DATA EVALUATION RECORD 1

5-cyclopropyl-4-(2-methanesulphonyl-4-trifluoromethylbenzoyl)isoxazole
§161-1

FORMULATION--00--ACTIVE INGREDIENT

STUDY ID 43573254
Corgier, M.M., J.M. Robin, and A.P. Plewa. May 2, 1994. ^{14}C-RPA 201772: Hydrolysis at 25 °C. Unpublished study performed by Rhone Poulenc, Lyon France, and submited by Rhone Poulenc, N.C.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. ^{14}C-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 ^{14}C-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 ^{14}C-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.

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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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