



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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| Summary for ARTG Entry: | 232011 | STERI-7 PTY LTD - S-7 XTRA Concentrate - Non-Sterile Hospital Grade Disinfectant - With Claims - benzalkonium chloride/ Poly(hexamethylene biguanide) hydrochloride/ Didecylidimethylammonium chloride |
| ARTG entry for | Other Therapeutic Good - Listed disinfectant | |
| Sponsor | Steri-7 Pty Ltd | |
| Postal Address | PO Box 22, Forestville, NSW, 2087 Australia | |
| ARTG Start Date | 19/12/2014 | |
| Product Category | Other Therapeutic Good | |
| Status | Active | |
| Approval Area | OTG Device | |

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. S-7XTRA Concentrate

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|-------------------------|--|-----------------------|-----------------------|
| Product Type | Single Device Product | Effective Date | 22/09/2021 2:33:56 PM |
| GMDN | 9950 Disinfectant, hospital grade | | |
| Intended Purpose | S7XTRA Concentrate is a hospital grade disinfectant effective against bacteria, viruses including SARS-CoV-2 (COVID-19), spores including C-Difficile and mould. S7XTRA Concentrate is also tuberculocidal, fungicidal and has residual activity against SARS-CoV-2 (COVID-19), bacteria and yeast for 24 hours and biostatic activity for up to 72 hours for SARS-CoV-2 (COVID-19) and bacteria. Hard surface disinfectant only. Not to be used on medical devices and other therapeutic goods, not to be used on skin. | | |

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, postmarketdevices@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.

2. S-7XTRA FRESH Concentrate

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|-------------------------|--|-----------------------|-----------------------|
| Product Type | Single Device Product | Effective Date | 22/09/2021 2:33:56 PM |
| GMDN | 9950 Disinfectant, hospital grade | | |
| Intended Purpose | S7XTRA Concentrate is a hospital grade disinfectant effective against mould, bacteria, viruses including SARS-CoV-2 (COVID-19), parvovirus and spores including C-Difficile. S7XTRA Concentrate is also tuberculocidal, fungicidal and has residual activity against SARS-CoV-2 (COVID-19), bacteria and yeast for 24 hours and biostatic activity for up to 72 hours for SARS-CoV-2 (COVID-19) and bacteria. Hard surface disinfectant only. Not to be used on medical devices and other therapeutic goods, not to be used on skin. | | |



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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, postmarketdevices@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.

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