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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Memorandum

Subject: PP#2F4086. Propiconazole (Tilt) in/on Oat Grain and Straw. Evaluation of Analytical Method and Residue Data. CBTS# 9325, 9603. MRID# 421829-01. DP Barcode# D174248, D175989.

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CIBA-GEIGY Corporation, Agricultural Division, has submitted a petition proposing tolerances for the fungicide propiconazole (1-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1*H*-1,2,4-triazole), and its metabolites determined as 2,4-dichlorobenzoic acid, on oat grain (0.1 ppm) and straw (1.0 ppm). Permanent tolerances have been established under 40 CFR §180.434 for residues of propiconazole and its metabolites determined as 2,4-dichlorobenzoic acid (expressed as parent compound) on the following raw agricultural and animal commodities:

Bananas	0.2 ppm	Rice, straw	3.0 ppm
Barley, grain	0.1	Rye, grain	0.1
Barley, straw	1.5	Rye, straw	1.5
Pecans	0.1	Wheat, grain	0.1
Rice, grain	0.1	Wheat, straw	1.5
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Animal*, fat	0.1	Animal*, meat	0.1
Animal*, mbyp (except liver and kidney)	0.1	Eggs	0.1
		Milk	0.05
Poultry, fat	0.1	Poultry, meat	0.1
Poultry, mbyp (except liver and kidney)	0.1	Poultry, liver & kidney	0.2

*Animal = cattle, goats, hogs, horses, and sheep.

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Temporary tolerances, extended through January 31, 1994 (telecon, S. Jackson, RD), have also been established for the following commodities: kidney and liver of cattle, goats, hogs, horses, and sheep (2.0 ppm each), grass forage (0.5 ppm), grass hay (5.0 ppm), and grass screenings (10.0 ppm). There are no food or feed additive tolerances currently established for propiconazole.

Propiconazole is a List C chemical. The Phase 4 review, completed 4/30/92, identified numerous reregistration data gaps, including the nature of the residue in plants and ruminants, storage stability, analytical method (plants), and residue data for several crops. Where possible, we will allow the petitioner to address these concerns in the reregistration process.

There are pending tolerances for corn, celery, pineapples, and legume vegetables (PP#8F3674), grass seed screenings, straw, and forage (PP#1F3974), peanuts (PP#8F3654), and mint (PP#2E4037). CBRS has recently registered no objections to a Section 18 registration allowing use of propiconazole on sweet corn and seed corn (92-FL-10, D. McNeilly, 7/27/92).

Conclusions

1a. CBTS is willing to accept previously submitted plant metabolism data in support of this petition, based on the existing tolerances for other cereal crops and the low tolerance levels proposed for oat grain and straw. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

1b. The Phase 4 Review for propiconazole has identified a data gap for plant metabolism, proposing additional radiolabeling studies for wheat, bananas, and pecans. CBTS concludes that this data gap can be addressed in the reregistration process.

2a. CBTS concludes that the nature of the residue in animals is understood, based on studies submitted with PP#4F3007. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

2b. CBTS has recently concluded (PP#1F3974) that the nature of the residue for both ruminants and poultry is not understood. However, this determination was made assuming an increased dietary burden due to the tolerances proposed in that petition. The tolerances proposed in this petition will not add to the dietary burden, since the commodities, oat grain and straw, would only replace other feed items for which identical tolerances have already been established. Therefore, the concerns about animal metabolism expressed in that petition do not apply to this petition.

3. The proposed analytical method for detection of propiconazole in oat grain and straw, AG-454A, has been shown to adequately recover the pesticide and its metabolites as a 2,4-dichlorobenzoic acid methyl ester derivative. The limit of detection is 0.05 ppm (propiconazole equivalents). Both AG-454A and the method for animal commodities, AG-517, have been successfully validated by the Agency's Analytical Chemistry Section/BEAD.

4. Product chemistry data has been previously submitted and reviewed by the Agency. All

requirements for this section have been met.

5. The petitioner has not submitted adequate storage stability data. Previously submitted data for peanuts and soybeans can not be translated to the oat grain and straw samples. In PP#1F3974, the petitioner indicated that a storage stability study for grass straw and forage is nearing completion. CBTS could translate this data to oats; however, to assure timely resolution of this deficiency, the petitioner should conduct storage stability studies on oats or another cereal grain crop.

