

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-410

ENVIRONMENTAL ASSESSMENT and/or FONSI

11 Nonconfidential Appendices

METFORMIN HCl DATA SUMMARY TABLE (a)	
Physical/Chemical Characterization	
Water Solubility	30.55%
Octanol/ Water Partition Coefficient	0.056, log Kow = -1.25
Vapor Pressure	virtually nil
Organic carbon adsorption coefficient	4.97 (estimated)
Depletion Mechanisms	
Hydrolysis	no hydrolysis at 50 °C in 5 days
Aquatic Biodegradation	0.6 % mineralization to CO ₂ in 28 days
Photolysis	not determined, no UV absorbance 290-800 nm
Indirect photolysis	estimated t _{1/2} ~28 days
Environmental Effects	
Microbial Inhibition: aspergillus, Penicillium, Chaetomium (fungi), Pseudomonas, Bacillus	no inhibition at 1000 ppm
Anabaena (algae)	MIC = 100 mg/l
Azobacter (N fixing bacterium)	MIC = 800 ppm
Daphnia magna Acute Toxicity (48 hr)	EC50 = 130 mg/l, NOEC = 78 mg/l
Fish (Bluegill) Acute Toxicity (96 hr)	NOEC = 982 mg/l
Activated Sludge, Respiration Inhibition (3 hr)	EC50 = 233 mg/l [7]
Activated Sludge, COD Removal (24 hr)	EC50 > 250 mg/l [7]
Activated Sludge, Nitrification Inhibition	EC50 = 48 to 65 mg/l [6]
(a) Data from Environmental Assessment for Metformin Hydrochloride, NDA 20-357, Bristol-Meyers Squibb Company, FONSI date (23 Nov 1994), except as noted by [literature citation].	

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