

FAXed to

Sandoz 12-13-91

Eugene W. Wicks

DATE: 11/27/91

PRODUCT CHEMIST/REVIEWER: MICHAEL J. CLIFFORD

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CONCURRED BY: Anna Skopets 12-10-91

COMPANY: SANDOZ CROP
PROTECTION CORP.

EPA REG. NO: 55947-RUG

PRODUCT NAME: BARRICADE 65WG HERBICIDE IN WATER SOLUBLE PACKS

TO PM NO: 23 ACTION CODE: 115

BACKGROUND: NEW REGISTRATION FOR BARRICADE 65WG
HERBICIDE IN WATER SOLUBLE PACKS.

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: 55947-UR

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

COMMENTS:

a) In reference to the two CSFs dated 1/25/91 for the basic and alternate formulations:

(1) The nominal concentration of PRODIAMINE in your product in pure active form is: $69.90\% \times 93\%$ or 65.0% which agrees with the label claim and is acceptable.

(2) The upper and lower certified limits for PRODIAMINE should be based on the pure active ingredient rather than the technical source product and thus should bracket (i.e., be higher and lower, respectively) the nominal concentration.

(3) The certified limits for PRODIAMINE should comply with the the standard certified limits specified in 40 CFR 158.175(b)(2). Otherwise, you will be required to submit the batch sample analyses as required in PR NOTICE 91-2.

(continued)

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- (4) The upper and lower certified limits for [REDACTED] should be reversed under Column #14a and 14b.
- b) In reference to the proposed labeling, the term "ACTIVE INGREDIENTS" should be made singular on the container and water soluble pack labels.
- c) In reference to the product chemistry data:
- (1) The product chemistry data were previously submitted in MRID NOS. 417688-20 through -29 and accepted by A. Acierro in Product Chemistry Review dated 6/28/91 in reference to EPA FILE SYMBOL 55947-UG for BARRICADE 65WG HERBICIDE not packaged in water soluble packs.
 - (2) Based on the fact that your product will be packaged in water soluble packs, one year storage stability data in [REDACTED] packs at ambient warehouse conditions must be submitted to EPA within 15 months after registration has been granted. The formulated product must be analyzed for its active ingredient at time zero and after one year of storage.
- NOTES TO PM: (1) The registration of EPA FILE SYMBOL 55947-RUG will be contingent on the registration of the technical PRODIAMINE submitted under EPA FILE SYMBOL 55947-UR.
- (2) Since PRODIAMINE is a dinitroaniline, the end-use product must be analyzed for nitrosamine contaminants at the time of commercial production. The nitrosamine sampling requirements appear in Appendix A of the 6/25/80 FEDERAL REGISTER NOTICE (45 FR 42854).

Michael J. Clifford 11/27/91