

DATE: 24/OCT/2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [] EP [X]

DP BARCODE No.: D284521

REG./File Symbol No.: 524-LUG

PRODUCT NAME: MON 78481

FROM: Linda L. Kutney, Chemist *Linda L. Kutney*
Product Chemistry Team *10/24/02*
Technical Review Branch/RD (7505C)

S. B. W.
10-24-02

TO: Jim Tompkins, Vickie Walters PM #25
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INTRODUCTION:

The Registrant, Monsanto, has submitted physical chemical data concerning their new product, MON 78481, Reg. No. 524-LUG, assigned MRID 45705301.

The proposed 6/19/02 basic CSF for MON 78481, and the corresponding proposed label, contains a nominal claim of 44.8% glyphosate, potassium salt and 0.19% Carfentrazone-ethyl.

Proposed uses for MON 78481 include the food use of weed control prior to crop planting-

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SUMMARY OF FINDINGS:

The following registration requirements are satisfied:

- The nominal concentration on the proposed CSF is identical to the label claim in compliance with PRN 91-2.
- The storage and disposal statement on the label is acceptable and complies with PRN 2001-6.

CONCLUSIONS:

TRB concludes this submission will not be acceptable for registration until the following deficiencies are adequately addressed:

Proposed 6/19/02 Basic CSF

1. Include the full Reg. No. in box 4, 524-LUG, in any updated proposed CSF.
2. Include the chemical names of the ais in column 10 of the CSF.
3. Include the CAS number of the second emulsifier listed on the CSF.
4. Include the supplier name and address, in Column 11, for the chemical used for pH adjustment.
5. Include the supplier name and address, in Column 11, for the carrier, as well as a MSDS, so that the nitrite content may be determined.
6. Provide the chemical composition (including relative percentages) and CAS numbers for dispersant inert which is not approved for use on foods (See Confidential Appendix), or eliminate it from the revised CSF.
7. Recalculate all of the upper and lower certified limits of all of the inerts (except the dye), in accordance with 40 CFR 158.175(b)(2), or provide a rationale for the need for their variance from 40 CFR 158.175.

Guideline 830, Subgroup A, Product Chemistry Data Requirements (See also the appropriate section of the 40 CFR 158, for additional details)

830.1550. Chemical Identity

830.175. Certified Limits

Guideline 830, Subgroup B, Product Chemistry Data Requirements - Must be provided.

830.6317. Storage Stability-Underway

830.6320. Corrosion Characteristics-Underway

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PRODUCT NAME: MON 78481

1. Reviewer: Linda L. Kutney
2. Company: Monsanto
3. Type of Submission: Registration [X] Reregistration [] New [X]
Resubmission [] Amendment [] "ME-TOO" [] Alternate Formulation
[] Experimental Use Permit [] Other (Specify) _____
4. If "Me-TOO" Registration, product is [] or is not [] substantially similar to
EPA's Reg. No.:
If not, comment in Confidential Appendix on the differences.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system.....[X]
 - Are all tgai's used in CSF registered? ● yes [X], ● no [], If no, specify
 - Integrated formulation system.....[]
- 6(a) Food use intended? ● yes [X] ● no []
Inerts cleared for use on food under 40CFR§180.1001? ● yes [] ● no [X]
- 6(b) Non-food use only? ● yes [] ● no [X]
Inerts cleared for non-food use: ● yes [] ● no []
- 6(c) Formulation cleared under FDA's 21CFR§170 to 199? e.g.(a) indirect food
additives, food surface sanitizers; adhesives, coatings, paper or paperboards
contacting food OR (b) generally recognized as safe (GRAS).
● yes [] ● no [X] ● Only partly [] If yes, cleared under 21CFR§_
7. Density, pH, and flammability on the CSF is consistent with the company
reported values? ● yes [X] ● no []
8. Nominal concentrations (NC), upper & lower certified limits (UCL & LCL):
% by weight

<u>Active ingredient(s)</u>	<u>NC</u>	<u>UCL</u>	<u>LCL</u>
Glyphosate, Potassium salt	44.8	46.1	43.4
Carfentrazone-ethyl	0.19	0.21	0.17

9. NC of ai(s) on CSF and label are identical? ● yes [X] ● no []

10. Certified limits comply with 40CFR§158.175? ● yes [] ● no [X]
If not, is adequate explanation given: ● yes [] ● no [X]

PRODUCT LABEL

11. Chemical name of the ai(s) on the label identical to the CSF?:
● yes [] ● no [X]
12. Physical chemical hazard statements for flammability or explosivity on the label appropriate? ● yes [X] ● no [] ● not applicable []
13. Storage and disposal instructions comply with PR Notice 2001-6 for household use products or PR Notice 83-3 for all other uses:
● yes [X] ● no []

PRODUCT CHEMISTRY DATA (SERIES 830 Subgroup A & Subgroup B)

14. Subgroup A, Data Guideline Requirement 830.--	<u>Data Satisfied?</u>	<u>MRID No.</u>
1550. Chemical Identity(CSF)	NO	CSF
1600. Beginning Materials	Yes	45705301
1650. Formulation Process	Yes	45705301
1670. Discussion of Impurities	Yes	45705301
1700. Preliminary Analysis	NA Not Required but a 5-batch analysis performed showed that Glyphosate-potassium averaged 44.8% and that the Carfentrazone-Ethyl ai averaged 0.19%.	45705301
1750. Certified Limits(CSF)	NO Not correct for the inerts, except for the dye.	CSF
1800 Enforcement Analytical Method	Determination of Glyphosate by HPLC, PC-ME-0672-01 Determination of Carfentrazone-Ethyl by HPLC, PC-ME-0673-01	45705301

<u>Physical/Chemical Properties</u> <u>Subgroup B, Guideline 830.-</u> <u>Data Requirement:</u>	<u>Data Satisfied?</u>	<u>Description</u>	<u>MRID No.</u>
6302 Color	Yes	Clear Yellow	45705301
6303 Physical State	Yes	Liquid	45705301
6304 Odor	Yes	Musky	45705301
6314 Oxidation/Reduction	Yes	Oxidized by 1% KMnO ₄ , Reduced by An, Not oxidized by NH ₄ H ₂ PO ₄	45705301
6315 Flammability/Flame Extension	Yes	> 200 F	45705301
6316 Explodability	Yes	Not explosive	45705301
6317 Storage Stability	NO	Storage and purity was tested at 55 C for 14 days. Results were acceptable for Glyphosate and Carfentrazone-Ethyl. Data reflecting storage in commercial packaging under ambient conditions for one year is required, with results reported at 0, 3, 6, 9 and 12 months. This test is underway.	45705301

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6319 Miscibility	Yes	Not required. Not intended for dilution with non-polar solvents.	45705301
6320 Corrosion Characteristics	NO	Corrosion characteristics were adequate following storage at 55 C for 14 days, but additional testing, done concurrently with the required storage stability test at 0, 3, 6, 9 and 12 months is necessary. This test is underway.	45705301
6321 Dielec Breakdown Voltage	Yes	NA Not Required. Not used around electrical equipment.	Proposed Label
7000 pH	Yes	3.8	45705301 CSF
7100 Viscosity	Yes	158/6, 152/12, 149/30, 145/60 centipoise/RPM @ 20 C 81/6, 75/12, 78/30, 77/60 centipoise/RPM @ 40 C	45705301
7300. Density/Bulk Density	Yes	1.3128 g/ml (= 10.95 lb/gal on CSF)	45705301

Explanations: NA = Not Applicable

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CONFIDENTIAL APPENDIX:

The inert(s) not approved for use in pesticides applied to food is:

[REDACTED]

The component chemical names and percentages, and CAS Nos. (when appropriate) must be submitted for the inert(s) listed above so that the Agency may determine whether an exemption from food tolerance is appropriate.

INERT INGREDIENT INFORMATION IS NOT INCLUDED

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