D-7665 / linuron SR 10-31-83

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

OCT 3 1 1983

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OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP #3E2920. Linuron in or on Taro, Dasheen and Ginger: Evaluation of Residue Data and Analytical Methodology

FROM: Frank Boyd, Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Tricholo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Minor Uses Officer
Hoyt Jamerson
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

The IR-4 National Director, on behalf of the IR-4 Technical Committee and the Agricultural Experiment Station of Hawaii, requests the establishment of a tolerance of 0.2 ppm for the residues of the herbicide linuron (3-(3,4-dichlorophenyl)-1-methoxy-1-methylurea) in or on the raw agricultural commodities taro, dasheen and ginger.

Tolerances have already been established for residues of linuron on various agricultural commodities ranging from 0.25 ppm to 3 ppm. Included in these commodities are vegetables, grains and meat and meat by-products of cattle, goats, hogs, horses and sheep. Temporary tolerances were established (PP#6G1791) for linuron in or on sugar beet roots at 0.2 ppm and sugar beet tops at 1 ppm in connection with an experimental use permit which expired in 1975. Also, a food additive regulation was established for residues of linuron on dried beet pulp at 1 ppm concurrent with the same permit.

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A letter of authorization was submitted in this petition, authorizing EPA to refer to DuPont data on linuron when considering this tolerance proposal (R. F. Holt to H. Jamerson, 6/17/83).

Conclusions:

1. The nature of the residue in plants is adequately understood. The residue of concern is the parent compound and its demethyl, desmethoxyl and aniline degradation products expressed as parent compound.

2a. Adequate analytical methodology is available for enforcement of the proposed tolerances. Bound residues are determined by the method.

b. The analytical method used to obtain the residue data is not submitted. Reference is made in one study in the petition that a DuPont colorimetric method was used. Also, there are no raw data submitted; i.e., standard curve, light absorption numbers for controls, treated or fortified samples. In addition, no indication is given as to how samples were stored before analysis and for how long samples were stored. The absence of these data do not enable us to evaluate the methodology used to generate the submitted residue data.

3a. The submitted residue data are identified as being for washed taro and ginger roots. Root crops should not be washed before analysis (EPA Guidelines). Therefore, these data for taro and ginger are of questionable value and do not allow us to draw a conclusion on the adequacy of the proposed tolerances.

b. Residue data are available in our petition files for the use of linuron on carrots and potatoes. These data reflect similar use patterns as those proposed for ginger and taro. Additionally, taro and ginger are in the same crop grouping (root and tuber vegetable) as carrots and potatoes. The carrot and potato residue data would support a 1 ppm tolerance for ginger and taro root (carrots and potatoes are established at 1 ppm also). We could recommend for a 1 ppm tolerance if the petitioner would propose this level for ginger and taro roots. If the petitioner does not wish to take this option, we will need residue data for ginger and taro reflecting the maximum proposed use pattern with analysis by a validated analytical method. Raw data should be submitted for these residue data.

c. Poi (from taro) is not considered an item of commerce and neither residue data nor food additive tolerances are a consideration.

d. It is our understanding that young leaves of taro are used as food; either some data on linuron residues in taro leaves are necessary, or a label restriction against the use of the leaves as food should be imposed.

5. Taro, dasheen and ginger are not used as livestock feed items; therefore, secondary residues in meat, milk, poultry and eggs are not expected to result from the proposed use.

6. The proposed use prohibits application on wetland taro; there is no concern for residues in water resulting from aquatic culture.

7. Dasheen is a type of taro; therefore, if and when a tolerance is established for taro it should be in terms of "taro (corms)".

8. The label refers to the use of a surfactant. The labeling should be revised to recommend for the use of a surfactant approved for agricultural use.

Recommendations:

We recommend against the proposed tolerance because of conclusions 2b, 3a, 3b, 3d and 8. For a favorable recommendation, the petitioner should resolve these questions as discussed in the above conclusions.

Detailed Considerations

Manufacturing Process

The manufacturing process for technical linuron has been delineated in earlier petitions for this chemical (See 1E2486, 1E1148 and 6G1791). Technical linuron is reported to be 95% pure with the remaining 5% consisting of [redacted]

Formulation information deleted.

The impurities in technical linuron are not likely to be a residue problem.

Formulation

Linuron is formulated as Lorox® wettable powder (EPA Reg. No. 352-270) and Lorox®L (EPA Reg. No. 352-391). The wettable powder contains 50% active ingredient and the liquid formulation contains 41% active ingredient (4 lb. linuron/gallon). The inert ingredients are all cleared in 40 CFR 180.1001.

Proposed Use

Lorox® should be applied at 1-2 lbs/A (0.5-1 lb. ai/A linuron) as a non-directed broadcast spray, preemergence/post-plant. A second application of 0.5-1 lb. ai/A, directed interrow spray, can be applied 4 weeks after preemergence application. Surfactant should be added at rate of 0.25% spray volume - this statement should be amended by the prefix "An approved agricultural...." Do not apply over plant crop. Do not exceed 4 lbs. Lorox per season. Do not apply to wetland taro.

The labeling restricts use to ginger, taro and dasheen grown in Hawaii.

Nature of Residue

Plant Metabolism

No metabolism data were submitted with this petition. However, we have considered the metabolism of linuron in previous petitions (PP#413, 7F0542, 1E1148). Metabolism studies were conducted with corn, soybeans and crabgrass.

It was determined that linuron is absorbed from the soil, metabolized and translocated by the plants. Metabolism involves demethylation to yield 3-(3,4-dichlorophenyl)-1-methoxyurea followed by demethoxylation and hydrolysis to yield 3,4-dichloroaniline.

