

**DATE OUT:** 4/ AUGUST / 2004

**SUBJECT:** FEE : PRODUCT CHEMISTRY REVIEW OF MP  EP   
DP BARCODE No.: 301003 File Symbol No.: 524-LLG  
PRODUCT NAME: 1626 Herbicide  
COMPANY: Monsanto Company  
FOOD USE  INTEGRATED FORMULATION   
PCC: 103613 Decision No. 341578

**FROM:** Debra Rate  
Product Chemistry Team  
Technical Review Branch/RD (7505C)

**TO:** Vickie Walters/ James Tompkins RM 25  
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**INTRODUCTION:**

The registrant has submitted a CSF for basic formulation (dated 02/23/04) and two alternative formulation CFSs (A and B)(dated 02/23/04) for the end-use product 1626 Herbicide. The proposed end-use product has MON 78623 Technical (glyphosate, potassium salt) (Reg. No.524-532, 58%) as its active ingredient (AI). The TRB has been asked to review the basic CSF and alternate formulation CFSs (all dated 02/23/04) and the determine if the product is "similar" enough to EPA Reg. No. 524-548 for registration to be supported by the data submitted under MRID No. 455011-01 and 458151-01.

**SUMMARY OF FINDINGS**

1. The proposed end-use product, 1626 Herbicide, contains MON 78623 Technical (glyphosate, potassium salt) (Reg. No.524-532, 58%) as its AI with a product label claim of 48.7%.
2. The registrant has submitted a CSF for basic formulation (dated 02/23/04) and alternate formulation CSFs (A and B) (dated 02/23/04) for the end-use product, 1626 Herbicide. The CSFs are filled out correctly and completely. The nominal concentration of the AI concurs with the product label claim nominal concentration. The CSFs are in compliance with PR Notice 91-2. All of the inert ingredients have been cleared by the Agency. The data submitted corresponding to guideline 830.1550(product identity and composition) and guideline 830.1750 (certified limits) satisfy the requirements of 40§CFR158.155 and 158.175, respectively.
3. The differences between the proposed end-use product basic formulation CSF and the currently registered product basic(Reg.No. 524-548) include only the change of one inert ingredient (See Confidential Attachment.). This inert ingredient was subsequently accepted as an alternative to the original on the alternative formulation CSF (dated 05/28/03) for the Reg. No. 524-548. All other items in the formulation are the same, including the same AI with the same nominal concentration.

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**CONCLUSIONS:**

The TRB has reviewed the submitted basic and alternative formulation CSFs (all dated 02/23/04) and product chemistry data for the proposed end-use product, 1626 Herbicide and has concluded that:

1. From a Product Chemistry point of view the proposed end-use product is substantially similar to the EPA Reg. No. 524-548. The data from the registered product may be cited and used to support the registration of the proposed end-use product. [MRID No. 455011.01 and 458151-01]
2. The product chemistry data cited corresponding to 830 Series Subgroup A are acceptable.
3. The CSFs for basic formulation (dated 02/23/04) is acceptable.
4. The alternate formulation CSFs (A and B) (dated 02/23/04) are acceptable.
5. The product chemistry data cited corresponding to 830 Series Subgroup B (physical/chemical properties) are acceptable.

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

Subgroup A	Data Required Fulfilled	MRID No.
830.1550. Chemical Identity (Basic CSF)	Y	02/23/04
830.1600. Beginning Materials	Y	455011-01
830.1650. Formulation Process	Y	455011-01
830.1670. Discussion of Impurities	Y	455011-01
830.1700. Preliminary Analysis	Y	455011-01
830.1750. Certified Limits (Basic CSF)	Y	02/23/04
830.1800. Enforcement Analytical Method	Y	455011-01

Subgroup B	Data Required Fulfilled	Value or Qualitat. Descrip.	MRID No.
830.6302. Color	Y	Light yello	455011-01
830.6303. Physical State	Y	liquid	455011-01
830.6304. Odor	Y	Mild musky	455011-01
830.6314. Oxidation/Reduction Action	Y	Reduced by Zinc, Oxidized by 1%KMnO <sub>4</sub>	455011-01
830.6315. Flammability	NA	water based liquid	455011-01
830.6316. Explodability	NA	Not explosive	455011-01
830.6317. Storage stability	Y	No or negligible change.	458151-01
830.6319. Miscibility	NA	Not intended...	455011-01
830.6320. Corrosion Characteristics	Y	No evidence of corrosion, container sustained a 0.07% weight loss during the study.	458151-01
830.6321. Dielec. Bkd. Vltg.	NA	Not intended...	455011-01
830.7000. pH	Y	pH = 4.66 1% solution	455011-01
830.7100. Viscosity	Y	84.4 cPs @ 20 °C 62.4 cPs @ 40 °C	455011-01
830.7300. Density/Bulk Density	Y	1.3579 g / ml	455011-01

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.

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**830.1800 Enforcement Analytical Method:** [MRID No. 455011-01]

This procedure uses HPLC / UV (195-205 nm) to determine the % glyphosate in the test samples.

**Equipment and Operating Conditions:**

HPLC chromatograph: Waters M6000A, Varian 2510, Varian 9010  
Column: Whatman Partisil 10 SAX (250 X 4.6 mm), Whatman MAXI, WCS analytical column(250 X 4.6 mm), #4120-001, or Alltech Adsorbosphere XL SAX(250 X 4.6 mm), #20314, with or without guard column.  
Injection volume: 10 - 100  $\mu$ l

**Reagents:**

Methanol: HPLC grade  
85% phosphoric acid:  
Potassium phosphate monobasic  
Water: HPLC grade  
Standard: Glyphosate from Monsanto Company

Mobil Phase: per liter (0.8425 g potassium phosphate monobasic, 960 ml water, 40 ml methanol: adjusted to pH 1.9-2.6 with 85%  $H_3PO_4$ )

Flow rate: 1 - 3 ml / minute

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