

6-15-1995

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D216288REG./File Symbol No.: 64405-5
PRODUCT NAME: RTU Wood Preservative/Pesticide

DATE: June 15, 1995

TO: Robert Taylor, PM 25
Fungicide-Herbicide Branch
Registration Division(7505C)

FROM: Shyam B. Mathur, Ph.D., Chemist
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Ph.D., Section Head
Product Chemistry Review Section
Registration Support Branch/RD(7505W)

S. Mathur
6-15-95
at 06/15/95

SUMMARY OF FINDINGS

1. 61-1 & 62-2: The basic formulation CSF(02-25-95) submitted for the product RTU Wood Preservative Pesticide needs upgrading. Please check total under column 17 of the CSF.
2. The Registrant did not submit data on Series 61-2 and 61-3. This is considered as data gap.
3. The data submitted for Series 62-1(Not applicable) and 62-3 satisfy the data requirements of 40CFR§158.170 and 158.180 respectively.
4. Since this end-use product has different composition, it is recommended that the Registrant generate new Product chemistry data on Series 63 [63-3, 7, 12, 14, 17, 18 and 20] and submit to the Agency for evaluation.
5. The product label is in compliance with PR Notice 91-2 and is Acceptable.

PRODUCT CHEMISTRY REVIEW OF MP ☐ EP ☒
 DP BARCODE No.: D216288 REG./File Symbol No.: 64405-5
 PRODUCT NAME: RTU Wood Preservative Pesticides
 DATE: June 15, 1995

1. Reviewer: S.B.Mathur 2. Company: Nisus Corporation
3. Type of Submission: Registration ☐ Reregistration ☒
 New ☐ Resubmission ☐ Amendment ☐ "ME-TOO" ☐
 Alternate Formulation ☐ Experimental Use Permit ☐
 Other (Specify) 8 MNTH RESP-PROD SPC DATA
4. 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.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....[X]
 - Are all technical grade active ingredients used registered?
 • yes ☒ • no ☐, If no, specify _____
 - Integrated formulation system.....[]
6. Clearance of intentionally added ingredients in the
 formulation for the intended use (indicate in the Confidential
 Appendix those that are not cleared; the PC Codes should be
 provided by the chemist on the CSF for those that are
 cleared):
 - 6(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 _____
 - 6(b) Formulation intended for non-food use:
 - yes ☒ • no ☐ • Some are cleared, others are not ☐
 - 6(c) Clearance by the FDA of certain formulations under 21CFR§170
 to 199. Examples: (a) indirect food additives, such as food
 contact surface sanitizers; adhesives, coatings, paper and
 paperboard products that may contact food in packaging or
 holding; and (b) substances generally recognized as safe
 (GRAS).
 • yes ☐ • no ☐ • Some are cleared, others are not ☐
 If yes, the entire formulation is cleared under 21CFR§_____.

7. The density, pH, and flammability values given on the CSF are identical with those of GRN 63-7; 63-12, and 63-15, respectively:
 • yes ☒ • no ☐

NOTE: No data was provided on Series 63 for this product.

8. 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
Bora-Care Manufacturing Concentrate	64405-3	21.25 (8.5)	8.76	8.24
Containing: Disodium octaborate tetrahydrate(40%)				

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
 • yes ☒ • no ☐
10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
 • yes ☒ • no ☐

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF:
 • yes ☒ • no ☐
12. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:
 • yes ☒ • no ☐ • not applicable ☐
13. 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 ☒ • no ☐

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63)

14. <u>Chemical IDs/Manufacture/</u> <u>Analytical Information</u>		<u>Data</u> <u>Required</u> <u>Fulfilled</u>	<u>MRID No.</u>
61-1	Chemical Identity	Y	435636-01
61-2	Starting Materials & Manufact or Formulation Process	G	
61-3	Discussion of Impurities	G	
62-1	Preliminary Analysis	NA	
62-2	Certified Limits(CSF)	U	02-25-95
62-3	Enforcement Analytical Method	Y	435636-02

15. <u>Physical/Chemical</u>	<u>Pro</u> <u>per</u> <u>tie</u> <u>s</u>	<u>Data</u> <u>Required</u> <u>Fulfil</u> <u>l</u>	<u>Value or</u> <u>Qualitat.</u> <u>Descrip.</u>	<u>MRID No.</u>
63-3	Physical State	G		
63-7	Density/Bulk Density	G		
63-12	pH of Product	G		
63-14	Oxid/Red Action	NA		
63-15a	Flammability-Flash Pt	NA		
63-15b	Flame Extension	NA		
63-16	Explodability	NA		
63-17	Storage Stability	G		
63-18	Viscosity	G		
63-19	Miscibility	NA		
63-20	Corrosion charac.	G		
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.