

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family

C(M)IT/MIT AQUEOUS 1.5-15

ECHA/BPC/273/2020

Adopted

3 December 2020

Opinion of the Biocidal Products Committee

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C(M)IT/MIT AQUEOUS 1.5-15

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product family: C(M)IT/MIT AQUEOUS 1.5-15

Authorisation holder: Nutrition & Biosciences Netherlands B.V.

Active substance common name: C(M)IT/MIT (3:1)

Product type(s): 2, 4, 6, 11, 12 and 13

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 21 June 2017, recorded in R4BP3 under case number BC-CY032700-28, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 31 March 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-37) and its Working Groups (WG III 2020). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: France

The BPC opinion on the Union authorisation of the biocidal product/biocidal product family was reached on 3 December 2020.

The BPC opinion was adopted by simple majority of the members present having the right to vote. The opinion, the minority position including their grounds are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The biocidal product family is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012 and falls within the scope of the Regulation (EU) No 528/2012 as defined in Article 3(s).

The biocidal product family meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of C(M)IT/MIT AQUEOUS 1.5-15 referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

The sections below are a concise summary of the evaluation and conclusions of the assessment of the biocidal product family.

General

The products of the biocidal family C(M)IT/MIT AQUEOUS 1.5-15 consist of products containing 1.5 to 15 % of the pure active substance reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) (C(M)IT/MIT) (CAS number 55965-84-9). According to the specifications of the active substance sources claimed, the maximum content of active substance cannot exceed 14.5%.

Biocidal product family (BPF) C(M)IT/MIT AQUEOUS 1.5-15 is applied to prevent or control growth of microorganisms (bacteria, fungi, yeasts and algae) depending of the uses, for industrial use only by trained professional users. The articles treated by the BPF C(M)IT/MIT AQUEOUS 1.5-15 could then be used by professional, non professional users and general public depending on the PTs.

The BPF does not contain any non-active substance (so called "co-formulant") which is considered as a substance of concern. The BPF should be considered not to have endocrine-disrupting properties. More information is available in section 2.1.2.7 of the PAR and in the confidential annex.

The biocidal product family is composed of 4 Meta SPCs: Meta SPC 1 (KATHON 13-15 Mg), Meta SPC 2 (KATHON 13-15 Na), Meta SPC 3 (KATHON 1.5-4.5 Mg) and Meta SPC 4 (1.5-3.5 Na). 28 Uses are claimed.

The biocidal product family C(M)IT/MIT AQUEOUS 1.5-15 is claimed to be used for:

PTs	Claimed uses	Concerned META SPC	
2	Use # 1 – Preservation of sump water in air conditioning and air washer systems.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
4	Use # 2 – Preservation of fluids in conveyor belts and pasteurisers.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 3 – Long term offline preservation of reverse osmosis membranes used in potable water.		
6	Use # 4 – Preservation of paints and coatings	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 5 – Preservation of detergents and household products.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg	
	Use # 6 – Preservation of fluids used in paper, textile and leather production.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 7 – Preservation of glues and adhesives.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 8 – Preservation of polymer lattices.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 9 – Preservation of biocides and fertilizers	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg	
	Use # 10 – Preservation of mineral slurries.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 11 – Preservation of building products.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 12 – Preservation of electronic chemicals.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg	
	Use # 13 – Preservation of inks.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 14 – Preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc.) - excluding fuel additives	Meta-SPC1 KATHON 13-15 Mg Meta-SPC2 KATHON 13-15 Na Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 15 – Preservation of laboratory reagents.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	Use # 16 – Offline preservation of industrial reverse osmosis membranes.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na	
	11	Use # 17 – Preservation of liquids used in closed recirculating cooling system.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na
		Use # 18 – Preservation of liquids used in open recirculating cooling systems.	

	Use # 19 – Preservation of liquids used in pasteurizers, conveyor belts and air washers.	
	Use # 20 – Preservation of wood treatment solutions.	
	Use # 21 – Preservation of recirculating fluids used in textile and fiber processing, leather processing, photo-processing and fountain solution systems	
	Use # 22 – Preservation of re-circulating liquids used in paint spray booths and electrodeposition coating systems	
	Use # 23 – Preservation of liquids used in closed recirculating heating systems and associated pipework.	
	Use # 24 – Preservation of polymers used in oilfield processes (e.g. enhanced oil recovery, drilling muds, etc.)	
12	Use # 25 – Slimicide treatment in the de-inking process of the pulp and paper.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg Meta-SPC4 KATHON 1.5-3.5 Na
	Use # 26 – Slimicide treatment in the wet-end stage of the paper manufacturing process.	
	Use # 27 – Preventive treatment (biofouling control) online and after cleaning in place for industrial RO/NF membranes	
13	Use # 28 – Products to control microbial deterioration in fluids used for working or cutting metal, glass or other materials.	Meta-SPC1 KATHON 13-15 Mg Meta-SPC3 KATHON 1.5-4.5 Mg

Physico-chemical properties

All products of the family are of the type “Another Liquid” (AL). All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. In 1% aqueous solution, products within the family have a pH value from 3.4 to 6.6 at 20 °C. For all the products of the BPF, there is no effect of high temperature on the stability of the formulations after 14 days at 54 °C, neither the active ingredient content nor the technical properties of the products were changed.

Therefore, the data provided are sufficient to support the BPF requested. The data provided on accelerated and long-term storage stability studies were sufficient to set a shelf life for all Meta SPC.

Based on the active substance content and content of the co-formulants, each Meta SPC in the biocidal product family is classified as follows:

Meta SPC 1, 2 and 3:

- Met Corr. 1, H290: May be corrosive to metal.

Meta SPC 4: not classified.

Analytical methods for the determination of the active substance in the representative formulations and residues are available and validated. No additional analytical method is required.

Efficacy

The BPF aims to control the following target organisms: bacteria, yeasts, fungi and algae.

The applicant's approach was accepted to consider the different formulations to be equivalent in term of efficacy and, to test the relevant matrices per use with at least one or more representative product(s) per Meta SPC of biocidal product family.

The C(M)IT/MIT AQUEOUS 1.5-15 BPF has been shown to be efficacious for all 4 Meta SPCs. Nevertheless, for some uses, specific target organisms and validated application rates cannot be authorised. More information are detailed in the table of overall conclusions below and in the SPC.

Human health

Based on the active substance and co-formulant contents, each Meta SPC in the biocidal product family is classified as follows:

Meta SPC 1 and 2

- Acute Tox. 4 (oral), H302: Harmful if swallowed.
- Acute Tox. 3 (dermal), H311: Toxic in contact with skin
- Acute Tox. 4 (inhalation), H332: Harmful if inhaled.
- Skin Corr. 1C, H314: Causes severe skin burns and eye damage;
- Skin Sens. 1, H317: May cause an allergic skin reaction;
- Eye Dam. 1, H318: Causes severe eye damage;
- Acute Tox. 4 (inhalation) and Skin Corr. 1C, EUH 071: Corrosive to the respiratory tract.

Meta SPC 3 and 4

- Acute Tox. 4 (oral), H302: Harmful if swallowed;
- Acute Tox. 4 (inhalation), H332: Harmful if inhaled;
- Skin Corr. 1C, H314: Causes severe skin burns and eye damage;
- Skin Sens. 1, H317: May cause an allergic skin reaction;
- Eye Dam. 1, H318: Causes severe eye damage;
- Acute Tox. 4 (inhalation) and Skin Corr. 1C, EUH 071: Corrosive to the respiratory tract.

Risk assessment related to primary exposure for industrial and professional users (all the PT, all uses)

During the handling of the concentrated products, the risk is deemed acceptable for industrial and professional users, considering appropriate PPE and specific RMMs as detailed in the SPC.

Moreover, for PT 2, 4, 11, 12 and 13 : A rinse step is required before the cleaning of the dispensing pumps.

Risk assessment related to indirect secondary exposure for general public for PT 2, 4, 11, 12 and 13

Acceptable levels of risk have been demonstrated for the proposed uses of the biocidal product family.

