

CENTRE FOR PLANT MEDICINE RESEARCH

PHARMACOLOGY & TOXICOLOGY DEPARTMENT

Product Code	Product Form	Date Received	Date Analysed	Test Conducted
Mw/003/22	Mouth Wash	4 th January, 2023	21 st February, 2023	Acute & Dermal Toxicity Test

1. ACUTE TOXICITY TEST

RESULTS:

Table Showing Results of Acute Toxicity Test on Mouth Wash (Mw/003/22) in Sprague Dawley Rats.

Animal Model	Sprague Dawley Rats		
No. of Animals	12		
Sex	Female		
No. of Groups	2(n=6)		
Route of Administration	Oral		
Formulation	Mouth Wash		
Preparation	Freeze-dried sample of Mw/003/22		
Dose Administered	5000 mg/kg		
Period of Observation	14 Days		
No. of Deaths Recorded	Nil		
Estimated Median Lethal Dose (LD ₅₀)	Greater than 5000 mg/kg		
Physical Signs of Toxicity	Nil		

REMARKS:

The LD_{50} is estimated to be greater than 5000 mg/kg which is greater or equal to level 5 on the Hodge and Sterner Scale¹ and also 26638 times more than the recommended dose (three drops daily, equivalent to 0.1877 mg/kg), as indicated by the manufacturer. Thus, the product, Mw/003/22, may not be toxic and is within the accepted margin of safety (Hodge and Sterner Scale) at the recommended dose.

2. DERMAL TOXICITY TEST

PROCEDURE:

An area of the hair on the lateral portion of the Sprague Dawley (SD) rats (about 9cm²) was trimmed and shaved with razor blade. Group one was injected intradermally with 0.1 ml of 1% lyophilized decoction in glycerol solution and group two with 0.1 ml of 5% w/v of the lyophilised decoction in glycerol. Group three served as control and was injected intradermally with only 0.1 ml glycerol. The Decoction was applied topically (0.1 - 1.0 g) to the shaved area of the first 2 groups while glycerol was applied to the control group. The animals where observed for a period of 48 hours for any signs of ulceration, irritation and/or inflammation as compared to the control groups.

RESULTS:

The experimental SD Rat in group 1 and 2 administered with 1% and 5% w/v of the Mouth Wash intradermally and topically (0.5-1 g), showed no ulceration, irritation and/or inflammations at the site of injection and shaved area, respectively.

REMARKS:

Mw/003/22 appears to be safe when applied to the skin.

Analysed by

Mr. Pharm System

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