2,4-D/TOX

#315 Inert ingredient information deleted from page 3. (17)

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: 11 OCT 1977

SUBJECT: 2, 4-D

Acceptable

FROM: R. Coberly
Toxicology Branch

10/4/77

TO: Mr. C. Fletcher, Minor Uses,
Special Registrations Section

Pesticide Petition No: 7E 1980

Petitioner: C. C. Compton
State Agricultural Experimental Station
Rutgers University, N.J.

Request: Establish the following tolerances:

0.5 ppm in or on the grain of millet
20 ppm in or on the forage or straw of millet

Recommendations:

1. The human health hazard associated with the consumption of 2, 4-D from existing tolerances will not be increased through the establishment of the requested tolerances.

2. Due to the lack of a teratology study, no comment will be made at this time concerning this potential danger area. Report by Collins et al. shows 2,4-D not to be a teratogen as dichlorodioxin was tested as well. 10/11/77

3. Due to the lack of a mutagenic study, no comment will be made at this time concerning this area.

4. The oncogenic study in a second species is needed to expand our knowledge of the chemical.

Related Petitions:

162, 272, 414, 459, 6F0477, 7F0589, 8F0670, 1E1046, 1E1122, 1E1136, 2E1293, 3E1326.

Existing Tolerances: 40 CFR 180.142

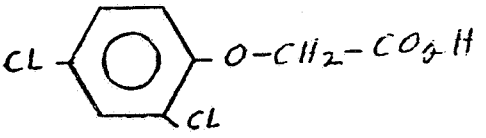
Commodity	PPM
Apples	5.0
Asparagus	5.0
Avocados	0.1
Barley, forage	20
Barley, grain	0.5
Blueberries	0.5
Citrus fruits	0.1
Citrus fruits (incl. Pre-H & Post H)	5.0
Corn, fresh, including sweet corn and corn grain	0.5
Corn (fodder and forage)	20
Cotton, seed	0.1
Cranberries	0.5
Cucurbits	0.1
Eggs	0.05
Fish & shellfish	1.0
Fruits, pome	0.1
Fruits, small	0.1
Fruits, stone	0.1
Grain crops	0.1
Grapes	0.5
Grasses, forage	0.1
Grasses, hay	300
Grasses (pasture & rangeland)	1000
Hops	0.1
Kidney of cattle, goats, hogs, horses & sheep	2.0
Legume, forage	0.1
Meat, fat and meat byproducts (other than kidneys) of cattle, goats, hogs, horses & sheep	0.2
Nuts	0.1
Oats, forage	2.0
Oats, grain	0.5
Pears	5.0
Potatoes	0.2
Poultry	0.05
Quinces	5.0
Rice	0.1

Commodity	PPM
Rice, straw	20
Rye, forage	20
Rye, grain	0.5
Sorghum	0.5
Sorghum (fodder & forage)	20
Strawberries	0.05
Strawberries	0.1
Sugar cane, forage	20
Sugar cane	2.0
Vegetables, seed and pod	0.1
Vegetables, fruiting	0.1
Vegetables, leafy	0.1
Vegetables, root crop	0.1
wheat forage	20
Wheat, grain	0.5

Chemical Name: 2, 4-dichlorophenoxyacetic acid

Common Name: 2, 4-D, CAS 94-75-7

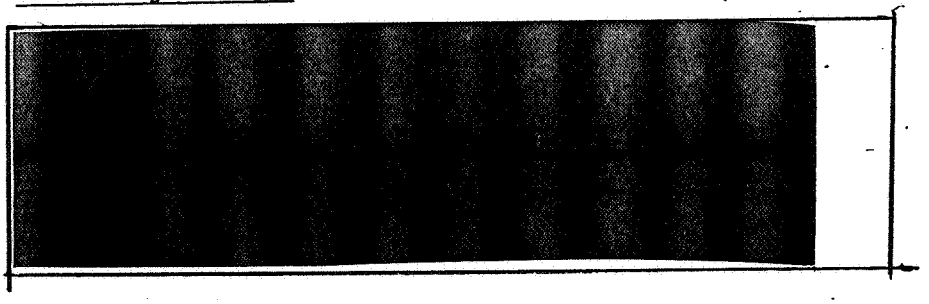
Chemical Structure:



Formulation: Formula 40 Herbicide (EPA No. 464-1)

Active Ingredient	% by weight
Alkanolamine Salts (of the Ethanol & Isopropanol series) of 2, 4-dichlorophenoxyacetic acid.	59.7

Inert Ingredients



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Use:

Herbicide to control certain annual and perennial broadleaf weeds in crop and noncrop areas.

Background Information:

The toxicity submitted in support of prior petitions are as follows:

Acute Rat Oral LD_{50}	2,4-D	300-470 mg/kg
	2,4-D sodium salt	610-1060 mg/kg
	2,4-D isopropyl ester	570-869 mg/kg
	2,4-D mixed butyl esters	320-950 mg/kg
	2,4-D mono, bi, tripropylene glycol butyl ester ethar	510-640 mg/kg

22 Week Cattle Feeding (PP#272 & 414)(12/5/63)	NEL = 50 mg/kg
32 Week Rat Feeding (Dept. of Pharmacology)	Minimal changes at 1,000 ppm
113 Day Rat Feeding (PP#162)(5/2/58)	NEL = 300 ppm
90 Day Dog Feeding (PP#162)(5/2/58)	NEL = 400 ppm
Chronic Dog Feeding (PP#272 & 414)(12/5/63)	NEL = 500 ppm
Rat Reproduction Study(PP#459)(3/11/66)	NEL = 500 ppm
2 Year Dog Feeding (PP#8F0670)(3/22/68)	NEL = 500 ppm
2 Year Rat Feeding (PP#8F0670)(2/22/68)	NEL = 1250 ppm

Dr. William E. Parkin stated in his review of 3E1326 on December 18, 1972 that the ADI for a 60 kg. man is 7.5 mg. 2,4-D/day based upon a 500 ppm systemic no effect level in a 2 year dog feeding study.

Present Action:

No new toxicity data was submitted with this petition. The aforelisted toxicity data do not provide information in the areas of teratology, oncogenicity in a second species and mutagenicity.

Considerations:

The ADI for a 60 kg. human as calculated by Dr. W.E. Parkin is 7.5 mg/day or 0.125 mg/kg body wgt/day is based on the 2 year dog study. It should

be recognized at this point that a 2 year dog study is a subacute exposure study rather than a lifetime exposure study. Normally, ADI's are based on the no effect levels of lifetime studies. Pro's and con's exist for the use of either value. In the case of this chemical, the no effect level in the 2 year rat study is 1250 mg/kg/day. This value supports the ADI of 0.625 mg/kg body wgt/day, which is five times greater than the ADI dog based value of 0.125 mg/kg body wt/day.

In considering these facts along with the calculated exposure level of 0.795 mg/day from existing tolerances, an extra 10 or 47 fold safety factor is evident with the dog and rat values, respectively. When this consideration is combined with the fact that the raising of the tolerance on millet from 0.1 ppm to 0.5 ppm does not consitute a meaningful increase of 2,4-D residues to the human diet. The human hazards are not increased over these already in existance.