

623A

RESIDUE CHEMISTRY BRANCH, HED  
PETITION REVIEW QUICK FORM

AUG 3 1982

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

mjn

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

TO: R. Taylor, P.M. Team 25  
Registration Division (TS-767)

and

Toxicology Branch  
Hazard Evaluation Division (TS-769)

1. Petition No(s):: 2F2718/2H5360
2. Chemical(s): oryzalin
3. Tolerance Proposal (RAC's & Levels): peppermint and spearmint hays (0.05 ppm) and oils (0.1 ppm - FAT)
4. Petitioner: Elanco Products Co.
5. Tolerance Expression: oryzalin (3,5-dinitro-N<sup>4</sup>, N<sup>4</sup>-dipropylsulfanilamide)
6. Established Tolerances: 40 CFR 180.304 0.05-0.1 ppm various rac's
7. Letter(s) of Authorization (if applicable): N/A
8. Formulation(s): Surflan<sup>®</sup> 75W (EPA Reg. No. 1471-96) and Surflan<sup>®</sup> A.S. (EPA Reg. No. 1471-112), an aqueous suspension containing 4 lbs ai/gal.
9. Inerts Status: cleared under 40 CFR 180.1001 for both formulations

INFORMATION WHICH MAY REVEAL THE IDENTITY OF A PRODUCT IMPURITY IS NOT INCLUDED

10. Manufacturing Process: See R. Loranger review of 6/18/82, PP# 2G2612 for discussion. Technical is ca 97-99% pure



See #32.

11. Proposed Use(s): For weed control, apply Surflan<sup>®</sup> (1-1.5 lbs ai/A) either alone or in tank-mix combo with Simbar<sup>®</sup> (terbacil; 0.8-1.6 lbs ai/A) to mint stubble before the mint emerges. Application may be either following fall harvest or prior to spring emergence. (Builds in a PHI of ≥ 2 months.) See labeling for precautions.

A terbacil/mint hay tolerance (2 ppm) is established (40 CFR 180.209); see PP# 6E1713 - use rate of 0.8-1.6 lbs ai/A (pre-E)

12. Plant Metabolism Data on: soybeans (PP# 2G1201 and 3E1347), wheat and Ganley (PP# 2G2612), and sweet potato (PP# 8E2075)

13. Plant Residues Comprised of: oryzalin (the proposed use results in essentially a "no residue" situation; see #25)

14. Plant Metabolism Data Translatable Here: # 12

15. Nature of Plant Metabolism Data (is/is not adequately defined. The Residue of Concern is: oryzalin per se for this PP#.

16. Animal Metabolism Data on: goats, rats, rabbits, ducks (PP# 2G1201) (also ref. PP# 2G2612)

17. Animal Residues Comprised of: oryzalin and uncharacterized metabolites. Since proposed use is not anticipated to result in any secondary residues arising in meat, milk, poultry, or eggs, we are not pursuing the inadequacies in animal metabolism in re this petition.
18. Animal Metabolism Data Applicable Here: #16
19. Nature of Animal Metabolism Data (is) is not adequately defined. for this PP#:  
The Residue of Concern is: oryzalin per se
20. Analytical Methods (reference or brief description): Procedure AM-AA-CA-R029-AA-755 (supersedes 5801615), "Detn of Oryzalin in Crops". Procedure entails organic solvent extraction of oryzalin residue from fresh or spent mint hay or oil, various clean-up steps (liquid-liquid partitionings; columns: alumina or C<sub>18</sub> Sep-Pak or Florisil or gel permeation), depending on substrate, derivatization to form the dimethyl derivative of oryzalin using iodomethane, clean-up (via liquid-liquid partitioning or alumina column) of the derivative, and measurement by EC-GC. Method sensitivity: 0.01 ppm. Basic procedure MTO'd in re soybeans (PP# 3F1347).  
For terbacil methodology, ref. PAM II.
21. Method Validation (crop recoveries): mint hay spiked at 0.04 ppm oryzalin; recoveries of 47-80%. Mint oil spiked at 0.1 or 0.2 ppm oryzalin; recoveries of 36-63% and 50-60%, respectively.
22. Method Validation (control values): hay (fresh and spent), NDR (<0.01 ppm) to <0.04 ppm; oil, NDR (<0.01 ppm) to <0.1 ppm
23. Residues Determined by Method: #20
24. Enforcement Methodology (is) is not available.

