

8-2-95

PRODUCT CHEMISTRY REVIEW

USE PRODUCT MANUFACTURING-USE PRODUCT
Reg. No. (or File Symbol No.) 58035-RR

Reregistration
Case No.: _____

Chemist: D217589 Anna Skapan 8-2-95

Product Name: XBINX

Company: PMC Specialties Group, Inc.

3. Type of Submission: New Resubmission Amendment
"ME-TOO" Alternate Formulation REPACK
Expt Use Permit Other (Specify) _____

4. CONFIDENTIAL STATEMENT OF FORMULA

4a. Type of formulation and source registration

- Non-integrated formulation system
- Are all TGAIs used registered: yes no
- Integrated formulation system
- If "ME-TOO", specify EPA Reg. No. of existing product: _____

4b. Clearance of inerts for non-food or food use:
Cleared for food use under 40CFR§180.1001:

- yes • no . If yes: • c • d • e
- Cleared for non-food use: • yes • no

4c. Physical state of product: Crystalline

4d. The chemical IDs, analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in GRN 61, 62, and 63-7, 63-12, and 63-15, respectively. • yes • no

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF:
A MANUFACTURING-USE [] OR AN END-USE PRODUCT []
DP Barcode 27589 Reg. No. or File Symbol No. 58035-RR

TO: (PM Team Reviewer)
PM Team No. 31 Marion Johnson / Marshall Swindell

FROM: (Chemist/Date) Anna Skapar 8-4-95
Product Chemistry Review Section
Registration Support Branch/RD (WH705W)

THRU: Harold Podall, Ph.D., Section Head
Registration Support Branch/RD (WH705W) *HP 8/4/95*

SUMMARY OF INFORMATION REVIEWED AND FINDINGS

This application is for registration of a new product for formulating use only.

- A. Confidential Statement of Formula dated 1-12-94 is not in compliance with PR Notice 91-2 and it should be revised to comply with PR Notice 91-2. Certified limit. The upper and lower limit must be given for each intentionally added component. For guidance please refer to 40 CFR part 158.175.
Please note that the Confidential Statement of Formula and the label must reflect the product that is being sold for manufacturing use.
- B. The correct label declaration for the active ingredient should be "1,2-Benzisothiazolin-3-one ... %"
- C. Enclosed product chemistry data in MRID No's 436630-02 - 436630-07 and ~~435840-01~~ includes data for Guideline Series 61, 62 and 63 and it is in compliance with 40 CFR part 158.150 - 158.190 and satisfies product chemistry data requirement for this product.

Anna Skapar
8-4-95

- 4e. Density (or bulk density for solids): at °C. *1.36 g/cc*
- 4f. pH (if dissolved or dispersed in water): *4.25 (1% slurry)*
- 4g. Flash point and/or flame extension: *N/A*
- 4h. NCs and CLs are acceptable: not acceptable
- 4i. Active ingredient(s) NC LCL UCL
- | | | | |
|----------------------------------------|-----|-----|------|
| A. <i>1, 2-Benzisothiazolin -3-one</i> | 97% | 97% | 100% |
| B. | | | |
| C. | | | |
| D. | | | |
- 4j. For products produced by an integrated formulation system:
- All impurities of toxicological significance have an UCL: yes no not applicable
 - All impurities $\geq 0.1\%$ in the product have been identified: yes no not applicable

5. PRODUCT LABEL

- 5a. The active ingredients statement (chemical IDs and NCs) is consistent with the CSF: yes no
- 5b. The formulation contains one of the following:
- 10% or more of a petroleum distillate: yes no
 - 1% or more of methyl alcohol: yes no
 - sodium nitrite at any level: yes no
 - a toxic List 1 inert at any level: yes no
 - arsenic in any form: yes no
- 5c. If yes to any of the above, does the inert ingredients statement contains a footnote indicating this? yes no not applicable
- 5d. The appropriate warning statement regarding flammability or explosive characteristics of the product are given on the label: yes no not applicable

- 5e. 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 []
- 6f. Does the product require an expiration date at which time the NC falls below the LCL (based on the one year storage stability data or other information):
 • yes [] • no

6. PRODUCT CHEMISTRY (GRN 61, 62, 63)

6a. <u>Chemical IDs/Manufacture/Analytical Information</u>	<u>Accept of Information</u>	<u>MRID No.</u>
61-1 Chemical ID (see Appendix) ¹	A	436630-02 -03
61-2a Manufacturing Process ²	A	436630-03
61-2b Formulation Method ³	A	436630-03
61-3 Discussion of Impurities ⁴	A	436630-04
62-1 Analysis ⁵	A	436630-04
62-2 Certified Limits ⁶		
62-3 Analytical Method for AIs ⁷	A	436630-06 -07

