

DATE OUT: JUNE 20, 1995

SUBJECT: EP [X] MP [] PRODUCT CHEMISTRY REVIEW
DP BARCODE No.: D216271 REG./File Symbol No.: 69117-R
PRODUCT NAME: POINTER INSECTICIDE
COMPANY: ARBOR SYSTEMS, INC.

TO: Portia Jenkins, PM Team 19
Insecticide-Rodenticide Branch
Registration Division (7505C)

FROM: Michael J. Clifford, Chemist *mjc 6/20/95* Personal privacy information*
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

THRU: Harold Podall, Section Head *HP 6/20/95*
Product Chemistry Review Section
Registration Support Branch/RD (7505W)

SUMMARY OF FINDINGS:

1. CSF dated 5/4/95 (Basic Formulation) is acceptable based on the following considerations:

a. EPA REG. [REDACTED] has recently been revised due to an improved manufacturing process resulting in an increase in the nominal concentration of Imidacloprid from 94% to 98%. Accordingly, the nominal concentration of Imidacloprid in Pointer Insecticide would be 5.21% (5.32% x 98%) which still approximates the label claim of 5.00%.

b. The use of the Surfactant identified in Confidential Appendix A is acceptable.

2. The proposed labeling (EPA Received 5/30/95) is acceptable. The label claim approximates the nominal concentration for Imidacloprid as specified in CSF dated 5/4/95 in compliance with PR Notice 91-2.

3. Pointer Insecticide, EPA FILE SYMBOL 69117-R is considered to be substantially similar to Bayer Inc.'s Merit 2 Insecticide, EPA REG. No.3125-418 (refer to Confidential Appendix A for details).

4. The product chemistry data submitted in MRID No. 436622-01 are acceptable and fulfill the requirements of 40CFR §§158.150 through 158.190 subject to the following comments:

a. Series 63-17 (Storage Stability): Storage Stability tests for at least one year at ambient warehouse conditions must be conducted on the commercially packaged product. Although the data need not be submitted to EPA subject to the criteria cited in PR Notice 92-5, the data should be available whenever EPA may request it.

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

7505W:RD:RSB:PCRS:MJCLIFFORD:mjc:06/20/95:703-308-8372:69117-R

Product ingredient source information may be entitled to confidential treatment

EP [X] MP [] PRODUCT CHEMISTRY REVIEW

1. DP BARCODE No.: D216271 2. REG./File Symbol No.: 69117-R
3. Registration [X] 4. Reregistration [], Rereg Case No. _____
5. Product Name: POINTER 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" [X] Alternate Formulation [] Repack []
 Experimental Use Permit [] Other (Specify) _____
9. If "Me-TOO" Registration, this product is [X] is not []
 similar or substantially similar to EPA's Reg. No.: 3125-418,
 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 5/4/95 :

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 [X] • no []
 c. Integrated formulation system..... []
12. Basic Properties:
 a. Physical state at ambient temperature: LIQUID
 b. Density (or bulk density for solids): 8.94 lb/gal
 c. pH of product: NA
 d. Flash point (or flame extension for aerosols): 165°F

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 5/30/95 :

18. The active ingredients statement (chemical identities, nominal concentrations) is consistent with the CSF • yes [X] • no []
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)

23. <u>Chemical IDs/Manufacture/ Analytical Information</u>	<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1 Chemical Identity	Y	436622-01
61-2 Starting Materials & Manufact or Formulation Process	Y	436622-01
61-3 Discussion of Impurities	Y	436622-01
62-1 Preliminary Analysis	NA	
62-2 Certified Limits	Y	CSF
62-3 Enforcement Analytical Method	Y	422563-02

PRODUCT CHEMISTRY DATA (SERIES 63)

24. <u>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	436622-01
63-7 Density/Bulk Density	Y	1.079 g/mL	436622-01
63-12 pH of Product	NA		
63-15a Flammability-Flash Point	Y	165°F	436622-01
63-15b Flame Extension	NA		
63-16 Explodability	NA		
63-17 Storage Stability	N		
63-18 Viscosity	Y	<150 cps	436622-01
63-19 Miscibility (With Hydrocarbon solvents)	NA		
63-20 Corrosion Characteristics	N		
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.

CONFIDENTIAL APPENDIX A

DATE OUT: JUNE 20, 1995

PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D216271 REG./File Symbol No.: 69117-R
PRODUCT NAME: POINTER INSECTICIDE
Reviewer: MJCLIFFORD Company: ARBOR SYSTEMS, INC.

1. In reference to CSF dated 5/4/95 (Basic Formulation):

a. As referenced in CR #85-0283 dated 6/16/95, the use of [REDACTED] as a surfactant in the formulation is acceptable. The Material Safety Data Sheet submitted for this surfactant has been placed in the supplier's master file.

2. Pointer Insecticide, EPA FILE SYMBOL 69117-R may be considered to be substantially similar to Bayer Inc.'s Merit 2 Insecticide, EPA REG. No.3125-418 based on the following considerations:

a. The pending product contains 5.0% Imidacloprid and approx. [REDACTED] solvent whereas the registered product contains 21.4% Imidacloprid, [REDACTED] and lesser amounts of wetting agents and thickeners.

b. Although the pending product is not compositionally similar to the registered product, it contains a lower level of Imidacloprid and is used for the same application, i.e., as an insecticide on landscape ornamentals. The method of dispensing the pending product is by injection into tree trunks which vastly increases the safety of the product to workers and to the environment.

c. Based on the fact that the pending product differs only from the registered product in ways that do not significantly increase the risk of unreasonable adverse effects on the environment, the two products are considered to be substantially similar.

Inert ingredient information may be entitled to confidential treatment