

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the biocidal product family:

LANXESS CMIT/MIT biocidal product family

ECHA/BPC/391/2023

Adopted

13 September 2023

Opinion of the Biocidal Products Committee

on the Union authorisation of LANXESS CMIT/MIT biocidal product family

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:	LANXESS CMIT/MIT biocidal product family
Authorisation holder:	Lanxess Deutschland GmbH
Active substance(s) common name:	Mixture of 5-chloro-2-ethyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)
Product types:	PT06, PT11, PT12, PT13

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 22 June 2017, recorded in R4BP3 under case number BC-HA032066-67, 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 8 March 2023. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-48) and its Working Groups (WG-II-2023). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: The Netherlands

The BPC opinion on the Union authorisation of the biocidal product family was reached on 13 September 2023.

The BPC opinion was adopted by simple majority of the members present having the right to vote.

The opinion and the minority position are published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that 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(6) of Regulation (EU) No 528/2012 and therefore may be authorised. The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of LANXESS CMIT/MIT biocidal product family 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.

General

This biocidal product family dossier of LANXESS CMIT/MIT biocidal product family is intended for the application of a Union authorization of a CMIT/MIT-based biocidal product family (BPF). The biocidal products within the biocidal product family are preservatives and show efficacy against bacteria, yeast and fungi in PT6, bacteria (incl. Legionella), yeast, fungi and algae for PT11, bacteria, and fungi for PT12 and bacteria, fungi and yeast for PT13 is substantiated.

The biocidal product family contains 26 biocidal products which are attributed to the following 6 meta SPCs:

Meta-SPC	Biocidal product	
Meta SPC 1	Preventol IT14	
	Preventol IT14 MV	
	Kurita F-5000	
	Preservative 01-04	
	Preservative 01-05	
Meta SPC 2	Preservative 02-01	
	Preservative 02-02	
Meta SPC 3	Preventol D7	
	Preventol D7 LT	
	Preservative 03-05	
	Preservative 03-06	
	Preservative 03-07	
	Preservative 03-09	
	Preservative 03-10	
	Wolsit SP	
	Meta SPC 4	Preventol D7 Plus
		Ferrocid 8583
Preservative 04-03		
Meta SPC 5	Preservative 04-04	
	Preservative 05-01	
Meta SPC 6	Preventol D7 CF	
	Preventol D7 CF2	

Meta-SPC	Biocidal product
	Kurita F-5106
	Aqualead BC 08 LA
	Preservative 06-05
	Preservative 06-06

The biocidal product family contains 4 product types which are attributed to the following claimed uses and concerned Meta SPCs:

PTs	Claimed uses	Concerned META SPC
6	Use #1.1; #3.1; #4.1; #6.1; - In-can preservation of washing and cleaning fluids	Meta SPC 1,3,4,6
	Use #1.2; #3.2, #4.2; #6.2; - In-can preservation of paints and coatings	Meta SPC 1,3,4,6
	Use #1.3; #3.3, #4.3; #6.3; - In-can preservation of fluids used in paper production	Meta SPC 1,3,4,6
	Use #1.4; #3.4, #4.4; #6.4; - In-can preservation of fluids used in textile production	Meta SPC 1,3,4,6
	Use #1.5; #3.5, #4.5; #6.5; - In-can preservation of fluids used in leather production	Meta SPC 1,3,4,6
	Use #1.6; #3.6, #4.6; #6.6; - In-can preservation of glues and adhesives	Meta SPC 1,3,4,6
	Use #1.7; #3.7, #4.7; #6.7; - In-can preservation of others (concrete additives and building material such as fillers/sealants, plasters and wax emulsions)	Meta SPC 1,3,4,6
	Use #1.8; #3.8, #4.8; #6.8; - In-can preservation of others (polymer dispersions/emulsions intended for use in paints and coatings, glues and adhesives, building materials and fluids used in textile production)	Meta SPC 1,3,4,6
	Use #1.9; #3.9, #4.9; #6.9; - In-can preservation of others (mineral slurries)	Meta SPC 1,3,4,6
11	Use #1.10a; #2.10a; ; #3.10a; #4.10a; #5.10a; #6.10a; - Preservation of cooling fluids in open recirculating systems	Meta SPC 1, 2, 3, 4, 5, 6
	Use #1.10b; #2.10b; #3.10b; #4.10b; #5.10b; #6.10b; - Preservation of cooling fluids in closed systems	Meta SPC 1, 2, 3, 4, 5, 6
	Use #1.11; #3.11; #4.11; #6.11; - Preservation of other liquids in e.g. air conditioning systems, air washers and pasteurizers	Meta SPC 1, 3, 4, 6
	Use #3.12; #4.12; - Preservation of wood preservative treatment solutions	Meta SPC 3, 4
	Use #1.13; #3.13; #4.13; #6.13; - Preservation of membrane module solutions	Meta SPC 1, 3, 4, 6

12	Use #1.14; #3.14; #4.14; #6.14; - Preservation of white water circuits in paper industry	Meta SPC 1, 3, 4, 6
13	Use #1.15; #3.15; #4.15; #6.15; - Preservation of liquids used to treat or cut metal and glass	Meta SPC 1, 3, 4, 6

Identity, physical and chemical properties and analytical methods:

The biocidal product family consists of 6 meta SPCs and 14 products, all of formulation type Any other liquid (AL). The identity of the products within the family is adequately described and the active substance is obtained from approved sources. The physical and chemical properties were addressed and allow conclusions to be drawn with regard to storage conditions and classification and labelling:

- All products within the family require protection from frost due to the lack of low temperature stability studies.
- All products within the family have a shelf-life of 12 months.
- Meta SPCs 1, 2 and 4 are classified as H290 – May be corrosive to metals. Meta SPCs 3, 5 and 6 are not classified for physical hazards.

Adequate analytical methods were provided for the determination of the active substance in the formulations.

Efficacy:

The 16 assessed uses fall into PT6, PT11, PT12 and PT13. Efficacy against bacteria, yeast and fungi in PT6, bacteria (incl. Legionella), yeast, fungi and algae for PT11, bacteria, and fungi for PT12 and bacteria, fungi and yeast for PT13 is substantiated.

Human toxicology

Overall conclusion: All intended uses as notified by the applicant could be authorised based on the assessment performed for human health. However, risk mitigation measures are required for the PT6, PT11, PT12 and PT13 professional uses of the products with C(M)IT/MIT at concentrations ranging between 0.6-14% when handling the concentrated product due to the corrosive and sensitization properties of the active substance.

PT6

The products pertaining to the C(M)IT/MIT BPF are classified with regard to local health hazards (corrosion, skin sensitisation), and thus suitable protective equipment for skin and mucous membranes should be applied (i.e. gloves, coveralls, goggles/faceshield) when handling the concentrated product.

Due to the skin sensitisation potential of products containing ≥ 15 ppm of C(M)IT/MIT, dermal contact should be avoided. With suitable PPE, concentrations of ≥ 15 ppm C(M)IT/MIT (3:1) in end-products are thus considered acceptable for the protected professional user.

In end-products intended for non-professional users, the C(M)IT/MIT (3:1) concentration is < 15 ppm, i.e. below the dermal AEC of 15 ppm (based on the skin sensitisation SCL of 15 ppm). Thus, local dermal exposure is considered acceptable.

For systemic effects, tasks associated with the usage of liquid detergents containing biocidal products as in-can preservatives have been assessed to bear an acceptable risk for professional workers and for non-professionals, including indirect exposure via food, without any risk mitigation measures.

PT11

The products pertaining to the C(M)IT/MIT BPF are classified with regard to local health hazards (corrosion, skin sensitisation), and thus suitable protective equipment for skin and mucous membranes should be applied (i.e. gloves, coveralls, goggles/faceshield) when handling the concentrated product.

Systemic exposure during application and post application is considered acceptable without the use of PPE/RPE based on the systemic exposure assessment. However, based on the qualitative local risk assessment, during these activities suitable PPE to protect skin should be applied (i.e. gloves, coveralls).

Secondary exposure of professional industrial bystanders to preserved recirculating systems is considered negligible and thus acceptable.

Non-professional use and consumer exposure to residues are not foreseen for the products of the C(M)IT/MIT BPF in PT 11.

PT12

The products pertaining to the C(M)IT/MIT BPF are classified with regard to local health hazards (corrosion, skin sensitisation), and thus suitable protective equipment for skin and mucous membranes should be applied (i.e. gloves, coveralls, goggles/faceshield) when handling the concentrated product and during application.

Systemic exposure caused by mouthing of paper/carton (chips) treated with CMIT/MIT-containing slimicides as well as the migration of CMIT/MIT residues from food packaging has been assessed to bear an acceptable risk for the general public.

Non-professional use is not foreseen for the products of the C(M)IT/MIT BPF in PT 12.

PT13

The products pertaining to the C(M)IT/MIT BPF are classified with regard to local health hazards (corrosion, skin sensitisation), and thus suitable protective equipment for skin and mucous membranes should be applied (i.e. gloves, coveralls, goggles/faceshield) when handling the concentrated product.

Based on the systemic risk assessment, no adverse health effects are expected for the unprotected professional user during application and post-application. The C(M)IT/MIT concentration in metal working fluids is above 15 ppm (30 ppm), and thus above the AEC_{dermal} . PPE (i.e. gloves, coveralls, goggles/faceshield) is required based on the qualitative risk assessment.

Non-professional uses and consumer exposure to residues are not foreseen for the products of the C(M)IT/MIT BPF in PT 13.

Environment:

All intended uses as notified by the applicant could be authorised. However, risk mitigation measures are required for the following uses:

PT06: In-can preservation of others (concrete additives and building material such as fillers/sealants, plasters and wax emulsions).

To avoid unacceptable risks for the environment, products could only be applied when the following requirements are met: The use should be restricted to preservation of concrete additives and building applied indoor only.

PT11: Preservation of cooling fluids:

To avoid unacceptable risks for the environment, products could only be applied when for open recirculating systems the following requirements are met:

- Products are applied in closed cooling systems or recirculating 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.
- Cooling towers shall be equipped with eliminators that reduce drift by at least 99%.

No measures are required for application in closed systems.

PT11: Preservation of wood preservative treatment solutions:

Considering that stocks of preserved wood and application in water results in unacceptable risks for the environment, products can only be applied safely when the following conditions are met:

- Not allowed to preserve wood that is intended for direct and continuous contact to soil and water (use class 4);
- Treated wood must be stored above liquid-proof floors.

PT12: Preservation of water circuits in paper industry:

Preservation of paper pulp and other processing fluids during paper manufacturing results in unacceptable risks for surface water that receives purified waste water unless the following conditions are met

- The product is only applicable in the white water circuit;
- Waste water is purified on-site according to the principle of the industrial emission directive. The factories effluent must be diluted at least 200 times in the receiving fresh water body;
- Paper factories that are exempted from the industrial emissions directive shall discharge to the municipal sewer;

Risk mitigation measures have been added to the SPC.

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 substances CMIT/MIT contained in the biocidal product family do not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and are not considered candidates for substitution. Therefore, a comparative assessment of the biocidal product family was not needed.

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/biocidal product family are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

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

1. the biocidal product/biocidal product family is sufficiently effective;
2. the biocidal product/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/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/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.

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