

DATE OUT: DECEMBER 4, 1995

SUBJECT: EP [] MP [X] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D220728 REG./File Symbol No.: 1021-RAIN
PRODUCT NAME: MULTICIDE Intermediate 2734 Insecticide
COMPANY: McLaughlin Gormley King Company

TO: Linda Deluise, PM Team 13
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Michael J. Clifford, Chemist *MJC 12/4/95*
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Section Head *HP 12/5/95*
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

SUMMARY OF FINDINGS:

1. CSF dated 9/14/95 (Basic Formulation) is not acceptable based on the following considerations:

a. Based on the fact that the source product for Imiprothrin, EPA FILE SYMBOL 10308-EU contains 50.5% active ingredient (MRID No. 437507-04), the nominal concentration of Imiprothrin in the product is 8.08% (16.0% x 50.5%) which does not agree with the label claim of 16.0%.

b. Based on the fact that the source product for Sumithrin, EPA REG. No. 1021-1383 contains 90% active ingredient, the nominal concentration of Sumithrin in the product is 10.08% (11.2% x 90%) which does not agree with the label claim of 11.2%.

c. Please revise your CSF so that the nominal concentrations of Imiprothrin and Sumithrin agree with the label claim as required in PR Notice 91-2.

d. Since the source product for Imiprothrin, EPA FILE SYMBOL 10308-EU is currently undergoing review and the registration is still pending, the registration of EPA FILE SYMBOL 1021-RAIN will be contingent on the registration of EPA FILE SYMBOL 10308-EU.

2. In reference to the proposed labeling (EPA Received 9/19/95), the following change should be made at the next label revision:

a. The chemical name for Imiprothrin as listed in the ingredient statement should be revised by deleting the hyphen between "-imidazolidinyl]" and "methyl."

7505W:RD:RSB:PCRS:MJCLIFFORD:mjc:12/04/95:703-308-8372:1021-RAI.N

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3. The product chemistry data submitted in MRID No. 437912-07 partially fulfill the requirements of 40CFR §§158.150 through 158.190. The following additional data are required:

a. Series 61-1 (Product Identity): Provide the structural formulas and molecular weights for the three active ingredients.

b. Series 61-2 (Formulation Process): Provide copies of the Material Safety Data Sheets for all active and inert ingredients. A description of the quality control processes should also be provided.

c. Series 62-3 (Enforcement Analytical Method): Provide a detailed description of the analytical method used to determine Imiprothrin in the product. Moreover, GLC curves with supporting calculations should be provided to show that the sample contains 16.0% Imiprothrin, 11.2% Sumithrin and 20.0% MGK 264.

d. Series 63-17 (Storage Stability): The applicant claims that a one year study is currently underway. The one year test should be conducted at ambient warehouse conditions on the commercially packaged product. Although the test results need not be submitted to the Agency unless one or more of the deficiencies cited in PR Notice 92-5 have been observed, the data should be available whenever the Agency requests it.

e. Series 63-20 (Corrosion Characteristics): This study should be conducted on the commercially packaged product in conjunction with the one year storage stability test.

EP [] MP [X] PRODUCT CHEMISTRY REVIEW

1. DP BARCODE No.: D220728 2. REG./File Symbol No.: 1021-RAIN
3. Registration [X] 4. Reregistration [], Rereg Case No. _____
5. Product Name: MULTICIDE INTERMEDIATE 2734 INSECTICIDE
6. Pesticide Type: a. Fungicide [] b. Herbicide []
 c. Insecticide [X] d. Rodenticide [] e. Antimicrobial []
 f. Plant Growth Regulator [] g. Others: _____
7. Uses: a. Food [] b. Non-food use [X]
8. Type of Submission: New [X] Resubmission [] Amendment []
 "ME-TOO" [] Alternate Formulation [] Repack []
 Experimental Use Permit [] Other (Specify) _____
9. If "Me-TOO" Registration, this product is [] is not []
 similar or substantially similar to EPA's Reg. No.: _____,
 If not, comment in Confidential Appendix A on the differences
 between the registered and the new source where significant.
10. Information to be reviewed:
- a. CSF [X]: Basic [X] Alternate []
 b. Label [X] c. Product Chemistry [X]

