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

JAN 31 1994

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: PP#8F3607: Glufosinate-Ammonium (IGNITE) in/on: Apples, Grapes, Nuts, and Almond Hulls. Outstanding Data Requirements for Requested Tolerances. DP Barcode D198267. CBTS No. 13115

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Tolerance Petition Section III
Chemistry Branch Tolerance Support (H7509c)

THROUGH: Debra Edwards, PhD, Chief *Robert S G*
Chemistry Branch Tolerance Support
Health Effects Division (H7509c)

TO: Joanne Miller / Jesse Mays, PM-23
Registration Division

Hoechst-Celanese has requested a conditional registration and tolerances for the herbicide glufosinate-ammonium (Ignite), monoammonium 2-amino-4-(hydroxymethylphosphinyl) butanoate, and its metabolite, 3-methylphosphinicopropionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid, in/on: almond hulls at 0.5 ppm; apples, grapes and nuts at 0.05 ppm; cattle fat, cattle meat, eggs, goat fat, goat meat, horse fat, horse meat, poultry meat, poultry fat, sheep fat, and sheep meat at 0.05 ppm; cattle mby, goat mby, horse mby, poultry mby, and sheep mby at 0.10 ppm; and milk at 0.02 ppm. Previous requests for tolerances on soybeans and field corn have been withdrawn. The request for tolerances on animal commodities arises from the potential of feeding almond hulls and apple and grape pomaces bearing the requested tolerance level. The requested animal commodities tolerances are based upon extrapolations from animal metabolism studies as animal feeding studies have not been conducted.

RD has asked CBTS whether there are any outstanding requirements remaining that would preclude an affirmative recommendation for the remaining requested tolerances.



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Background

In its original petition the company had also requested tolerances for soybeans and field corn. The petitioner had not found detectable residue levels in the feed items derived from these commodities and apparently reasoned that feeding studies and subsequent secondary tolerances and associated methods for animal tissues, milk, and eggs were not needed.

CBTS in its review of the petition as originally submitted noted that the inclusion of these commodities would require the proposal of secondary tolerances for animal commodities, milk, and eggs. CBTS reason for this request was based upon the results of the submitted animal metabolism studies as no feeding studies were submitted. Assuming tolerance levels and the feeding of corn grain and almond hulls, and using the residue level of total radioactivity (in equivalent ppm's) found in tissues, CBTS calculated that finite residues of the residue of concern could potentially be present in animal tissues. Consequently, CBTS requested the submission of animal feeding studies, the proposal of secondary tolerances for animal tissues and milk, and the submission of validated methods for animal tissues.

The petitioner responded by: 1) dropping soybeans and field corn from the commodities for which tolerances were requested, 2) submitting tolerance requests for animal tissues, milk, and eggs, and 3) submitting independently validated analytical methods for animal tissues, milk, and eggs. The levels requested for the proposed secondary tolerances were the limits of detection of the analytical methods for the specific commodities.

With these amendments of the original petition, CBTS recommended for the use of glufosinate on apples, grapes, and nuts (J. Garbus, memo, 12/28/92). In doing so, CBTS reasoned that with the removal of corn and soybeans from the proposed treated commodities the potential for secondary residues was considerably diminished, considering the use of almond hulls and apple and grape pomaces as feed items and the fact that the need for the secondary residues was based upon extrapolations from metabolism studies with uncharacterized residues and not from actual feeding studies. CBTS implied that if registrations for corn and soybeans were requested again, feeding studies and agency validated methods would be needed.

However, because of TOX considerations at the time, permanent tolerances on apples, grapes, and the nut grouping and for the secondary animal tolerances were not granted. RD has now asked CBTS if any outstanding data deficiencies exist for a positive tolerance recommendation for the remaining tolerance requests.

CBTS cannot recommend for the remaining tolerances until we have received a successful method validation from the ACL. Alternatively, the petitioner can submit a revised Section F requesting tolerances for the Tree Nut Group (except almonds) only.

2

cc: PP#8F3607, Reviewer, RF, and Circ.
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