6. CBTS has found the following deficiencies in the proposed labeling. The petitioner must remove the uses of thiabendazole and thiophanate-methyl on barley, rye, and oats, as there are no tolerances for those chemicals on those commodities. Also, the petitioner should clarify that only one application of propiconazole at 50 g ai/A is allowed per season for control of foot rot. The petitioner should also express the time of applications as days before harvest as well as by plant growth stage, and indicate the amount and kind of solvent used to dilute the product (if any is used).

7a. The submitted data supports the proposed tolerances of 0.1 ppm in oat grain and 1.0 ppm in oat straw (however, see Conclusion 7c). Observed residues in grain treated at the 1X rate were $\leq$0.06 ppm in all cases. The highest observed residue in straw from 1X-rate trials was 0.62 ppm.

7b. The petitioner has also submitted residue data on oat forage. This data would support a tolerance of 10.0 ppm, if the petitioner wishes to remove the label restriction against feeding oat forage. In this case, appropriately revised Sections B and F should be submitted to the Agency.

7c. CBTS concludes that no food or feed additive tolerances are necessary for oat processing fractions. The two fractions in which propiconazole seemed to concentrate at the 5X treatment rate, hulls and feed oats, did not show any concentration at the 3X treatment rate. Also, in the 5X treatment rate trials, the amount by which the residue levels for those fractions exceeded the levels for whole oats, 0.03 and 0.02 ppm, are within the error of the analytical method. Therefore, there is no evidence that propoiconazole residues concentrate in oat fractions.

7d. CBTS cannot recommend for appropriate tolerance levels for propiconazole in oats grain and straw until storage stability (Conclusion 5) and proposed labeling (Conclusion 6) deficiencies have been corrected.

8. Since recent concerns of an increased dietary burden for animals (see Conclusion 2b) do not apply to this petition, CBTS concludes that no further animal feeding data needs to be submitted for this petition. Adequate animal tissue, milk, and egg tolerances exist to cover residues in those commodities incurred from the proposed use.

9a. There are no Canadian or Mexican tolerances for propiconazole in oat grain or straw; therefore, no compatibility problems are expected. There is a Codex tolerance, for parent only, on oat grain at 0.05 ppm. Due to the data gap in plant metabolism

identified in the Phase 4 review, CBTS can not discuss at this time the feasibility of harmonization of the U.S. and Codex tolerance expressions.

9b. No Craven data are associated with this petition.

Recommendations

CBTS recommends against the proposed tolerances for propiconazole of 0.1 ppm in oat grain and 1.0 ppm in oat straw for the reasons outlined in Conclusions 5, 6, and 7d.

Note to PM: Please be aware of our Conclusion 7b regarding a potential tolerance for oat forage.

Detailed Considerations

Manufacturing Procedure

The product chemistry data for propiconazole has been reviewed previously by the Agency (W.T. Chin memo of 5/20/88). There are no outstanding deficiencies associated with this section. The TGAi is 88% pure; its impurities are not expected to produce a residue problem. The proposed formulation, **Tilt**, contains 3.6 lbs ai/gallon liquid concentrate, or 47.6% TGAI by weight.

Proposed Use

Tilt 3.6E is proposed for use on cereal grains (wheat, barley, rye, and oats) for control of rusts, powdery mildew, leaf and glume blotch, tan spot, Helminthosporium leaf blight, barley scald, and net blotch. One application of 50 g ai/A may be made per season. This application may be made up to Feekes growth stage 8, when the ligule of the flag leaf emerges. The timing of this application is approximately 5-7 weeks prior to harvest,[1] with the range of PHIs depending on temperature. The petitioner should confirm this estimate and indicate the appropriate time intervals on the label. The petitioner should also indicate the amount and kind of solvent used to dilute the product (if any is used).

Tilt, in combination with the fungicides **Benlate** (benomyl), **Mertect** (thiabendazole), and **Topsin M** (thiophanate-methyl), may also be applied for control of foot rot. The proposed application rate is 50 g ai/A (plus half-rates of the other fungicides), with application at tillering but before elongation has occurred. CBTS notes that there are tolerances for benomyl on wheat, barley, rye, and oats (40 CFR §180.294). However, for thiabendazole (§180.242) and thiophanate-methyl (§180.371), there are only tolerances for wheat. Therefore, the petitioner must remove from the label the inferred uses of thiabendazole and thiophanate-methyl on barley,

[1]. From 11/18/92 telecon with Prof. D. Peterson, Univ. of Wisconsin, Dept. of Agronomy (608) 262-4482.

rye, and oats.

