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

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Memorandum

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: PP#1F2568 Pydrin on Sugarcane and Sunflowers. Evaluation of analytical method and residue data.

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TO: Franklin D.R. Gee, Product Manager No. 17
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and
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THRU: Charles Trichilo, Chief
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Shell Chemical Co. proposes tolerances for residues of the insecticide Pydrin (aka fenvalerate, cyano(3-phenoxyphenyl)methyl 4-chloro-alpha-(1-methylthyethyl)benzeneacetate) on sugarcane at 2.0 ppm and on sunflower seeds at 1.0 ppm.

Pydrin tolerances are established for several commodities ranging from 0.02 ppm on apples to 1 ppm for soybeans hulls. Several tolerances are pending.

Conclusions

1a. The nature of residue in plants is adequately understood. The residue of concern consists of the parent compound.

1b. We can draw no conclusion at this time as to whether the nature the residue in meat is adequately understood. A recently submitted cow metabolism study has addressed this question. In our review of that study (PP#0F2367, memo of 1/5/82, K. Arne) we deferred to Toxicology Branch as to their concern over (1) identified metabolites, (2) unidentified water soluble conjugates, and (3) other unidentified metabolites, all of which were uncovered in the liver and kidney. We can make no conclusion until TOX answers this deferrel.

1c. The residue of concern in milk is the parent compound.

2. Adequate analytical techniques are available for enforcement purposes in terms of the parent compound. Should TOX consider other animal metabolites to be in need of regulation (see conclusion 1b above) additional methodology may be needed.

3a. The proposed tolerance for sunflower seeds will accomodate expected residues in seeds, meal, refined oil, and soapstock. No food additive tolerances are needed for these commodities.

3b. Pydrin residues are higher in sunflower hulls than seeds by a factor of 2. A food additive tolerance proposal of 2 ppm is needed for sunflower hulls.

3c. The residue data for sunflower forage is too limited to be the basis of a tolerance. Either additional residue data or a label feeding restriction prohibiting the use of Pydrin treated sunflower forage for animal feed is needed.

3d. No sugarcane residue data from Hawaii are submitted. This will be needed before we can make a conclusion as to an appropriate tolerance.

3e. Residues in molasses and sugar are not expected to exceed the residue level in sugarcane and food additive tolerances are not needed for these commodities.

3f. A processing study shows that residues in bagasse may be about 10X that found in the stalk. Therefore a food additive tolerance of 10X the residue level determined to be necessary for sugarcane is needed for bagasse and should be proposed.

3g. No residue data are submitted for sugarcane forage. Either residue data and an appropriate tolerance proposal or a label restriction prohibiting its feed use is needed for sugarcane forage.

4a. We can make no conclusion concerning secondary residues in meat of livestock until the questions concerning metabolites (conclusion 1b) and the questions in conclusion 3(c), 3(d), 3(f) and 3(g) are resolved.

4b. With respect to poultry and eggs, we classify the proposed uses in 40 CFR 180.6(a)(3).

4c. We can make no conclusions regarding residues in milk until the questions raised in conclusions 3(c), 3(d) and 3(f) are resolved.

5. An International Residue Limit Status sheet is attached. The CODEX MRL for sunflower seed is 0.1 ppm (expressed as parent).

The proposed tolerance for sunflower seeds is not compatible and cannot be made compatible with the CODEX MRL. No foreign or CODEX tolerances are established for sugarcane.

Recommendations

For the reasons in conclusions 1b, 3b, 3c, 3d, 3f, 4a, and 4c we recommend against the proposed tolerances. Before a favorable recommendation can be made, the following are needed:

1. Either additional sunflower forage residue data and tolerance proposal or a label restriction prohibiting the feeding of sunflower forage or fodder to livestock.

2. A feed additive tolerance proposal of 2 ppm for sunflower hulls.

3. Resolution of questions raised concerning metabolites found in the liver and kidney in a cow metabolism study (conclusion 1b). We defer to TOX in this issue.

4. Residue data for sugarcane from Hawaii.

5. A feed additive proposal of 10 x the residue level deemed necessary for sugercane is needed for sugarcane bagasse and should be proposed.

6. Residue data and an appropriate tolerance proposal for sugarcane forage or a label restriction prohibiting its feeding use.

A CODEX MRL is established for sunflower seed at 0.1 ppm. Since higher residues are expected as a result of the proposed use, the proposed tolerance cannot be made compatible with the MRL.

Any future use that result in real residues in a poultry feed item will require a poultry feeding study at an appropriate level (the only such study to date is at 0.03 ppm).

Detailed Considerations

Manufacture

The manufacturing process for Pydrin was submitted with PP #0F2013 and reviewed in conjunction with that petition (memo of 4/21/78, E. L. Gunderson).

