

### **Department of Health**

Therapeutic Goods Administration

# **Australian Register of Therapeutic Goods Certificate**

Issued to

# **Diversey Australia Pty Ltd**

for approval to supply

# Diversey Australia Pty Limited - Oxivir Tb, Hospital Grade Disinfectant with claims, Non-Sterile

ARTG Identifier 165058

ARTG Start date 8/09/2009

Product Category Other Therapeutic Good Registered

Intended Purpose Oxivir Tb is a one step disinfectant, cleaner and odour neutraliser. It

requires no post use rinsing when used on non-food contact surfaces. It will clean and disinfect most surfaces found in health, educational and recreational environments. Oxivir Tb is highly effective against a wide variety of pathogenic microorganisms including bacteria, antibiotic resistant bacteria, viruses such as SARS-CoV-2 (COVID-19 virus) and fungi. Hard surface disinfectant only. Not to be used on skin. Not intended to be used on medical devices or other therapeutic goods.

Manufacturer DetailsAddressCertificate number(s)Virox Technologies Inc2815 Bristol Circuit Unit 4<br/>Oakville, Ontario, L6H6X5<br/>Canada

#### **ARTG Standard Conditions**

The above Other Therapeutic Good Registered has been entered on the Register subject to the following conditions:

- Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions
  Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act
  1989" effective 1 July 1995.
- Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

#### **Products Covered by This Entry**

#### 1. Oxivir Tb - Disinfectant, hospital grade with claims

Container	Container	Container	Container	Shelf Life	Shelf Life	Shelf Life
Type	Material	Condition	Closure	Time	Temperature	Conditions
Not recorded	Not recorded	Not recorded	Not recorded	36 Mont hs	Not recorded	

## **Product Specific Conditions**

Standard Conditions

For the hard surface disinfectants that are retained on the part of the ARTG for registered goods, you, as sponsor, are required to comply with the standard and specific conditions for registered goods in Appendix 4, Standard Conditions applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989 of DR4 applied at the time of registration and is ongoing. AUST R

Pursuant to Section 28(2B) of the Therapeutic Goods Act 1989, I have decided to impose "The listing number must be placed on the label of the device by writing the number, immediately preceded by "AUST R" so that it is clearly visible to the user on (i) the label of the device; or (ii)the label on the outermost level of packaging in which the device is to be supplied to the user

- · Acceptable data has been provided to support a 36 month shelf life.
- This product is approved with an 18 month shelf life stored below 25 degree Celsius. Batches of product must be tested during and at the end of the closed shelf life period. End of shelf life period

testing must be generated from the most stringest test, in this case Mycobacterium.

Therapeutic Goods Administration
PO Box 100, Woden ACT 2606 Australia
Phone: 1800 020 653

Email: info@tga.gov.au

ARTG Identifier: 165058 ARTG Start Date: 8/09/2009