With regards to the foot rot use, it is implied, but not clearly stated, that only one application per season is allowed. The petitioner should explicitly mention this restriction in a revised Section B.

Restrictions include, "Do not graze or feed livestock treated forage or cut the green crop for hay or silage. After harvest, the straw may be used for bedding or feed." Oat forage is considered to be under grower control. Thus, this restriction is valid.

To summarize, CBTS has found the following deficiencies in the proposed labeling. The petitioner must remove the uses of thiabendazole and thiophanate-methyl on barley, rye, and oats, as there are no tolerances for those chemicals on those commodities. Also, the petitioner should clarify that only one application of propiconazole at 50 g ai/A is allowed per season for control of foot rot. The petitioner should also express the time of applications as days before harvest as well as by plant growth stage, and indicate the amount and kind of solvent used to dilute the product (if any is used).

Nature of the Residue - Plants

Plant metabolism data were not submitted with this petition. The Phase 4 Review (4/30/92) has identified a data gap in this area, stating,

Phenyl-^{14}C-propiconazole should be applied to wheat, bananas, and pecans reflecting the currently registered use patterns. The specific activity and/or application rate should be high enough to allow for adequate identification of the metabolites/degradates. If metabolism is similar in these three unrelated crops then only these three must be tested. The plant material from the metabolism studies should be tested using the data collection method(s) and enforcement analytical method(s).

CBTS concludes that this data gap can be addressed in the reregistration process. Based on the existing tolerances for cereal crops, and the low tolerance levels proposed for oat grain and straw, CBTS is willing to accept previously submitted plant metabolism data in support of this petition. Therefore, the residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

Full reviews of those plant metabolism studies can be found in PP#4F3007, A. Smith memo of 5/15/84. A summary of the wheat metabolism is presented as relevant to the proposed oats tolerances. Two separate studies were performed, one with ^{14}C-triazole label, and one with ^{14}C-phenyl label. Each was applied at the rate of 0.11 lb ai/A. Triazole samples were harvested 49 days, and phenyl samples 41 days, after application. Total radioactivity was measured by combustion analysis with LSC. Residue components were characterized and quantitated by GLC, HPLC, and electrophoresis. Conjugated components were released by hydrolysis with HCl. In both cases, the parent compound was absorbed, metabolized, and translocated to the grain. Residues were higher for the triazole label, with 54% of the residue identified as the alanine conjugate of 1,2,4-triazole (CGA-131013). No parent was observed in the grain. In straw, the primary components were parent and the free and bound forms of four bridge-intact

metabolites, all hydroxylated on the n-propyl side chain of the dioxolane ring.

Nature of the Residue - Animals

Animal metabolism data was not submitted with this petition. Although tolerances exist for animal products, CBTS has recently concluded (PP#1F3974, S. Willett, 6/11/91) that the nature of the residue for both ruminants and poultry is not understood. In previous ruminant metabolism studies (reviewed in PP#4F3007, A. Smith, 5/15/84), some low levels of activity were not characterized. At that time, the anticipated dietary burden was small, as the only existing tolerances were at low levels. The low activity levels found in those studies may be significant now due to several proposed tolerances which will increase the exposure of cattle and poultry. These petitions include 9F3706 and 1F3974 (grass seed screenings), 8F3654 (peanuts), and 8F3674 (corn). The proposed tolerances for the grass and corn feed items are:

grass seed screenings	70 ppm	corn grain	0.1 ppm
grass straw	40 ppm	corn forage	10.0 ppm
grass forage	2 ppm	corn fodder	10.0 ppm

New ruminant (MRID# 418233-01) and poultry (418233-02) metabolism studies were reviewed in connection with PP#1F3974. CBTS withheld its decision on the adequacy of both metabolism studies until appropriate tolerances were determined for grass seed screenings, straw and forage, and corn grain, forage, and fodder, and a subsequently better estimate of the dietary burden to cattle and poultry could be made. Additional characterization of residues in cattle liver and kidney may be necessary if the residue levels in the feed items approach those used in the metabolism studies (67 to 90 ppm). The poultry metabolism study was found to be generally acceptable, again pending the final decisions on the grass seed and corn tolerances. However, for both studies, no details on sample handling and length of storage were supplied, and no data from storage stability studies on animal commodities were submitted or referenced.

