleneacetic acid or the ethyl ester of 1-naphthaleneacetic acid.

The data submitted in the petition and other relevant material have been evaluated. The toxicology data evaluated included an acute oral LD_{50} rat (1-NAA) with a LD_{50} of 1 milligram (mg)/kilogram(kg); an I.P. LD_{50} (rat) (1-NAA) with a LD_{50} of 100 mg/kg; a 3-generation mouse (methyl ester of 1-NAA) with a no-observable-effect-level (NOEL) of 600 ppm (highest dose); a 90-day rat feeding study (1-NAA) with a NOEL of 100 mg/kg; a 90-day dog feeding (1-NAA) with a NOEL of 10 mg/kg; a 2-year rat feeding study (methyl ester of 1-NAA) with a NOEL of 2,500 ppm; several mutagenicity tests including an Ames test and a dominant lethal assay (all negative); a teratology study (rat) (technical 1-NAA) with a NOEL of 50 mg/kg/day; an eye irritation study (rabbits) (technical ethyl ester of NAA)—washed and unwashed eyes scored 0.0 on the Draize Scale; an acute inhalation LC_{50} study (rats) (technical ethyl ester of NAA) with a LC_{50} of greater than 206.5 mg/l; an acute dermal LD_{50} study (rabbits) (technical ester of NAA) with a LD_{50} greater than 5,000 mg/kg; an acute oral LD_{50} study (rats) (technical ethyl ester of NAA) with a LD_{50} of 3,580 mg/kg; an acute dermal LD_{50} study (rabbits) (formulation) with a LD_{50} greater than 5,000 mg/kg; an eye irritation study (rabbits) (formulation) showing corneal opacity, iritis, and conjunctivitis in washed and unwashed eyes at day 7; an acute inhalation LC_{50} study (rats) (formulation) with a LC_{50} greater than 217.1 mg/l; an acute oral LD_{50} study (rats) (formulation) with a LD_{50} of 5,585 mg/kg; an oncogenicity study (mice) (1-NAA) which was negative at 215 mg/kg; a 90-day feeding (rats) (technical NAA) with a NOEL of 150 mg/kg/day; and a 6-month dog feeding study (NAA, technical) which did not show a NOEL.

Data desirable but lacking are a repeat of the 6-month dog study and a teratology study on a second species. These studies are not necessary for this action because the current tolerance is being amended by the inclusion of an additional formulation, the ethyl ester, of 1-naphthaleneacetic acid in the tolerance regulation and new tolerances are not being proposed. The 6-month dog study will be necessary for any new or additional tolerances.

Tolerances have previously been established for 1-naphthaleneacetic acid on apples, pears, and quinces at 1.0 ppm and olives at 0.1 ppm. A tolerance of 0.05 has been established on pineapples resulting from the application of the sodium salt. This regulation permits use of the ethyl ester of 1-naphthaleneacetic acid on apples, pears, and olives. The published tolerances utilize 14.18 percent of the maximum permissible daily intake (MPI). Because no new tolerances are being added, the (MPI) does not change with this action. The allowable daily intake (ADI) of 0.005 mg/kg/day is based on the 90-day feeding study with a 2,000-fold safety factor.

There are no regulatory actions pending against the continued registration of this chemical, and the nature of the residue is adequately understood. An adequate analytical method (liquid chromatography and ultraviolet absorption) is available for enforcement. Since no residues are expected in feed items, it is concluded that no residues are likely to occur in eggs, milk, and meat of livestock. It is concluded that the tolerances will protect the public health. Therefore, 40 CFR Part 180 is amended as set forth below.

Any person adversely affected by this regulation may, on or before December 26, 1980, file written objections with the Hearing Clerk, EPA, Rm. M-3708 (A-110), 401 M St. SW., Washington, D.C. 20460. Such objections should be

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Chemical:	**1-Naphthaleneacetic acid**
PC Code:	**056002**
HED File Code	**13000 Tox Reviews**
Memo Date:	**01/13/81**
File ID:	**TX000455**
Accession Number:	**412-03-0114**

HED Records Reference Center
05/22/2003