UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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SUBJECT PP#OF2416 Metolachlor on sunflowers. Evaluation of analytical method and residue data.

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The Agricultural Division of CIBA-GEIGY Corporation proposes a tolerance of 0.3 ppm for residues of the herbicide metolachlor [2-chloro-N-(2-ethyl-6-methylphenyl)-N-(2-Methoxy-1-methylethyl)acetamide] and its metabolites 2-(2-ethyl-6-methylphenyl)amino-1-propanol (CGA-37913) and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone (CGA-49751), each expressed as the parent compound, on the RAC sunflowers.

Tolerances for metolachlor are established for eggs, milk and the meat, fat and meat byproducts of cattle, goats, hogs, horses, poultry and sheep (all at 0.02 ppm) and for corn grain (except popcorn) and soybeans, both at 0.1 ppm. PP#OF2417, recently submitted, proposes a tolerance of 0.3 ppm for residues of metolachlor in flax seed. There is also a tolerance of 0.1 ppm for residues of amiben on sunflower seed.

Conclusions

1. The nature of the residue is adequately understood.

2. Adequate analytical techniques are available for enforcement purposes.

3a. Residues of metolachlor in sunflower seeds will not exceed 0.3 ppm. This tolerance should be established in terms of sunflower seeds.

b. The data submitted for sunflower forage is too limited to be the basis of a tolerance. We require a label restriction that prohibits the feeding of sunflower forage or fodder to livestock.

c. Fractionation studies show residues in sunflower meal and hulls to be twice that in the seeds. Feed additive tolerances of 0.6 ppm are needed for sunflower meal and hulls.

4. The established tolerance for amiben on sunflower seed will not be exceeded as a result of the proposed metolachlor-amiben tank mix. (Amiben treated sunflower forage may not be fed to livestock).

5. Any secondary residues in meat, milk, poultry and eggs will be covered by existing tolerances.

6. An International Residue Limit Status sheet is attached. No tolerances for metolachlor on sunflower seeds are established outside the U.S.

Recommendation

We recommend against the proposed tolerance. For a favorable recomendation we require:

1) A revised Section F in which feed additive tolerances of 0.6 ppm are proposed for sunflower meal and hulls. A tolerance of 0.3 ppm for sunflower seeds rather than sunflowers, should be included in the revised Section F.

2) The imposition of a label restriction that prohibits the use of any metolachlor treated sunflower forage as livestock feed.

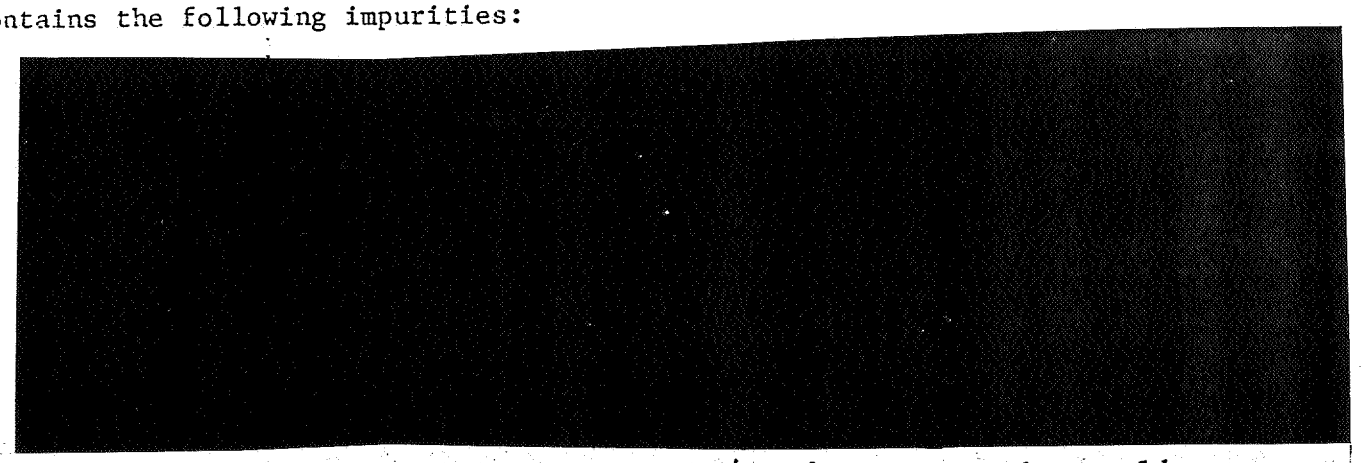
DETAILED CONSIDERATIONS

Formulation

The formulation proposed for use on sunflowers is DUAL® 8E herbicide, an emulsifiable concentrate that contains 8 lbs a.i./gal. The inert ingredients are cleared under Section 180.1001.