Risk assessment related to direct and indirect secondary exposure for professional users and general public users of treated articles for PT 6

• For professionnels users of treated articles

- for uses # 4 to 15 but except use # 5, the maximal product concentration used being above the threshold value of 15 ppm, exposure has to be limited by use of PPE protecting skin and mucous membranes potentially exposed, application of technical and organisational RMM as detailed in the SPC.

- for the use # 5 – Preservation of detergents and household products, due to the skin sensitizing properties of the active substance and considering that no personal protective equipment (PPE) can be used to reduce the risk when using detergents; the maximum concentration of C(M)IT/MIT in detergents product must be below the threshold value of 15 ppm C(M)IT/MIT.
 - for use # 4 – Preservation of paints and coatings, due to potential direct dermal contact of by-stander and the skin sensitizing properties of the active substance, a decrease of the maximum concentration contained in paint below the threshold value of 15 ppm C(M)IT/MIT is required to reach an acceptable risk.
- **For general public users of treated articles** for the uses #4, 5, 7 and 13, due to direct dermal contact and considering that no personal protective equipment (PPE) can be used a maximum C(M)IT/MIT concentration below the threshold value of 15 ppm is required in these products to reach an acceptable risk.
 - **For indirect secondary exposure of general public**, acceptable levels of risk have been demonstrated for the proposed PT6 uses of the biocidal product family.

Indirect exposure via food

Due to the complexity of the C(M)IT/MIT AQUEOUS 1.5-15 BPF, the dietary scenarios and derived risk mitigation measures per use are detailed in the PAR and SPC and are not fully repeated here.

For PT 2 (use #1), PT 4 (use #3), PT 6 (uses #11, 12, 14, 15 and 16), PT 11, PT 12 (use #27) and PT 13 (use #28), indirect or direct contact with food or feeding stuffs is not expected and no exposure assessment was performed. For use#3 of PT 4 and use # 20 of PT 11, instruction of use or risk mitigation measures are necessary to prevent indirect exposure via food.

For uses of PT 4 (use #2), PT 6 (uses #4, 5, 6, 7, 8, 9, 10 and 13) and PT 12 (uses #25 and 26), an assessment of indirect exposure via food was performed, when necessary, according to agreements made within the active substance approval assessment of C(M)IT/MIT and to the European guidance¹. Acceptable levels of risk for consumer have been demonstrated for the proposed uses of the biocidal product family considering risk mitigation measures as proposed in the SPC.

Environment

C(M)IT/MIT AQUEOUS 1.5-15 biocidal product family is classified for the environment as:

- Aquatic Acute 1, H400: Very toxic to aquatic life;
- Aquatic Chronic 1, H410: Very toxic to aquatic life with long lasting effects.

The environmental risk assessment for the C(M)IT/MIT AQUEOUS 1.5-15 has followed the agreements made within the active substance approval assessment of C(M)IT/MIT with the application of the new available methods.

Acceptable levels of risk to all environmental compartments have been demonstrated for the proposed uses of the biocidal product family considering specific use conditions and risk mitigation measures as proposed in the table of overall conclusions below and detailed in the SPC.

¹ Guidance on the Biocidal Products Regulation -Volume III Human Health - Assessment & Evaluation (Parts B+C).

Overall conclusions

Uses	Target organisms	User categories	Authorised application rates	Use conditions : risk mitigations measures
Use # 1 – PT 2 Preservation of sump water in air conditioning and air washer systems.	Bacteria (including <i>Legionella pneumophila</i>) Yeasts Fungi	Industrials users	<u>Curative application</u> When the system is noticeably fouled, apply 5 to 14.9 mg C(M)IT/MIT (3:1) per L of water to be treated, as post treatment after a shock dose of a minimum of 0.3 ppm free chlorine.	The CMIT/MIT biocide products are used after a shock dose of free chlorine in this application as standard industry practice. For human health: <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
	Algae		<u>Preventive application:</u> When control is obtained, add a continuous or semi continuous feed of 3 to 5 mg C(M)IT/MIT (3:1) per L of water to be treated.	
Use # 2 – PT 4 Preservation of fluids in conveyor belts and pasteurisers.	Bacteria Yeasts Fungi	Industrials users	<u>Curative application</u> When the system is noticeably fouled, apply 10 to 14.9 g C(M)IT/MIT (3:1) per m ³ of water to be treated, as post treatment after a shock dose of a minimum of 0.3 ppm free chlorine.	The CMIT/MIT biocide products are used after a shock dose of free chlorine in this application as standard industry practice. For human health: <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
	Bacteria		<u>Preventive application:</u> When control is obtained, add a continuous or semi continuous feed of 2.5 to 5 g C(M)IT/MIT (3:1) per m ³ of water to be treated.	

Use # 3 – PT 4 Long term offline preservation of reverse osmosis membranes used in potable water.	Bacteria	Industrials users	7.5 – 20 g C(M)IT/MIT (3:1) /m ³ of water	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the whole system (including the dispensing pumps), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
Use # 4 – PT 6 Preservation of paints and coatings	Bacteria Yeasts	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional and general public users of treated articles:</p> <p>The maximal concentration of products from Meta SPC 1, 2, 3 & 4 to be added in paints and coatings must be below the threshold value of 15 ppm.</p>
		Users of treated articles: professional and general public	7.5 - 14.9 mg/kg C(M)IT/MIT (3:1) in final products	

Use # 5 – PT 6 Preservation of detergents and household products.	Bacteria Yeasts Fungi	Industrials users	1.5 - 14.5% C(M)IT/MIT in concentrated products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional and general public users of treated articles:</p> <p>The maximal concentration of products from Meta SPC 1 and 3 to be added in detergents and household products must be below the threshold value of 15 ppm.</p>
		Users of treated articles: professional and general public	6 - 14.9 mg/kg C(M)IT/MIT (3:1) in final products	
Use # 6 – PT 6 Preservation of fluids used in paper, textile and leather production - Curative treatment.	Bacteria	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of fluids used in paper, textile and leather production being above the threshold value of 15 ppm, exposure has to be limited by use of PPE protecting skin and mucous membranes potentially exposed and application of technical and organisational RMM.</p>
		Users of treated articles: professional	16 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	

Use # 7 – PT 6 Preservation of glues and adhesives.	Bacteria Yeasts	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>For professional users, the maximal products concentration used for the preservation of glues and adhesives being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
		Users of treated articles: professional	8 - 30 mg/kg C(M)IT/MIT (3:1) in final products	
		Users of treated articles: general public	8 - 14.9 mg/kg C(M)IT/MIT (3:1) in final products	
Use # 8 – PT 6 Preservation of polymer lattices.	Bacteria Yeasts Fungi	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of polymer lattices being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
		Users of treated articles: professional	14.9 - 50 mg/kg of C(M)IT/MIT (3:1) in final products	

Use # 9 – PT 6 Preservation of fertilizers and biocides.	Bacteria	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of biocides and fertilizers being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
	Yeasts	Users of treated articles: professional	10 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	
Use # 10 – PT 6 Preservation of mineral slurries.	Bacteria	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of mineral slurries being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and</p>
		Users of treated articles: professional	10 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	

				organisational RMM.
Use # 11 – PT 6 Preservation of building products - applied indoor only	Bacteria Yeasts	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of building products being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p> <p>For environment:</p> <p>The use should be restricted to preservation of building materials applied indoor only.</p>
		Users of treated articles: professional	16.2 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	
Use # 12 – PT 6 Preservation of electronic chemicals. Curative treatment	Bacteria Yeasts Fungi	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.

		Users of treated articles: professional	10 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	<p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of electronic chemicals being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
Use # 13 – PT 6 Preservation of inks.	Bacteria Yeasts	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
		Users of treated articles: professional	6 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	
		Users of treated articles: general public	6 - 14.9 mg/kg of C(M)IT/MIT (3:1) in final products	<p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of inks being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>

Use # 14 – PT 6 Preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc. - excluding fuel additives)	Bacteria	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of functional fluids (hydraulic fluids, antifreeze, corrosion inhibitors, etc.) being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
		Users of treated articles: professional	6 - 30 mg/kg of C(M)IT/MIT (3:1) in final products	
Use # 15 – PT6 Preservation of laboratory reagents.	Bacteria Yeasts	Industrials users	1.5 - 14.5% C(M)IT/MIT in the biocidal products	<p>For industrials users:</p> <ul style="list-style-type: none"> - During the filling of products to be preserved: PPE and specific RMM. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.

