

JUL 28 1987

RESIDUE CHEMISTRY BRANCH, HED
PETITION REVIEW QUICK FORM

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

mjn

THRU: Robert S. Quick, Section Head
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Hazard Evaluation Division (TS-769)

DM

TO: Lois Rossi, PM 21
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

1. Petition No(s): 7F3542 RCB#: 2568 MRID#: 402440-01
2. Chemical(s): iprodione
3. Tolerance Proposal (RAC's & Levels):
caneberries (defined in 40 CFR 180.1(h)) @ 25 ppm
4. Petitioner: Rhône-Poulenc Inc.
5. Tolerance Expression: combined residue, expressed as iprodione
equivalents, as per 40 CFR 180.399(a)
6. Established Tolerances: 40 CFR 180.399:
(a) various RACs @ 0.05-150 ppm, incl. boysenberries and raspberries @ 15 ppm.
(b) various commodities of animal origin
7. Letter(s) of Authorization (if applicable): N/A
8. Formulation(s): Rovral[®] Fungicide, EPA Reg. No. 359-685,
a 50% wettable powder formulation.
9. Inerts Status: Under RD purview

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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): _____

HOW TO USE ROVRAL ON CANBERRIES

Apply Rovral as a foliar spray with ground equipment in sufficient water to obtain thorough coverage at bloom and/or fruit (minimum of 100 gallons) in accordance with the directions in the following table:

DISEASE	Lbs. Product/ Acre	TIMING OF APPLICATIONS
Botrytis fruit rot (<i>Botrytis cinerea</i>)	1.0 - 2.0	Apply Rovral first at early bloom (5-10% bloom) and make a repeat application again at full bloom. Up to 3 subsequent applications can be applied at 14 day intervals or as required. The final application can be made up to and including the day of harvest.

12. Plant Metabolism Data on: strawberries and wheat (PP# 8G2087),
peaches (PP# 2F2596), lettuce (PP# 3G2801), peanuts (PP# 4G3037),
and rice (PP# 6F3443/FAP# 6H5507).
13. Plant Residues Comprised of: parent compound (RP-26019), its
isomer (RP-30228), and its des-isopropyl metabolite (RP-32490).
Parent is the predominant residue (>90% on canberries).
14. Plant Metabolism Data Translatable Here: #12.
15. Nature of Plant Metabolism Data (is) ~~is not~~ adequately defined.
 The Residue of Concern is: Per #13, which is the regulated
residue (ref. #5).
16. Animal Metabolism Data on: N/A. There are no animal feed
items associated with this petition.

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-Poulenc Analytical Method 151 (EC-GLC)
Discussed in R. Cook review of PP# 3F3443, 3/17/87.
Similar method MTD'd in re PP# OE2414 successfully.
Method 151 has been submitted (2/87) to FDA for inclusion in PAM II,
but not yet published. In interim, PMSD can supply copy.
Limit of detection = 0.05 ppm.
21. Method Validation (crop recoveries): Blackberries and raspberries
RP-26019 fortified at 1-20 ppm, 84-127% recoveries (103% avg)
RP-30228 " " 0.2-1 " 99-120% " (107% ")
RP-32490 " " 0.2-1 " 106-123% " (112% ")
22. Method Validation (control values): Blackberries and raspberries
RP-26019: ND (<0.05 ppm); RP-30228: ND-0.12 ppm; RP-32490: ND.
23. Residues Determined by Method: RP-26019, RP-30228, and
RP-32490, separately.
24. Enforcement Methodology (is) ~~is not~~ available. in PAM I and II.
[Additionally, Method 151 has been sent to FDA for inclusion in PAM II.] (3)

25. Residue Data (crop and residue range (ppm) from Proposed Use):

MAID

402440-01

Crop: red raspberries 1.2 - 13.9 ppm

blackberries* 6.1 - 22.8 "

6 raspberry trials (OR, WA, MI, OH-1986)

4 blackberry trials (OR-1986)

5 applications/trial (2 @ bloom + 3 biweekly)

0-day PHI; 1X maximum rate (1 lb ai/A) applications

both E irrigation

50-100 gpa spray mix

spring/summer applications

*blackberry trials included marionberries and boysenberries (dewberries)

Other Comments: ① Samples were frozen stored 1-5 months prior to analysis.
The stability of iprodione residues under frozen storage for ca 1 year
was demonstrated in re PP# 862087 (Tab 2, 6/27/79 amendment -
peaches and cherries). ② "Caneberries" are adequately represented by these
field trial data. ③ Other data (of little value) are in PP# 553214.

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

Caneberries (25 ppm)

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 _____

N/A

N/A

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31. Livestock Tolerances Need to be Established: yes/no. If yes (species/levels): N/A. See #16.

32. Other Comments: ① There is no Iprodione Registration Standard.
 ② Geographic representation is adequate (Aq. Stat. 1981).
 ③ Representative chromatograms and calculations were submitted.
 ④ PP# 5E3214 contains boysenberry and raspberry data to support use in New Zealand.

33. Other Considerations: To support any future tolerance request, the petitioner should be advised that iprodione, its isomer, and metabolite (per §180.399(a)) will each need to be tested through all 4 of the FDA multiresidue procedures for which recovery data are
 34. ~~Additional Data Needed~~ not presently available. (see PAM I, Appendix II). [Ref. 40 CFR 180.158(h)(5) and FR, Vol. 51, p. 34249, 9/26/86 and memo from J. Corneliusen, FDA, 6/9/87.]
Note: partial data are available for iprodione and its isomer.

35. Recommendations: TOX considerations permitting, we recommend in favor of the establishment of the proposed tolerance: caneberries @ 25 ppm.

36. Other Comments under Recommendations: ① Advise the petitioner re #33. ② If/when this caneberry tolerance is established, the separate commodity listings for boysenberries and raspberries need to be deleted from 40 CFR 180.399(a).

37. Compatibility with Codex Tolerances: No. See Attachment.
[Also ref. 7/1/83 review, K. Arne, PP# 3F2840, Nature of the Residue, for discussion why isomer and metabolite should be retained in the tolerance expression.]

Attachment: International Residue Limits Status Sheet

cc: RF, Circ, Reviewer, TOX, PMSD/ISB, PP# 7F3542, FDA.

Approved: Quick R/E RNL 7/27/87; Schmitt R D# 7/27/87

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INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Iprodione

CODEX NO. III

CODEX STATUS:

☒ No Codex Proposal
Step 6 or above

Residue(if Step 8): _____

Iprodione only

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Raspberries, red, black</u>	<u>5</u>
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1. 1/22/87

PROPOSED U.S. TOLERANCES:

Petition No. 7F3542

RCB Reviewer Nelson

Residue: combined residue

per 40 CFR 180.399(a)

<u>Crop(s)</u>	<u>Limit (mg/kg)</u>
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<u>Caneberries</u>	<u>25</u>
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CANADIAN LIMITS:

☒ No Canadian limit (on caneberries)

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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