The proposed tolerance for oat grain, 0.1 ppm, is identical to the established tolerances for barley, rice, rye, and wheat grains. The proposed oat straw tolerance, 1.0 ppm, is less than the existing tolerances for the straw of those other cereal crops. It is also likely that the use of oat grain and straw in animal feed would replace the use of other cereal crop feed items. Therefore, the establishment of this tolerance would not add to the current dietary burden to farm animals. Thus, the concerns over the feeding levels of the recent metabolism studies do not apply in this case.

CBTS concludes that the nature of the residue in animals is understood, based on studies submitted with PP#4F3007. The residues of concern are the parent compound, propiconazole, and its metabolites determined as 2,4-dichlorobenzoic acid.

Analytical Method

Analtical methodologies for the determination of propiconazole and its metabolites in plant and animal commodities (Ciba-Geigy Analytical Methods AG-454A and AG-517, respectively) have

been successfully validated by the Agency's Analytical Chemistry Section and have been approved for publication in PAM II for enforcement purposes (letter, S. Malak to A. Marcotte (FDA), 5/28/87). The petitioner has included recovery data for oat grain, straw, forage, and processed products, which are summarized in Table 1. Adequate chromatograms have also been submitted. The apparent level of detection for all oat products is 0.05 ppm (propiconazole equivalents). CBTS concludes that the proposed analytical methods are adequate for data collection purposes. We note, however, that recoveries from straw are marginal.

In the method, crop samples are extracted by refluxing with 20% concentrated NH_4OH/MeOH for one hour. An aliquot taken for analysis is concentrated and refluxed with $KMnO_3$ in NaOH for 1h 15min. The acidified extract is then partitioned with 10% diethyl ether/hexane. The organic phase is evaporated to dryness and derivatized with diazomethane. The derivative, 2,4-dichlorobenzoic acid methyl ester is cleaned up using an acidic alumina Sep-Pak. Residues are determined by capillary GC/electron capture detection.

The Phase 4 review indicated that new validation studies for AG-454A are necessary for recovery from bananas, and that a new method for all commodities may be necessary may be necessary if new metabolites are found in the required plant and/or animal metabolism studies. The Phase 4 review has also requested that the petitioner submit information indicating why appropriate methylating agents cannot be substituted for diazomethane. These concerns can be addressed in the reregistration process.

Table 1. Procedural Recoveries for Propiconazole from Oat Products Using AG-454A.

	Recoveries (%)			
Spike (ppm)	Grain	Straw	Forage	Processed Products[1]
0.05	109,65,72,67	58,79,59	96,87	65[e],88[e],(89,81,86)[e], 85[e],86[e],63[i]
0.10	69,84,72	77	---	77[f],82[h]
0.20	70,71,73	62,57,64	---	61[b]
0.50	79,87	55,66,54,50	66,54,69	(102,85,86)[b]
1.0	84,85	81	72,73,70	138[i]
2.0	---	65	87	
≥5.0	---	67	78,72,74[3],75, 82,66,74	
Average	77.6 ± 11.6	63.6 ± 9.6	74.7 ± 9.9	

1 - Processed products include: a- whole oats, b- hulls, c- rolled oats, d- bran, e-flour, f-light impurities, g- feed oats, h- groats, i- fines (oat feed).
2 - All controls less than 0.05 ppm except as noted, which was 0.25 ppm (spike of 5.0 ppm).

Multiresidue methodology data have been sent to the FDA (4/28/87). Recovery of propiconazole via FDA Multiresidue Protocol D (PAM II 232.4) is complete while recovery of

propiconazole metabolites (CGA-91305, CGA-118244, and 1,2,4-triazole) via this method is variable.

Storage Stability

Field samples in this petition were stored frozen (-20°C) for 5-19 months. The petitioner has not submitted any storage stability data. Instead, data from soybean and peanut commodity studies was referenced. This data was previously reviewed in PP#4F3007. The data for soybeans indicate no significant degradation of residues for 4-6 months of frozen storage. However, the Phase 4 review has indicated that the storage stability data for peanut fodder, shells, and nutmeat are completely inadequate, and has concluded that new studies must be conducted on all crops and processed products for which a field trial and/or processing study has been or will be conducted, as well as representative livestock studies.

