

## **Department of Health**Therapeutic Goods Administration

File Reference: D21-3240218

Sent by email

The Regulatory Affairs Manager Edgewell Personal Care Australia Pty Ltd 11 Talavera Road Level 5 Building C Macquarie Park NSW 2113 Email: ap.others.australia@edgewell.com

Dear Sir/Madam,

## NOTICE OF COMPLIANCE TEST PASS

**Notice informing** Edgewell Personal Care Australia Pty Ltd **of the testing results of** 'Hawaiian Tropic Silk Hydration Very High Protection Sunscreen Spray SPF 50+' **from the Australian Register of Therapeutic Goods entry number** 298692.

ARTG Number: 298692

**Product Name:** Hawaiian Tropic Silk Hydration Very High Protection

Sunscreen Spray SPF 50+

**Batch Number:** 18360GF **Expiry Date:** 11/2021 **TGA Sample Number:** 2108002963

A sample of the above mentioned product was recently tested by the TGA Laboratories as part of a problem investigation following a report published in May 2021 by the US based laboratory Valisure.

The samples were tested for compliance with the requirements for residual solvents as specified in the ICH guideline Q3C (R8) on impurities: guideline for residual solvents, which has been adopted by the BP and USP pharmacopoeia. In particular, the products were tested for the presence of the class 1 solvent benzene.

The enclosed Certificate of Responsible Analyst indicates that the above mentioned product complies with specifications outlined in the ICH guideline Q3C (R8) on impurities: guideline for residual solvents with regards to benzene.

No further action is required.

Please note that outcomes of laboratory testing are published on the TGA Database of Laboratory Testing Results <a href="http://www.tga.gov.au/ws-labs-index">http://www.tga.gov.au/ws-labs-index</a>.

Yours Sincerely,



## Signed electronically by

A/g Principal Chemist Chemistry Section Laboratories Branch Email: \$22

@health.gov.au

9 December 2021 Sent by email