



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	164850	Diversey Australia Pty Limited - Oxivir Tb Wipes - Hospital Grade Disinfectant - With Claims, Non-Sterile
ARTG entry for	Other Therapeutic Good - Registered disinfectant	
Sponsor	Diversey Australia Pty Ltd	
Postal Address	29 Chifley Street, SMITHFIELD, NSW, 2164 Australia	
ARTG Start Date	1/09/2009	
Product Category	Other Therapeutic Good	
Status	Active	
Approval Area	Medical Devices	

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

1 . Oxivir Tb Wipes Large Refill - Disinfectant, hospital grade with claims

Product Type	Single Device Product	Effective Date	9/11/2017 9:48:50 AM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Oxivir Tb wipes is a hospital grade disinfectant for use on hard surfaces that is effective against a wide range of pathogenic micro-organisms including bacteria, viruses such as SARS-CoV-2 (COVID-19 virus) and fungi. Not for use on medical devices or other therapeutic goods. Not to be used on skin.		

Specific Conditions

Acceptable data has been provided to support a 36 month shelf life.

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

This product is approved with a 12 month shelf life stored below 25 degrees 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 stringent test, in this case Mycobacterium.

2 . Oxivir Tb Wipes Large - Disinfectant, hospital grade with claims

Product Type	Single Device Product	Effective Date	9/11/2017 9:48:50 AM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Oxivir Tb wipes is a hospital grade disinfectant for use on hard surfaces that is effective against a wide range of pathogenic micro-organisms including bacteria, viruses such as SARS-CoV-2 (COVID-19 virus) and fungi. Not for use on medical devices or other therapeutic goods. Not to be used on skin.		

Specific Conditions

Acceptable data has been provided to support a 36 month shelf life.

This product is approved with a 12 month shelf life stored below 25 degrees 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 stringent test, in this case Mycobacterium.

3 . Oxivir Tb Wipes - Disinfectant, hospital grade with specific claims

Product Type	Single Device Product	Effective Date	9/11/2017 9:48:43 AM
GMDN	9950 Disinfectant, hospital grade		
Intended Purpose	Oxivir Tb wipes is a hospital grade disinfectant for use on hard surfaces that is effective against a wide range of pathogenic micro-organisms including bacteria, viruses such as SARS-CoV-2 (COVID-19 virus) and fungi. Not for use on medical devices or		



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other therapeutic goods. Not to be used on skin.

Specific Conditions

Acceptable data has been provided to support a 36 month shelf life.

This product is approved with a 12 month shelf life stored below 25 degrees 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 stringent test, in this case Mycobacterium.

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