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PP#8E2122/TAF#0H5135. Glyphosate (sodium sesqui salt) in or on sugarcane. Comments on letters of 6/16/80 and 6/20/80.

H. Nelson, Chemist
Residue Chemistry Branch, HED (TS-769)

R. Taylor, Fd. Team 25
Fungicide/Herbicide Branch, RD (TS-767)

and

Toxicology Branch (TS-769)
Hazard Evaluation Division

THRU: Richard D. Schmitt, Acting Chief
Residue Chemistry Branch, HED (TS-769)

The petitioner has now submitted a Confidential Statement of Formula for Polador, which is as follows:

INERT INGREDIENT INFORMATION DELETED

Component	% by weight	Purpose
trisodium diglyphosate (97.1%)	75.00	a.i.
[redacted]	[redacted]	impurities
[redacted]	[redacted]	wetting agent
[redacted]	[redacted]	diluent

This removes the only contingency (see H. Nelson review of 5/23/80) to our favorable recommendation, toxicological considerations permitting, for the establishment of the proposed tolerances in or on sugarcane (2 ppm) and sugarcane molasses (30 ppm), resulting from domestic usage of the sodium sesqui salt of glyphosate as a plant growth regulator, and for the raising to 0.2 ppm of the existing tolerance on liver and kidney of cattle, goats, hogs, horses, poultry, and sheep.

Other Considerations

Also in our aforereferenced review, and in the 6/3/80 (R. Taylor) letter sent to the petitioner, which see, is a listing of the information/data (4 items) which needed to be submitted for further consideration of a foreign usage on sugarcane.

In the 6/16/80 letter, the petitioner responded to 3 of the 4 items in question. Specifically,

1. The countries under consideration as potential markets for Polado® include: Argentina, Australia, Brazil, Costa Rica, Guatemala, Guyana, Honduras, India, Jamaica, Mauritius, Mexico, Nicaragua, Panama, South Africa, Taiwan, Trinidad, and Venezuela.

2. The proposed use rate for Polado® in the foreign countries will be as previously indicated (see 10/9/79 review, M. Nelson). Because sugarcane growth and cultural practices vary relatively little for sugarcane on a worldwide basis, it is anticipated that there will be no changes in the timing for application, which is designed to maximize the effect of Polado® on the cane crop. The maximum rate recommended is unlikely to be increased because excess rates will kill sugarcane.

3. The petitioner assures us that all regulatory requirements of the countries in question will be complied with before commercial introduction of Polado®, including proper preparation and filing of use directions as required.

Re the 4th item, no residue data from foreign field studies is as yet available. The petitioner has indicated (conference of 8/4/80 and amendment of 12/17/79) they will be gathering such information in future (and presumably will submit copies to the Agency for our files) in conjunction with their foreign marketing plans and will propose an increase in tolerance if necessary.

Conclusion: While no foreign residue data has been submitted, the petitioner apparently has no intent to enter the foreign market at this time. Therefore, we see no reason to deny this petition because of a lack of foreign residue data.

Recommendation

Toxicological considerations permitting, we recommend the proposed tolerances be established.

P.H.: also see Note to P.M., Recommendations section, aforecited 5/23/80 review for a commentary in re the establishment of the tolerances.

TS-769:RCB:M. Nelson:gs:X77324:CM#2:RM810:8/12/80
cc: RF, Circ., M. Nelson, Watts, FDA, TOX, EEB, EFB, PP#8E2122/FAP#9H5196
RDI: R.S. Quick:8/8/80:R.D. Schmitt:8/8/80