

CONFIDENTIAL



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

MAY 27 1988

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: EPA Reg. No. 279-3052. Command^R Technical Herbicide.
Application for amended registration.
(MRID#'s 405002-01 through -07) [RCB# 3492]

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

THRU: Andrew Rathman, Section Head *ARR*
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

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

The FMC Corporation has requested an amended registration for their Command^R Technical Herbicide (2-[(2-chlorophenyl)methyl]-4,4-dimethyl-3-isoxazolidinone; proposed common name=clomazone). The amendment includes a lowering of the minimum active ingredient level [REDACTED]

The product chemistry data to support the original registration of Command were submitted in PP#4F3128 (Accession # 072769). FMC later (October 1986) requested an amended registration when production started at a new facility. RCB approved the revised Confidential Statement of Formula (CSF) submitted at that time, but required that analyses of five batches for all impurities present at $\geq 0.1\%$ be provided within one year (R. Loranger, 12/31/86). These analyses have now been furnished and serve as the basis for the proposed amended registration.

CONCLUSIONS AND RECOMMENDATION

A complete product chemistry package has been provided for the Command Technical Herbicide. Due to the lower minimum level of active ingredient [REDACTED] we can not consider the amended technical identical to the material that received the initial registration. The compositions of the two technicals and the original toxicology sample are compared on pages 3-4 of Confidential Appendix A to this memorandum.

PENDING REGISTRATION INFORMATION HAS BEEN DELETED.

XX 816
106

We defer to Toxicology Branch for an incremental risk assessment according to SOP 3068.2. In addition to receiving a complete copy of this review, Toxicology Branch should be given Books 8 and 9 of the current submission (MRID#'s 405002-06 and -07) as they contain FMC's discussion regarding the need for toxicological testing of certain impurities.

DETAILED CONSIDERATIONS

Each of the sections of the Product Chemistry Guidelines will be discussed below with emphasis on the changes in production and chemical composition.

§61-1 Product Identity and Composition (MRID# 405002-01)

The proposed common name for Command is now clomazone instead of dimethazone. The chemical content of the technical is shown in the table on page 3 of Confidential Appendix A to this review. This table uses "common" names for the impurities. Refer to Confidential Appendix B for full chemical names and structures.

Adequate information has been provided on the chemical composition of the Command Technical Herbicide produced at the new facility.

§61-2 Description of Beginning Materials and Manuf. Process (MRID# 405002-01)

The same sequence of chemical reactions as described in PP#4F3128 is being utilized for production of Command. These are given in Confidential Appendix A. Some changes have been made in duration and conditions. Also, some additional impurity information has been provided for starting materials.

Sufficient details have been supplied on this topic.

§61-3 Discussion of the Formation of Impurities (405002-01)

The registrant has once again submitted a thorough discussion of impurities that could be expected from starting materials, side reactions, and incomplete reactions. The revisions from the previous discussion include addition of several pages to address newly discovered contaminants and changes in the %'s observed for numerous impurities.

An acceptable discussion has been supplied to meet this requirement.

§62-1 Preliminary Analysis of Product Samples §62-2 Certification of Ingredient Limits §62-3 Analytical Methods for Enforcement of Limits (MRID#'s 405002-02 and -03)

Five samples of Command (FMC 57020) technical (Lot #'s 86-46, 87-13, 87-17, 87-22, 87-30) were analyzed for active ingredient and

817

(0)

assorted impurities. All analyses employed multiple sample weighings. The analytical methods for clomazone and its impurities are described in Confidential Appendix A. Spreadsheets showing sample concentrations, peak heights/areas, and response factors for samples and analytical standards were provided for the analyses of all components. The method of calculating wt/wt% from these raw data was explained. We have randomly checked the spreadsheets and find the reported results consistent with the raw data. The table on page 3 of Confidential Appendix A shows the composition of the five batches and the original toxicology sample plus the approved and proposed CSF's. We note that the approved CSF is the original one submitted August 1984 and not the modified one we examined in December 1986.

The submitted analyses are satisfactory. The proposed certified limits are reasonable based on the results of the present analyses and those conducted for the original registration.

§63 Physical/Chemical Characteristics (MRID# 405002-05)

FMC is not reporting any changes in physical/chemical properties for Command. However, since they were not listed in our previous reviews, we will summarize them below for future reference.

§63-2/63-3 Color and Physical State Clear, colorless to very pale yellow viscous liquid above room temperature; white, crystalline solid when cooled.

§63-4 Odor-light fatty acid

§63-5 Melting Point 25°C (broad range)

§63-6 Boiling Point 275°C at atm. pressure (extrapolated from vapor pressure curve).

§63-7 Density 1.187 g/ml at 25°C

§63-8 Solubilities	1100 mg/liter (ppm) in water	
	<u>organic solvent</u>	<u>grams technical per 100 ml</u>
	Tenneco 500-100*	≥200
	Isopar M**	4.5-5.0
	Refined soybean oil	≥90
	Dimethyl formamide	infinite
	Cyclohexanone	infinite

*Polar, aromatic solvent-complex mixture of mononuclear hydrocarbons with ≈10% xylene

**Nonpolar, aliphatic solvent-mixture of isoparaffins

§63-9 Vapor pressure 1.92×10^{-2} Pa (1.44×10^{-4} mm Hg) at 25°C

§63-10 Dissociation Constant-not applicable since clomazone neither acidic nor basic

§63-11 Octanol-Water Partition Coefficient 350 (log p=2.54)

§63-12 pH Agitated slurry in water was allowed to settle and pH of supernatant found to be 6.89 ± 0.14 (versus 6.93 ± 0.06 for distilled water)

§63-13 Stability

Temperature: no loss at ambient T for one year; no loss at 50°C for 3 months.

818

106

Metals:stainless steel filings lower stability of clomazone at high temperatures (decomp. T lowered from 240°C to 200°C)

Hydrolysis:at 25°C no hydrolysis observed over 30 days at pH's 4.65 and 7.00; less than 10% hydrolyzed at pH 9.25.

Photolysis:with natural sunlight or sunlamp the estimated times for 50% degradation of clomazone in aqueous solution exceeded 30 days.

- §63-14 Oxidizing or Reducing Action-no visible change in appearance or temperature rise (<1°C) observed with water, monoammonium phosphate, or zinc.
- §63-15 Flammability-not flammable Flash point=314°F (157°C)
- §63-16 Explodability-not explodable when 3.6 kg weight dropped from height of 38 cm.
- §63-17 Storage Stability-see §63-13
- §63-18 Viscosity 47.05 centistokes at 25°C
- §63-19 Miscibility-see §63- 8
- §63-20 Corrosion Characteristics:carbon steel, stainless steel, high density polyethylene and linear low density polyethylene all found to be acceptable containers.

The above is an adequate description of the physical/chemical characteristics of technical clomazone.

Attachments: Confidential Appendix A (5 pages) and Confidential Appendix B (8 pages)

cc with Attachments: RF, PMSD/ISB, PM-23, TOX, Loranger, Command SF, PP#4F3128

cc without Attachments: Circu

RDI:Section Head:ARRathman:5/26/88:RDSchmitt:5/26/88

TS-769:RCB:557-7887:RAL:ral:CM#2:Room 810:Date:5/26/88

Disk 01:Files COMMAND1.AR and COMMAND2.AR