Also, it was noted that 15-25% linuron absorbed in the root uptake study was in the form of "bound" residue at intervals up to 14 days. These bound residues increased with time. This does not present an enforcement problem, however, because of the vigorous hydrolysis step in the analytical method which will release these residues.

Although we have no metabolism data on taro or ginger, it is reasonable to asume that the degradation products in these crops will be similar to those in the crops on which studies were conducted. We consider the metabolism of linuron adequately delineated in plants. All metabolites of significance are analyzed and reported as parent compound.

Animal Metabolism

No animal metabolism data were submitted. The topical discussion in the RCB part of the linuron Registration Standard does discuss the available animal metabolism data. Data are available for goats, dogs and rats. It was concluded that the residues of concern are linuron; 3,4-dichlorophenyl methyl urea; 3,4-dichlorophenyl urea; and 3,4-dichloroaniline.

Analytical Method

Two analytical methods are available for residue determinations. A gas chromatographic procedure as described by Imre Baunok and Hans Geissbuehler, Bull. of Env. Contam. and Tox, 3, 7-17 (1968) and a colorimetric procedure by H.L. Pease J. Ag. Food Chem. 10, 279-281 (1962). A colorimetric procedure (DuPont) was used for taro corms and ginger root samples.

Both procedures involve hydrolysis of the residue under reflux condition in a strongly alkaline medium which quantitatively hydrolyzes linuron to 3,4-dichloroaniline (DCA) while simultaneously partitioning DCA into an organic solvent. DCA is then diazotized and either (1) coupled with ethylenediamine and determined colorimetrically (Pease) or (2) The diazo moiety is exchanged to iodine and the resulting iodinated derivative determined by gas chromatography (Baunok and Geissbuehler). We assume that the colorimetric method of Pease was employed for residue analyses reported in this

petition. Adequate analytical methodology is available for determining residues of linuron. An enforcement method is in PAM II, Method I. Also, a paper chromatographic confirmation method is available, PAM Method II. The latter method will distinguish interfering urea herbicides in the colorimetric procedure.

For the residue studies submitted, the petitioner has not submitted to us or indicated to us what colorimetric procedure(s) was used and, generally, how it was applied to samples of taro corms or ginger root. Furthermore, no raw data are submitted; i.e., no absorbance values are presented to indicate validity of magnitude or viability for background, control samples, recovery samples, and treated samples.

Because of these reasons, we are unable to draw any conclusions as to the adequacy of the methodology used by the petitioner to generate residue data.

Residue Data

The geographical distribution and amount of residue data (two locations for taro and dasheen and no location for ginger) are considered adequate to support the request, including restriction of use to Hawaii. Taro and ginger are grown predominantly in Hawaii (Agric. Statistics 1981 and review of PP#2E1215, 5/23/72).

The residue data submitted which reports maximum linuron residues of 0.11 ppm in taro corns and 0.115 ppm in ginger roots are not adequate to show that the proposed 0.2 ppm tolerance is adequate because of the following deficiencies:

1. There is no information given regarding the time interval between sampling and analysis.

2. Storage stability data would be needed if samples were stored for a long period.

3. There are no raw data submitted for the methodology; i.e., absorbance values of various determination types, i.e., control, background, recovery, etc., and standard curve for colorimeteric procedure (see Analytical Method above).

4. The residue data submitted are reported as being for washed roots. According to EPA guidelines for root crops the root is to be shaken free or rubbed free of soil prior to analysis, but is not to be washed.

Examination of other root crop data (from rinsed samples) show maximum linuron residues as high as 0.5 ppm justifying a 1.0 ppm tolerance as estabished for potatoes, carrots and parsnips. These data are submitted in previous linuron petitions. In lieu of data to the contrary, a 1.0 ppm tolerance would seem appropriate for taro (corms) and ginger.

5. No data on green leaves (tops) of taro plants were presented. Residue data on taro greens (tops) are required unless petitioner submits a new label prohibiting use of leaves from treated plants.

For the roots of taro and ginger, the petitioner has the option of either proposing a 1 ppm tolerance for these commodities or submitting additional residue data on the unwashed roots by a validated method. The method and raw analytical data should be submitted. For the taro leaves, the petitioner has the option of either submitting residue data for leaves or imposing a label restriction prohibiting their use.

Meat, Milk, Poultry and Eggs

Taro (corms) or ginger are not used as livestock feed items; therefore, no secondary residues are expected to result in meat, milk, poultry and eggs from the proposed use.

Other Considerations

There is no Codex tolerance proposal for linuron on taro or ginger at step 6 or above. The "International Residue Limit Status" sheet is attached.

cc: Regular

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Linuron

PETITION NO. 3E2920

CCPR NO.

Boyd 9/23/83
F.I. 9/23/83

Codex Status

Propsed U.S. Tolerances

/ x / No Codex Proposal Step 6 or above

Residue (if Step 9):

Residue: Linuron

Crop(s)	Limit (mg/kg)

Crop(s)	Tol. (ppm)
Taro, Dasheen and Ginger	0.2

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
None (on above commodities)	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
None	

Notes:

cc: R.F.,
Circu,
Reviewer,
Tox,
EEB,
EAB,
Petition No. 3E2920
FDA, Robert Thompson
RDI:Section Head:RSQ:Date:10/16/83:RDS:Date:10/16/83
TS-769:RCB:Reviewer:F.B.,:tar:RM:810:CM#2:Date:10/31/83
DCR-26609:F.Boyd:CBI-5-RCB:10/24/83:Del.11/2/83:pjb
DCR-26638:tar:revised 10/31/83