

APR 5 1990

R.F.

CONFIDENTIAL



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM:

SUBJECT: Metsulfuron Methyl (Escort): Additional Product
Chemistry and Revised CSF. MRID No 413932-01
DEB Nos. 6519 and 6520

FROM: J. Garbus, Chemist
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (H7509c)

THRU: P. V. Errico, Head
Tolerance Petition Section III
Dietary Exposure Branch
Health Effects Division (H7509c)

TO: R. Taylor / V. Walters PM-25
Registration Division (H7505c)

E.I. du Pont de Nemours and Company, Wilmington, DE has submitted additional product chemistry for its herbicide metsulfuron methyl (Escort), (methyl 2-[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl) amino]carbonyl]amino]sulfonyl] benzoate). The registrant has detected an additional impurity in production batches manufactured at a new facility. Analytical data is presented regarding levels of the impurity in 9 production lots. Du Pont states a revised manufacturing procedure has been instituted that should lower the levels of the impurity. A revised CSF has been submitted that now includes limits for the impurity.

The qualitative and quantitative aspects of the impurity and the revised CSF are given in the Confidential Appendix to this memorandum.

TOX has concluded:

Based on the information available, exposure to the "new" impurity is likely to be minimal and of no toxicological concern, provided that data can be provided to support the statement that the "new" impurity is [REDACTED]

IDENTITY OF PRODUCT IMPURITIES NOT INCLUDED

[REDACTED]

Du Pont has submitted toxicological data addressing the issue of the conversion of the new impurity to [REDACTED]. These data are being reviewed by TOX.

Conclusion

DEB finds that the submitted CSF is unacceptable as it is not based upon the levels of [REDACTED] found in 5 or more production batches but is based upon the level expected from the revised manufacturing procedure. An acceptable CSF can either be based upon the levels actually determined for [REDACTED] or upon the analyses of 5 or more production batches made with the altered process.

DEB concludes that the analyses were conducted with a validated analytical procedure.

cc with CBI: R.F., S.F., PP#8F3647, Reviewer, R. Schmitt,
C. Furlow PIB/FOD

cc without CBI: Circ.

RDI:PE:4/2/90:RAL:4/3/90

JG:jg:Rm803c:CM-2:(H7509c):(703) 557-1405:4/3/90

IDENTITY OF PRODUCT IMPURITIES NOT INCLUDED
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METSULFURON-METHYL

Page ____ is not included in this copy.

Pages B through S 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.
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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.
