2025/807

29.4.2025

COMMISSION IMPLEMENTING REGULATION (EU) 2025/807

of 28 April 2025

granting a Union authorisation for the single biocidal product 'C(M)IT/MIT & Glutaraldehyde Formulations' in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Official Journal

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 1 February 2020, Solenis Switzerland 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 single biocidal product named 'C(M)IT/MIT & Glutaraldehyde Formulations' of product-types 6, 11 and 12 as described in Annex V to that Regulation, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-JP057170-35 in the Register for Biocidal Products.
- (2) 'C(M)IT/MIT & Glutaraldehyde Formulations' contains C(M)IT/MIT (3:1) and glutaraldehyde as active substances, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-types 6, 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 27 June 2024, the Agency submitted to the Commission its opinion (²), the draft summary of the biocidal product characteristics ('SPC') of 'C(M)IT/MIT & Glutaraldehyde Formulations' and the final assessment report on the single biocidal product, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'C(M)IT/MIT & Glutaraldehyde Formulations' is a single biocidal product within the meaning of Article 3(1), point (r), 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(1) of that Regulation.
- (6) The active substance glutaraldehyde meets the criteria for classification as a substance that can lead to respiratory sensitisation as defined in section 3.4.1.1 of Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council (³). Therefore, that active substance meets the conditions for being considered a candidate for substitution in accordance with Article 10(1), point (b), of Regulation (EU) No 528/2012 and the evaluating competent authority performed a comparative assessment of the biocidal product in accordance with Article 23(1) of that Regulation. In the comparative assessment no alternative could be identified as the chemical diversity was considered insufficient to substitute 'C(M)IT/MIT & Glutaraldehyde Formulations'. Therefore, the biocidal product should be authorised for a period not exceeding 5 years in accordance with Article 23(6) of Regulation (EU) No 528/2012.

⁽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 'C(M)IT/MIT & Glutaraldehyde Formulations' (ECHA/BPC/435/2024), https://echa.europa.eu/opinions-on-union-authorisation.

⁽³⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(7) On 16 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.

- (8) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for the single biocidal product 'C(M)IT/MIT & Glutaraldehyde Formulations' for 5 years.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0032888-0000 is hereby granted to Solenis Switzerland GmbH for the making available on the market and use of the single biocidal product 'C(M)IT/MIT & Glutaraldehyde Formulations' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 19 May 2025 until 30 April 2030.

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, 28 April 2025.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT

C(M)IT/MIT & Glutaraldehyde Formulations

Product type(s)

PT06: Preservatives for products during storage

PT11: Preservatives for liquid-cooling and processing systems

PT12: Slimicides

Authorisation number: EU-0032888-0000

R4BP asset number: EU-0032888-0000

1. ADMINISTRATIVE INFORMATION

1.1. Trade name(s) of the product

Trade name(s)	Spectrum™ RX7848 MICROBIOCIDE Biosperse™ CN7848 MICROBIOCIDE
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1.2. Authorisation holder

Name and address of the authorisation holder	Name	Solenis Switzerland GmbH
	Address	Mühlentalstrasse 38 8200 Schaffhausen CH
Authorisation number		EU-0032888-0000
R4BP asset number		EU-0032888-0000
Date of the authorisation		19 May 2025
Expiry date of the authorisation		30 April 2030

1.3. Manufacturer(s) of the product

Solenis Technologies Deutschland GmbH
Fütingsweg 20 D-47805 Krefeld Germany
Solenis Technologies Deutschland GmbH site 1 Fütingsweg 20 D-47805 Krefeld Germany

Name of manufacturer	AD International B.V.
Address of manufacturer	Markweg Zuid 27 4794 SN Heijningen P.O. Box 102 4793 Fijnaart Netherlands (the)
Location of manufacturing sites	AD International B.V. Markweg Zuid 27 4794 SN Heijningen P.O. Box 102 4793 Fijnaart Netherlands (the)

Name of manufacturer	Solenis UK Ltd.
Address of manufacturer	Wimsey Way DE55 4LR Somercotes, Alfreton, Derbyshire United Kingdom of Great Britain and Northern Ireland (the)
Location of manufacturing sites	Solenis UK Ltd. Wimsey Way DE55 4LR Somercotes, Alfreton, Derbyshire United Kingdom of Great Britain and Northern Ireland (the)

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

Active substance	Glutaraldehyde
Name of manufacturer	MC (US) 3 LLC
Address of manufacturer	Route 25, Institute 25112 West Virginia United States (the)
Location of manufacturing sites	MC (US) 3 LLC Route 25, Institute 25112 West Virginia United States (the)
Active substance	Glutaraldehyde
Name of manufacturer	BASF SE
Address of manufacturer	Carl-Bosch Str. 38 67056 Ludwigshafen Germany
Location of manufacturing sites	BASF SE Carl-Bosch Str. 38 67056 Ludwigshafen Germany
Active substance	CMIT/MIT (3:1)
Name of manufacturer	Jiangsu FOPIA Chemicals Co., Ltd
Address of manufacturer	224555, Touzeng Village, Binhuai Town, Binhai County - Yancheng City, Jiangsu China
Location of manufacturing sites	Jiangsu FOPIA Chemicals Co., Ltd 224555, Touzeng Village, Binhuai Town, Binhai County- Yancheng City, Jiangsu China
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Active substance	CMIT/MIT (3:1)
Name of manufacturer	Thor GmbH
Address of manufacturer	Landwehrstraße 1 67346 Speyer Germany
Location of manufacturing sites	Thor GmbH Landwehrstraβe 1 67346 Speyer Germany
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Active substance	CMIT/MIT (3:1)
Name of manufacturer	Dalian Xingyuan Chemistry Co., Ltd

Address of manufacturer	Room 1205/1206, Pearl River International Building, No.99, Xinkai Road, Xigang District 116011 Dalian China
Location of manufacturing sites	Dalian Xingyuan Chemistry Co., Ltd Songmudao Chemical Industry Zone, Puwan New District 116308 Dalian, Liaoning China
Active substance	CMIT/MIT (3:1)
Name of manufacturer	Weifang Heaven-sent New Materials Technology Co., Ltd
Address of manufacturer	Binhai Road, Changyi Coastal Economic Development Zone 261312 Weifang, Shandong China
Location of manufacturing sites	Weifang Heaven-sent New Materials Technology Co., Ltd Binhai Road, Changyi Coastal Economic Development Zone 261312 Weifang, Shandong China
Active substance	CMIT/MIT (3:1)
Name of manufacturer	Dalian Bio-Chem Company Limited
Address of manufacturer	Songmudao Plant: Songmudao Chemical Industry Zone, Puwan New District 116308 Liaoning China
Location of manufacturing sites	Dalian Bio-Chem Company Limited Songmudao Plant: Songmudao Chemical Industry Zone, Puwan New District 116308 Liaoning China

2. PRODUCT COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Glutaraldehyde		active substance	111-30-8	203-856-5	7,8 % (w/w)
CMIT/MIT (3:1)		active substance	55965-84-9		2,89 % (w/w)

2.2. Type(s) of formulation

AL Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS

Hazard statements	H302: Harmful if swallowed.
	H314: Causes severe skin burns and eye damage.
	H317: May cause an allergic skin reaction.
	H332: Harmful if inhaled.
	H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
	H410: Very toxic to aquatic life with long lasting effects.
	EUH071: Corrosive to the respiratory tract.
Precautionary statements	P260: Do not breathe vapours.
	P260: Do not breathe spray.
	P501: Dispose of container to a hazardous waste disposal service in accordance with the statutory regulations.
	P264: Wash hands thoroughly after handling.
	P270: Do not eat, drink or smoke when using this product.
	P284: [In case of inadequate ventilation] wear respiratory protection.
	P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
	P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER/doctor.
	P391: Collect spillage.
	P501: Dispose of contents to a hazardous waste disposal service in accordance with the statutory regulations.
	P271: Use only outdoors or in a well-ventilated area.
	P272: Contaminated work clothing should not be allowed out of the workplace.
	P280: Wear protective gloves.
	P280: Wear protective clothing.
	P280: Wear eye protection.
	P273: Avoid release to the environment.
	P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
	P301+P330+P331: IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
	P403: Store in a well-ventilated place.
	P405: Store locked up.
	P333+P313: If skin irritation or rash occurs: Get medical attention.

P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P362+P364: Take off contaminated clothing and wash it before reuse.
P310: Immediately call a POISON CENTER.
P310: Immediately call a doctor.

4. **AUTHORISED USE(S)**

4.1. Use description

Table 1

Preservation of diluted wet-end fluids (mineral slurries, paper wet-end additives and paper coatings additives) and white water during storage

Product type	PT06: Preservatives for products during storage
Where relevant, an exact description of the authorised use	
Target organism(s) (including development stage)	Scientific name: Common name: - bacteria Development stage: Scientific name:
	Common name: yeast Development stage:
Field(s) of use	indoor use outdoor use
	Intended for the control the growth of yeast and bacteria in diluted wet-end additives (mineral slurries, paper wet-end additives and paper coatings additives) and white-water (short circulation) during storage (short-term preservation up to 21 to 35 days) e.g. during paper machine shutdown, transportation between facilities. Not intended to preserve during the ongoing paper process.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dosed to the additive or coating at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: bacteria : 25-300 mg/l of product, yeast: 50-300 mg/l of product
	Number and timing of application: The biocidal product shall be added as a single dose into the storage tank, once per day.
Category(ies) of users	industrial

	High-density polyethylene (HDPE) 25 l pail, 220 l drum, 1000 l container, bulk
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4.1.1. Use-specific instructions

- Consult the authorisation holder (as specified in the contact details on the label) to determine the optimal
 dosage for the various products to be preserved.
- The duration and storage conditions of the preserved matrices may impact the efficacy of the product. Microbiological tests shall be conducted to determine the appropriate application rate without exceeding the maximum authorised application rate.

4.1.2. Use-specific risk mitigation measures

- Use a respiratory protective equipment (RPE) in accordance with the European Standards EN 140 or EN 136 and EN 14387 or equivalent providing a minimum protection factor of 10 while loading and unloading slurry tanks if slurries/fluids or wet-end additives are not pumped in automatic procedures.
- At least a powered air purifying respirator with helmet/hood/mask (TH1/TM1), or a half/full mask with combination filter gas/P2 is required (filter type (code letter, colour) shall be specified by the authorisation holder within the product information). 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.
- Minimize the manual phase during the loading and unloading slurry tanks.
- Rinse with water before the cleaning of the dispensing pump used to add the product into product to be preserved.

For the preservation of white waters in paper production:

- The product shall be used only for the treatment of white waters (short-circulation).
- Application is only allowed in paper factories that comply with Directive 2010/75/EU of the European Parliament and of the Council where waste water 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 shall be diluted at least 200 times.
- Paper factories that are exempted from Directive 2010/75/EU shall discharge their waste water to the municipal sewer.
- 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

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.2. Use description

Table 2
Preservation of water used in closed recirculating cooling systems

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: Common name: - cyanobacteria Development stage:
	Scientific name: Common name: green algae Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of water used in closed recirculating cooling systems to control the growth of green algae, cyanobacteria and anaerobic bacteria. The biocidal product inhibits the growth of microorganisms.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dosed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
	Number and timing of application: The biocidal product may only be added up to 7 times per week via automated or manual dosing.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.2.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.2.2. Use-specific risk mitigation measures

 Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.

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

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.3. Use description

Table 3

Preservation of water used in open recirculating cooling systems

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: Common name: - green algae Development stage:
	Scientific name: Common name: cyanobacteria Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of water used in open recirculating cooling systems to control the growth of green algae, cyanobacteria and anaerobic bacteria. The biocidal product inhibits the growth of microorganisms.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dosed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
	Number and timing of application: The biocidal product may only be added up to 7 times per week via automated or manual dosing.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.3.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.3.2. Use-specific risk mitigation measures

- Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.
- The product may only be applied when the cooling towers are equipped with drift eliminators that reduce drift with at least 99 %.
- The use is restricted to small cooling systems with a maximum blowdown of 2 m³/h.
- Waste water shall be discharged to the municipal sewer or purified in an on-site industrial sewage treatment plant including a biological treatment step.
- 4.3.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.4. Use description

Table 4

Preservation of water used in pasteurisers, conveyor belts and air washers

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: Common name: - green algae Development stage:
	Scientific name: Common name: - cyanobacteria Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of water used in pasteurisers, conveyor belts and air washers. The biocidal product is applied to control the growth of green algae, cyanobacteria and anaerobic bacteria in pasteurisers, conveyor belts and air washers. The biocidal product inhibits the growth of microorganisms.

Method: closed system
Detailed description: The biocidal product shall be dosed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
Number and timing of application: The biocidal product may only be added once per batch or up to 7 times per week via automated or manual dosing depending on the system being treated.
industrial
HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.4.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.4.2. Use-specific risk mitigation measures

- Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.
- 4.4.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.5. Use description

Table 5

Preservation of recirculating water used in Textile and fiber processing, photoprocessing and fountain solution

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: Common name: - green algae Development stage:
	Scientific name: Common name: - cyanobacteria Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of recirculating water used in textile and fibre processing, photo-processing and fountain solution systems to control the growth of green algae, cyanobacteria and anaerobic bacteria. The biocidal product inhibits the growth of microorganisms.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dispensed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
	Number and timing of application: The biocidal product may only be added once per batch or up to 7 times per week via automated or manual dosing depending on the system being treated.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.5.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.5.2. Use-specific risk mitigation measures

- Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.
- 4.5.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.6. Use description

Table 6

Preservation of re-circulating water used in Paint spray booths and electrodeposition coating systems

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: Common name: - green algae Development stage:
	Scientific name: Common name: - cyanobacteria Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of re-circulating water used in Paint spray booths and electrodeposition coating systems to control the growth of green algae, cyanobacteria and anaerobic bacteria. The biocidal product inhibits the growth of microorganisms.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dispensed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
	Number and timing of application: The biocidal product may only be added once per batch or up to 7 times per week via automated or manual dosing depending on the system being treated.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.6.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.6.2. Use-specific risk mitigation measures

See Section 5.2.

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

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.7. Use description

Table 7

Preservation of recirculating water in heating systems

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: Common name: - green algae Development stage:
	Scientific name: Common name: - cyanobacteria Development stage:
	Scientific name: Common name: - anaerobic bacteria Development stage:
Field(s) of use	indoor use outdoor use
	Preservation of recirculating water in heating systems to control the growth of green algae, cyanobacteria and anaerobic bacteria in recirculating water in heating systems. The biocidal product inhibits the growth of microorganisms.
Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dispensed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.

Application rate(s) and frequency	Application rate: green algae and cyanobacteria: 5-200 mg/l of product, anaerobic bacteria: 25-200 mg/l of product
	Number and timing of application: The biocidal product may only be added once per batch or up to 7 times per week via automated or manual dosing depending on the system being treated.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.7.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.7.2. Use-specific risk mitigation measures

- Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.
- 4.7.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

4.8. Use description

 $\label{eq:Table 8}$ Slimicide treatment in the wet end stage of the pulp and paper manufacturing process

Product type	PT12: Slimicides
Target organism(s) (including development stage)	Scientific name: Common name: - bacteria Development stage:
Field(s) of use	indoor use outdoor use
	The biocidal product is applied as a slimicide treatment in the wet-end stage of the pulp and paper manufacturing process to prevent the growth of slime. The biocidal product inhibits the growth of microorganisms.

Application method(s)	Method: closed system
	Detailed description: The biocidal product shall be dispensed at a point to ensure adequate mixing using preferably automated metering pump or by manual addition.
Application rate(s) and frequency	Application rate: 5-40 mg/l of product Number and timing of application: The biocidal product may only be added 4-12 times per day via automated or manual dosing.
Category(ies) of users	industrial
Pack sizes and packaging material	HDPE 25 l pail, 220 l drum, 1000 l container, bulk

4.8.1. Use-specific instructions

— Microbiological tests to prove adequacy of preservation shall be undertaken by the user in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the authorisation holder (as specified in the contact details on the label) to determine the optimal dosage for the various products to be preserved.

4.8.2. Use-specific risk mitigation measures

- Rinse with water before the cleaning of the dispensing pump used to add the biocidal product into liquid to be preserved.
- Application is only allowed in paper factories that comply with Directive 2010/75/EU, where waste water 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 shall be diluted at least 200 times.
- Paper factories that are exempted from Directive 2010/75/EU shall discharge their waste water to the municipal sewer.
- 4.8.3. Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See Section 5.3.

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

See Section 5.4.

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

See Section 5.5.

5. **GENERAL DIRECTIONS FOR USE** (1)

5.1. **Instructions for use**

— Inform the authorisation holder if the treatment is ineffective.

5.2. Risk mitigation measures

- Wear protective chemical resistant gloves in accordance with the European Standard EN 374 or equivalent (glove material shall be specified by the authorisation holder within the product information) during product handling phase.
- Wear a protective coverall (type 3 or 4) in accordance with the European Standard EN 14605 or equivalent (coverall material shall be specified by the authorisation holder within the product information) during product handling phase.
- Use eye protection in accordance with the European Standard EN 166 or equivalent during product handling phase.
- Use a respiratory protection equipment in accordance with the European Standard EN 140 or EN 136 and European Standard EN 14387 or equivalent providing a minimum protection factor of 10 during product handling phase. At least a powered air purifying respirator with helmet, hood or mask (TH1/TM1), or a half or full mask with combination filter gas/P2 is required (filter type (code letter, colour) shall be specified by the authorisation holder within the product information).
- Minimize the manual phase during the handling of the product.

This is without prejudice to the application of Directive 98/24/EC and other Union legislation in the area of health and safety at work.

See section 6 for the full references.

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

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 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 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.

IF SWALLOWED: Immediately rinse mouth. Give something to drink to exposed person if that person is able to swallow.

Do NOT induce vomiting. Call 112/ambulance for medical assistance.

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

- Do not discharge unused product on the ground, into water courses, into pipes (e.g. sink, toilets) nor down the
 drains.
- Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

⁽¹⁾ Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses.

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

- The shelf-life of the biocidal product is 12 months.
- Protect from frost
- Do not store at a temperature above 30 °C
- Protect against light

6. **OTHER INFORMATION**

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

Full titles of quoted legislation

Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)

Commission Implementing Decision of 26 September 2014 establishing the best available techniques (BAT) conclusions, under Directive 2010/75/EU of the European Parliament and of the Council, for the production of pulp, paper and board (2014/687/EU)

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)

Full titles of European Standards

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

EN 14605 - Protective clothing against liquid chemicals

EN 166 - Personal eye-protection

EN 136 - Respiratory protective devices - Full face masks

EN 140 - Respiratory protective devices - Half masks and quarter masks

EN 14387 - Respiratory protective devices - Gas filter(s) and combined filter(s) - Requirements, testing, marking

ELI: http://data.europa.eu/eli/reg_impl/2025/807/oj