

US EPA ARCHIVE DOCUMENT



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

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

AUG 26 1987

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: FAP #7H5532 (RCB #2688). Metalaxyl (Ridomil®)
on Hops. Amendment of 8/10/87. (No Accession #).

FROM: Nancy D. Dodd, Chemist *Nancy Dodd*
Tolerance Petition Section II
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

TO: Lois A. Rossi, PM #21
Fungicide-Herbicide Branch
Registration Division (TS-767C)

and

Toxicology Branch
Hazard Evaluation Division (TS-769C)

The petitioner, Ciba-Geigy Corporation, has submitted an amendment to PP#7H5532 concerning proposed tolerances for metalaxyl and its metabolites on dry hops and spent hops. The amendment consists of a letter and a revised Section F, both dated 8/10/87. This amendment is submitted in response to deficiencies cited in RCB's review of PP#7H5532 dated 8/6/87. The revised Section F increases the proposed tolerances for dry hops and spent hops from 10 to 50.0 ppm.

Conclusions

1. The petitioner has proposed "feed additive tolerances" for dry hops and spent hops at 50.0 ppm. RCB previously concluded that the petitioner should propose a 50 ppm tolerance for dry hops in 21 CFR 193.277 for human consumption and for spent hops in 21 CFR 561.273 for animal feeds to cover total residues of parent and metabolites.
2. RCB has calculated from available data on the 2E formulation that total residues of parent plus metabolites on dry hops and spent hops are not likely to exceed parent residues by more than

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a factor of 10 when the 2E formulation is applied. Since the proposed use is for the 5GR and 50WP formulations instead of the 2E formulation and the use patterns are different, the 10X factor is only an estimate for the proposed use. RCB will reconsider this estimate upon receipt of additional analyses of samples with residues resulting from the proposed use of the 5GR and 50WP formulations.

3. The deficiencies which were detailed by RCB in the 7/28/87 review of FAP#7H5532 remain outstanding.

Recommendations

TOX and EAB considerations permitting, RCB has no objection to the establishment of a tolerance of 50 ppm with an expiration date of one year for metalaxyl on dry hops and spent hops provided that the following deficiencies are addressed during that time period:

1. The petitioner should submit a revised Section B/label with the correct calculations of Ridomil plus from 19.8 kg/ha formulation per year to 3.18 kg/ha metalaxyl (ai) per year.
2. The petitioner should submit additional residue data on samples which are analyzed by the PAM-II procedure or another proven procedure that determines parent and the metabolites which are included in the U.S. tolerance expression. To use reanalyzed samples from the monitoring studies, RCB will need raw data including information such as application rates, sampling dates, sampling to analysis intervals, and storage conditions for the samples between sampling and analysis. If this information is not available or if the application rates/number of applications do not represent the heaviest uses, new residue studies would be needed since storage stability data have not been submitted to support use of samples obtained before 1986.
3. The petitioner should submit some residue data on dry hops samples analyzed by the PAM-II method, which involves refluxing in 80% (v/v) methanol/water for 2 hours; This will resolve RCB's concern over extraction efficiency from dry hops.
4. Storage intervals between sampling and analysis and storage conditions should be reported for all residue data.
5. The petitioner should identify the formulations which are referred to by the product codes A-6335A and A-6339A in table 2, page 10, volume 3 of 5, dated January 9, 1987.

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6. The Section F should be revised to read "Proposed Food and Feed Additive Tolerances" and "the following food or feed additive commodities", rather than "Proposed Feed Additive Tolerance" and "the following feed additive commodities". A 50 ppm tolerance for dry hops will be listed in 21 CFR 193.277 for human (ie. food) consumption. A 50 ppm tolerance for spent hops will be listed in 21 CFR 561.273 for animal feeds.

Other Considerations

An International Residue Limits (IRL) Status sheet is attached. Codex has proposed a 10 mg/kg limit for metalaxyl and its metabolites containing the 2,6-dimethylaniline moiety on dry hops. The Codex residue expression will probably be changed to parent only. This Codex limit will not be the same as the proposed tolerance of the U.S.A., which is now 50 ppm and includes metabolites. There are no Canadian or Mexican proposals on hops.

Attachment: International Residue Limit Status Sheet

cc: SF, Circu., RF, Reviewer-N.Dodd, FAP#7H5532, PM#21, TOX,
PMSD/ISB-Eldredge

RDI:J.H.Onley:8/25/87:RDSchmitt:8/25/87

TS-769:RCB:CM#2:RM800:X1681:N.Dodd:N.Dodd:8/25/87

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL metolaxyl

*1. Does
8/25/87*

CODEX NO. 138

CODEX STATUS:

No Codex Proposal
Step 6 or above

PROPOSED U.S. TOLERANCES:

Petition No. 7H5532

RCB Reviewer Nancy Swobed

Residue: metolaxyl* and
metabolites**

Residue (if Step 8): Sum of metolaxyl and
its metabolites con-
taining the 2,6-dimethylaniline moiety determined
as the latter and calculated and expressed as
Metolaxyl -1

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
<u>Hops (dry)</u>	<u>10</u>

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
<u>dry hops</u>	<u>50.0</u>
<u>spent hops</u>	<u>50.0</u>

CANADIAN LIMITS:

No Canadian limit (on Hops)

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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MEXICAN LIMITS:

No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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-1 likely to be changed to parent-only against U.S. directions.

NOTES:

* N-(2,6-dimethylphenyl)-N-(methoxyacetyl)alanine methyl ester

** metabolites containing the 2,6-dimethylaniline moiety,
and N-(2-hydroxymethyl-6-methylphenyl)-N-(methoxyacetyl)alanine methyl ester