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

Reading File

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MAY 11 1984

SUBJECT: Reg. No. 602-GNU. Chlorpyrifos as dermal treatment for hogs and horses.
Reg. No. 602-304. Protocol for residue data for chlorpyrifos as dip for hogs.

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THRU: Charles L. Trichilo, Chief
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CT

TO: Dennis Edwards, PM Team 12
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Ralston Purina Company has submitted a swine feeding study in support of its request to register Purina® Defender for dermal use on hogs and horses. Ralston Purina has also submitted a protocol for obtaining residue data from dermal application to swine; our comments on the protocol will be discussed later in this review.

This is RCB's third review of this request for registration. Our previous review (L. S. Propst, 12/6/83) recommended against registering this product for four reasons:

1. We need the specific identity of the [redacted] used in the formulation.

2. We requested a definition of "one application per season."

3. We require data reflecting residues of chlorpyrifos and its metabolite, 3,5,6-trichloropyridinol, in livestock fat and tissues after treatment with the maximum proposed dosage; these data should reflect residue levels in samples taken on the day of treatment.

4. We require a letter of authorization from Dow allowing us to refer to their data in our files while reviewing this registration.

DAI

Since there are no data from Dow in our files which would support the proposed dermal use on hogs and horses, the previously requested letter of authorization from Dow will not be required.

Our requests for information about the specific identity of the [redacted] used in the formulation and clarification of "one application per season" have not been addressed.

Since our earlier review, this formulation has been registered for use on cattle and sheep, based on a revised label bearing use directions identical to already registered uses. (0.025% active solution as spray and dip for cattle, 2.5% active as pour-on for sheep and cattle at 0.25 oz active/100 lbs, and as spot treatment at 0.025 oz active/100 lbs.)

Also since our previous review, RCB has recommended in favor of higher tolerances for chlorpyrifos, reflecting the use of additional feed items bearing residues and also specifying how much of the total residue may be chlorpyrifos. These tolerances are not yet in effect. The existing and proposed amended levels are given below:

Meat, fat, and meat byproducts of:	Tolerance (40 CFR 180.342) Existing	Proposed (Max. Chlorpyrifos)
Cattle	1.5 ppm	2.5 ppm (2.0 ppm)
Goats and sheep	0.1 ppm	2.0 ppm (1.0 ppm)
Hogs	0.1 ppm	0.5 ppm (0.3 ppm)
Horses	0.1 ppm	1.5 ppm (0.8 ppm)

The higher level for cattle reflects the registered dermal uses in addition to feed items. There are no dermal uses currently registered for hogs or horses.

The hog feeding study now submitted for review was reviewed in connection with PP#3F1306 (F. D. R. Gee, 3/1/73). We do not consider data from a feeding study (oral ingestion) pertinent to a dermal use, and have thus not re-reviewed the data. Although we have data reflecting dermal application to cattle, those data reflect extended preslaughter intervals (the registered uses have preslaughter intervals of 14 days for cattle and 35 days for sheep). We no longer consider preslaughter intervals to be practical or enforceable, and therefore require data reflecting residue levels within 24 hours after treatment.

We have reviewed the protocol for a tissue residue depletion study in swine, submitted by Ralston Purina, dated 4/12/84, and offer the following comments:

1. A residue depletion study is not necessary. Residue decline data are available in PP#3F1306 (F.D.R. Gee,3/1/73). What is required are actual residue data reflecting the proposed use, in order that we may determine whether or not the existing tolerances will be adequate to cover the residues from the proposed use. Since preslaughter intervals are no longer considered practicable, test animals should be slaughtered within 24 hours after being treated with the maximum proposed dose.

2. The article submitted by Ralston Purina [Ivey and Palmer, J. Econ. Entomology 72 (6):837-38] containing residue data for the pour-on treatment for hogs does not report residue levels for day one after treatment. Registrant should perform another residue study using the pour-on treatment at the maximum proposed rate, and slaughter within 24 hours. Separate controls will not be necessary, provided this study is performed concurrent with the dip/spray study.

3. Concerning the dose level for swine, the protocol proposes to use 1 oz product/gal for dipping (0.2%), whereas the proposed label reads 1 oz product/6.625 gal (0.03% a.i.) for dipping, but 1 oz product/gal for spray. All things being equal, we would expect residues from dipping to exceed those from a spray application; thus, residue data obtained from the proposed study may be higher than those likely to occur from the actual proposed use (spray with 0.2% a.i.). We would suggest performing a spray treatment at 1 oz product/gal or else dipping an additional group of animals in a solution where the chlorpyrifos concentration approximates the proposed use for dipping. Our purpose is to avoid possibly setting a tolerance level higher than necessary.

Additionally, residue data for horses will not be required. Since horses are not a common human food item in the U.S., we are willing to translate the day 1 residue data from swine for the purposes of this registration request.

Ralston Purina should be advised that a (higher) tolerance proposal for hogs and horses will likely be necessary prior to registering these uses. TOX Branch advises that they may have serious concerns about raising tolerance levels (personal communication, G. Burin, 5/7/84); RCB recommends that Ralston Purina also be advised of the TOX concern prior to commencing the residue studies proposed.

CONCLUSIONS AND RECOMMENDATIONS

We continue to be unable to conclude that residues of chlorpyrifos and 3,5,6-TCP in hogs and horses will not exceed the established tolerance levels from the proposed use. Ralston Purina needs to submit the following:

1. Residue data reflecting the maximum treatment rate, from samples taken at <24 hrs after treatment;
2. Data on the specific identity of the [redacted] used in the formulation; and
3. Clarification of "one application per season."

RCB recommends against this registration of chlorpyrifos for dermal use on hogs and horses.

For our comments on the protocol for gathering residue data on swine, please refer to text above (p. 3). Data for horses will not be required.

cc: R.F., Circu, Chlorpyrifos, S.F., PP#3F2884, Amended use file
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