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

Crop: immature fresh hay (peppermint) - NDR (<0.01 ppm)

fresh hay (peppermint + spearmint) - NDR to 0.04 ppm

spent hay (" + ") - NDR to <0.04 ppm

steam-distilled oil (" + ") - NDR to <0.1 ppm

9 field studies (WA, OR, WI)

1978-80 crop years

4AS or 75W formulation

fall or spring appln; TSI = 70-246 days

1.5-4 lb (ai?)/A rate

3 mint varieties; 3 soil types

Other Comments: <sup>(1)</sup> No residue data was submitted for terfacil, but residues (if any) would not exceed established tolerance (which was based on pre-E and post-E uses); ref. PP# 6F1713. <sup>(2)</sup> In 8 of 9 studies, NDR of oryzalin in mint oil; the one study with reported residue (<0.1 ppm) was exaggerated rate (4 lbs (ai?)/A).

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

peppermint or spearmint hays or oils

and will exceed proposed tolerance on (commodities) \_\_\_\_\_

27. Livestock Feeding Studies on (species): cattle, swine,

and hens (PP# 2G2612) and lactating goat (PP# 3F1347)

28. Animal Feeding Levels: 0.2-1.2 ppm (see discussion in

R. Loranger review of 6/18/82, PP# 2G2612)

29. Animal Residue Ingestion Levels from Proposed Crop Tolerance

Levels (proposed tol. level x % in diet): 0.0125 ppm in

beef cattle; 0.03 ppm in dairy cattle/goats; N/A

ppm in hogs; N/A ppm in horses; 0.0125 ppm

in sheep; N/A ppm in poultry.

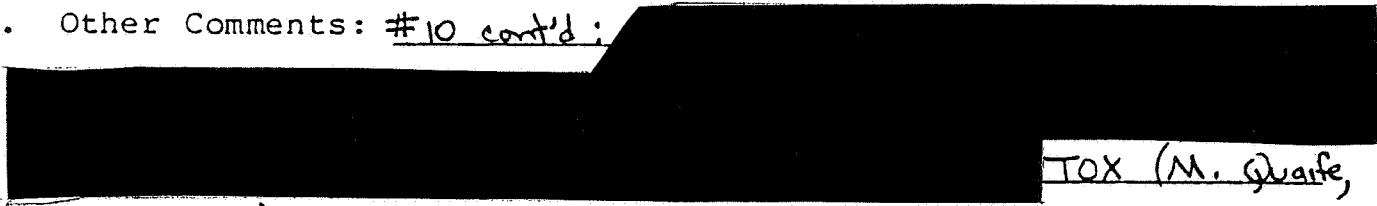
30. Livestock Tolerances are Adequate in (species) N/A. Proposed

use results in NDR in feed item (spent mint hay); no

secondary residues expected in meat or milk.

INFORMATION WHICH MAY REVEAL THE IDENTITY OF A PRODUCT IMPURITY IS NOT INCLUDED

31. Livestock Tolerances Need to be Established: yes no. If yes (species/levels): \_\_\_\_\_

32. Other Comments: #10 cont'd: 

TOX (M. Quarte, oral, 6/2/81) has indicated this compound is a mutagen (Ames test).

33. Other Considerations: Grazing? Mint fields are not grazed.  
\_\_\_\_\_  
\_\_\_\_\_

34. Additional Data Needed: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

35. Recommendations: TOX considerations permitting (#10 and #32), we recommend for the establishment of the proposed tolerances.  
\_\_\_\_\_  
\_\_\_\_\_

36. Other Comments under Recommendations: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

37. Compatability with Codex Tolerances: N/A. See attachment  
\_\_\_\_\_

cc: RF, Circ, Reviewer, Thompson, TOX, EEB, EFB, FDA, PP# 2FA718  
Approved: Quick RMB 8/2/82; Schmitt MS Schmitt  
8-2-82

INTERNATIONAL RESIDUE LIMIT STATUS

CHEMICAL Oryzalin

PETITION No 2F2718/2H5360

CCPR NO. NOA-2

Codex Status

Proposed U. S. Tolerances

No Codex Proposal  
Step 6 or above

for 180.304

Residue (if Step 9): \_\_\_\_\_

Residue: oryzalin

Crop(s) Limit (mg/kg)

Crop(s) Tol. (ppm)

NOA-2

peppermint hay 0.05  
spearmint hay 0.05

peppermint oil 0.1 (FA)  
spearmint oil 0.1 (FA)

CANADIAN LIMIT

MEXICAN TOLERANCIA

Residue: \_\_\_\_\_

Residue: \_\_\_\_\_

Crop Limit (ppm)

Crop Tolerancia (ppm)

NOA-2

NOA-2

Notes: