2025/263

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COMMISSION IMPLEMENTING REGULATION (EU) 2025/263

of 10 February 2025

granting a Union authorisation for the biocidal product family 'Ecolab CMIT-MIT BPF' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (¹), and in particular Article 44(5), first subparagraph, thereof.

Whereas:

- (1) On 23 June 2017, Ecolab Deutschland GmbH submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'Ecolab CMIT-MIT BPF' of product-types 4, 11 and 12, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-SP032736-15 in the Register for Biocidal Products.
- (2) 'Ecolab CMIT-MIT BPF' contains C(M)IT/MIT (3:1) as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 4, 11 and 12.
- (3) On 1 December 2023, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 26 June 2024, the Agency submitted to the Commission its opinion (²), the draft summary of the biocidal product characteristics ('SPC') of 'Ecolab CMIT-MIT BPF' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'Ecolab CMIT-MIT BPF' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(6) of that Regulation.
- (6) On 15 July 2024, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the biocidal product family 'Ecolab CMIT-MIT BPF'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1, ELI: http://data.europa.eu/eli/reg/2012/528/oj.

⁽²) ECHA opinion of 30 May 2024 on the Union authorisation of 'Ecolab CMIT-MIT BPF' (ECHA/BPC/436/2024), https://echa.europa.eu/opinions-on-union-authorisation.

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032881-0000 is granted to Ecolab Deutschland GmbH for the making available on the market and use of the biocidal product family 'Ecolab CMIT-MIT BPF' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 3 March 2025 until 28 February 2035.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 February 2025.

For the Commission The President Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

Ecolab CMIT-MIT BPF

Product type(s)

PT11: Preservatives for liquid-cooling and processing systems

PT12: Slimicides

PT04: Food and feed area

Authorisation number EU-0032881-0000

R4BP asset number EU-0032881-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

| Name | Ecolab CMIT-MIT BPF |
|------|---------------------|

1.2. **Product type(s)**

| Product type(s) | PT11: Preservatives for liquid-cooling and processing systems |
|-----------------|---|
| | PT12: Slimicides |
| | PT04: Food and feed area |

1.3. Authorisation holder

| Name and address of the authorisation holder | Name | Ecolab Deutschland GmbH |
|--|---------------|--|
| | Address | Ecolab Allee 1 40789 Monheim am Rhein Germany |
| Authorisation number | | EU-0032881-0000 |
| R4BP asset number | | EU-0032881-0000 |
| Date of the authorisation | 3 March 202 | 5 |
| Expiry date of the authorisation | 28 February 2 | 2035 |

1.4. Manufacturer(s) of the product

| Name of manufacturer | Ecolab Europe GmbH |
|---------------------------------|--|
| Address of manufacturer | Richtistrasse 7 8304 Walliselen Switzerland |
| Location of manufacturing sites | Ecolab Europe GmbH site 1 Richtistrasse 7 8304 Walliselen Switzerland |
| Name of manufacturer | Ecolab Limited |
| Address of manufacturer | Brunel Way, Baglan Energy Park SA11 2GA Neath United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Ecolab Limited site 1 Brunel Way, Baglan Energy Park SA11 2GA Neath United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | Laboratoires Prodene Klint |
| Address of manufacturer | Rue Denis Papin, 2 Z.I. Mitry Compans F-77290 Mitry Mory France |
| Location of manufacturing sites | Laboratoires Prodene Klint site 1 Rue Denis Papin, 2 Z.I. Mitry Compans F-77290 Mitry Mory France |
| | |
| Name of manufacturer | Ecolab Leeds |
| Address of manufacturer | Lotherton Way, Garforth LS25 2JY Leeds United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Ecolab Leeds site 1 Lotherton Way, Garforth LS25 2JY Leeds United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | Ecolab SRL |
| Address of manufacturer | Viale del Lavoro 10 45100 Rovigo Italy |
| Location of manufacturing sites | Ecolab SRL site 1 Viale del Lavoro 10 45100 Rovigo Italy |
| | W1 B . 11 12 C |
| Name of manufacturer | Nalco Deutschland Manufacturing GmbH und Co.KG |
| Address of manufacturer | Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany |
| Location of manufacturing sites | Nalco Deutschland Manufacturing GmbH und Co.KG site 1 Justus-von-Liebig-Str. 11 D-64584 Biebesheim Germany |

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| Name of manufacturer | Ecolab NETHERLANDS BV |
|---------------------------------|--|
| Address of manufacturer | BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands (the |
| Location of manufacturing sites | Ecolab NETHERLANDS BV site 1 BRUGWAL 11 3432NZ NIEUWEGEIN Netherlands (the |
| | |
| Name of manufacturer | Ecolab Weavergate |
| Address of manufacturer | Winnington Avenue, Northwich CW8 3AA Cheshire United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Ecolab Weavergate site 1 Winnington Avenue, Northwich CW8 3AA Cheshire United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | Ecolab Mullingar, Ireland |
| Address of manufacturer | Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar Ireland |
| Location of manufacturing sites | Ecolab Mullingar, Ireland site 1 Forest Park, Zone C Mullingar Ind. Estate N91 Mullingar Ireland |
| | |
| Name of manufacturer | Ecolab d.o.o. |
| Address of manufacturer | Vajngerlova 4 2000 Maribor Slovenia |
| Location of manufacturing sites | Ecolab d.o.o. site 1 Vajngerlova 4 2000 Maribor Slovenia |
| | |
| Name of manufacturer | Ecolab Rozzano |
| Address of manufacturer | VIA GRANDI 9/11 20089 Rozzano Italy |
| Location of manufacturing sites | Ecolab Rozzano site 1 VIA GRANDI 9/11 20089 Rozzano Italy |
| Name of manufacturer | Ecolab BVBA |
| | |
| Address of manufacturer | Havenlaan 4 3980 Tessenderlo Belgium |
| Location of manufacturing sites | Ecolab BVBA site 1 Havenlaan 4 3980 Tessenderlo Belgium |
| <u> </u> | |

| Name of manufacturer | Nalco Española Manufacturing, SLU |
|---------------------------------|--|
| Address of manufacturer | C/Tramuntana s/n Polígono Industrial de Celrà 17460 CELRÀ 17460 Girona Spain |
| Location of manufacturing sites | Nalco Española Manufacturing, SLU site 1 C/Tramuntana s/n Polígono Industrial de Celrà 17460 CELRÀ 17460 Girona Spain |
| | |
| Name of manufacturer | Ecolab production France SAS |
| Address of manufacturer | BP509, Avenue de Général Patton 51006 Châlons-en- Champagne France |
| Location of manufacturing sites | Ecolab production France SAS site 1 BP509, Avenue de Général Patton 51006 Châlons-en- Champagne France |
| | |
| Name of manufacturer | Ecolab Mandra, Greece |
| Address of manufacturer | 25KLM Old National Road 19600 Attica Mandra Greece |
| Location of manufacturing sites | Ecolab Mandra, Greece site 1 25KLM Old National Road 19600 Attica Mandra Greece |
| | |
| Name of manufacturer | NALCO FINLAND MANUFACTURING OY |
| Address of manufacturer | Kivikummuntie 1 FIN-07955 Tesjoki Finland |
| Location of manufacturing sites | NALCO FINLAND MANUFACTURING OY site 1 Kivikummuntie 1 FIN-07955 Tesjoki Finland |
| | |
| Name of manufacturer | NALCO Water Italy |
| Address of manufacturer | Via Ninfina II 04012 Cisterna Di Latina Italy |
| Location of manufacturing sites | NALCO Water Italy site 1 Via Ninfina II 04012 Cisterna Di Latina Italy |
| | |
| Name of manufacturer | Manufacturing Plant Fawley Nalco |
| Address of manufacturer | One business centre 1180 SO45 3NP Hardley United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Manufacturing Plant Fawley Nalco site 1 One business centre 1180 SO45 3NP Hardley United Kingdom of Great Britain and Northern Ireland (the) |

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| Name of manufacturer | Nalco Ltd Scotland |
|---------------------------------|---|
| Address of manufacturer | Minto Avenue, Alten Industrial Estate AB12 3JZ Aberdeen United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Nalco Ltd Scotland site 1 Minto Avenue, Alten Industrial Estate AB12 3JZ Aberdeen United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | Microtek Medical B.V. |
| Address of manufacturer | Hekkehorst, 24 7207 Zutphen Netherlands (the) |
| Location of manufacturing sites | Microtek Medical B.V. site 1 Hekkehorst, 24 7207 Zutphen Netherlands (the) |
| Name of manufacturer | Dow Europe GmbH |
| Address of manufacturer | Bachtobelstrasse 3 8810 Horgen Switzerland |
| Location of manufacturing sites | Dow Europe GmbH site 1 Bachtobelstrasse 3 8810 Horgen Switzerland |
| | |
| Name of manufacturer | Troy Chemical Company B.V. Troy |
| Address of manufacturer | Uiverlaan 12e 3145 XN Maassluis Netherlands (the) |
| Location of manufacturing sites | Troy Chemical Company B.V. Troy site 1 Uiverlaan 12e 3145 XN Maassluis Netherlands (the) |
| | |
| Name of manufacturer | Thor GmbH |
| Address of manufacturer | Landwehrstrasse 1 67346 Speyer Germany |
| Location of manufacturing sites | Thor GmbH site 1 Landwehrstrasse 1 67346 Speyer Germany |
| Name of manufacturer | A.F.P. GmbH |
| Address of manufacturer | Otto-Brenner-Strasse 16-18 21337 Lueneburg Germany |
| Location of manufacturing sites | A.F.P. GmbH site 1 Otto-Brenner-Strasse 16-18 21337 Lueneburg Germany |
| | |

| Name of manufacturer | ANIOS |
|---------------------------------|---|
| Address of manufacturer | Pavé du moulin 59260 Lille-Hellemmes France |
| Location of manufacturing sites | ANIOS site 1 Pavé du moulin 59260 Lille-Hellemmes France |
| | |
| Name of manufacturer | BELINKA-LJUBLJANA |
| Address of manufacturer | Belinka Zasavska Cesta 95 1001 Ljubljana Slovenia |
| Location of manufacturing sites | BELINKA-LJUBLJANA site 1 Belinka Zasavska Cesta 95 1001 Ljubljana Slovenia |
| Name of manufacturer | Bentus Laboratories Ltd |
| Address of manufacturer | RADIO STREET, 24 BLD.1 105005 Moscow Russian Federation (the) |
| Location of manufacturing sites | Bentus Laboratories Ltd site 1 RADIO STREET, 24 BLD.1 105005 Moscow Russian Federation (the) |
| | |
| Name of manufacturer | BIO_PRODUCTIONS Ltd Inc STAPRO |
| Address of manufacturer | 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE RH15 9LH BURGESS HILL United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | BIO_PRODUCTIONS Ltd Inc STAPRO site 1 72 VICTORIA ROAD, VICTORIA INDUSTRIAL ESTATE RH15 9LH BURGESS HILL United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | BORES S.R.L. |
| Address of manufacturer | Via Pioppa, 179 44030 Pontegradella (FE) Italy |
| Location of manufacturing sites | BORES S.R.L. site 1 Via Pioppa, 179 44030 Pontegradella (FE) Italy |
| Name of manufacturer | BRENNTAG CEE - GUNTRAMSDORF |
| Address of manufacturer | Bahnstr. 13 A-2353 Guntramsdorf Austria |
| Location of manufacturing sites | BRENNTAG CEE - GUNTRAMSDORF site 1 Bahnstr. 13 A-2353 Guntramsdorf Austria |

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| Name of manufacturer | BRENNTAG GmbH Duisburg |
|---------------------------------|--|
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG GmbH Duisburg site 1 Humboldtring 15 45472 Muehlheim Germany |
| | |
| Name of manufacturer | BRENNTAG Glauchau |
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG Glauchau site 1 Humboldtring 15 45472 Muehlheim Germany |
| | |
| Name of manufacturer | BRENNTAG Hamburg |
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG Hamburg site 1 Humboldtring 15 45472 Muehlheim Germany |
| Name of manufacturer | BRENNTAG Heilbronn |
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG Heilbronn site 1 Humboldtring 15 45472 Muehlheim Germany |
| | |
| Name of manufacturer | BRENNTAG Kaiserslaute |
| Address of manufacturer | Merkurstr. 47 67663 Kaiserslautern Germany |
| Location of manufacturing sites | BRENNTAG Kaiserslaute site 1 Merkurstr. 47 67663 Kaiserslautern Germany |
| | |
| Name of manufacturer | BRENNTAG Kleinkarlbac |
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG Kleinkarlbac site 1 Humboldtring 15 45472 Muehlheim Germany |
| | |
| Name of manufacturer | BRENNTAG Lohfelden |
| Address of manufacturer | Humboldtring 15 45472 Muehlheim Germany |
| Location of manufacturing sites | BRENNTAG Lohfelden site 1 Humboldtring 15 45472 Muehlheim Germany |

| Name of manufacturer | BRENNTAG Nordic - HASLEV |
|---------------------------------|---|
| Address of manufacturer | Høsten Teglværksvej 47 4690 Haslev Denmark |
| Location of manufacturing sites | BRENNTAG Nordic - HASLEV site 1 Høsten Teglværksvej 47 4690 Haslev Denmark |
| | |
| Name of manufacturer | BRENNTAG Nordic - VEJLE |
| Address of manufacturer | Vivaa 7100 Vejle Denmark |
| Location of manufacturing sites | BRENNTAG Nordic - VEJLE site 1 Vivaa 7100 Vejle Denmark |
| Name of manufacturer | BRENNTAG Normandy |
| Address of manufacturer | 12 Sente des Jumelles - BP 11 76710 Montville France |
| Location of manufacturing sites | BRENNTAG Normandy site 1 12 Sente des Jumelles - BP 11 76710 Montville France |
| | |
| Name of manufacturer | BRENNTAG PL -Zgierz |
| Address of manufacturer | ul. Kwasowa 5 95-100 Zgierz Poland |
| Location of manufacturing sites | BRENNTAG PL -Zgierz site 1 ul. Kwasowa 5 95-100 Zgierz Poland |
| Name of manufacturer | PREMIUTAC Ocionias Madrid |
| | BRENNTAG Quimica - Madrid |
| Address of manufacturer | Calle Gutemberg nº 22, Poligono Industrial El Lomo. 28906 Getafe (Madrid) C/ Gutemberg, 22 Polig. Ind. El Lomo 28906 Madrid Spain |
| Location of manufacturing sites | BRENNTAG Quimica - Madrid site 1 Calle Gutemberg nº 22,,Poligono Industrial El Lomo. 28906 Getafe (Madrid) C/ Gutemberg, 22 Polig. Ind. El Lomo 28906 Madrid Spain |
| Name of manufacturer | BRENNTAG Schweizerhall |
| Address of manufacturer | Elsaesserstr. 231 C-4056 Basel Switzerland |
| | |
| Location of manufacturing sites | BRENNTAG Schweizerhall site 1 Elsaesserstr. 231 C-4056 Basel Switzerland |

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| Name of manufacturer | Budich International GmbH |
|---------------------------------|---|
| Address of manufacturer | Dieselstrasse 10 32120 Hiddenhause Germany |
| Location of manufacturing sites | Budich International GmbH site 1 Dieselstrasse 10 32120 Hiddenhause Germany |
| | |
| Name of manufacturer | Caldic Deutschland Chemie B.V |
| Address of manufacturer | Am Karlshof 10 D 40231 Duesseldorf Germany |
| Location of manufacturing sites | Caldic Deutschland Chemie B.V site 1 Am Karlshof 10 D 40231 Duesseldorf Germany |
| | |
| Name of manufacturer | CARBON GROUP |
| Address of manufacturer | Ringaskiddy P43 R772 Cork Ireland |
| Location of manufacturing sites | CARBON GROUP site 1 Ringaskiddy P43 R772 Cork Ireland |
| | |
| Name of manufacturer | COMERCIAL GODO SL |
| Address of manufacturer | Carrer de Franca, Igualada 13 08700 Barcelona Spain |
| Location of manufacturing sites | COMERCIAL GODO SL site 1 Carrer de Franca, Igualada 13 08700 Barcelona Spain |
| | |
| Name of manufacturer | DAN MOR (DR WIPE) Natural Products and Chemicals Ltd. |
| Address of manufacturer | Or Akiva Industrial Zone 30600 Or Akiva Israel |
| Location of manufacturing sites | DAN MOR (DR WIPE) Natural Products and Chemicals Ltd. site 1 Or Akiva Industrial Zone 30600 Or Akiva Israel |
| | |
| Name of manufacturer | DETERGENTS BURGUERA |
| Address of manufacturer | S.L. Joan Ballester 50 07630 CAMPOS (ILLES BALEARES) Spain |
| Location of manufacturing sites | DETERGENTS BURGUERA site 1 S.L. Joan Ballester 50 07630 CAMPOS (ILLES BALEARES) Spain |
| | |
| Name of manufacturer | ECL MICROTEK BV |
| Address of manufacturer | GESINKKAMPSTRAAT 19 705 HR VARSSEVELD Netherlands (the) |
| Location of manufacturing sites | ECL MICROTEK BV site 1 GESINKKAMPSTRAAT 19 705 HR VARSSEVELD Netherlands (the) |
| | · |

| Name of manufacturer | ECL MICROTEK MOSTA |
|---------------------------------|--|
| Address of manufacturer | SORBONNE CENTRE, F20 MOSTA TECHNOPARK MST |
| Address of mandiacturer | 3000 MOSTA Malta |
| Location of manufacturing sites | ECL MICROTEK MOSTA site 1 SORBONNE CENTRE, F20 MOSTA TECHNOPARK MST 3000 MOSTA Malta |
| | |
| Name of manufacturer | Ferdinand Eimermacher GmbH & Co. KG |
| Address of manufacturer | Westring 24 48356 Nordwalde Germany |
| Location of manufacturing sites | Ferdinand Eimermacher GmbH & Co. KG site 1 Westring 24 48356 Nordwalde Germany |
| Name of manufacturer | GALLOWS GREEN SERVICES LTD |
| Address of manufacturer | Cod Beck Mill Industrial Estate Dalton Lane YO7 3HR Thirsk United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | GALLOWS GREEN SERVICES LTD site 1 Cod Beck Mill Industrial Estate Dalton Lane YO7 3HR Thirsk United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | GIRASOL NATURAL PRODUCTS BV |
| Address of manufacturer | De Veldoven 12-14 3342 GR Hendrik-Ido-Ambacht Netherlands (the) |
| Location of manufacturing sites | GIRASOL NATURAL PRODUCTS BV site 1 De Veldoven 12-14 3342 GR Hendrik-Ido-Ambacht Netherlands (the) |
| | |
| Name of manufacturer | HENKEL ENGELS |
| Address of manufacturer | Prospekt Stroitelei 413116 Engels Russian Federation (the) |
| Location of manufacturing sites | HENKEL ENGELS site 1 Prospekt Stroitelei 413116 Engels Russian Federation (the) |
| | |
| Name of manufacturer | imeco GmbH & Co. KG |
| Address of manufacturer | Boschstraße 5 D-63768 Hösbach Germany |
| Location of manufacturing sites | imeco GmbH & Co. KG site 1 Boschstraße 5 D-63768 Hösbach Germany |

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| Name of manufacturer | INNOVATE GmbH |
|---------------------------------|--|
| Address of manufacturer | Am Hohen Stein 11 06618 Naumburg Germany |
| Location of manufacturing sites | INNOVATE GmbH site 1 Am Hohen Stein 11 06618 Naumburg Germany |
| | |
| Name of manufacturer | INTERFILL LLC-TOSNO |
| Address of manufacturer | Moskovskoye shosse 1 Tosno 187000 Leningradskaya oblast Russian Federation (the) |
| Location of manufacturing sites | INTERFILL LLC-TOSNO site 1 Moskovskoye shosse 1 Tosno 187000 Leningradskaya oblast Russian Federation (the) |
| | |
| Name of manufacturer | Kleinmann GmbH |
| Address of manufacturer | Am Trieb 13 72820 Sonnenbühl Germany |
| Location of manufacturing sites | Kleinmann GmbH site 1 Am Trieb 13 72820 Sonnenbühl Germany |
| | |
| Name of manufacturer | KOMPAK NEDERLAND BV |
| Address of manufacturer | Ambachtsweg 4 4854 Bavel Netherlands (the) |
| Location of manufacturing sites | KOMPAK NEDERLAND BV site 1 Ambachtsweg 4 4854 Bavel Netherlands (the) |
| | |
| Name of manufacturer | La Antigua Lavandera SL |
| Address of manufacturer | Ctra. Antigua Sevilla-Alcalá Km.1,5 (SE-410) Apartado de Correos, 58 41500 Alcal de Guadaira, Seville Spain |
| Location of manufacturing sites | La Antigua Lavandera SL site 1 Ctra. Antigua Sevilla-Alcalá Km.1,5 (SE-410) Apartado de Correos, 58 41500 Alcal de Guadaira, Seville Spain |
| | |
| Name of manufacturer | LICHTENHELDT GmbH |
| Address of manufacturer | Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt Germany |
| Location of manufacturing sites | LICHTENHELDT GmbH site 1 Lichtenheldt Industriestrasse 7-9 23812 Wahlstedt Germany |
| | |
| Name of manufacturer | Multifill B.V. |
| Address of manufacturer | Constructieweg 25-A 3641 SB Mijdrecht Netherlands (the) |
| Location of manufacturing sites | Multifill B.V. site 1 Constructieweg 25-A 3641 SB Mijdrecht Netherlands (the) |
| | |

| Name of manufacturer | PAL INTERNATIONAL LTD |
|---------------------------------|--|
| Address of manufacturer | Sandhurst Street LE2 5AR Leicester United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | PAL INTERNATIONAL LTD site 1 Sandhurst Street LE2 5AR Leicester United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | PLANOL GmbH |
| Address of manufacturer | Maybachstr. 17 63456 Hanau Germany |
| Location of manufacturing sites | PLANOL GmbH site 1 Maybachstr. 17 63456 Hanau Germany |
| | |
| Name of manufacturer | PLUM A/S |
| Address of manufacturer | Frederik Plums Vej 2 DK 5610 Assens Denmark |
| Location of manufacturing sites | PLUM A/S site 1 Frederik Plums Vej 2 DK 5610 Assens Denmark |
| | |
| Name of manufacturer | QUIMICAS MORALES |
| Address of manufacturer | Misiones, 11 - Urb. El Sebadal 05005 LAS PALMAS DE GRAN CANARIA Spain |
| Location of manufacturing sites | QUIMICAS MORALES site 1 Misiones, 11 - Urb. El Sebadal 05005 LAS PALMAS DE GRAN CANARIA Spain |
| | |
| Name of manufacturer | RNM PRODUCTOS QUIMICOS |
| Address of manufacturer | Lda Rua da Fabrica, 123, Segada 4765-080 Carreira Vila Nova de Famalicao Portugal |
| Location of manufacturing sites | RNM PRODUCTOS QUIMICOS site 1 Lda Rua da Fabrica, 123, Segada 4765-080 Carreira Vila Nova de Famalicao Portugal |
| | |
| Name of manufacturer | ROQUETTE & BARENTZ |
| Address of manufacturer | Roquette Freres Route De La Gorgue F-62136 Lestrem France |
| Location of manufacturing sites | ROQUETTE & BARENTZ site 1 Roquette Freres Route De La Gorgue F-62136 Lestrem France |

