

K.T.
APR 8 1987

RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

FROM: Maxie Jo Nelson, Ph.D., Chemist
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

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

TO: Lois Rossi, P.M. Team 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

1. Petition No(s): 7F3481 [RCB #: 1754] [Acces. #: 265154]
2. Chemical(s): Iprodione
3. Tolerance Proposal (RAC's & Levels):
leaf lettuce @ 25 ppm
4. Petitioner: Rhône-Poulenc Inc.
5. Tolerance Expression: combined residue of parent + isomer + metabolite, per 40 CFR 180.399(a).
6. Established Tolerances: 40 CFR 180.399(a) - various rac's @ levels of 0.05-150 ppm, including head lettuce at 15 ppm.
40 CFR 180.399(b) - various commodities of animal origin.
7. Letter(s) of Authorization (if applicable): N/A.
8. Formulation(s): Revral[®] Fungicide, EPA Reg. No. 359-685,
a 50% wettable powder formulation.
9. Inerts Status: All cleared under 40 CFR 180.1001.

10. Manufacturing Process: Reviewed in conjunction with PP# 8G2087
(memo of A. Rathman, 3/2/79). Impurities in the technical product
are not expected to present a residue problem.
11. Proposed Use(s): For fungal control. Apply 1.5-2 lbs of product
(0.75-1.0 lb ai)/A as a directed, foliar spray (ground equipment) in
sufficient water to obtain thorough coverage (50-100 gpa).
Apply at the 3-leaf stage of growth and again 10 days later. If
needed, a third application may be made 10 days after the second
spray.
Do not make more than 3 applications/season. Do not
apply within 14 days of harvest.
This use pattern is the same as that presently registered for
head lettuce.
12. Plant Metabolism Data on: lettuce (PP# 3G2801), strawberries
and wheat (PP# 8G2087), peaches (PP# 2F2596), peanuts
(PP# 4G3037), and rice (PP# 6F3443/EAP# 6H5507).
13. Plant Residues Comprised of: parent compound (RP 26019),
its isomer (RP 30228), and its des-isopropyl metabolite
(RP 32490). (Predominantly parent)
14. Plant Metabolism Data Translatable Here: # 12.
15. Nature of Plant Metabolism Data (19) is not adequately defined.
 The Residue of Concern is: Per #13 and #5.
16. Animal Metabolism Data on: N/A. Table II of the Pesticide
Assessment Guidelines, Subdivision D - Residue Chemistry does
not list lettuce as an animal feed item. ②

17. Animal Residues Comprised of: N/A. See #16.
18. Animal Metabolism Data Applicable Here: N/A. See #16.
19. Nature of Animal Metabolism Data is/is not adequately defined.
The Residue of Concern is: N/A. See #16.
20. Analytical Methods (reference or brief description):
Rhône-Paulenc Analytical Method 151 (EC-GLC).
Discussed in R. Cook review of PP# 3F3443, 3/17/87.
Similar method MTO'd in re PP# OE2414 successfully.
Method 151 has been submitted (2/87) to FDA for inclusion
in PAM, but not yet published. PMSD can supply copy.
Limit of detection is 0.05 ppm for each compound measured.
21. Method Validation (crop recoveries): leaf lettuce

RP-26019	fortified at 1-30 ppm,	67-128% recoveries
RP-30228	" " 0.1-1.0 "	69-126% "
RP-32490	" " 0.1-1.0 "	74-125% "
22. Method Validation (control values): leaf lettuce
RP-26019: ND-0.12 ppm; RP-30228: ND-0.29 ppm; RP-32490: ND-0.10 ppm
23. Residues Determined by Method: RP 26019, RP 30228, and
RP 32490, as separate entities.
24. Enforcement Methodology is is not available. In PAM II. (3)
 [Additionally, Method 151 has been sent to FDA for inclusion in the
 PAM II.]

- leaf lettuce varieties Combined residue corrected for recovery
25. Residue Data (crop and residue range--(ppm) from Proposed Use):

Crop: <u>escarole</u>	<u>0.22-22.5 ppm</u>	<u>10-15 day PHI</u>
<u>endive</u>	<u>0.00-16.1 ppm</u>	<u>" " "</u>
<u>romaine</u>	<u>0.12-20.5 ppm</u>	<u>10-14 " "</u>
<u>bibb</u>	<u>1.02-14.2 ppm</u>	<u>5-14 " "</u>
<u>bunching</u>	<u>0.00-14.1 ppm</u>	<u>" " "</u>

46 residue tests all seasons represented
 CA, AZ, OH, FL, NJ both irrigated and non-irrigated
 1984-1986 all trials were 3 applications at 1X rate
 50-100 gpa H₂O used directed foliar ground sprays

Other Comments: Harvested lettuce was frozen stored 1-10 1/2 months
prior to analysis. The stability of iprodione residues under frozen
storage for ca 1 year was demonstrated in re. PP# 842087 (Tab 2,
6/27/79 amendment - peaches and cherries).

26. Residues will not exceed proposed tolerance on (commodities)

leaf lettuce

and will exceed proposed tolerance on (commodities) _____

27. Livestock Feeding Studies on (species): N/A. See #16.

28. Animal Feeding Levels: N/A. See #16.

29. Animal Residue Ingestion Levels from Proposed Crop Tolerance Levels (proposed tol. level x % in diet): _____ ppm in beef cattle; _____ ppm in dairy cattle/goats; _____ ppm in hogs; _____ ppm in horses; _____ ppm in sheep; _____ ppm in poultry.

30. Livestock Tolerances are Adequate in (species) _____

_____, but not adequate in _____

(4)

31. Livestock Tolerances Need to be Established: yes/no. If yes (species/levels): N/A, See #16, -
32. Other Comments: We note there are rotational crop instructions on the proposed supplemental labeling. These are within EAB's purview.
33. Other Considerations: ① Iprodione is completely recovered by an FDA multiresidue procedure (III-Luke).
 ② There is no Registration Standard for iprodione.
 ③ The geographic representation is adequate.
34. Additional Data Needed: _____
35. Recommendations: EAB (see #32) and TOX considerations permitting, we recommend for the establishment of the proposed tolerance.
36. Other Comments under Recommendations: _____
37. Compatibility with Codex Tolerances: Not achievable. See Attachment. Also ref. 7/1/83 review, K. Arne, PP#3F2840, Nature of the Residue for a discussion as to why the isomer and metabolite should continue to be included in the tolerance expression.
- Attachment: International Residue Limits Status sheet
- cc: RF, Circ, Reviewer, Thompson, TOX, EEB, EAB, FDA, PP# 7F3481, PMSD
- Approved: Quick R/E RSG 4/7/87 ; Schmitt AD 4/8/87

(5)

INTERNATIONAL RESIDUE LIMIT STATUS

214:

Handwritten: 3/23/87

CHEMICAL Iprodione

CODEX NO. ///

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8):
Iprodione

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

PROPOSED U.S. TOLERANCES:

Petition No. 7F3481

RCB Reviewer Nelson

Residue: combined residue,
per 40 CFR 180.399(a)

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
leaf lettuce	25

CANADIAN LIMITS:

☒ No Canadian limit (on lettuce)

Residue: Iprodione and metabolites
3-isopropyl-N-(3,5-dichlorophenyl)-
2,4-dichlorobenzoate 1-carboxamide and 3-(3,5-
dichlorophenyl)-2,4-dichlorobenzoate-1-
carboxamide.

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
----------------	--------------------------

MEXICAN LIMITS:

☒ No Mexican limit

Residue: _____

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
----------------	--------------------------

NOTES:

(6)