CONFIDENTIAL STATEMENT OF FORMULA, DATED 9/14/95 :

11. Type of formulation and the sources of active ingredients:
- a. Non-integrated formulation system.....[X]
- b. Are all technical grade active ingredients used
 registered? • yes [] • no [X]
- c. Integrated formulation system.....[]
12. Basic Properties:
- a. Physical state at ambient temperature: Liquid
- b. Density (or bulk density for solids): 8.24 lb/gal
- c. pH of product: 8.0 (5% in H₂O)
- d. Flash point (or flame extension for aerosols): >200°F

13. Composition: The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

Active ingredient(s)	% by weight		
	NC	UCL	LCL
Imiprothrin	8.08	16.8	15.2
Sumithrin	10.08	11.8	10.6
N-Octyl Bicycloheptene Dicarboximide	20.00	21.0	19.0

14. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:

• yes [] • no [X]

15. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:

• yes [X] • no []

16. Clearance of intentionally added ingredients in the formulation for the intended use:

- a. Formulation intended for food use under 40CFR§180.1001:

• yes [] • no [] • Some are cleared, others are not []

• Cleared under list: • c [] • d [] • e []

• Are there any limitations for use as an inert under 40CFR§180.1001?

• yes [] • no [], If yes, specify: _____

- b. Formulation intended for non-food use:

• yes [X] • no [] • Some are cleared, others are not []

c. Clearance by the FDA of certain formulations under 21CFR §170 to 199.

• yes [] • no [] • Some are cleared, others are not []

If yes, the entire formulation is cleared under 21CFR§__

17. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL:
 - yes []
 - no []
 - not applicable [X]
 - All other impurities $\geq 0.1\%$ associated with the active ingredient in the product are reported at their nominal concentrations:
 - yes []
 - no []
 - not applicable [X]

PRODUCT LABEL, EPA RECEIVED 9/19/95 :

18. The active ingredients statement (chemical identities, nominal concentrations) is consistent with the CSF • yes [] • no [X]
19. The formulation contains one of the following:
- 10% or more of a petroleum distillate: • yes [] • no [X]
 - 1% or more of methyl alcohol: • yes [] • no [X]
 - sodium nitrite at any level: • yes [] • no [X]
 - a toxic List 1 inert at any level: • yes [] • no [X]
 - arsenic in any form: • yes [] • no [X]
20. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this?
- yes [] • no [] • not applicable [X]
21. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
- yes [] • no [] • not applicable [X]
22. The storage and disposal instructions for the pesticide and container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:
- yes [X] • no []

PRODUCT CHEMISTRY DATA (SERIES 61 and 62)

<u>23. Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1 Chemical Identity	U	437912-07
61-2 Starting Materials & Manufact or Formulation Process	U	437912-07
61-3 Discussion of Impurities	Y	437912-07
62-1 Preliminary Analysis	NA	
62-2 Certified Limits	Y	CSF
62-3 Enforcement Analytical Method	U (GLC)	00121261

PRODUCT CHEMISTRY DATA (SERIES 63)

<u>24. Physical/Chemical Properties</u>	<u>Data Required Fulfilled</u>	<u>Value or Qualitative Description</u>	<u>MRID No.</u>
63-3 Physical State	Y	Liquid	437912-07
63-7 Density/Bulk Density	Y	0.988 (20°C)	437912-07
63-12 pH of Product	Y	8.0 (5%/H ₂ O)	437912-07
63-15a Flammability-Flash Point	Y	>200°F	437912-07
63-15b Flame Extension	NA		
63-16 Explodability	NA		
63-17 Storage Stability	I	Test Underway	437912-07
63-18 Viscosity	Y	130.5 cps (23°C)	437912-07
63-19 Miscibility (With Hydrocarbon solvents)	Y	Data Accepted	437912-07
63-20 Corrosion Characteristics	I		
63-21 Dielectric Breakdown Voltage	NA		

Explanations: Y = The Requirements Were Fulfilled; N = The Requirements Were Not Fulfilled;
 NA = Not Applicable; G = Data Gap; U = Requires Upgrading; I = Incomplete or In Progress; W
 = Waived.