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| Name of manufacturer | RUTPEN LTD. |
|---------------------------------|--|
| Address of manufacturer | MEMBURY AIRFIELD RG16 7TJ Lambourn United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | RUTPEN LTD. site 1 MEMBURY AIRFIELD RG16 7TJ Lambourn United Kingdom of Great Britain and Northern Ireland (the) |
| | |
| Name of manufacturer | SOLIMIX Montseny |
| Address of manufacturer | 17-19 Pol. Ind. Sant Pere Molanta 08799 Olerdola, Barcelona Spain |
| Location of manufacturing sites | SOLIMIX Montseny site 1 17-19 Pol. Ind. Sant Pere Molanta 08799 Olerdola, Barcelona Spain |
| Name of manufacturer | STAUB & CO - SILBERMAN GMBH |
| Address of manufacturer | Industriestraße 3 86456 Gablingen Germany |
| Location of manufacturing sites | STAUB & CO - SILBERMAN GMBH site 1 Industriestraße 3 86456 Gablingen Germany |
| | <u>'</u> |
| Name of manufacturer | SYNERLOGIC BV (- IN2FOOD) |
| Address of manufacturer | L.J. Costerstraat 5 6827 Arnhem Netherlands (the) |
| Location of manufacturing sites | SYNERLOGIC BV (- IN2FOOD) site 1 L.J. Costerstraat 5 6827 Arnhem Netherlands (the) |
| | · |
| Name of manufacturer | Univar Ltd |
| Address of manufacturer | Argyle House, Epsom Avenue SK9 3RN Wilmslow. United Kingdom of Great Britain and Northern Ireland (the) |
| Location of manufacturing sites | Univar Ltd site 1 Argyle House, Epsom Avenue SK9 3RN Wilmslow United Kingdom of Great Britain and Northern Ireland (the) |
| Name of manufacturer | VAN DAM BODEGRAVEN |
| Address of manufacturer | Postbus 48 NL 2410 AA Bodegraven Netherlands (the) |
| Location of manufacturing sites | VAN DAM BODEGRAVEN site 1 Postbus 48 NL 2410 AA Bodegraven Netherlands (the) |

1.5. Manufacturer(s) of the active substance(s)

| Active substance | C(M)IT/MIT (3:1) |
|---------------------------------|--|
| Name of manufacturer | Microbial Control (Switzerland) GmbH |
| Address of manufacturer | Hungerbüelstrasse 22 8500 Frauenfeld Switzerland |
| Location of manufacturing sites | Microbial Control (MC) Jiangsu FOPIA Chemicals Co. Ltd., Touzeng Village, Binhuai Town, Binhai Country, Jiangsu, 224555 Yancheng City China |

2. **PRODUCT FAMILY COMPOSITION AND FORMULATION**

2.1. Qualitative and quantitative information on the composition of the family

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------|---|------------------|------------|-----------|--------------------|
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol- 3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | 55965-84-9 | | 2,6 - 7,51 % (w/w) |

2.2. Type(s) of formulation

| Formulation type(s) | AL Any other liquid |
|---------------------|---------------------|
|---------------------|---------------------|

PART II

SECOND INFORMATION LEVEL - META SPC(S)

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 1 identifier

1.2. Suffix to the authorisation number

| Number | 1-1 |
|--------|-----|
| | |

1.3. **Product type(s)**

| Product type(s) | PT11: Preservatives for liquid-cooling and processing systems |
|-----------------|---|
| | PT12: Slimicides |

2. META SPC 1 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 1

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------|---|------------------|------------|-----------|-------------------|
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol- 3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | 55965-84-9 | | 2,6 - 2,9 % (w/w) |

2.2. Type(s) of formulation of the meta SPC 1

| Formulation type(s) | AL Any other liquid |
|---------------------|---------------------|
|---------------------|---------------------|

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

| Hazard statements | H290: May be corrosive to metals. |
|-------------------|---|
| | H314: Causes severe skin burns and eye damage. |
| | H317: May cause an allergic skin reaction. |
| | H410: Very toxic to aquatic life with long lasting effects. |

| Precautionary statements | P391: Collect spillage. |
|--------------------------|--|
| | P234: Keep only in original packaging. |
| | P260: Do not breathe mist. |
| | P272: Contaminated work clothing should not be allowed out of the workplace. |
| | P273: Avoid release to the environment. |
| | P280: Wear gloves/protective clothing/eye protection/ face protection. |
| | P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |
| | P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. |
| | P310: Immediately call a POISON CENTER or doctor/physician. |
| | P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| | P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| | P333+P313: If skin irritation or rash occurs: Get medical POISON CENTER or doctor/ physician. |
| | P362+P364: Take off contaminated clothing and wash it before reuse. |
| | P390: Absorb spillage to prevent material damage. |
| | P405: Store locked up. |
| | P501: Dispose of contents to a hazardous waste disposal service in accordance with the statutory regulations. |
| | P501: Dispose of container to a hazardous waste disposal service in accordance with the statutory regulations. |
| | 1 |

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Table 1

Use 1.1 Preservatives for liquid-cooling and processing systems (Preservatives)

| Product type | PT11: Preservatives for liquid-cooling and processing systems |
|--|---|
| Where relevant, an exact description of the authorised use | - |

OJ L, 11.2.2025 EN

| Target organism(s) (including development stage) | Scientific name: no data Common name: bacteria Development stage: no data |
|--|--|
| | Scientific name: no data Common name: yeasts Development stage: no data |
| | Scientific name: no data Common name: fungi Development stage: no data |
| | Scientific name: no data Common name: algae Development stage: no data |
| | Scientific name: no data Common name: Legionella pneumophila Development stage: no data |
| | Scientific name: no data Common name: biofilm Development stage: no data |
| Field(s) of use | indoor use outdoor use |
| | Preservation of fluids in cooling systems with discharge to the municipal sewer in: Open recirculating cooling systems, closed cooling system. Preservation of processing liquids in: Pasteurizers and sterilizers, air washers and scrubbers. |
| Application method(s) | Method: closed system |
| | Detailed description: Feed the product via a closed feed system. Product applied via automated process with use of pumps or injection. Product can be added whilst the process is in operation. |
| Application rate(s) and frequency | Application rate: Maintenance: Bacteria 100-200 ppm product (1,5-3 mg as/l (active substance per liter of fluid to be preserved)) Legionella 50-200 ppm product (0,75-3 mg as/l) Biofilm 200 ppm product (3 mg as/l) Curative: Bacteria 400 ppm product 6 hours contact time (6 mg as/l) Legionella 100-400 ppm product 6 hours contact time (1,5-6 mg as/l) Yeast and fungi 200-400 ppm product 6 hours contact time (3-6 mg as/l) Algae 100-400 ppm product 6 hours contact time (1,5-6 mg as/l) - |
| | Number and timing of application: Maintenance frequency: four times daily to once per week. Curative: This may be implemented when control is lost or when monitoring data suggests that curative implementation is required, however this should not be more than once every two months in cases of heavy fouling. |

| Category(ies) of users | industrial; professional |
|-----------------------------------|--|
| Pack sizes and packaging material | 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene Intermediate bulk container (IBC) |

4.1.1. Use-specific instructions

The product should be slug-fed to recirculating cooling and process water in such a way to achieve maximum dispersion and exposure to the areas of the system with the highest level of microorganisms. The product should be added to the system according to the size of the system, for example to achieve a 100 ppm concentration in a 10 000 liter system 1 000 ml (1 liter) of product will need to be added.

The interval between two doses depends on the system's hydraulic retention time and removal of the active substance by degradation and blow-down. The product may accumulate in preserved fluids when dosed too often. It is the responsibility of the end-user to determine the effective dose on-site (e.g. by chemical or microbiological tests) for the specific location/system to ensure that the system is efficacious under the use conditions. If needed, consult the authorisation holder (as specified in the label).

4.1.2. Use-specific risk mitigation measures

Wear compatible Personal Protective Equipment:

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection consistent with the European Standard EN ISO166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

The use is restricted to small cooling systems with a maximum blowdown of 2 m³/h. Waste water must be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.

The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use.

4.2. Use description

Table 2

Use 1.2 Slimicide in the pulp and paper industry (Preservatives)

| Product type | PT12: Slimicides |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: no data Common name: bacteria Development stage: no data Scientific name: no data Common name: yeasts Development stage: no data Scientific name: no data Common name: fungi Development stage: no data Scientific name: no data Common name: biofilm |
| | Development stage: no data |
| Field(s) of use | indoor use For use as a slimicide in the pulp and paper industry, de-inking process, wet end / white water, pulp including during machine shutdown. Thick stock (including broke, blend, machine chests as well as the recycled pulp). White water, cloudy water and clear water. Thin stock. Control of Microbiologically Induced Corrosion (MIC) and biofouling of deaerators and filters. Control of slime growth in additives specifically intended to be used in the paper production process. |
| Application method(s) | Method: closed system Detailed description: Feed the product via a closed feed system. Product applied via automated process with use of pumps or injection. Product can be added whilst the process is in operation. |
| Application rate(s) and frequency | Application rate: For pulp and paper industry, feed on an intermittent (slug) basis: Additives used in paper production: Maintenance: Bacteria 50-400 ppm product (0,75-6 mg as/l) Curative: Bacteria 50-400 ppm product (1,5-6 mg as/l) Curative: Bacteria 50-400 ppm product 24 hours contact time (0,75-6 mg as/l) Yeast and fungi 200-400 ppm product 6 hours contact time (3 - 6 mg as/l) Paper machine system (including wet end, white water and pulp) Maintenance: Bacteria and yeast 25-400 ppm product (0,38-6 mg as/l) Biofilm 200-400 ppm product (3 - 6 mg as/l) Curative: Bacteria 200-400 ppm product 24 hours contact time (3-6 mg as/l) Yeast 25-400 ppm product 24 hours contact time (0,38-6 mg as/l) Fungi 400 ppm product 6 hours contact time (6 mg as/l) - |

| | Number and timing of application: For pulp and paper industry, feed on an intermittent (slug) basis. Additives used in paper production and paper machine system (including wet end, white water and pulp): — Maintenance frequency: four times daily to once per week. — Curative: this may be implemented when control is lost or when monitoring data suggests that curative implementation is required, however this should not be more than once every two months. |
|-----------------------------------|--|
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene IBCs |

4.2.1. Use-specific instructions

Feed the product on an intermittent basis to provide preservation of acceptable (low level) microbial counts in the paper machine system. Feed the product in the wet-end intermittently in the machine chest or similar stock chest or to additives used in paper production. Alone, it should never be used in the short loop but back in the system.

The dose strongly depends on the formulation and intended use of the matrix to which the preservative is added. The interval between two doses also depends on the system's hydraulic retention time and removal of the active substance by e.g. degradation and dilution. The product may accumulate in processing fluids when dosed too often. It is the responsibility of the end-user to determine the effective dose on-site (e.g. by chemical or microbiological tests) for the specific location/system to ensure that the system is efficacious under the use conditions. If needed, consult the authorisation holder (as specified in the label).

The product should be added based on the volume of the system, for example to achieve a 100 ppm concentration in a 10 000 liter system 1 000 ml (1 liter) of product will need to be added.

4.2.2. Use-specific risk mitigation measures

Human Health:

Wear compatible Personal Protective Equipment:

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection consistent with the European Standard EN ISO166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

Environment:

Application is only allowed in paper factories that comply to the Industrial Emission directive 2010/75/EU where wastewater is purified in an on-site industrial sewage treatment plant including a biological treatment step in accordance with the Best Available Techniques (BAT) as prescribed in the BAT reference document (BREF) for the production of pulp, paper and board, the effluent must be diluted at least 200 times. Paper factories that are exempted from the Industrial Emission Directive must discharge to the municipal sewer.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 1

5.1. Instructions for use

Resistance management procedures shall be adopted in use as follows:

- products shall always be used in accordance with label recommendations
- elimination of microbial growth shall be attempted by using application rates demonstrated to be efficacious
- levels of effectiveness shall be monitored and instances of reduced effectiveness shall be investigated for possible evidence of resistance.

In commercial use, C(M)IT/MIT is often used in combination or rotation with other biocides in various applications. Microbial resistance to C(M)IT/MIT can be avoided by switching or alternating biocides or using combinations with other actives.

All workers and individuals handling the product shall have access to the Safety Data Sheets (SDS) and Technical Data Sheets (TDS)

5.2. Risk mitigation measures

Refer to use-specific risk mitigation measures

Organisational risk management measures:

- Loading should be restricted to automated processes.
- Workers involved in performing repairs or cleaning activities should rinse the system before opening and cleaning.
- Eye wash station and safety shower are necessary.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Protection of first-aiders: Wear adequate personal protective equipment.

First aid instructions:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation or rash occur: Get medical advice.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions:

In the event of a spill, prevent material from entering sewers or waterways. Do not allow material to contaminate ground water system. Prevent product from entering drains. If drains, streams, soil or sewers become contaminated, notify local authority. Spilled product may pose a risk to the aquatic ecosystem if released.

Methods and materials for containment and cleaning up:

SMALL SPILLS: Dike and absorb with inert material (e.g. dry earth, sand), shovel all contaminated solids into a pail or drum and then treat with enough deactivation solution to wet the solids thoroughly. Let these containers stand open for 48 hours to prevent pressure build up and then seal for disposal. Equipment containing residues should be decontaminated before carrying out maintenance or repair work or using for other service. Contaminated surfaces should be swabbed with deactivation solution, wait for the reaction to subside and rinse thoroughly with clean water.

LARGE SPILLS: Soak up with inert absorbent material. Transfer contaminated material to suitable containers for disposal. Contaminated surfaces should be swabbed with deactivation solution, let stand for 30 minutes and rinse thoroughly with clean water.

DO NOT add deactivation solution to the waste container to deactivate the absorbed material.

* DEACTIVATION SOLUTION - prepare fresh a solution of 5% Sodium bicarbonate and 5% Sodium hypochlorite in water. Use a ratio of 10 volumes decontamination solution per estimated volume of residual spill. Contact an approved waste hauler for disposal of contaminated recovered material. Dispose of material in compliance with regulations indicated in Safety Data Sheet.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

The product must not be released to soil, water courses or any kind of sewer. Where possible recycling is preferred to disposal. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site. Do not re-use empty containers.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months.

Do not store at temperatures above 40°C.

Keep container tightly closed. Store in suitable labelled containers.

6. **OTHER INFORMATION**

The full titles of the EN standards referenced in sections "Use-specific risk mitigation measures" are:

EN ISO 374 - Protective gloves against dangerous chemicals and micro-organisms.

EN ISO 166 - Personal eye protection standard

EN 13034 - Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB equipment)

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 1

7.1. Trade name(s), authorisation number and specific composition of each individual product

| Trade name(s) | | NALCO® WT-735 | | Market area: EU | | | |
|-------------------|---|------------------|---------------|-----------------|------------|-------------|-------------|
| | | | NALC 77352 | | Market are | ea: EU | |
| Authorisation num | ber | | | | EU-00328 | 81-0001 1-1 | |
| Common name | IUPAC name | Function | | CAS number | | EC number | Content (%) |
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol-3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | | 5596 | 5-84-9 | | 2,9 % (w/w) |

7.2. Trade name(s), authorisation number and specific composition of each individual product

| Trade name(s) | | NALCO® WT-730 | | Market area: EU | | | |
|-------------------|---|------------------|---------------------|-----------------|----------|-----------|-------------|
| | | NALCO® 7330 | | Market area: EU | | | |
| Authorisation num | lber | | EU-0032881-0002 1-1 | | | | |
| Common name | IUPAC name | Functio | Function C | | S number | EC number | Content (%) |
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol- 3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | | 5596 | 5-84-9 | | 2,6 % (w/w) |

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 2 identifier

| Identifier | Meta SPC: META 2 |
|------------|------------------|
| | |

1.2. Suffix to the authorisation number

| Number | 1-2 |
|--------|-----|
| | |

1.3. **Product type(s)**

| 71 () | PT04: Food and feed area PT12: Slimicides |
|--------|--|
| | |

2. META SPC 2 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 2

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------|---|------------------|------------|-----------|-------------------|
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol- 3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | 55965-84-9 | | 5,2 - 5,2 % (w/w) |

2.2. Type(s) of formulation of the meta SPC 2

| Formulation type(s) | AL Any other liquid |
|---------------------|---------------------|
| | |

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

| Hazard statements | H290: May be corrosive to metals. |
|--------------------------|--|
| | H314: Causes severe skin burns and eye damage. |
| | H317: May cause an allergic skin reaction. |
| | H410: Very toxic to aquatic life with long lasting effects |
| Precautionary statements | P391: Collect spillage. |
| | P234: Keep only in original packaging. |
| | P260: Do not breathe mist. |
| | P272: Contaminated work clothing should not be allowed out of the workplace. |
| | P273: Avoid release to the environment. |
| | P280: Wear gloves/protective clothing/eye protection/face protection. |
| | P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |
| | P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. |
| | P310: Immediately call a POISON CENTER or doctor/physician. |
| | P304+P340: IF INHALED: Remove person to fresh air an keep comfortable for breathing. |
| | P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| | P333+P313: If skin irritation or rash occurs: Get medica POISON CENTER or doctor/ physician. |
| | P362+P364: Take off contaminated clothing and wash i before reuse. |
| | P390: Absorb spillage to prevent material damage. |
| | P405: Store locked up. |
| | P501: Dispose of contents to a hazardous waste disposa service in accordance with the statutory regulations. |
| | P501: Dispose of container to a hazardous waste disposa service in accordance with the statutory regulations. |
| | |

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

 $\label{eq:Table 1} \label{eq:Table 1}$ Use 2.4 Off-line preservative for RO membranes in the food and feed industry

| PT04: Food and feed area | |
|--|--|
| - | |
| Scientific name: no data Common name: bacteria Development stage: no data | |
| Scientific name: no data Common name: yeasts Development stage: no data | |
| Scientific name: no data Common name: biofilm Development stage: no data | |
| indoor use | |
| For use as off-line preservation of cleaned filtration membranes and reverse osmose (RO) in the food and feed industry. Intended to produce a biostatic effect. | |
| Method: closed system | |
| Detailed description: Feed the product to the filtration system upstream of any peripheral equipment that may contain biological growth. Feed the product via a closed feed system. Product applied via automated process with use of pumps or injection. | |
| Application rate: Maintenance: Bacteria 50 ppm product (1,5 mg as/l(active substance per liter)) Yeast 12,5 ppm product (0,38 mg as/l) Biofilm 100 ppm product (3 mg as/l) - | |
| Number and timing of application: As a membrane preservative during prolonged storage periods up to 6 months, dosage as stated above based on an active content of 3 % and a product density of 1,199 g/mL (dependent on the length of time the systems will be off-line). | |
| industrial; professional | |
| 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene IBCs | |
| | |

4.1.1. Use-specific instructions

Membranes must be clean prior to storage off-line.

The product is intended only for off-line preservation of filtration membranes or preservation of filtration membranes during shutdown up to 6 months (which may include RO membrane in the production of potable water). The stored filtration membrane and treated storage solution should be checked on a regular (weekly) basis. The solution shall be assessed for the total microbial content. Additional biocide should be added if required. After both events proper rinsing (min 5x) and/or cleaning in place (after prolonged preservation) procedures should take place before the system restarts again. Ensure that there is no residual biocide present in the final rinse water and ensure neutralization of the biocide in the discharge water.

4.1.2. Use-specific risk mitigation measures

Wear compatible Personal Protective Equipment:

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection according to the European Standard EN ISO 166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

A minimum of 5 rinsing procedures is obligatory before the system restarts.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the general directions for use.

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use.

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use.

4.2. Use description

Use 2.2 Slimicide in non-potable water systems

Table 2

| Product type | PT12: Slimicides |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: no data Common name: Bacteria Development stage: no data |
| | Scientific name: no data Common name: Yeasts Development stage: no data |
| | Scientific name: no data Common name: Biofilm Development stage: no data |

| Field(s) of use | indoor use |
|-----------------------------------|---|
| | Used for the on-line maintenance of non-potable (not drinking water) water systems by prevention of slime growth on equipment |
| Application method(s) | Method: closed system |
| | Detailed description: Feed the product to the RO or UF system upstream of any peripheral equipment that may contain biological growth. Should be fed via a closed feed system. Product applied via automated process with use of pumps or injection. |
| Application rate(s) and frequency | Application rate: Maintenance: Bacteria 50 ppm product (1,5 mg as/l(active substance per liter)) Yeast 12,5 ppm product (0,38 mg as/l) Biofilm 100 ppm product (3 mg as/l) Curative: Bacteria 200 ppm product 6 hours contact time (6 mg as/l) Yeast 25 ppm product 6 hours contact time (0,75 mg as/l) - |
| | Number and timing of application: Feed on an intermittent (slug) or continuous basis. Maintenance frequency: once per day to once per week Curative: this may be implemented when control is lost or when monitoring data suggests that curative implementation is required, however this should not be more than once every two months in case of heavy fouling. |
| Category(ies) of users | industrial ; professional |
| Pack sizes and packaging material | 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene IBCs |

4.2.1. Use-specific instructions

For best results, it is important to start with clean membranes.

An on-line preventive maintenance program in non-potable water systems aims to prevent increasing differential pressure (inlet and outlet of the system) due to biofilm growth.

When the on-line preventive maintenance biocidal program is correctly used, the RO membrane can maintain differential pressure, and therefore, maintain membrane performance over time. The frequency of addition varies from every day for heavily fouled systems to every 7 days for lightly fouled systems. When differential membrane pressure increases by 10 to 15% from startup conditions, corrective actions should be undertaken.

The product should be added to the system according to the size of the system, for example to achieve a 100 ppm concentration in a 10 000 liter system 1 000 ml (1 liter) of product will need to be added.

4.2.2. Use-specific risk mitigation measures

Wear compatible Personal Protective Equipment:

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection according to the European Standard EN ISO166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

Use product only in premises that are connected to a sewage treatment plant.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the general directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 2

5.1. **Instructions for use**

Resistance management procedures shall be adopted in use as follows:

- products shall always be used in accordance with label recommendations
- elimination of microbial growth shall be attempted by using application rates demonstrated to be efficacious
- levels of effectiveness shall be monitored and instances of reduced effectiveness shall be investigated for possible evidence of resistance.

In commercial use, CMIT/MIT is often used in combination or rotation with other biocides in various applications. Microbial resistance to CMIT/MIT can be avoided by switching or alternating biocides or using combinations with other actives.

5.2. Risk mitigation measures

Refer to use-specific risk mitigation measures

Organisational risk management measures:

- Loading should be restricted to automated processes.
- Workers involved in performing repairs or cleaning activities should rinse the system before opening and cleaning.
- Eye wash station and safety shower are necessary.

All workers and individuals handling the product shall have access to the Safety Data Sheets (SDS) and Technical Data Sheets (TDS).

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Protection of first-aiders: Wear adequate personal protective equipment.

First aid instructions:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation or rash occur: Get medical advice.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions:

In the event of a spill, prevent material from entering sewers or waterways. Do not allow material to contaminate ground water system. Prevent product from entering drains. If drains, streams, soil or sewers become contaminated, notify local authority. Spilled product may pose a risk to the aquatic ecosystem if released.

Methods and materials for containment and cleaning up:

SMALL SPILLS: Dike and absorb with inert material (e.g. dry earth, sand), shovel all contaminated solids into a pail or drum and then treat with enough deactivation solution to wet the solids thoroughly. Let these containers stand open for 48 hours to prevent pressure build up and then seal for disposal. Equipment containing residues should be decontaminated before carrying out maintenance or repair work or using for other service. Contaminated surfaces should be swabbed with deactivation solution, wait for the reaction to subside and rinse thoroughly with clean water.

LARGE SPILLS: Soak up with inert absorbent material. Transfer contaminated material to suitable containers for disposal. Contaminated surfaces should be swabbed with deactivation solution, let stand for 30 minutes and rinse thoroughly with clean water.

DO NOT add deactivation solution to the waste container to deactivate the absorbed material.

* DEACTIVATION SOLUTION - prepare fresh a solution of 5% Sodium bicarbonate and 5% Sodium hypochlorite in water. Use a ratio of 10 volumes decontamination solution per estimated volume of residual spill. Contact an approved waste hauler for disposal of contaminated recovered material. Dispose of material in compliance with regulations indicated in Safety Data Sheet.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

The product must not be released to soil, water courses or any kind of sewer. Where possible recycling is preferred to disposal. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site. Do not re-use empty containers.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months

Keep container tightly closed. Store in suitable labelled containers.

6. OTHER INFORMATION

The full titles of the EN standards referenced in sections "Use-specific risk mitigation measures" are:

EN ISO 374 - Protective gloves against dangerous chemicals and micro-organisms

EN ISO 166 – Personal eye protection standard

EN 13034 - Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB equipment)

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 2

7.1. Trade name(s), authorisation number and specific composition of each individual product

| Trade name(s) | | | Perma Clean PC-55 | R | Market area: EU | | |
|----------------------|---|------------------|-------------------------|------|-----------------|-----------|-------------|
| Authorisation number | | | EU-0032881-0003 1-2 | | | | |
| Common name | IUPAC name | Function | | CAS | S number | EC number | Content (%) |
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol-3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | | 5596 | 5-84-9 | | 5,2 % (w/w) |

1. META SPC 3 ADMINISTRATIVE INFORMATION

1.1. Meta SPC 3 identifier

| Identifier | Meta SPC: META 3 |
|------------|------------------|
| | 1 |

1.2. Suffix to the authorisation number

| Number | 1-3 |
|--------|-----|
|--------|-----|

1.3. **Product type(s)**

| Product type(s) | PT11: Preservatives for liquid-cooling and processing systems | | |
|-----------------|---|--|--|
| | PT12: Slimicides | | |

2. META SPC 3 COMPOSITION

2.1. Qualitative and quantitative information on the composition of the meta SPC 3

| Common name | IUPAC name | Function | CAS number | EC number | Content (%) |
|------------------|---|------------------|------------|-----------|-------------------------|
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol- 3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | 55965-84-9 | | 7,51 - 7,51 % (w/ w) |

2.2. Type(s) of formulation of the meta SPC 3

| Formulation type(s) | AL Any other liquid |
|---------------------|---------------------|
| | |

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 3

| Hazard statements | H290: May be corrosive to metals. |
|--------------------------|--|
| | H302: Harmful if swallowed. |
| | H332: Harmful if inhaled. |
| | H314: Causes severe skin burns and eye damage. |
| | H317: May cause an allergic skin reaction. |
| | H410: Very toxic to aquatic life with long lasting effects. |
| Precautionary statements | P391: Collect spillage. |
| | P234: Keep only in original packaging. |
| | P260: Do not breathe mist. |
| | P270: Do not eat, drink or smoke when using this product. |
| | P271: Use only outdoors or in a well-ventilated area. |
| | P272: Contaminated work clothing should not be allowed out of the workplace. |
| | P273: Avoid release to the environment. |

| P280: Wear gloves/protective clothing/eye protection/face protection. |
|--|
| P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting. |
| P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower]. |
| P310: Immediately call a POISON CENTER or doctor/physician. |
| P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. |
| P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. |
| P333+P313: If skin irritation or rash occurs: Get medical contents. |
| P362+P364: Take off contaminated clothing and wash it before reuse. |
| P390: Absorb spillage to prevent material damage. |
| P405: Store locked up. |
| P501: Dispose of contents to a hazardous waste disposal service in accordance with the statutory regulations. |
| P501: Dispose of container to a hazardous waste disposal service in accordance with the statutory regulations. |

4. AUTHORISED USE(S) OF THE META SPC

4.1. Use description

Use 3.1 Preservatives for liquid-cooling and processing systems (Preservatives)

Table 1

| Product type | PT11: Preservatives for liquid-cooling and processing systems | | | | |
|--|---|--|--|--|--|
| Where relevant, an exact description of the authorised use | - | | | | |
| Target organism(s) (including development stage) | Scientific name: no data Common name: bacteria Development stage: no data Scientific name: no data Common name: yeasts Development stage: no data | | | | |

| | Scientific name: no data Common name: fungi Development stage: no data | | | | |
|-----------------------------------|--|--|--|--|--|
| | Scientific name: no data Common name: algae Development stage: no data | | | | |
| | Scientific name: no data Common name: Legionella pneumophila Development stage: no data | | | | |
| | Scientific name: no data Common name: biofilm Development stage: no data | | | | |
| Field(s) of use | indoor use outdoor use | | | | |
| | Preservation of fluids in cooling systems with discharge to the municipal sewer in: Open recirculating cooling systems, Closed cooling system. Preservation of processing liquids in: Pasteurizers and sterilizers, Air washers and scrubbers. | | | | |
| Application method(s) | Method: closed system Detailed description: Feed the product via a closed feed system. Product applied via automated process with use of pumps or injection. Product can be added whilst the process is in operation. | | | | |
| Application rate(s) and frequency | Application rate: Maintenance: Bacteria 34-69 ppm product (1,5-3 mg as/l (active substance per liter)) Legionella 17-69 ppm product (0,75-3 mg as/l) Biofilm 69 ppm product (3 mg as/l) Curative: Bacteria 137 ppm product 6 hours contact time (6 mg as/l) Legionella 33-137 ppm product 6 hours contact time (1,5-6 mg as/l) Yeast and fungi 69-137 ppm product 6 hours contact time (3-6 mg as/l) Algae 33-137 ppm product 6 hours contact time (1,5-6 mg as/l) - Number and timing of application: Maintenance frequency: once per day to once per week. Curative: this may be implemented when control is lost or when monitoring data suggests that curative implementation is required, | | | | |
| | however this should not be more than once every two months in cases of heavy fouling. | | | | |
| Category(ies) of users | industrial; professional | | | | |
| Pack sizes and packaging material | 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene IBCs | | | | |
| | | | | | |

4.1.1. Use-specific instructions

The product should be slug-fed to recirculating cooling and process water in such a way to achieve maximum dispersion and exposure to the areas of the system with the highest level of microorganisms.

The product should be added to the system according to the size of the system, for example to achieve a 100 ppm concentration in a 10 000 liter system 1 000 ml (1 liter) of product will need to be added.

The interval between two doses depends on the system's hydraulic retention time and removal of the active substance by degradation and blow-down. The product may accumulate in preserved fluids when dosed too often. It is the responsibility of the end-user to determine the effective dose on-site (e.g. by chemical or microbiological tests) for the specific location/system to ensure that the system is efficacious under the use conditions. If needed, consult the authorisation holder (as specified in the label).

4.1.2. Use-specific risk mitigation measures

Wear compatible Personal Protective Equipment:

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the authorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection according to the European Standard EN ISO166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

The use is restricted to small cooling systems with a maximum blowdown of 2 m³/h. Waste water must be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.

The product can only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99%.

4.1.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the general direction for use

4.1.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use

4.1.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use

4.2. Use description

Table 2

Use 3.2 Slimicide in the pulp and paper industry (Preservatives)

| Product type | PT12: Slimicides |
|--|---|
| Where relevant, an exact description of the authorised use | - |
| Target organism(s) (including development stage) | Scientific name: no data Common name: bacteria Development stage: no data |

| | Scientific name: no data Common name: yeasts Development stage: no data | | | | |
|-----------------------------------|--|--|--|--|--|
| | Scientific name: no data Common name: fungi Development stage: no data | | | | |
| | Scientific name: no data Common name: biofilm Development stage: no data | | | | |
| Field(s) of use | indoor use | | | | |
| | For use as a slimicide in the pulp and paper industry, de-inking process, wet end / white water, pulp including during machine shutdown. Thick stock (including broke, blend, machine chests as well as the recycled pulp). White water, cloudy water and clear water. Thin stock. Control of Microbiologically Induced Corrosion (MIC) and biofouling of deaerators and filters. Control of slime growth in additives specifically intended to be used in the paper production process. | | | | |
| Application method(s) | Method: closed system | | | | |
| | Detailed description: Feed the product via a closed feed system. Product applied via automated process with use of pumps or injection. Product can be added whilst the process is in operation. | | | | |
| Application rate(s) and frequency | Application rate: Additives used in paper production Maintenance: Bacteria 17-137 ppm product (0,75-6 mg as/l (active substance per liter)) Yeast 34-137 ppm product (1,5-6 mg as/l) Curative: Bacteria 17-137 ppm product 24 hours contact time (0,75-6 mg as/l) Yeast and fungi 68-137 ppm product 6 hours contact time (3-6 mg as/l) Paper machine system (including wet end, white water and pulp) Maintenance: Bacteria and yeast 9-137 ppm product (0,38-6 mg as/l) Biofilm 69-137 ppm product (3-6 mg as/l) Curative: Bacteria 69-137 ppm product 24 hours contact time (3-6 mg as/l) Yeast 9-137 ppm product 24 hours contact time (0,38-6 mg as/l) Fungi 137 ppm product 6 hours contact time (6 mg as/l) - | | | | |
| | Number and timing of application: For pulp and paper industry, feed on an intermittent (slug) basis: Additives used in paper production and Paper machine system (including wet end, white water and pulp) Maintenance frequency: four times daily to once per week. Curative: In cases of heavy fouling this may be implemented when control is lost or when monitoring data suggests that curative implementation is required, however this should not be more than once every two months. | | | | |

| Category(ies) of users | industrial; professional |
|-----------------------------------|---|
| Pack sizes and packaging material | 20-100 kg opaque polyethylene pails 50-500 kg opaque polyethylene drums 1 000-2 000 kg opaque polyethylene IBCs |

4.2.1. Use-specific instructions

Feed the product on an intermittent basis to provide preservation of acceptable (low level) microbial counts in the paper machine system. Feed the product in the wet-end intermittently in the machine chest or similar stock chest or to additives used in paper production. Alone, it should never be used in the short loop but back in the system.

The dose strongly depends on the formulation and intended use of the matrix to which the preservative is added. The interval between two doses also depends on the system's hydraulic retention time and removal of the active substance by e.g. degradation and dilution. The product may accumulate in processing fluids when dosed too often. It is the responsibility of the end-user to determine the effective dose on-site (e.g. by chemical or microbiological tests) for the specific location/system to ensure that the system is efficacious under the use conditions. If needed, consult the authorisation holder (as specified in the label).

The product should be added based on the volume of the system, for example to achieve a 100 ppm concentration in a 10 000 liter system 1 000 ml (1 liter) of product will need to be added.

4.2.2. Use-specific risk mitigation measures

Human Health:

Wear compatible Personal Protective Equipment (PPE)

Wear protective chemical resistant gloves meeting the requirements of European Standard EN ISO 374 or equivalent during product handling phase (glove material to be specified by the uthorisation holder within the product information).

Wear a protective coverall type 6, consistent with the European Standard EN 13034 or equivalent.

The use of eye protection according to the European Standard EN ISO 166 or equivalent during handling of the product is mandatory.

This is without prejudice to the application of Council Directive 98/24/EC and other Union legislation in the area of health and safety at work. See section 6 for the full references to this act and the European Standards.

Environment:

Application is only allowed in paper factories that comply to the Industrial Emission directive 2010/75/EU where wastewater is purified in an on-site industrial sewage treatment plant including a biological treatment step in accordance with the Best Available Techniques (BAT) as prescribed in the BAT reference document (BREF) for the production of pulp, paper and board, the effluent must be diluted at least 200 times. Paper factories that are exempted from the Industrial Emission Directive must discharge to the municipal sewer.

4.2.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to the General directions for use.

4.2.4. Where specific to the use, the instructions for safe disposal of the product and its packaging

Please refer to the general directions for use.

4.2.5. Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

Please refer to the general directions for use.

5. GENERAL DIRECTIONS FOR USE OF THE META SPC 3

5.1. **Instructions for use**

Resistance management procedures shall be adopted in use as follows:

- products shall always be used in accordance with label recommendations
- elimination of microbial growth shall be attempted by using application rates demonstrated to be efficacious
- levels of effectiveness shall be monitored and instances of reduced effectiveness shall be investigated for possible evidence of resistance.

In commercial use, CMIT/MIT is often used in combination or rotation with other biocides in various applications. Microbial resistance to CMIT/MIT can be avoided by switching or alternating biocides or using combinations with other actives.

All workers and individuals handling the product shall be trained, have access to the Safety Data Sheets (SDS) and Technical Data Sheets (TDS).

5.2. Risk mitigation measures

Refer to use-specific risk mitigation measures

Organisational risk management measures:

- Loading should be restricted to automated processes.
- Workers involved in performing repairs or cleaning activities should rinse the system before opening and cleaning.
- Eye wash station and safety shower are necessary.

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Refer to Sections 4.1.3 and 4.2.3 'Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment'.

Protection of first-aiders: Wear adequate personal protective equipment.

First aid instructions:

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. If symptoms: Call 112/ambulance for medical assistance. If no symptoms: Call a POISON CENTRE or a doctor. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance. Information to Healthcare personnel/doctor: Initiate life support measures if needed, thereafter call a POISON CENTRE.

IF ON SKIN: Immediately wash skin with plenty of water. Thereafter take off all contaminated clothing and wash it before reuse. Continue to wash the skin with water for 15 minutes. Call a POISON CENTRE or a doctor. If skin irritation or rash occur: Get medical advice.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Call 112/ambulance for medical assistance.

Environmental precautions:

In the event of a spill, prevent material from entering sewers or waterways. Do not allow material to contaminate ground water system. Prevent product from entering drains. If drains, streams, soil or sewers become contaminated, notify local authority. Spilled product may pose a risk to the aquatic ecosystem if released.

Methods and materials for containment and cleaning up:

SMALL SPILLS: Dike and absorb with inert material (e.g. dry earth, sand), shovel all contaminated solids into a pail or drum and then treat with enough deactivation solution to wet the solids thoroughly. Let these containers stand open for 48 hours to prevent pressure build up and then seal for disposal. Equipment containing residues should be decontaminated before carrying out maintenance or repair work or using for other service. Contaminated surfaces should be swabbed with deactivation solution, wait for the reaction to subside and rinse thoroughly with clean water.

LARGE SPILLS: Soak up with inert absorbent material. Transfer contaminated material to suitable containers for disposal. Contaminated surfaces should be swabbed with deactivation solution, let stand for 30 minutes and rinse thoroughly with clean water.

DO NOT add deactivation solution to the waste container to deactivate the absorbed material.

* DEACTIVATION SOLUTION - prepare fresh a solution of 5% Sodium bicarbonate and 5% Sodium hypochlorite in water. Use a ratio of 10 volumes decontamination solution per estimated volume of residual spill. Contact an approved waste hauler for disposal of contaminated recovered material. Dispose of material in compliance with regulations indicated in Safety Data Sheet.

5.4. Instructions for safe disposal of the product and its packaging

Dispose of in accordance with the European Directives on waste and hazardous waste. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

The product must not be released to soil, water courses or any kind of sewer. Where possible recycling is preferred to disposal. If recycling is not practicable, dispose of in compliance with local regulations. Dispose of wastes in an approved waste disposal facility.

Contaminated packaging: Dispose of as unused product. Empty containers should be taken to an approved waste handling site. Do not re-use empty containers.

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

Shelf life: 24 months.

Do not store above ambient storage temperature (25°C).

Keep container tightly closed. Store in suitable labelled containers.

6. **OTHER INFORMATION**

The full titles of the EN standards referenced in sections "Use-specific risk mitigation measures" are:

EN ISO 374 - Protective gloves against dangerous chemicals and micro-organisms

EN ISO 166 - Personal eye protection standard

EN 13034 - Protective clothing against liquid chemicals - Performance requirements for chemical protective clothing offering limited protective performance against liquid chemicals (Type 6 and Type PB equipment)

Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

With respect to the "Category (ies) of users" note: "Professionals (including industrial users)" means trained professionals if this is required by national legislation.

7. THIRD INFORMATION LEVEL: INDIVIDUAL PRODUCTS IN THE META SPC 3

7.1. Trade name(s), authorisation number and specific composition of each individual product

| Trade name(s) | | NALCO® BACTO- LYSE 74824 | | Market area: EU | | | |
|----------------------|---|--------------------------------|---------------------|-----------------|--------|-----------|--------------|
| | | NALCO® 74824 | | Market area: EU | | | |
| Authorisation number | | | EU-0032881-0004 1-3 | | | | |
| Common name | IUPAC name | Function | | CAS number | | EC number | Content (%) |
| C(M)IT/MIT (3:1) | Reaction mass of 5-chloro- 2-methyl-2h- isothiazol-3-one and 2-methyl- 2h-isothiazol- 3-one (3:1) | active substance | | 5596 | 5-84-9 | | 7,51 % (w/w) |