CBTS concludes that the soybean storage stability study does not support this petition. We are generally reluctant to translate storage stability data between crop groupings, and the duration of the soybean storage study is too short to support the field trial data in this petition. In PP#1F3974, the petitioner has indicated that a storage stability study for weathered residues of propiconazole in grass straw and forage has been initiated and will run through December 1992. (In that petition, grass samples were stored frozen for a maximum of 16 months.) CBTS may decide that the grass straw and forage storage stability study results would support the oat straw and grain data. However, to assure timely resolution of this deficiency, the petitioner should conduct storage stability studies on oats (or another cereal grain) reflecting the storage intervals in the residue data.

Residue Data

The petitioner has conducted both residue and processing trials for propiconazole in oats. The results of these trials are contained in MRID# 421829-01 (Ciba-Geigy Project No. ABR-89012). Eleven trials were conducted, one each in the following states: MN, NE, CA, IL, OR, LA, ND, SD, IA, NY, and WI. This group of states includes all major oats producing states (i.e. >5% of US production) and in total represents 73% of 1990 US production (1991 Agricultural Statistics). Geographical representation is adequate. Propiconazole (Tilt 3.6E) was applied to oats one time at rates of 50, 100, 150, or 250 lbs ai/A (1X, 2X, 3X, or 5X the proposed rate). Dilution of Tilt in water ranged from 19 to 44 gallons/acre. PHIs ranged from 35 to 80 days. Oats grain, forage, and straw samples were collected from each site, stored frozen for 5-19 months, and analysed using Ciba-Geigy Method No. AG-454A. The limit of detection for grain and straw is 0.05 ppm. Analytical data is supplemented with sample chromatograms. Detailed results are presented in Table 2. Control samples in most cases (see Table 2) contained <0.05 ppm residues.

Table 2. Propiconazole Residues in Oats Grain, Forage, and Straw (from MRID# 421829-01).

				Residues (ppm)[2]		
Site	Rate[1]	GPA	PHI (days)	Grain	Forage	Straw
MN	1X	20	41	<0.05, <0.05	2.3, 2.6	(0.15, 0.14), (0.22, 0.19)
NE	1X	20	40	<0.05, <0.05	3.9, 3.7	0.49, 0.35
CA	1X 2X	44	80	<0.05, <0.05 <0.05	4.7, 3.9 8.1	0.33, 0.29 0.57
IL	1X 2X	20	35	<0.05, <0.05 0.08	2.2, 4.0 9.5	0.20, 0.56 1.1
OR	1X	24.2	78	<0.05, <0.05	1.3, 1.2	0.16, 0.12
LA	1X	28.3	75	<0.05, <0.05	2.4, 4.8	(0.28, 0.29), (0.30, 0.31)
ND	1X	20	46	(0.06, 0.06), (<0.05, <0.05)	(6.3, 4.5)[3], (5.8, 5.9)	0.13, 0.11
SD	1X 2X	19	50	(0.05, <0.05), (<0.05, <0.05) (0.08, 0.07)	(5.8, 4.9), (7.5, 5.9) (23, 19)	0.19, 0.19 0.58
IA	1X 3X 5X	20	49	<0.05 <0.05 <0.05	3.3, 2.1 9.8 16.	0.58, 0.44 2.0 3.4
NY	1X 2X	30	41	<0.05, <0.05 <0.05	2.5, 2.5 5.6	(0.53, 0.56), (0.43, 0.46) (1.1, 1.1)
WI	1X 3X 5X	27.36	63	<0.05, <0.05 0.07, 0.06 0.16, 0.09	2.1, 2.4 7.3 16.	0.59, 0.62 2.0 8.9

1 - 1X = 50 g ai/A.
2 - Numbers in parentheses represent duplicate analyses of the same sample. Residues were detected as 2,4-dichlorobenzoic acid and converted to propiconazole equivalents.
3 - ND forage control sample showed 0.27 and 0.25 ppm in two analyses.

The petitioner has not proposed any tolerances for processed oat fractions. In support of this, a processing study was also conducted with samples from the WI trial. Processing products include whole oats, hulls, rolled oats, flour, fines, feed oats, groats, bran, and light impurities. Also included is a processing flowchart for oat fractions, which can be found in Appendix 2. Processing took place at Texas A&M University, following SOP No. 8.18 (included as an attachment in the petitioner's report). The methods used are consistent with industrial processing procedures. Details of the analysis are presented in Table 3.

