

US EPA ARCHIVE DOCUMENT

OCT 7 1980

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5E1564) to EPA on behalf of the IR-4 Technical Committee and the Agricultural Experiment Stations of North Dakota and Minnesota.

This petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for residues of the insecticide carbaryl (1-naphthyl N-methylcarbamate), including its hydrolysis product, 1-naphthol, calculated as 1-naphthyl N-methylcarbamate, in or on the raw agricultural commodity sunflower seeds at 1 ppm.

The data submitted in the petition and all other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerance is sought. The toxicology data considered in support of the proposed tolerance included a two-year rat feeding/oncogenicity study with a no-observable effect-level (NOEL) of 200 ppm; a one-year dog subchronic feeding study with a NOEL of 400 ppm; a Rhesus monkey teratology study which was negative at 20 milligrams (mg)/kilogram (kg) of body weight (bw), the highest level fed; an 18-month mouse oncogenicity study, negative at 400 ppm; a three-generation rat reproduction study with a NOEL of 200 mg/kg of bw/day; a dog teratology study with a NOEL of 3 mg/kg of bw. The acceptable daily intake (ADI) in humans is calculated to be 0.1 mg/kg of bw/day based on the two-year rat feeding study using a 100-fold safety factor. The maximum permitted intake (MPI) for a 60 kg human has been calculated to be 6 mg/day. Tolerances have previously been established for residues of carbaryl on a variety of raw agricultural commodities at levels ranging from 100 ppm to zero ppm. The theoretical maximal residue contribution (TMRC) for the proposed and existing tolerances is calculated to be 4.6 mg/day.

Carbaryl is a candidate for a rebuttable presumption against registration (RPAR) since it may exceed the risk criteria described in 40 CFR 182.11(a)(3)(ii)(B) for some registered uses. However, the amount of carbaryl added to the diet from the proposed use is too small to substantially increase the risk for humans. Thus, the proposed tolerance is considered to pose a negligible increment in risk.

The metabolism of carbaryl is adequately understood and an adequate analytical method (colorimetry) is available. The existing tolerances in poultry fat, meat and eggs will adequately cover any secondary residues occurring from the sunflower feed items. Even though there are no

existing meat and milk tolerances, there are existing tolerances (5-100 ppm) on a number of feed items (e.g., alfalfa hay, barley fodder, corn fodder and forage, cottonseed, etc.). Considering the established tolerances for these feed items, the agency believes that the use of carbaryl-treated sunflower hulls, meal, and soapstock will result in an increase in the carbaryl residue burden in livestock.

Thus, based on the above information considered by the Agency it is concluded that the tolerance of 1 ppm in or on sunflower seed established by amending 40 CFR Part 180 would protect the public health. It is proposed, therefore, that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide, under the Federal Insecticide, Fungicide, and Rodenticide Act, which contains any of the ingredients listed herein, may request by November 6, 1980 that this rulemaking proposal be referred to an advisory committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. The comments must bear a notation indicating both the subject and the petition and document control number, "PP 5E1564/P152". All written comments filed in response to this petition will be available for public inspection in the office of Clinton Fletcher from 8:00 a.m. to 4 p.m., Monday through Friday.

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 proposed 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.

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

Dated: September 29, 1980.

Douglas D. Campit,

Director, Registration Division Office of Pesticide Programs.

Therefore, it is proposed that Subpart C of 40 CFR Part 180 be amended by alphabetically inserting sunflower seeds under § 180.169 to read as follows:

§ 180.169 Carbaryl; tolerances for residues.

Commodity	Parts per million
Sunflower seeds	1

40 CFR PART 180

[PP 5E1564/P152; PH-FRL-1627-1]

Carbaryl; Proposed Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This notice proposes that a tolerance be established for residues of the insecticide carbaryl (1-naphthyl N-methylcarbamate), including its hydrolysis product 1-naphthol, calculated as 1-naphthyl N-methylcarbamate) on sunflower seeds at 1 part per million (ppm). This proposal was submitted by the Interregional Research Project No. 4 (IR-4). This amendment will establish a maximum permissible level for residues of carbaryl on sunflower seeds.

DATE: Comments must be received on or before November 6, 1980.

ADDRESS: Written comments to: Clinton Fletcher, Rm. E-124, Emergency Response Section, Registration Division (TS-767), Environmental Protection Agency, 401 M St. SW, Washington, DC 20460.

FOR FURTHER INFORMATION CONTACT: Clinton Fletcher, (202-426-0223).

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted a pesticide petition (PP

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