Manufacture

The manufacturing process was reviewed in conjunction with PP#5G1553 (memo of 2/12/75, D. Reed). The technical material is 95% pure; it contains the following impurities:



We do not expect any residue problems from these impurities as they would be present in extremely low levels from the proposed use.

Identification of product impurities

Proposed Use

For the control of a variety of weeds DUAL 8E is to be used as a preplant treatment incorporated in the soil or as a pre-emergence surface applied treatment. The rate varies from 1.5 to 3.0 lbs a.i./A depending on the soil type and the per cent organic matter.

Also proposed is a tank mix in which 2-3 lbs a.i./A Amiben is added to 1-1/2-3 lbs. metolachlor. Amiben is registered as a herbicide for sunflowers at 2-3 lbs. a.i./A applied at or immediately after seeding.

Neither application is to be used on muck or peat soils.

There are a number of rotational crop and replacement crop planting instructions.

Nature of the Residue

Studies designed to determine the metabolism of metolachlor in corn and soybeans were submitted with PP#s 5G1553, 6F1606 and 6G1708 and were discussed in our review of those petitions.

In both corn and soybeans the major metabolic pathway involves conjugation with glutathione, formation of the mercaptan, conjugation of the mercaptan with glucuronic acid, hydrolysis of the methyl ether and conjugation of the alcohol with a neutral sugar.

Animal metabolism studies have been carried out in rats and goats using ^{14}C labeled metolachlor and in goats only using ^{14}C biosynthesized metabolites. These studies were discussed in our review of PP#5G1553 (memo of 2/12/75, D. Reed). It was shown that metolachlor is rapidly eliminated with only trace residues in liver. Comparison of the urine metabolites with those found in corn indicate that, although the conjugating natural compounds are different, the hydrolyzed pesticide moieties are similar in plants and animals.

The significant components of the residues consist of the parent compound and its metabolites: 2-(2-ethyl-6-methylphenyl)amino-1-propanol; and 4-(2-ethyl-6-methylphenyl)-2-hydroxy-5-methyl-3-morpholinone. The analytical method determines these components and their conjugates.

The metabolism of metolachlor in plants and animals is adequately understood.

Analytical Methods

The method used to collect residue data is a variation of Analytical Method AG-286 (CIBA-GEIGY) which has undergone a successful method trial. (PP#5F1606, memos of 7/28/76 and 7/29/76, R.R. Watts). The method involves the hydrolysis (boiling overnight with 6N hydrochloric acid) of metolachlor and metabolite residues to CGA-37913 and CGA-49751 which are then determined separately.

CGA-49751 is partitioned into dichloromethane from an aliquot of the acid extract. The dichloromethane phase (which contains the CGA-49751) is washed with 5% sodium carbonate then chromatographed on a 16% moisture silica gel column. The CGA 49751 is then converted to the chloroethanol derivative which is extracted into hexane and cleaned up on a 16% moisture silica gel column; quantitation is by GC equipped with a Dohrmann microcoulometric detector specific for chloride or an alkali flame ionization detector in the nitrogen mode.

CGA-37913 is partitioned into hexane from a second aliquot of the hydrolysis mixture which has been made basic with 50% sodium hydroxide solution. The hexane portion is chromatographed on an 18% moisture alumina column, then on a silica gel column. Quantitation is by GC equipped with a Hall Electrolytic conductivity detector specfic for nitrogen.

The average recovery of CGA-37913 from sunflower greenheads was 87% (range=68-125%) at fortifications of 0.02 to 0.5 ppm; from seeds the average recovery was 98% (range 65-140%; fortification 0.02 to 0.2 ppm). The average recovery of CGA-49751 from greenheads was 93% (range 69-120%; fortification, 0.05 to 0.2 ppm). GCA-49751 recovery from seeds averaged 86% (range 64 to 128%, fortification, 0.05 to 0.2 ppm). Other plant parts and products (fodder, hulls, meal, crude oil, refined oil and soapstock) gave comparable recoveries. Control values were less than the sensitivity of the anlytical methods (<0.05 ppm for CGA-49751) except in one instance the CGA-39713 control value from greenheads was 0.09 ppm. <0.03 for CGA-37913

Residues of Amiben were determined by a method very similar to the PAM II enforcement method but with modifictions that were required to achieve adequate recoveries when applied to sunflowers. We conclude that adquate analytical techniques are available for enforcement purposes.

Residue Data

Experiments to determine residues of metolachlor in sunflowers were conducted in California, Texas, Kansas and Minnesota. Additional tests to determine residues resulting from tank mix applications of metolachlor plus amiben were carried out in North Dakota, Minnesota and Illinois. The geographic representation is adequate.

