

DATE: 17/OCT/2000

SUBJECT: PRODUCT CHEMISTRY REVIEW OF MP [X] EP []
DP BARCODE No.: D268522 REG./File Symbol No: 056077-00060
PRODUCT NAME: Pendimethalin Technical
COMPANY: Cedar Chemical Corporation

FROM: Linda L. Kutney, Chemist. *Linda L. Kutney*
Product Chemistry Team
Technical Review Branch/RD (7505C) *10-17-00*

TO: James Tompkins/Wesley Allen, PM-25
Herbicide Branch/RD(7505C)

INTRODUCTION

This review is an update on the previous October 5, 2000, submission, (L. Kutney) where the Cedar Chemical Corporation applied for an new source of technical for the herbicide pendimethalin, used on various crops. In a letter dated August 4, 2000, Chemical Consultants International, Inc., agents for Cedar asserted that the new material was cleaner than Cyanamid's earlier version of pendimethalin, and contained virtually no toxic nitrosamine impurities.

Cedar's pendimethalin technical is a liquid containing a nominal concentration of 96.47% pendimethalin, Reg. No. 56077-60. Cyanamid's pendimethalin technical, Reg. No. 241-245, contains a nominal concentration of 93.0% active ingredient.

Cedar's alternate CSF and proposed label were dated August 4, 2000. Cyanamid's basic CSF was dated June 9, 1999; and their most recent label, dated July, 2000, was expected to be accepted by the Agency, shortly after the time of this review.

The current submission addresses deficiencies listed in the Conclusion.

FINDINGS:

TRB previously (10-5-00, L. Kutney) reviewed the product chemistry data submitted for the subject end-use product and concluded:

1. The pH listed on the CSF is "N/A," but listed as 7.0 on p. 9 of MRID 451874-01. In addition, it is noted that the pH on the Prowl technical CSF is listed as 4.7. Although pendimethalin is only soluble to 0.3 mg/l in water at 20 C, Cedar should explain the difference between the pH listed in the report, the pH in the CSF, and that of the Prowl technical. This physical property must be the same for the two technical products to be judged substantially similar.
2. Details required as specified in 158.160 for materials used in production need to be clarified. See conclusion included in the Confidential Appendix.
3. The level N-nitrosopendimethalin impurity was reported to be below 100 ppm. The sum total of the level of impurity for the "group of 7 nitrosamines" was reported to be below 1 ppm for samples of the technical pendimethalin. The appropriate precautionary language should be added to the label and to the CSF.

CONCLUSIONS:

TRB NOW concludes the following, with respect to the product chemistry data for pendimethalin technical:

1. The pH listed on the revised CSF (dated 10-17-00) is consistent with the pH listed in the text are now both 7.0. Although the pH on the Prowl technical CSF is 4.7, the very low water solubility for pendimethalin (0.3 mg/l in water at 20 C), may be, in part, responsible for the difference in pH. This deficiency is satisfied.
2. Details required in 158.160 for materials used in production are still needed, but may be provided subsequent to conditional registration. See conclusion in the Confidential Appendix.
3. The label and CSF should contain the following, "WARNING: CONTAINS NITROSAMINES AT LEVELS LESS THAN 135 ppm," prior to registration, in order to comply with 40 CFR Part 180: FR Vol. 45, No. 145, p. 49600. Cedar may wish to include a lower number in their statement, provided it is supported by analytical data.

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1. Reviewer: Linda L. Kutney
2. Company: Cedar Chemical Corporation
3. Type of Submission: Registration [X] Reregistration []
 New [] Resubmission [] Amendment [] "ME-TOO" [X]
 Alternate Formulation [] Experimental Use Permit []
 Other [X] Registration of alternate Technical Source
4. If "Me-TOO" Registration, this product is [X] is not []
 similar or substantially similar to EPA's Reg. No.:
241-245
 If not, comment in Confidential Appendix on the significant
 differences between the registered and the new source.

CONFIDENTIAL STATEMENT OF FORMULA

5. Type of formulation and the sources of active ingredients:
 - Non-integrated formulation system..... []
 - Are all technical grade active ingredients used
 registered? • yes [X] • no [], If no, specify
 - Integrated formulation system..... [X]
6. Clearance of intentionally added ingredients in the
 formulation for the intended use (indicate in the
 Confidential Appendix those that are not cleared; the PC
 Codes should be provided by the chemist on the CSF for those
 that are cleared):
 - 6(a) Formulation intended for food use under 40CFR§180.1001:
 - yes [X] • no [] • Some are cleared, others are not []
 - Cleared under list: • c [] • d [] • e []
 Are there any limitations for use as an inert under
 40CFR§180.1001?
 - yes [] • no [X], If yes, specify
 - 6(b) Formulation intended for non-food use:
 - yes [] • no [] • Some are cleared, others are not []
- 6© Clearance by the FDA of certain formulations under 21CFR§170
 to 199, e.g., (a) indirect food additives, such as food
 contact surface sanitizers; adhesives, coatings, paper and
 paperboard products that may contact food in packaging or
 holding; & (b) substances generally recognized as safe, GRAS
 - yes [] • no [X] • Some are cleared, others not []
 If yes, the entire formulation is cleared under 21CFR§