6b. <u>Physical/Chemical Properties</u>	<u>Accept of Data</u>	<u>Value or qualitat descrip⁵</u>	<u>MRID No.</u>
63-3 Physical State	A	off white	435840-01
63-7 Density/Bulk Density (g/cc)	A	1.36 g/cc	435840-01
63-12 pH of product ⁹	A	4.25 (1%)	435840-01
63-14 Oxid/Red Action	A	neither oxidize or reduce	— " —
67-15a Flash Point (°C) ¹⁰	A	do not contain flamm. mat. liq.	— " —
63-15b Flame Extension	N/A		
63-16 Explodability	A	not potentially explosive	— " —
63-17 Storage Stability (% degradation of AIs at 20-30 C for ≥ 1 year)	A	14 days 55°C Stable	— " —
63-18 Viscosity	N/A	Solid	
63-19 Miscibility (with hydrocarbon solvents) ¹¹	N/A	Solid	
63-20 Corrosivity (specify metals/conditions)	A	Not corrosive to packaging	— " —
63-21 Dielectric Breakdown Voltage ¹²	N/A	Not intended for use around electric equip.	

Explanations: A = Acceptable; N = not acceptable; NA = technically not applicable; G = data gap; U = requires upgrading; W = waived; E = EPA estimate.

Footnotes: ¹ See Confidential appendix A for additional information; ² For MP/EP products produced by an integrated formulation system; ³ For products produced from a TGAI or MP; ⁴ May be waived unless actual/possible impurities are of tox concern; ⁵ Five batch analysis required for products produced by an integrated formulation system; ⁶ If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A; ⁷ Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc. ⁸ Provide brief description, e.g., color - yellow or property value, e.g. density 1.25 g/cc. Unless otherwise indicated, the property should be at 25 C; ⁹ If product is a water solution or dispersion; ¹⁰ Not required for aerosols; ¹¹ Emulsifiable liquids only; ¹² For end-use products used near electrical equipment.

Attachment: Confidential Appendix A (page 3).

cc: Reviewer's Name and Central File (Reg. No. or Rereg Case No.)
 1: Rxxxx: Reviewer's Name: Typist Initials: xx/xx/94: 703-308-xxxx: Code (Reg or Rereg No.)
 <PCFORM>

H7505W:RD:RSB:PCRS:CS-

5

TABLE 1: SUMMARY OF PRODUCT CHEMISTRY DATA REQUIREMENTS

GLR #	TITLES		
Series 61-Product Identity and Composition (40CFR§158.155, 160, 162, 165 & 167)			
61-1	Product Identity & Disclosure of Ingredients	A	MRLD No. 436630-02
61-2	Description of Starting Materials & Manufacturing Process	A	436630-03
61-3	Discussion of Formation of Impurities	A	436630-04
Series 62-Analysis and Certification of Product Ingredients (40CFR§158.170, 175 & 180)			
62-1	Preliminary Analysis of Product Samples	A	436630-06, -
62-2	Certification of Ingredient Limits	A	CSF
62-3	Analytical Methods to Verify Certified Limits	A	436630-06, 0
Series 63-Physical and Chemical Characteristics (40CFR§158.190)			
63-2	Color	A	435840-01
63-3	Physical State	A	"
63-4	Odor	A	"
63-5	Melting Point	A	"
63-6	Boiling Point	W	"
63-7	Density, Bulk Density, or Specific Gravity	A	"
63-8	Solubility	A	"
63-9	Vapor Pressure	A	"
63-10	Dissociation Constant	A	"
63-11	Octanol/Water Partition Coefficient	A	"
63-12	pH	A	"
63-13	Stability	A	"
63-14	Oxidizing or Reducing Action	W	"
63-15	Flammability	W	"
63-16	Explosibility	W	"
63-17	Storage stability	A	"
63-18	Viscosity	W	"
63-19	Miscibility	W	"
63-20	Corrosion Characteristics	A	"
63-21	Dielectric Breakdown Voltage	W	"

A - Acceptable
W - Waived
NA - Not Applicable
DG - Data Gap

Reviewer: _____

Section Head: _____

Date: _____

Review For MRLD 43584001 From EPA Reg. NO. 70465-

Page _____ is not included in this copy.

Pages 7 through 8 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients.
- Identity of product impurities.
- Description of the product manufacturing process.
- Description of quality control procedures.
- Identity of the source of product ingredients.
- Sales or other commercial/financial information.
- A draft product label.
- The product confidential statement of formula.
- Information about a pending registration action.
- FIFRA registration data.
- The document is a duplicate of page(s) _____.
- The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.