



**Australian Government**

**Department of Health**  
Therapeutic Goods Administration

The Regulatory Affairs Manager  
16 Halsey Road  
AIRPORT WEST VIC 3042

TGA Sample Number 1509003562

Dear Sir/Madam

**Subject: Aussen Revolution Hospital Grade Disinfectant, ARTG 179069, batch from single supply**

Please find enclosed a Laboratory Report for a sample of your product, Aussen Revolution Hospital Grade Disinfectant, which was recently tested by the Laboratories Branch (LB) of the TGA.


The product was tested by the Microbiology Laboratory of the LB as part of routine surveillance of disinfectants currently marketed in Australia.

*\*It is acknowledged that the sample provided was not in the marketed final product container. Labelling claims were therefore not assessed.*

The product was tested for bactericidal efficacy using the TGA Disinfectant Test as specified in Clause 3(5)(a) of TGO 54, Standard for Disinfectants and Sterilants, and 54A & 54B. The ARTG entry states that "*used as a hospital grade disinfectant to kill micro-organisms on hard surfaces. It is made 100% from natural ingredients and is nontoxic and non-corrosive. Uses include disinfection of food processing equipment. Can be diluted to form a general purpose sanitiser*", therefore the TGA Disinfectant Test Option A (clean conditions) was performed.

The results obtained for the product show that the pass requirements for Option A were met with regards *S. aureus*, *P. aeruginosa*, *E. coli* and *P. vulgaris*, and in this respect, no action is required.

Yours faithfully

Zenna Siljak   
Analyst  
Laboratories Branch  
Therapeutic Goods Administration

3 May 2017



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**Laboratory Report**

Certificate Number 1509003562  
Issued 3 May 2017

I, Joanne Michele Wilson, being an Official Analyst appointed under Regulation No. 25 of the Therapeutic Goods Regulations 1990, certify that a sample of therapeutic goods, bearing TGA Sample Number 1509003562 has been examined and analysed.

The sample consisted of five bottles containing 100mL of liquid. The sample was obtained from the sponsor, Environmental Affairs Pty Ltd, 16 Halsey Road, AIRPORT WEST, VIC 3042.

The label attached to the sample stated the following:

Trade Name:	Aussan Revolution Hospital Grade Disinfectant
Sponsor:	Not stated
Active constituents:	Not stated
Net content:	Not stated
Batch number:	Not stated
ARTG number:	Not stated
Expiry date:	Not stated

*\*Note: The sample was not supplied in the final product container. A temporary label was affixed.*

Sampling category:	Compliance
TRIM container:	2015/034118

Three containers of Aussan Revolution Hospital Grade Disinfectant were tested for bactericidal activity using the TGA Test, Option A for clean conditions as per Method M6.2. According to the instructions for use, an undiluted portion of the sample was tested. The results were as follows:

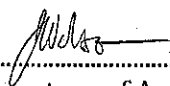
Organism	Test number	Number of test tubes with growth of organism (#/5)	
		1 <sup>st</sup> Challenge	2 <sup>nd</sup> Challenge
<i>S. aureus</i>	1	0	0
	2	0	0
	3	0	0
<i>P. aeruginosa</i>	1	0	0
	2	0	0
	3	0	0
<i>E. coli</i>	1	0	0
	2	0	0
	3	0	0
<i>P. vulgaris</i>	1	0	0
	2	0	0
	3	0	0

To obtain a pass result, the product must show no apparent growth in at least two out of the five recovery broths from the first challenge and no apparent growth in at least two out of the five broths from the second challenge, on all three occasions, using all four organisms.

The results obtained show that the requirements of the TGA Test with regard to Option A were met for the portion of sample tested for *S. aureus*, *P. aeruginosa*, *E. coli* and *P. vulgaris*. These results comply with the criteria specified in TGO 54 - *Standard for Disinfectants and Sterilants*, clause 3(5)(a) for hospital grade disinfectants.

### Conclusion

The sample meets the requirements for the tests performed.

  
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Signature of Analyst