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FDA Docket No. 2004N-0050

Safety and Effectiveness Information for Piroctone Olamine

Submitted Pursuant to 21 C.F.R. § 330.14(f) and § 330.10(a)(2)

August 13, 2004

References (Safety)
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Safety References
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(R1) Acute oral toxicity of H 72 6146 A (Octopirox) in female SPF-Wistar rats, Study-No. 74.0229, Hoechst AG.

(R2) Acute oral toxicity of H 72 6146 A (Octopirox) in male and female beagle-dogs; Study No. 74.0205, Hoechst AG.

(R3) Acute dermal toxicity of Octopirox® in male and female Wistar rats; Study-No. 86.1448, Hoechst AG.

(R4) Octopirox® - Test for primary dermal irritation in the rabbit; Study-No. 86.1390, Hoechst AG.

(R5) Primary skin irritation of a preparation of 0.5 % Octopirox, 12.5 % Steinapol SBFA 30 (40 %), 0.11 % citric acid and 86.89 % water (pH 7.0) in rabbits (patch test); Report No. 79.0735, Hoechst AG.

(R6) Primary skin irritation of a preparation of 1 % Octopirox, 0.33 % citric acid, 75 % PEG 400 and 23.67 % water (pH 7.0) in rabbits (patch test); Report No. 79.0736, Hoechst AG.

(R7) Skin tolerance of a preparation of 1.0 % Octopirox (Op. E 001), 0.3 % citric acid and 98.7 % 1,2-propylene glycol (pH 7.0) in rabbits; Report-No. 79.0737, Hoechst AG.

(R8) Primary skin irritation of a preparation of 0.5 % Octopirox, 12.5 % Steinapol SBFA 30 (40 %), 0.11 % citric acid and 86.89 % water (pH 7.0) in New Zealand rabbits (patch test); Report-No. 79.0763, Hoechst AG.

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(R 13) Study of eye irritation of MA REF 0380 (Shampoo with 0.3 Octopirox) in rabbits; Report-No. 77.1092, Hoechst AG.

(R 14) Study of eye irritation of MA REF 03801 (Shampoo without Octopirox) in rabbits; Report-No. 77.1128, Hoechst AG.

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