

US EPA ARCHIVE DOCUMENT

DATA EVALUATION RECORD 1

5-cyclopropyl-4-(2-methanesulphonyl-4-trifluoromethylbenzoyl)isoxazole
S161-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 43573254

Corgier, M.M., J.M. Robin, and A.P. Plewa. May 2, 1994. ¹⁴C-RPA 201772:
Hydrolysis at 25 °C. Unpublished study performed by Rhone Poulenc, Lyon
France, and submitted by Rhone Poulenc, N.C.

DIRECT REVIEW TIME = 9

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CONCLUSIONS:

Degradation - Hydrolysis

1. The hydrolysis study is acceptable and satisfies the 161-1 data requirement.
2. ¹⁴C-isoxaflutole [5-cyclopropyl-4-(2-methanesulphonyl-4-trifluoromethylbenzoyl)isoxazole; RPA-201772] hydrolyzed with pH-dependent half-lives of 11.1 days in pH 5 solutions, 20.1 hours in pH 7 solutions, and 3.2 hours in pH 9 buffered solutions containing 300 ug/ml of RPA-201772. The only degradate identified in the study was RPA-202248 [2-cyano-3-cyclopropyl-1-(2-methylsulphonyl-4-

trifluoromethyl phenyl)propan-1,3-dione; **isoxaflutole with the isoxazole-ring opened**]. RPA-202248 was 53-58% of the applied dose in the pH 5 and 7 solutions, but reached 98.5 % of the applied dose in the pH 9 solutions. There was no evidence of any degradation of RPA-202248 in the study, showing stability in sterile, dark buffered aqueous solutions. In all the experiments, the material balance ranged from 98-103 % of the applied dose for all pH values studied.

METHODOLOGY:

Benzyl-labeled ¹⁴C-isoxaflutole [5-cyclopropyl-4-(2-methanesulphonyl-4-trifluoromethylbenzoyl)isoxazole; RPA 201772; radiochemical purity 98%, specific activity 679 MBQ/mmol (18.35 mCi/mMol, Rhone Poulenc)], was made into an acetonitrile solution containing 300 ug/ml of RPA-201772. Duplicate one (1) ml aliquots of this solution were transferred to separate, sterile 100-ml borosilicate glass bottles, and diluted with 99 ml of the pH 5 (0.02 M monohydrate citric acid), pH 7 (0.02 M imidazole), and pH 9 (0.02 M dinatrium tetra-borate) buffer solutions. The nominal concentration of the study samples was 3 ug/ml, and the co-solvent did not exceed 1 % v/v. The test solutions were incubated in an environmental chamber in the dark at 25 ± 1 °C for various times, depending on the pH. For the pH 5 samples, the sampling times were 0, 3, 5, 7, 10, 12, and 14 days. For the pH 7 samples, the sampling times were 0, 3, 5, 7, 16, 19, and 24 hours. For the pH 9 samples, the sampling times were 0, 1, 1.5, 2, 2.3, 3, 4, and 24 hours. Both tubes for each sampling interval for each pH were removed at the appropriate time. Following some workup, the samples were sub-sampled and analyzed using liquid scintillation counting and HPLC. HPLC/MS was also used to further confirm the identity of parent isoxaflutole and the degradate RPA-202248 [2-cyano-3-cyclopropyl-1-(2-methylsulphonyl-4-trifluoromethyl phenyl)propan-1,3-dione; **isoxaflutole with the isoxazole-ring opened**]. At the last sampling time for each pH, volatility was measured on each sample. More details about the analytical procedure may be seen in the attachments to this DER.

DATA SUMMARY:

Benzyl-labeled ¹⁴C-isoxaflutole [5-cyclopropyl-4-(2-methanesulphonyl-4-trifluoromethylbenzoyl)isoxazole] hydrolyzed with pH-dependent half-lives of 11.1 days in pH 5 solutions, 20.1 hours in pH 7 solutions, and 3.2 hours in pH 9 buffered solutions containing 300 ug/ml of RPA-201772. The only degradate identified in the study was RPA-202248 (**isoxaflutole with the isoxazole-ring opened**). RPA-202248 was 53-58 % of the applied dose in the pH 5 and 7 solutions, but reached 98.5 % of the applied dose in the pH 9 solutions. There was no evidence of any degradation of RPA-202248 in the study, showing stability in sterile, dark buffered aqueous solutions. In all the experiments, the material balance ranged from 98-103 % of the applied dose for all pH values studied.

COMMENTS:

1. Storage stability for pH 7 and 9 solutions was not conducted in the study. However, the registrant stabilized the contents of the pH 7 and 9 samples after the appropriate incubation times using glacial acetic acid. This lowered the pH to approximately 4.5, at which isoxaflutole degradation was observed to cease.

ISOXAFLUTOLE

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