Australian Government

Department of Health

Therapeutic Goods Administration

Record Summary	371654	Ozkem Pty Ltd - Coil Defender Enzymatic Sanitiser and Cleaner - Disinfectant, household/commercial grade
Sponsor	Ozkem Pty Ltd	
Therapeutic Type	Other Therapeutic Good	
Product Category	Other Therapeutic Good - Listed disinfectant	
ARTG Start Date	26/07/2021	
Postal Address	PO Box 864, Five Dock, NSW, 2046 Australia	
Billing Address	PO Box 864, Five Dock, NSW, 2046 Australia	
Product Type	Other Therapeutic Good - - Other Therapeutic Good - Listed disinfectant	
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.

Manufacturers

Name	Address	Certificate number(s)
Ozkem Pty Ltd	Unit 34 34-36 Ralph Street Alexandria , NSW , 2015 Australia	

Products

1 . Coil Defender Enzymatic Sanitiser and Cleaner - Disinfectant, household/commercial grade

Product Type	Single Device Product	**Status**	Current
		Effective Date	26/07/2021
GMDN	9951 Disinfectant, household/commercial grade		
Functional Description	Not included on record		
Intended Purpose	Commercial Grade Disinfectant, Sanitiser and Cleaner- disinfects and sanitises surfaces. Suitable for simultaneous cleaning and sanitising of any hard non-porous surface, for example removable air conditioning filters and air conditioning heat exchange coils. Kills Covid-19.		

Variant Information

Device Information

09 Reusable devices

Specific Conditions

1. Standards
The listed goods must comply with standards applicable to those goods under part 3 of the Act;

2. Changes to Goods
Changes to Goods Changes or variations in respect of any information concerning the listed therapeutic goods, being information that would have been relevant* to a decision to list the goods in the Register, including information on the formulation of the listed goods or other aspects of their manufacture, and the labelling of the goods, shall forthwith be notified to the Secretary, or the Secretary's delegate appointed for the purposes of section 28 of the Act, and where necessary*, the change or variation shall not be implemented until approved by the Secretary. (*Reference should also be made to the Guidance on the Regulation of Disinfectants in Australia).

3. Records Held
i. The sponsor of the listed goods shall keep such records relating to the goods as are necessary: (a) to expedite recall if necessary of any batch of the listed goods; (b) to identify the manufacturer(s) of each batch of the listed goods. Where any part of or step in the manufacture in Australia of the listed goods is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relating to such manufacture shall be kept.
ii. Each sponsor shall retain records of the distribution of all of the sponsor's listed goods for a period of five years and upon the request of the Therapeutic Goods Administration, shall provide the records or copies of the records.

4. Sampling
The sponsor of the listed goods shall permit officers who have been authorised under the Regulations to do so to take samples of therapeutic goods and carry out related duties in accordance with the Regulations.

5. Overseas Regulatory Actions
Where the listed goods are distributed regularly overseas as well as in Australia, product recall or any actions other similar regulatory action taken in relation to the goods outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia must be notified to the Therapeutic Goods Administration via Post Market Devices email, MedicalDeviceSurveillance@health.gov.au as soon as the action or information is known to the sponsor.

6. Indications
In relation to listed goods, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods and, upon the request of the Therapeutic Goods Administration, shall produce such evidence.

Components

1 . MEDICAL DEVICE COMPONENT

Dosage Form

Route of Administration

Formulations

Excipient Ingredients	Category	Quantity	Units
Amylase	ABN	.002	% w/w
benzalkonium chloride	AAN	.98	% w/w
borax	AAN	.27	% w/w
C12-14 pareth-7	AAN	6	% w/w
cellulase	ABN	.002	% w/w
dipropylene glycol monomethyl ether	AAN	3	% w/w
lipase	ABN	.0016	% w/w
potable water	AAN	73.4544	% w/w
propylene glycol	AAN	7	% w/w
protease	ABN	.14	% w/w
sodium xylenesulfonate	AAN	4.8	% w/w
trisodium citrate	ADN	4.35	% w/w