SN - Mw1264/22/221107

CENTRE FOR PLANT MEDICINE RESEARCH

PHARMACOLOGY & TOXICOLOGY DEPARTMENT

Product Code	Product Form	Date Received	Date Analysed	Test Conducted
Mw/003/22	Mouth Wash	4th January, 2023	21st 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 Scale[1] 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 hair on the lateral portion of the Sprague Dawley rats (about 9 cm^2) was trimmed and shaved with a razor blade. The rats were divided into two groups (n=5). Group one was injected intradermally with 0.1 ml of 10 % w/v of the lyophilized decoction of the mouth-wash dissolved in glycerol and group two as control was treated with only 0.1 ml glycerol. The lyophilized decoction of the mouth-wash was also applied topically (0.5 -1.0 g) to the shaved area of the first group of rats and the animals were observed for a period of 48 hours for signs of ulceration, irritation and/or inflammation as compared to the control group.

RESULTS:

The Sprague Dawley rats in group one administered with 10% w/v of the lyophilized decoction intradermally and topically (0.5 -1.0 g), showed no ulceration, irritation and/or inflammation at the site of injection and shaved area.

REMARKS:

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

Analysed by
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Mr. Stephen Antwi
Research Scientist

Approved by
Image not found or type unknown

Dr. Olga Quasie
Snr. Research Scientist