[redacted]

We expect no residue problems from these impurities as they would be present in extremely low levels from the proposed use.

Formulation

A 2.4 lb a.i./gallon EC is proposed for use. It is comprised (by weight) of 30% a.i., [redacted] ingredients are cleared under Section 180.001.

Proposed Use

Sugarcane

For control of sugarcane borers Pydrin is to be applied at the rate of 0.1-0.2 lb a.i./A. This to be repeated as necessary to maintain control up to 0.8 lb a.i/A/season. The PHI is 21 days.

Sunflowers

For control of sunflower head moths Pydrin is to be applied at the rate of 0.1-0.2 lb a.i./A. This is to be repeated as necessary to maintain control up to 0.8 lb a.i./A/season. The PHI is 28 days.

Nature of the residue

Radiolabel metabolism studies have been carried out on cotton (PP#6G1755, see review of 5/14/76 E. L. Gunderson), apples and lettuce (PP#8E2024, memo of 6/21/78, E. L. Gunderson) and tomatoes (PP#1F2367, memo of 1/7/81, K. Arne).

In these studies it was shown that Pydrin does not readily translocate. All studies indicate that degradation is slow, the parent accounting for 90, 71-81 and 90-94% of the terminal residue in apples, lettuce, and tomatoes respectively. Of Pydrin applied to tomato leaves 80% was present at harvest, 32-48 days later, indicating slow dissipation.

In conjunction with PP#0F2367 we deferred to Toxicology Branch as to the significance of a photodegrate of Pydrin, 4-chloro-beta-(1-methylethyl)-alpha-(3-phenoxyphenyl)benzenepropanenitrile on tomatoes, lettuce, and apples. TOX concluded that, because the levels of this compound are low (less than 0.1 ppm), it was not of concern (memo of 8/24/81, A. Kocialski).

We reiterate our previous conclusion that the residue of concern in plants consists of the parent. Since we do not expect residues of the above photodegradate to be greater than 0.1 ppm we will not raise any questions for the present uses.

Questions concerning the metabolism of Pydrin in animals were raised in our review of PP#0F2367 (memo of 1/7/81, K. Arne). These questions have been addressed (a cow metabolism study was submitted) but are not yet resolved. We have deferred to Toxicology as to their concern over (1) identified metabolites, (2) undentified water soluble metabolites, and (3) other unidentified metabolites, all of which were uncovered in the cow metabolism study (liver and kidney). Should TOX be concerned over the above metabolites, further elucidation of these residues will be needed. Should TOX deem that the metabolites noted above need to be regulated, appropriate analytical methods will need to be developed and these metabolites will have to be included in the tolerance. The nature of the residue in tissues other than liver and kidney and in milk is adequately understood. The residue of concern is the parent compound.

Analytical Method

The method used to collect data for this petition is described in Shell Report No. MMS-R-478-1. A successful method trial was carried out in conjunction with PP#7F2013 (memo of 7/24/78, J. H. Onley). Briefly, the method involves extracting the residue into hexane/isopropanol (3:1) then partitioning the isopropanol into water. The hexane extracts of oily crops are partitioned with acetonitrile to separate lipids from Pydrin. The acetonitrile is extracted with hexane; the hexane solution is washed with water, then cleaned up on a florisil column. Hexane extracts of non-oily crops are cleaned up directly without acetonitrile partitioning. The isolated Pydrin is quantitated by GLC incorporating and electron capture detector.

The following check and recovery values are presented:

		Recovery		
Crop	Check (ppm)	Fort. (ppm)	Range (%)	Avg.(%)
Sunflower				
seeds	<0.01-0.06	0.05-2	81-102	91
stover	0.01	4	85	-
hulls	0.10	0.05-1	85-99	92
071	0.01	0.1	89	-
soapstock	<0.01	0.05-0.1	87-98	93
Sugarcane				
stalks	<0.01	0.05-1	81-107	94
bagasse	<0.01	0.1	93	-
molasses	<0.01	0.1	65	-
raw sugar	<0.01	0.05	89	-

We conclude that adequate analytical techniques are available for enforcement pruposes.

Residue data

Sunflowers

Residue experiments were carried out in California, Georgia, Minnesota and Texas. As part of the Texas experiment a processing study was carried out. The results of these studies are tabulated below:

Plant part	(rate a.i./A)	No applications	Method	PHI	Residue (ppm)
seeds	0.2	4	ground	20-21	<0.01-0.75
seeds	0.4	4	ground	20-21	<0.01-0.75
seeds	0.2	4	fixed wing aircraft	21-29	0.03-0.3
stover	0.2	4	fixed wing aircraft	29	0.14
hulls	0.2	4	fixed wing aircraft	28	0.36
solvent extracted meal	0.2	4	fixed wing aircraft	28	<0.01
refined oil	0.2	4	fixed wing aircraft	28 28	0.08 0.08
soapstock	0.2	4	fixed wing aircraft	28	<0.01

The processing study showed no concentration of residues in the meal, oil, or soapstock but a concentration of about 2 x in the hulls (seeds containing 0.19 ppm Pydrin were processed; the hulls were found to contain 0.36 ppm Pydrin). We therefore require a food additive tolerance proposal of 2 ppm for sunflower seed hulls.

