DATE OUT: 27/OCT/1999

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]**
DP BARCODE No.: D258467 **REG./File Symbol No.:** 70829-E
PRODUCT NAME: Clearout 41

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PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

INTRODUCTION:

The registrant has submitted the product chemistry data to support the registration of the subject product. Th end-use product Clearout 41 is formulated by using the unregistered source product Glyphosate technical [redacted]. The registrant has provided the analysis and physical-chemical properties of the unregistered source product.

SUMMARY OF FINDINGS:

A. For the end-use product Clearout 41:

1. The subject end-use product contains Glyphosate isopropylamine salt (unregistered source) as the active ingredient with product label claim of 41.0%.

2. The basic formulation CSF (dated 08-05-99) for the end-use product clearout 41 is not filled out correctly and is not in compliance with PR Notice 91-2. The data submitted corresponding to the guideline reference 61-1[830.1550] and 62-2[830.1750] does not satisfy the data requirements of 40CFR§158.155 and 158.175 respectively.

3. The data submitted corresponding to the guideline reference 61-2 [830.1650] and 61-3[830.1670] for the end use product clearout 41 satisfy the data requirements of 40CFR158.165 and 158.167 respectively.

4. The data submitted corresponding to the guideline reference 62-3 [830.1800] for the end use product clearout 41 satisfy the data requirements of 40CFR§158.180.

5. The data submitted for the end-use product clearout 41 corresponding to the guideline reference Physical state(830.6303), density(830.7300), pH(830.7000), Oxidation/Reduction (830.6314), Flammability(830.6315), Explodability(830.6316), Storage stability (830.6317), Viscosity (830.7100), Miscibility(830.6319), Corrosion characteristics(830.6320), & Dielectric breakdown voltage(830.6321) satisfy the data requirements of 40CFR§158.190.

6. The registration of the end-use product clearout 41 is subject to the acceptance and satisfaction of all the product chemistry data requirements for the unregistered technical source product[redacted]

B. For unregistered technical source product:

1. The registrant did not submit product chemistry data corresponding to guideline reference 830.1550(Product identity), 830.1620(Production process), and 830.1670(Discussion on the formation of impurities) for the technical.

2. The data submitted under MRID No. 448831-19 corresponding to guideline reference 830.1700 could not be evaluated since there was no information available on the discussion on the formation of impurities and its manufacturing process. For the Preliminary analysis, the registrant is also required to identify the samples which were subjected to analysis. The name of the manufacturing facility from where the samples were obtained must be indicated for the samples.

3. The data submitted corresponding to Series 830 Subgroup B(Physical/chemical)properties satisfy the data requirements of 40CFR§158.190.

CONCLUSIONS:

The TRB has reviewed the product chemistry data submitted for the unregistered technical Glyphosate and for the end-use Clearout 41 and has concluded that:

For the end-use product Clearout 41:

1. All the product chemistry data submitted for the end-use product Clearout 41 satisfy the data requirements of 40CFR§158.150 to 158--190 and are acceptable, except for the CSF.

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2. Registrant is required to revise the basic formulation CSF so that it is in compliance with PR Notice 91-2. For more details, please refer to Confidential Appendix.

3. The registration of the end-use product clearout 41 is subject to the acceptance and satisfaction of all the product chemistry data requirements for the unregistered technical source product [redacted]

4. The registrant is required to generate one year corrosion characteristics study on the test substance stored in the commercial container under warehouse conditions. This study is generally done along with one year storage stability study.

For the unregistered technical Glyphosate:

1. The registrant must submit product chemistry data corresponding to guideline references numbers:

830.1550(Product identity),
830.1620(Production process), and
830.1670(Discussion on the formation of impurities)
These are considered as data gaps.

2. The data submitted corresponding to guideline reference 830.1700 (Preliminary analysis)would be reviewed together with additional data required as mentioned in item 1. The registrant must identify the source(Manufacturing facility)of the sample which was subjected to analysis.

3. The registrant must also submit data corresponding to guideline reference:

830.7200(Melting point)
830.7370(Dissociation constant)
830.7550(Octanol/water partition coefficient)
830.7840(water solubility)
830.7950(Vapor pressure)

4. Other data submitted corresponding to Series 830 Subgroup B(Physical/chemical)properties satisfy the data requirements of 40CFR§158.190 and are acceptable.

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PRODUCT CHEMISTRY REVIEW OF MP [ ] EP [X]
DP BARCODE No.: D258467 **REG./File Symbol No.:** 70829-E
PRODUCT NAME: Clearout 41
DATE: 10-27-99

1. Reviewer: S.B.Mathur 2. Company: Chemical Products Technology

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, 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 [X], If no, specify **The registrant is using an un-registered technical source product to formulate this end-use product**.
- 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 [X] • no [ ] • Some are cleared, others are not [ ]

Cleared under list: • c[X] • d[ ] • e [X]

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 [X] • 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 [X] • no [ ]

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
Glyphosate Isopropyl amine salt	(41.0)	(42.23)	(39.77)

Prepared by:

[redacted]

9. The calculated NCs, based on the pure active ingredients (PAI), are identical to those on the label:
• yes [X] • no [ ]

10. The certified limits are within the standard limits as per 40CFR§158.175 or are adequately explained if different:
• yes [X] • no [ ]

PRODUCT LABEL

11. The chemical names of the active ingredients on the label are identical to those on the CSF: • yes [ ] • no [X]

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 [X]

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 [X] • no [ ]

PRODUCT INGREDIENT SOURCE INFORMATION IS NOT INCLUDED

PRODUCT CHEMISTRY DATA (SERIES 61, 62, 63) For EP Clearout 41

14. Chemical IDs/Manufacture/ Analytical Information New Guideline:830.--	Data Required Fulfilled	MRID No.
1550.(61-1) Chemical Identity(CSF)	U	08-05-99
1600.(61-2a) Beginning Materials 1620.(61-2b) Formulation Process	Y	448831-01
1670.(61-3) Discussion of Impurities	Y	" "
1700.(62-1) Preliminary Analysis	NA	
1750.(62-2) Certified Limits(CSF)	U	08-05-99
1800.(62-3) Enforcmnt. of Anal.Method	Y	448831-02

15. Physical/Chemical Properties New Guideline No. 830.---	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
6303.(63-3) Physical State	Y	Viscous liquid	" "-03
7300.(63-7) Density/Bulk Den.	Y	1.1560 g/ml	" "
7000.(63-12) pH	Y	4.42	" "
6314.(63-14) Oxid/Red Action	Y	Note 1	" "
6315.(63-15a) Flamm.-Flsh Pt.	NA		
6315.(63-15b) Flame Exten.	NA		
6316.(63-16) Explodability	NA		
6317.(63-17) Storage Stablty.	PR 92-5		
7100.(63-18) Viscosity	Y	13.6 cPs 20°C 6.7 cPs 40°C	" "
6319.(63-19) Miscibility	NA		
6320.(63-20) Corrosion Charac	Y	non-corrosive	" "
6321.(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.

Note 1. 830.6314(Oxi/Red action):

The test substance was treated(in 1:1 proportion) with potassium permanganate(PP), tap water, zinc granules, iron granules, kerosene, and monoammonium phosphate. None of these reagents, except PP, caused a change in temperature greater 5°C, or the evolution of gases, noxious fumes, or splattering.

At the addition of PP, the following observations were noted: an immediate reaction occurred, the color changed from clear to pink, then to dark brown, a change in odor was observed, splattering, and a single ball of black solid material with a tint of pink liquid developed. The temperature rose to 59°C. At the end splattering occurred, which caused black and brown particles on the side of the container and almost all of the liquid layer had disappeared.

Physical/Chemical properties of technical Glyphosate:
(MRID No. 448831-20)

830.6302. Color	White
830.6303. Physical State	Solid
830.6304. Odor	Odorless
830.7300. Density	1.71 g/ml
830.7000. pH	1.72
830.6313. Stability:	
Ambient temperature 25°C(2 weeks)	1.1% degradation
Elevated temperature 54°C(2 weeks)	1.0% degradation
Exposure to Zinc metal	1.8% degradation
Exposure to Fe metal	3.1% degradation
Exposure to Al metal	Stable
Exposure to Zn salt	37.4% degradation
Exposure to Fe salt	49.2% degradation
Exposure to Al salt	1.9% degradation
Exposure to sunlight	2.0% degradation

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Page 8 is not included in this copy.

Pages _____ through _____ are not included.

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.