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PRODUCT CHEMISTRY REVIEW

**Product Chemistry Review Section
Registration Support Branch**

Registration Division, Office Of Pesticide Programs

DATE: 6/28/91
PRODUCT CHEMIST/REVIEWER: Amelia M. Acierto *[Handwritten signature]*
PAGE: 1 of 6
COMPANY: Sandoz Crop Protection Corporation
EPA REG. NO: 55947-UG
PRODUCT NAME: Barricade 65 WG Herbicide
TO PM NO: 23
ACTION CODE: 116
BACKGROUND:

Barricade® 65WG is the other trade name for Prodiamine® 65WDG which was reviewed on 7/24/90 simultaneously with Prodiamine Technical by R. Lozada. The following deficiencies were found for this end-use product: (1) The manufacturing/formulation process has not been submitted (2) The impurities formed during the formulation process, in packaging, or during storage has not been described nor has it been stated that no impurities are expected to form during the various stages of formulation. (3) The physicochemical properties required for end-use products have not been submitted. In addition to the deficiencies, it was required that nitrosamine contaminants at the time of commercial production should be analyzed.

This submission from Sandoz Crop Protection Corporation dated 1/29/91 for Barricade® 65 WG includes a new label, four Confidential Statements of Formula for the basic and three alternate formulations dated 1/25/91 and data requirement for Guidance Series 61 through 63. This review will address the submitted data as it relates to the deficiencies noted in an earlier review for the end-use product. The Technical Prodiamine has been reviewed separately.

ACTIVE INGREDIENT LABEL CLAIM/LATEST LABEL CLAIM (DATED)

Prodiamine [N^3, N^3 -Di-n-propyl-2,4-dinitro-6-(trifluoromethyl)-m-phenylenediamine] 65.0%

REFERENCES USED: MRID #s 417688-20 to -29 55947-UR

FOOD USE () INERTS CLEARED: C (), D () NON FOOD USE (x)
21 CFR PARTS 170-199: () TOXIC INERTS LIST 1(), 2()

NOTE TO PM/INTER-OFFICE USE ONLY:

The summary table is for the Agency file. The product chemistry comments (see Summary Table) applies only to the basic (Formulation #1) and one alternate (Formulation #2). The 2 new formulations (Formulation #s 3 and 4) which were submitted by the applicant as potential formulations, are considered unacceptable alternates and may be separately registered.

COMMENTS:

(1) The new product chemistry information found in MRID Nos. 417688-20 thru 29 has been reviewed for your basic (Formulation #1) and one alternate (Formulation #2):

(a) The information on the manufacturing/formulation process is sufficient and satisfies the deficiencies noted in the review dated 6/24/90. No further information is required.

(b) The information on the impurities is sufficient but the analytical data on the nitrosamine contaminant is expected to be provided to the Agency at the time of commercial production. This is based on the statement found in MRID 417688-20 that Barricade 65WG Herbicide will be analyzed in accordance with the Agency's proposed nitrosamine policy when production begins.

(c) The physicochemical properties of this product have been reviewed. The information is sufficient and satisfies the deficiency noted in the earlier review. No further information is required on this subject.

(2) Your 4 Confidential Statements of Formula for the basic and 3 alternate formulations have been reviewed:



INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

(3) Your label claim is supported by your formula statements (Formulation #1 and #2) and is acceptable provided the asterisks after the chemical name in the ingredient statement is referenced.

SUMMARY REVIEW TABLE GUIDELINES SUBDIVISION D

Product Name: Barricade® 65 WG Herbicide [EPA Reg No. 55947-UG]
[Comments pertain to Formulation #1 (basic) and #2 (alternate) ONLY. Excludes formulation #3 & #4 containing [REDACTED]]

Section	Comments	MRID#
61-1 Product Identity and Disclosure of ingredients.	Composition of product was identified and supports the information contained in the CSFs Formulation #1 & 2 (basic and one alternate formulation dated 1/25/91) [REDACTED] No further information is required for this topic.	417688 -20
61-2 Description of Beginning Materials and Manufacturing process	Information on beginning materials and manufacturing process including a flow diagram was provided. This satisfies deficiency noted in the previous review. No further information is required for this topic.	-20
61-3 Discussion of the Formation of Impurities	The CSFs for EPs include statement that N-nitrosamine contamination associated with prodiamine is not greater than [REDACTED] Under "Discussion on the formation of impurities" an internal limit of [REDACTED] N-nitrosamine has been set for the TGAI and that the EP will be analyzed for nitrosamine when production begins. Therefore, analytical data for nitrosamine contaminants is expected to be submitted at time of production of the EP.	-20

INERT INGREDIENT INFORMATION IS NOT INCLUDED

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

Section	Comments	MRID# 417688
62-1 Preliminary Analysis of Product Samples.	Analytical data has been provided. No further information is required for this topic.	-20
62-2 Certification of Ingredient limits	The CSF provided the certified limits. The brief statement that the limits will be maintained is found in MRID# 417688-20.	-20
62-3 Analytical Methods to Verify Certified Limits	Prodiamine in the technical and formulated products is determined by gas chromatography. Precision and accuracy of the method were included. Method validation was supported by analytical data with the comparison of experimental and theoretical values for spiked samples of technical and formulated products. No further information is required for this topic.	-20
63-2 Color*	Munsell color: 5.0 Y 7/10.8 (greenish yellow) at 23.2°C	-21/22
63-3 Physical State*	greenish yellow solid granules	-21/23
63-4 Odor*	weak, neutral, foliar or aromatic odor	-21,24
63-7 Density*	0.63 g/ml at 25°C	-21,25
63-12 pH*	9.21 at 24.9°C	-21,26
63-14 Oxidising or Reducing Action*	Slight oxidising and reducing potential	-21,27
63-15 Flammability*	N.R. Barricade contains no combustible liquids.	-21
63-16 Explodability*	Non-explosive	-21,28
63-17 Storage Stability*	Stable for 2 years at ambient temperature and for 84 days at 54°C	-21,29

Section	Comments	MRID# 417688
63-18 Viscosity*	N.R. Barricade 65WG Herbicide is not a liquid	-21
63-19 Miscibility*	N.G. Barricade 65WG Herbicide is not an emulsifiable liquid	-21
63-20 Corrosion Characteristics*	Not expected to have any appreciable reactivity towards the solid packaging material	-21
63-21 Dielectric breakdown voltage*	N.R. Herbicide is not a liquid	-21

N.R. = not required.

*Information on Physical and Chemical Properties taken from submission

Conclusion:

(1) Except for data on nitrosamine contaminant, which according to registrant will be analyzed at time of production, the product chemistry requirements for the basic formulation and one alternate formulation (Formulation #1 and Formulation #2) of Barricade® 65WG Herbicide have been satisfied. The analytical data on the nitrosamine contaminant is expected to be provided to this Agency when this EP is produced.

MANUFACTURING PROCESS INFORMATION IS NOT INCLUDED

INERT INGREDIENT INFORMATION IS NOT INCLUDED