The data submitted for sunflower forage is insufficient to establish a tolerance; we therefore require either additional residue data or a label restriction prohibiting the feeding of the sunflower forage or fodder to livestock.

The tolerance proposed for seeds is adequate and will also accommodate expected residues in solvent extracted meal, oil and soapstock.

Sugarcane

Residue experiments were carried out in Texas, Florida, Louisana and Puerto Rico. These data are tabulated below.

Plant parts	Rate (a.i/A)	No. applications	Method	PHI	Residue (ppm)
cane	0.2	4	aerial	21	<0.01-1.2
cane	0.4	4	aerial	21	<0.01-1.0
cane	0.1	4	aerial	31	<0.08-0.12
cane	0.2	4	aerial	31	<0.08-0.09
bagasse	0.2	4	aerial	31	0.99
molasses	0.2	4	aerial	31	<0.01
raw sugar	0.2	4	aerial	31	<0.01

We do not consider the above data adequate as no data from Hawaii are included. The petitioner should submit residue data from Hawaii; we will then determine an appropriate tolerance. No residue data are submitted for sugarcane forage. Either residue data should be submitted for forage or a label restriction prohibiting its feeding should be imposed.

The processing study shows that residues concentrate in the bagasse (ca. 10x) but not in molasses. The petitioner should propose a food additive tolerance for bagasse at a level 10x that deemed necessary for sugarcane.

The processing study shows that no detectable residues (<0.01 ppm) result in molasses and sugar processed from treated sugarcane. No food additive tolerances are needed for these processed commodities.

In conclusion, residue data are needed for sugarcane grown in Hawaii. Residue data are needed for sugarcane forage or a label restriction prohibiting its feed use is needed. A food additive tolerance proposal for bagasse is needed.

Meat, Milk, Poultry and Eggs

Sunflower seed, meal, hulls, soapstock, sugarcane, bagasse, molasses, and sugarcane forage are potential livestock feed items. Sunflower meal and sugarcane molasses are potential poultry feed items.

Tolerances of 1.0 ppm have seen proposed for the meat, fat and meat by-products of cattle (PP#0F2367 memo of 1/5/82, K. Arne). While these tolerances might not accommodate secondary residues resulting from proposed uses on corn (PP#0F2430) we expect that the presently proposed uses in this petition will not cause them to be exceeded. However, no final conclusion will be made until (1) residue data for sunflower forage is submitted or a label feeding restriction imposed (2) residue data for sugarcane forage are submitted or a label feeding restriction is imposed (3) an appropriate tolerance for sugarcane bagasse is determined and (4) the animal metabolism question is resolved.

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A milkfat tolerance of 2.0 ppm (reflecting no more than 0.1 ppm in whole milk) was proposed in conjunction with PP#0F2367. We do not expect that these tolerances will be exceeded as a result of the proposed uses but will make no conclusions until the amount of residue ingested as the result of feeding sunflower and/or sugarcane forage and bagasse can be determined (see preceeding paragraph).

Processing studies show that no detectable residues are expected in either molasses or sunflower meal (i.e., <0.01 ppm). Since these are relative minor poultry feed items (molasses may be up to 4% of the diet; sunflower meal up to 15% of the diet) and since poultry feeding studies at 0.03 ppm (PP#7F2013) show no residue in any tissue or eggs we classify this use in 40CFR 180.6(a)(3).

For any future uses that may result in real residues in poultry feed items, a poultry feeding study will be needed.

cc: RF, Circ, Arne, Watts, FDA, TOX, EEB, EFB, PP#1F2568
TS-769:RCB:Reviewer:K.Arne:Gwen:Date:1/18/82
RDI:Section Head:Quick:1/15/82:Schmitt:1/15/82

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Pydrin (fenvalerate) PETITION NO. 1F2568

CCPR NO. 119

Codex Status

[X] No Codex Proposal Step 6 or above

Proposed U.S. Tolerances

Residue (if Step 9): Determined and expressed as parent*

Residue: Parent

Crop(s)	Limit (mg/kg)
Sunflower seed	0.1*

Crop(s)	Tol. (ppm)
Sunflower seeds	1
Sugarcane	2

CANADIAN LIMIT

Residue:

Crop	Limit (ppm)
None (on above commodities)	

MEXICAN TOLERANCIA

Residue:

Crop	Tolerancia (ppm)
None	

* Step 5 Temporary Limit

Notes:

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