Residues of metolachlor as a result of the highest proposed rate ranged from <0.08 to 0.26 ppm in greenheads, <0.09 to 0.12 ppm in fodder and from 0.08 to 0.17 ppm in mature seeds. The PHI ranged form 64 to 147 days. These figures represent the sum of CGA-37913 and CGA-49751 residues found expressed as metolachlor equivalents. The type of application (preplant incorporated or preemergence) made no significant difference in the amount of residue found in any test.

Residues found as a result of proposed tank mix of metolachlor plus amiben were lower than the proposed tolerance for the former or the existing tolerance for the latter.

A sunflower fractionation study was submitted with this petition. Seeds (bearing residues of 0.14 to 0.17 ppm) were processed into meal, hulls, crude oil, refined oil and soapstock. Metolachlor residues were concentrated in the meal (0.25 to 0.30 ppm) and hulls (0.24 to 0.26 ppm); all other fractions carried less residue than the seed. These data indicate the need for feed additive tolerances for the meal and hulls; we calculate that a tolerance of 0.6 ppm (twice that of the seeds) would be appropriate for these items.

The proposed tolerance for sunflower seeds will accommodate any expected residue from the proposed use. However, tolerances are needed for sunflower hulls and meal. The petitioner should submit a revised Section F in which proposes tolerances of 0.6 ppm for sunflower meal and hulls.

Since there is no residue data for forage and only one residue experiment for fodder that includes the proposed use we can make no conclusion as to the expected residue level. Therefore we require a label restriction prohibiting the feeding of sunflower forage or fodder to livestock.

Meat, Milk, Poultry and Eggs

Sunflower forage and meal are used in varying amounts for livestock feed. The following is a diet that would be expected to supply the maximum possible amount of metolachlor to cattle feed (this includes items for which tolerances have been proposed or are established).

Commodity	% in diet	Tolerance	ppm in diet
Sunflower meal	20	0.6	0.12 ?
Peanut forage/hay	30	3.0	0.9
Corn grain	30	0.1	0.03
			1.2

Feeding studies were submitted with PP#7F1913 (memo of 6/14/77, D Reed). Cattle were fed at levels of up to 5 ppm metolachlor in the total diet for 28 days. No detectable residues were found in the milk (0.006 ppm CGA-37913, 0.01 ppm CGA-49751) or in any of the tissues (0.002 ppm CGA-37913, 0.04 ppm CGA-47951).

In a ruminant metabolism study goats were fed 4.7 ppm of ^{14}C labeled metolachlor for 10 days. Activity levels (in metolachlor equivalents) ranged from <0.006 in most tissues to 0.07 ppm in the liver; the residue in milk was 0.01 ppm.

From these studies we conclude that the feeding of meal and hulls to livestock will not cause the existing tolerance for milk and for the meat, fat and meat byproducts of cattle, horses, hogs and sheep to be surpassed.

Sunflower meal is a minor feed item for poultry. The following is a diet that would be expected to supply the maximum amount of metolachlor to poultry feed.

	% in diet	Tolerance	ppm in diet
Sunflower meal	15	0.6	0.09
Peanut meal	10	0.1	0.01
Soybean seed	40	0.1	0.04
Corn grain	35	0.1	0.035
			0.2

Feeding studies in which chickens were fed metolachlor at levels ranging from 0-2.0 ppm in the total diet for 28 days were submitted with PP#7F1913 (memo of 6/14/77, D. Reed). No detectable residues (<0.002 ppm CGA-37913, <0.04 ppm CGA-49751) were found in eggs, muscle or fat. Residues of 0.02 and 0.03 ppm of CGA-37913 were found in livers of chickens fed 0.5 and 2.0 ppm respectively.

We conclude that the established tolerances for poultry and eggs will not be surpassed if sunflower meal is used as a feed item.

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Metolachlor

PETITION NO. OF2416 (K. Arne)

CCPR NO. --

Codex Status

/ / No Codex Proposal Step 6 or above

Residue: (if Step 9): NONE

Crop(s)	Limit (mg/kg)
NONE	

Proposed U.S. Tolerances

1. Parent and 2 metabolites 2-(2-ethyl-6-methylphenyl)amino-1-propanol.
2. 4-(2-ethyl-6-methyl(phenyl)-2-hydroxy-5-methyl-3-morpholuione.

Residue:

Crop(s)	Tol. (ppm)
Sunflowers	0.3 ppm

CANADIAN LIMIT

Residue: 2-chloro-6'-ethyl-N-(2-methoxy-1-methylethyl)-o-acetotoluidide.

Crop	Limit (ppm)
NONE ON THIS COMMODITY	

MEXICAN TOLERANCIA

Residue: NONE

Crop	Tolerancia (ppm)
NONE	

Note: