

(7-11-96)

DATE OUT: _____

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]
DP BARCODE No.: D226296 REG./File Symbol No.: 10465-30
PRODUCT NAME: Impel Rods

DATE: July 11, 1996

TO: Connie Welch, PM 22
Fungicide-Herbicide Branch
Registration Division(7505C)

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

S. Mathur
7-11-96

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

SUMMARY OF FINDINGS

1. The basic formulation CSF(dated 03-07-95) is filled out correctly & completely in compliance with PR Notice 91-2 and agree with the label claim nominal concentration. [61-1 & 62-2]
Note: On the CSF the Registrant has used the old EPA Reg. No. It is recommended that the registrant correct the EPA Reg. No. to 10465-30 and submit the revised CSF.
2. The data submitted corresponding to Guideline reference 61-2 [Formulation process] satisfy the data requirements of 40CFR§158.165.
3. The data submitted corresponding to Guideline reference 61-3 [Discussion on the formation of impurities] satisfy the data requirements 40CFR§158.167.
4. The data submitted corresponding to Guideline reference 62-1 [Preliminary analysis] satisfy the data requirements 40CFR §158.170. None of the studies on Series 62 were carried out under GLP
4. The data submitted corresponding to Guideline reference 62-3 [Analytical methods to verify certified limits] satisfy the data requirements 40CFR§158.180.
5. The data submitted corresponding to Guideline reference 63-3, 7,12,14,18,20 satisfy the data requirements 40CFR§158.190.
6. The product label is acceptable.

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1. Reviewer: S.B.Mathur 2. Company: Chemical Specialties Inc.
3. Type of Submission: Registration Reregistration
 New Resubmission Amendment "ME-TOO"
 Alternate Formulation Experimental Use Permit
 Other (Specify) 674 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.....[]
 - Are all technical grade active ingredients used registered?
 • yes • no , If no, specify _____
 - Integrated formulation system.....[X]
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 []
8. The nominal concentrations (NC) of the active ingredients and the upper and lower certified limits (UCL & LCL) are as follows:

<u>Active ingredient(s)</u>	<u>% by weight</u>		
	<u>NC</u>	<u>UCL</u>	<u>LCL</u>
Disodium Octaborate Anhd.	100.00	100.0	99.60

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/ Analytical Information</u>		<u>Data Required Fulfilled</u>	<u>MRID No.</u>
61-1	Chemical Identity(CSF)	Y	03-07-95
61-2	Starting Materials & Manufact or Formulation Process	Y	435679-01
61-3	Discussion of Impurities	Y	" "
62-1	Preliminary Analysis	Y	405340-02
62-2	Certified Limits(CSF)	Y	03-07-95
62-3	Enforcement Analytical Method	Y	435679-02

15. <u>Physical/Chemical</u>	<u>Pro per tie s</u>	<u>Data Required Fulfile d</u>	<u>Value or Qualitat. Descrip.</u>	<u>MRID No.</u>
63-3	Physical State	Y	Solid	435679- 03
63-7	Density/Bulk Density	Y	2.0 gms/ cc	" "
63-12	pH of Product	NA		" "
63-14	Oxid/Red Action	Y	None	" "
63-15a	Flamm.-Flsh Pt.	NA		
63-15b	Flame Extension	NA		
63-16	Explodability	NA		
63-17	Storage Stability	PR 92-5		" "
63-18	Viscosity	NA		" "
63-19	Miscibility	NA		
63-20	Corro.Character.	Y	None	" "
63-21	Dielec.Bkd.Vltg.	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.