Table 3. Propiconazole Residues in Processed Oat Fractions (from MRID# 421829-01).[1]			
	Residues (ppm)[2]		
Substrate	1X Rate	3X Rate	5X Rate
whole oats	<0.05	0.09	0.14
hulls	<0.05	0.09	0.17
rolled oats	<0.05	<0.05	0.09
flour	<0.05	0.05	0.07
fines (oat feed)	<0.05	<0.05	<0.05
bran[3]	<0.05, <0.05, <0.05	0.08, 0.06, 0.11	<0.05, <0.05, 0.06
feed oats	<0.05	0.06	0.16
groats	<0.05	<0.05	0.09
light impurities[4]	<0.05	0.18	0.26

1 - Details of the WI residue trial from which these samples were taken are in Table 2.
2 - Detected as 2,4-dichlorobenzoic acid and converted to propiconazole equivalents.
3 - Residues in control samples were 0.13, 0.09, and 0.15 ppm (triple analysis). See text for discussion. Residues in all other control samples were <0.05 ppm.
4 - The petitioner notes, "The light impurities fraction samples contained oat straw, which is atypical of this fraction when obtained from commerical processing. These samples, therefore, do not represent a commercially produced light impurities fraction."

As indicated in Footnote 3 of Table 2, residues in control samples processed for bran were higher than residues in treated bran. The petitioner states, "Control bran samples and the 5X bran sample appear to be switched. Samples were realiquotted from original extract and reanalyzed, then reextracted and reanalyzed. Samples were analyzed as labeled by the commercial processor."

The petitioner did not undertake any analysis of grain dust. The petitioner states,

The Agency's current policy on the necessity of grain dust data is outlined in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance, December 24, 1989, page E-11. It states that "The grain dust data are needed only in those cases in which detectable, primarily surface residues are found on the grain. Early season herbicide uses usually result in low residues that would not be concentrated on the grain surface. Therefore, grain dust data would seldom be required in those cases. At the other extreme, postharvest treatments of stored grains virtually always trigger the need for grain dust data. Late season foliar uses to exposed grains such as wheat would also usually require such data." The use of propoiconazole in oats involves no application to exposed grain, and would not, therefore, be expected to trigger the requirement of grain dust data. This conclusion is further supported by the lack of detectable residues in most of the grain samples.

CBTS Comments: The submitted data supports the proposed tolerances of 0.1 ppm in oat grain and 1.0 ppm in oat straw. (However, see below.) Observed residues in grain treated at the 1X rate were ≤0.06 ppm in all cases. The highest observed residue in straw from 1X-rate trials was 0.62 ppm. Seven of the eleven trials were conducted at PHIs which correspond to the range associated with the application for control of rusts, powdery mildew, etc. The remaining four

trials are at PHI's appropriate for the use for control of foot rot. (See the **Proposed Use** section.)

As indicated in the processing scheme in Appendix 2, processed oat products are created from whole oats. Therefore, whole oats are the commodity to which the processed products must be compared in order to determine the concentration of residues. At the 1X application rate, no residues are detected in whole oats or in the processed commodities. No concentration of residues are observed at the 3X rate, except for light impurities (see below). At the 5X rate, concentration factors of 1.2X were found in hulls, and 1.1X in feed oats; residues in all other processed fractions did not concentrate (except for light impurities). Residues in bran samples were estimated by averaging the results of the three replicate analyses for each treatment rate.

Note that the petitioner states that the light impurities samples were contaminated with straw, contrary to commercial practice. This is a reasonable explanation of the high residues found in that fraction. Also, the Agency does not set tolerances on the light impurities fraction. Therefore, neither a food nor a feed additive tolerance is necessary for this commodity.

CBTS concludes that no food or feed additive tolerances are necessary for oat processing fractions. The two fractions in which propiconazole seemed to concentrate at the 5X treatment rate, hulls and feed oats, did not show any concentration at the 3X treatment rate. Also, in the 5X treatment rate trials, the amount by which the residue levels for those fractions exceeded the levels for whole oats, 0.03 and 0.02 ppm, are within the error of the analytical method. Therefore, there is no evidence that propoiconazole residues concentrate in oat fractions.

Note, however, that CBTS can not recommend for appropriate tolerance levels for propiconazole in oats grain and straw until storage stability and proposed labeling deficiencies have been corrected.

Meat, Milk, Poultry, and Eggs

No information on animal feeding studies has been submitted with this petition. CBTS has previously reviewed (PP#4F3074/4F3007/4E3026, S. Malak memo of 5/14/87) and accepted livestock and poultry feeding studies. Since recent concerns of an increased dietary burden for animals (see **Nature of the Residue - Animals**) do not apply to this petition, CBTS concludes that no further animal feeding data needs to be submitted for this petition. Adequate animal tissue, milk, and egg tolerances exist to cover residues in those commodities incurred from the proposed use.

A summary of those studies is presented below. Lactating cows were fed propiconazole at levels of 15, 75, and 150 ppm for periods of 14, 21, or 28 days. Milk samples were collected daily and the animals sacrificed at 14, 21, and 28 days during the study period. Laying hens were fed propiconazole in their daily ration at levels of 7.5, 37.5, and 75 ppm for 14, 21, and 28 days. Egg samples were collected daily and chickens were sacrificed at weekly intervals. All samples were analyzed using method AG-359, which determines propiconazole and its metabolites containing the 2,4-dichlorophenyl moiety. This method was found adequate for the purposes of data collection. Method sensitivity was reported at 0.01 ppm for milk and kidney,

0.10 ppm for liver, and 0.05 ppm for other tissues. The following residue levels were found:

Table 4. Propiconazole Residues in Cattle and Poultry Commodities.

Feeding Length	14 days			21 days			28 days		
Cattle	15	75	150	15	75	150	15	75	150
Tissues	<.05	0.11	0.18	<.05	0.08	0.13	<.05	0.05	0.11
Kidney	0.61	3.04	6.48	0.56	4.68	5.0	0.63	3.68	5.5
Liver	0.5	4.0	4.6	0.81	4.3	5.3	0.57	2.7	5.6
Fat	<.05	0.23	0.26	<.05	0.15	0.19	<.05	0.08	0.17
Poultry	7.5	37.5	75	7.5	37.5	75	7.5	37.5	75
Tissues	<.05	---	---	<.05	<.05	0.07	<.05	<.05	0.06
Liver	<0.1	0.1	0.47	---	0.08	0.39	<0.1	0.16	0.3
Fat	---	<.05	0.11	---	<.05	0.06	---	<.05	0.05

In milk, no detectable residues were found at the 15 ppm feeding level (<0.01 ppm). A maximum of 0.1 ppm and 0.11 ppm, respectively, were found at the 75 and 150 ppm feeding levels. In eggs, no residues were found at the lowest feeding level. At the 37.5 ppm level, residues did not appear until Day 3, peaked at 0.18 ppm on Day 14, and decreased to 0.06 ppm by Day 28. A similar response was seen for the highest feeding level, with appearance at Day 3, peaking on Day 21 at 0.37 ppm, and decrease to 0.22 ppm by Day 28.

Other Considerations

There are no Canadian or Mexican tolerances for propiconazole in oat grain or straw; therefore, no compatibility problems are expected. There is a Codex tolerance, for parent only, on oat grain at 0.05 ppm. Due to the data gap in plant metabolism identified in the Phase 4 review, CBTS can not discuss at this time the feasibility of harmonization of the U.S. and Codex tolerance expressions.

No Craven data are associated with this petition.

cc: R. Lascola, SF, RF, Circulation(7), D. Edwards, PP#2F4086,
J. Fleuchaus, Pesticides and Toxic Substances Division (LE-132P)

H7509C:CBTS:RLascola/rjl:CM#2:Rm805B:305-7478:11/18/92.
RDI: P.V.Errico:7/13/93; R.Loranger:7/13/93.
[redacted]:Disk\4086.TXT

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I Kovacs
3/27/92

Attachment:

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL propiconazole *

CODEX NO. 162

CODEX STATUS:

[ ] No Codex Proposal
Step 6 or Above

Residue (if Step 8): propiconazole

Crop(s)	Limit (mg/kg)
Oats grain	0.05 **

PROPOSED U.S. TOLERANCES:

Petition No. 2F4056

DEB Reviewer R Lusola

Residue: parent only & its metabolites expressed as 2,4-dichlorobenzoic acid

Crop(s)	Limit (mg/kg)
oats, grain	0.1
, straw	1.0

CANADIAN LIMITS:

M No Canadian Limit

Residue:

Crop(s)	Limit (mg/kg)

MEXICAN LIMITS:

M No Mexican Limit

Residue:

Crop(s)	Limit (mg/kg)

NOTES

* Cl-[[2-(2,4-dichlorophenyl)-4-propyl-1,3-dioxolan-2-yl] methyl]-1H-1,2,4-triazole)

** at or about the limit of determination