

US EPA ARCHIVE DOCUMENT



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

DEC 8 1986

EXPEDITE

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: EPA Reg. No. 279-3052. Amended statement of formula for Command Technical Herbicide. [RCB# 1618]

FROM: Richard Loranger, Chemist *R. Loranger*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: R. Taylor/J. Yowell, PM Team 25, HFB
Registration Division (TS-767)
and
Toxicology Branch
Hazard Evaluation Division (TS-769)

FMC Corporation has proposed an amended registration for Command Technical Herbicide containing the active ingredient dimethazone (2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone). In their 10/29/86 letter the registrant states that production recently started at a new facility. The product chemistry data (Accession No. D72769, PP#4F3128) used to obtain the registration were based on pilot plant batches. The new material contains impurities which were not found at the 0.1% level in the original batches and the technical used for toxicology studies. Therefore, FMC has submitted an amended Confidential Statement of Formula with certified limits for the new impurities. See the Confidential Appendix for identities and limits of these compounds.

CONCLUSIONS AND RECOMMENDATION

1. Since there has been no apparent change in the production of Command other than switching to a new facility, additional information is not required concerning beginning materials and manufacturing process (\$61-2) and the formation of impurities (\$61-3).
2. To support the certified limits (\$62-2) given in the amended Confidential Statement of Formula raw data and chromatograms must be provided for five batches (\$62-1) of Command Technical produced at the new facility. All impurities present at >0.1% should be reported. Analytical methods employed for these analyses must be described (or referenced if submitted previously) (\$62-3). Also, an error in the Timit for the active ingredient on the CSF should be corrected (see Confidential Appendix).

3. Provided the data requested in Conclusion 2 supports the new statement of formula, the changes in composition are so slight that additional determinations of physical and chemical characteristics (§63) are not necessary.

We recommend against acceptance of the amended formula for Command Technical Herbicide until the data requested in Conclusion 2 have been submitted. We also defer to Toxicology Branch for their concern over the presence of [REDACTED] new impurities. Taking into account the use pattern of this herbicide (pre-emergence) and its method sensitivity tolerance we expect no detectable residues (<<0.01 ppm) of these new impurities in crops.

Attachment-Confidential Appendix (Copies to PM-25, TOX, PP#4F3128, RF, Reviewer, PMSD/ISB only)

cc: Circu, RF, PP#4F3128, Command SF, Reviewer, PMSD/ISB
RDI: Section Head:ARRathman:12/1/86:RDSchmitt:12/1/86
TS-769:RCB:R.Loranger:557-7324:RAL(8):CM#2:RM.810:Date:12/1/86

MANUFACTURING PROCESS INFORMATION HAS BEEN DELETED.

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