		Users of treated articles: professional	15.2 mg/kg of C(M)IT/MIT (3:1) in final products	<p>For professional users of treated articles:</p> <p>The maximal products concentration used for the preservation of laboratory reagents being above the threshold value of 15 ppm, exposure has to be limited by use of PPE, protecting skin and mucous membranes potentially exposed, and application of technical and organisational RMM.</p>
Use # 16 – PT6 Offline preservation of industrial reverse osmosis membranes.	Bacteria	Industrials users	7.5–20 g/m ³ (ppm w/v) of C(M)IT/MIT (3:1)	<p>For industrials users:</p> <ul style="list-style-type: none"> - Rinse the system with water prior to perform the maintenance of the system. - During handling phases (mixing and loading), the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.

Use # 17 – PT11 Preservation of liquids used in closed recirculating cooling system.	Bacteria (including <i>Legionella pneumophila</i>)	Industrials users	<u>Curative treatment:</u> Against bacteria (including <i>L. pneumophila</i>): 5 - 14.9 g C(M)IT/MIT (3:1) / m ³ of water Against biofilm: 14.9 g C(M)IT/MIT (3:1) / m ³ of water <u>Preventive treatment:</u> Against bacteria (including <i>L. pneumophila</i>) at 3 – 14.9 g C(M)IT/MIT (3:1) / m ³ of water Against biofilm (including <i>L. pneumophila</i>): 3 g C(M)IT/MIT (3:1) / m ³ of water	For human health: <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
	Yeasts Fungi		<u>Curative treatment:</u> 1 – 3 g C(M)IT/MIT (3:1) / m ³ of water	
Use # 18 – PT11 Preservation of liquids used in small open recirculating cooling systems.	Bacteria (including <i>Legionella pneumophila</i>)	Industrials users	<u>Curative treatment:</u> Against bacteria (including <i>L. pneumophila</i>): 5 – 14.9 g C(M)IT/MIT (3:1) / m ³ of water Against biofilm (including <i>L. pneumophila</i>) at 1.5 to 14.9 g C(M)IT/MIT (3:1) / m ³ of water <u>Preventive treatment:</u> Against bacteria and biofilm (including <i>L. pneumophila</i>): 3 g C(M)IT/MIT (3:1) / m ³ of water	For human health: <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. For environment: For the small cooling system (blowdown and recirculating flow rates, as well as total volume of water limited to 2 m ³ /h, 100 m ³ /h and 300 m ³ respectively): <ul style="list-style-type: none"> - Cooling fluid must not enter surface water directly. Use product only in premises that are connected to a STP
	Yeasts Fungi		<u>Curative treatment:</u> 1 – 14.9 g C(M)IT/MIT (3:1) / m ³ of water	
	Algae (green algae and		<u>Preventive treatment:</u> 3 g C(M)IT/MIT (3:1) / m ³ of water	

	cyano-bacteria)			- The product can only be used when the cooling towers are equipped with drift eliminators that reduce the drift at least by 99%.
Use # 19 – PT11 Preservation of liquids used in pasteurizers, conveyor belts and air washers.	Bacteria (including <i>Legionella pneumophila</i>)	Industrials users	<u>Curative treatment:</u> Against bacteria: 5 - 14.9 g C(M)IT/MIT (3:1) / m ³ of water Against biofilm (including <i>L. pneumophila</i>) at 1.5 - 14.9 g C(M)IT/MIT (3:1) / m ³ of water	For human health: - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
	Yeasts Fungi		<u>Curative treatment:</u> 1 – 14.9 g C(M)IT/MIT (3:1) / m ³ of water	
	Algae (green algae and cyano-bacteria)		<u>Preventive treatment:</u> 3 g C(M)IT/MIT (3:1) / m ³ of water	
Use # 20 – PT11 Preservation of wood treatment solutions.	Fungi	Industrials users	<u>Preventive treatment:</u> 15 – 50 mg C(M)IT/MIT (3:1) / L of in use wood preservation solution	For human health: - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. - Do not use on wood which may come in direct contact with food, feeding stuff and livestock animals. - Treated wood should not be intended for uses involving contact with food, feed or livestock. For environment: The use of wood treatment solutions preserved by C(M)IT/MIT (3:1) is restricted for the treatment of

				<p>wood in use classes 1, 2 and 3.</p> <p>For the industrial application (including storage), mandatory risk mitigation measures for wood treatment plants should be applied:</p> <ul style="list-style-type: none"> - All industrial application processes must be carried out within a contained area situated on impermeable hard standing with bunding to prevent run-off and a recovery system in place (e.g. sump). - Freshly treated timber must be stored after treatment under shelter or on impermeable hard standing, or both, to prevent direct losses to soil, sewer or water. Any losses of wood treatment solution shall be collected for reuse or disposal. - Application solution and wood treatment solution must be collected and reused or disposed of as hazardous waste. They must not be released to soil, ground- and surface water or any kind of sewer. - To avoid leakage into the soil, store treated objects or materials until completely dried on impermeable ground and under roof.
<p>Use # 21 – PT11 Preservation of recirculating fluids used in textile and fiber processing, leather processing, photo-processing and fountain solution systems.</p>	<p>Bacteria</p>	<p>Industrials users</p>	<p><u>Curative treatment:</u> 16 - 30 mg C(M)IT/MIT / L of fluid</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For environment: RMM are needed to ensure acceptable risks to the environment:</p> <ul style="list-style-type: none"> - Liquids used in textile and fiber processing fluids must not enter surface water directly. Use product only

				<p>in premises that are connected to a STP.</p> <ul style="list-style-type: none"> - Recirculating liquids in photoprocessing systems and fountain solution systems must not enter surface water directly. Use product only in premises that are connected to a STP.
<p>Use # 22 – PT11 Preservation of re-circulating liquids used in paint spray booths and electrodeposition coating systems.</p>	<p>Bacteria Yeasts</p>	<p>Industrials users</p>	<p><u>Preventive treatment:</u> 7.5 - 30 mg C(M)IT/MIT / kg of final product</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
<p>Use # 23 – PT11 Preservation of liquids used in closed recirculating heating systems and associated pipework.</p>	<p>Bacteria (anaerobic and aerobic including <i>L. pneumophila</i>) Fungi Yeasts</p>	<p>Industrials users</p>	<p><u>Curative treatment:</u> Against bacteria (including <i>L. pneumophila</i>) at 5 g C(M)IT/MIT (3:1) / m³ of water Against biofilm at 14.9 g C(M)IT/MIT (3:1) / m³ of water Against fungi and yeasts: 1 g C(M)IT/MIT / m³ of water</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
	<p>Bacteria (anaerobic and aerobic including <i>L. pneumophila</i>)</p>		<p><u>Preventive treatment:</u> Against bacteria at 3 g C(M)IT/MIT (3:1) / m³ of water Against biofilm at 3 g C(M)IT/MIT (3:1) / m³ of water</p>	

<p>Use # 24 – PT11 Preservation of polymers used in oilfield processes (e.g. enhanced oil recovery, drilling muds, etc.)</p>	<p>Bacteria</p>	<p>Industrials users</p>	<p>Polymers used in the injection water: Preventive treatment: Xanthan polymer: 30 - 50 g C(M)IT/MIT/ m³ solution HPAM polymer: 30 - 50 g C(M)IT/MIT/m³ solution</p> <hr/> <p>Polymers used in the drilling muds: Preventive treatment: Xanthan polymer: 30 g C(M)IT/MIT/ m³ solution HPAM polymer: 30 g C(M)IT/MIT/m³ solution</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For environment: The use of treated polymers in drilling muds must be restricted to 30 g/m³ solution.</p>
<p>Use # 25 – PT12 Slimicide treatment in the de-inking process of the pulp and paper.</p>	<p>Bacteria Yeasts Fungi</p>	<p>Industrials users</p>	<p><u>Curative treatment:</u> 10 to 14.9 g C(M)IT/MIT (3:1) / m³ of water to be treated</p> <p><u>Preventive treatment:</u> 5 g C(M)IT/MIT (3:1) / m³ of water to be treated Against biofilm at 5 g C(M)IT/MIT (3:1) / m³ of water</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
<p>Use # 26 – PT12 Slimicide treatment in the wet-end stage of the paper manufacturing process.</p>	<p>Bacteria Yeasts Fungi</p>	<p>Industrials users</p>	<p><u>Curative treatment:</u> 10 to 14.9 g C(M)IT/MIT (3:1) / m³ of water to be treated</p> <p><u>Preventive treatment:</u> 5 g C(M)IT/MIT (3:1) / m³ of water to be treated Against biofilm at 5 g C(M)IT/MIT (3:1) / m³ of water</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For environment:</p>

				<p>The use of C(M)IT/MIT (3:1) containing products for the slimicide treatment in the wet-end stage of the paper manufacturing process is restricted to:</p> <ul style="list-style-type: none"> - curative treatments in plants connected to a slimicide-free water from a pulp mill and only for the treatment of the short circulation of the paper mill; <p>as well as</p> <ul style="list-style-type: none"> - preventive treatments, <p>and, for both cases, only if the factory's waste water is purified in an on-site (full) industrial sewage treatment plant with a minimal capacity of 5000 m³ per day as described in the Industrial Emission Directive 2010/75/EU (Best Available Techniques for the production of pulp, paper and board) and if a dilution of at least 200 times in surface water is achieved after the industrial sewage treatment plant.</p>
Use # 27 – PT12 Preventive treatment (biofouling control) online and after cleaning in place for industrial RO/NF membranes.	Bacteria	Industrials users	<p><u>Preventive treatment:</u> 5 g C(M)IT/MIT / m³ of fluid</p>	<p>For human health:</p> <ul style="list-style-type: none"> - Rinse the system (especially the dispensing pumps) with water prior to perform the cleaning step. - During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM. <p>For environment: Use product only in premises that are connected to a STP.</p>
Use # 28 – PT13 Products to control microbial	Bacteria Yeasts Fungi	Industrials users	<p><u>Curative treatment:</u> 14.9 g C(M)IT/MIT (3:1) per m³ of fluid to be treated</p>	<p>For human health: During handling phases (mixing and loading) and cleaning of the dispensing pumps, the exposure</p>

deterioration in fluids used for working or cutting metal, glass or other materials.			<u>Preventive treatment:</u> 10 g C(M)IT/MIT (3:1) per m ³ of fluid to be treated	concentration being above the threshold value of 15 ppm set for sensitization properties: PPE and application of technical and organisational RMM.
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Use-specific instructions for use of the BPF and use-specific risk mitigation measures are included in SPC of the PAR for each use (2.1.4). General directions for uses and general risk mitigation measures are described in section 2.1.5 of the PAR.

To summarise, taking all information into consideration and noting that:

- physical, chemical and technical properties of the biocidal product family are considered to be acceptable;
- the biocidal product family is efficacious against bacteria, yeasts, fungi, algae, depending on the uses;
- no unacceptable risks related to primary exposure is identified for industrial and professional users with appropriate PPE and specific RMMs;
- no unacceptable risk related to secondary exposure is identified for professional users with appropriate PPE and specific RMMs and for the general public when the end-use concentration of C(M)IT/MIT in the preserved products is below the threshold value of 15 ppm;
- no unacceptable risk via food is identified for consumers with appropriate RMMs;
- no unacceptable risk is identified the environment with appropriate RMMs.

The BPC considers that, using the products belonging to this biocidal product family according to the conditions as stated in the SPC, the products will be efficacious and will not present an unacceptable risk to human and animal health or the environment.

b) Presentation of the biocidal product/biocidal product family including classification and labelling

The description of the biocidal product and of the structure of the family is available in the SPC.

The hazard and precautionary statements of the biocidal product family according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance C(M)IT/MIT contained in the biocidal product family does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product family is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended uses of the biocidal product family have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance in the biocidal product family are met.

The physico-chemical properties of the biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product family is sufficiently effective;
2. the biocidal product family has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product family has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product family has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the uses described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product family

As the conditions of Article 19(1) are met it is proposed that the biocidal product family shall be authorised for the uses described under section 2.1 of this opinion, subject to compliance with the proposed SPC.