II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/402

of 22 February 2023

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

(1) On 14 June 2017, Dow Europe GmbH ('the applicant') submitted an application to the European Chemicals Agency ('the Agency') in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'CMIT/MIT SOLVENT BASED' of product-type 6, as described in Annex V to that Regulation, for preservation of aviation fuel, crude oil and middle distillate fuel, providing written confirmation that the competent authority of France had agreed to evaluate the application. The application was recorded under case number BC-NN032576-24 in the Register for Biocidal Products. On 16 April 2020, the applicant withdrew the application as regards use of 'CMIT/MIT SOLVENT BASED' in aviation fuels. On 31 October 2020, the application was transferred by the applicant to Nutrition & Biosciences Netherlands B.V.

(2) The biocidal product family 'CMIT/MIT SOLVENT BASED' comprises products for preservation of de-watered crude oil and refined products (middle and light distillate fuels) containing 5-chloro-2-methylisothiazol-3(2H)-one and 2-methylisothiazol-3(2H)-one ('C(M)IT/MIT') as the active substance, which is included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012.

(3) On 28 August 2019, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, the assessment report and the conclusions of its evaluation to the Agency.

(4) On 7 April 2020, the Agency submitted an opinion ([2]), the draft summary of the biocidal product characteristics ('SPC') of 'CMIT/MIT SOLVENT BASED' and the final assessment report on the biocidal product family to the Commission in accordance with Article 44(3) of Regulation (EU) No 528/2012.

([1]) OJ L 167, 27.6.2012, p. 1.

([2]) ECHA opinion of 5 March 2020 on the Union authorisation of the biocidal product family 'CMIT-MIT Solvent Based' (ECHA/BPC/246/2020), https://echa.europa.eu/bpc-opinions-on-union-authorisation.

(5) The opinion concludes that 'CMIT/MIT SOLVENT BASED' is a biocidal product family within the meaning of Article 3(1), point (s), of Regulation (EU) No 528/2012, that it is eligible for Union authorisation in accordance with Article 42(1) of that Regulation and that, subject to compliance with the draft SPC, it meets the conditions laid down in Article 19(1) and (6) of that Regulation. The opinion included a minority position expressed by the member appointed by Germany, which concluded that the use of 'CMIT/MIT SOLVENT BASED' as a preservative in fuels conflicts with the national legislation of that Member State (10th Federal Emission Control Ordinance §2 (1) and (2)), which forbids that fuels for on-road motor vehicles contain additives with chlorine or bromine compounds and which forbids the placing on the market of additives that contain chlorine or bromine as these compounds cause formation of dioxins during the fuel combustion.

(6) On 15 January 2021, the Agency transmitted the draft SPC to the Commission in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.

(7) To address the concerns on dioxin formation expressed in the minority position to the opinion, on 24 July 2020, the Commission requested an opinion from the Agency under Article 75(1), point (g), of Regulation (EU) No 528/2012 to estimate the amount of formation of dioxins and the overall contribution to the emissions of dioxins due to the use of the biocidal product family 'CMIT/MIT SOLVENT BASED' in fuels used for road and water transport. The Commission also requested the Agency to clarify the level of the risks to the environment and human health due to the exposure to dioxins via the environment from the use of the biocidal product family 'CMIT/MIT SOLVENT BASED'.

(8) On 5 July 2021, the Agency submitted the requested opinion to the Commission ([3]) concluding that although the potential consequences of the use of C(M)IT/MIT as a preservative in oil and fuel cannot be neglected, it is not possible to draw any conclusions on the magnitude of the potential contribution of the use of C(M)IT/MIT in fuels with respect to dioxin exposure, nor on the potential consequences of chlorine additives such as C(M)IT/MIT in fuels on human health and on the environment.

(9) The objectives of the Stockholm Convention on Persistent Organic Pollutants ('Stockholm Convention') ([4]) and Regulation (EU) 2019/1021 of the European Parliament and of the Council ([5]) are to protect human health and the environment from persistent organic pollutants (POPs), which include dioxins. The Commission considers that refusing the Union authorisation for the biocidal product family 'CMIT/MIT SOLVENT BASED' would not lead to a significant decrease of dioxin emissions compared to granting it, as the same or similar chlorine-containing additives are currently allowed to be placed on the market under transitional measures of Regulation (EU) No 528/2012 by the Member States or could be authorised under national authorisations granted in accordance with Regulation (EU) No 528/2012. Furthermore, as a consequence of the ambitions of the European Green Deal ([6]) and Regulation (EU) 2021/1119 of the European Parliament and of the Council ([7]) (the European Climate Law ([8])) to achieve climate neutrality by 2050, the overall amount of fuel that may potentially be treated with the biocidal product family and combusted in motors or heating systems is expected to decline significantly in the coming decades. Consequently, the possible formation of dioxins associated with the use of the biocidal product family 'CMIT/MIT SOLVENT BASED' will decrease accordingly, thus contributing to achieve the objectives of the Stockholm Convention and Regulation (EU) 2019/1021.

([3]) Biocidal Products Committee (BPC) Opinion on a request according to Article 75(1)(g) of Regulation (EU) No 528/2012 on the evaluation of dioxins emissions from the use of the biocidal product family (BPF) 'CMIT/MIT SOLVENT BASED' in fuels used in road and ship transport (ECHA/BPC/283/2021).

([4]) Stockholm Convention on Persistent Organic Pollutants (OJ L 209, 31.7.2006, p. 3).

([5]) Regulation (EU) 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants (OJ L 169, 25.6.2019, p. 45).

([6]) A European Green Deal | European Commission (europa.eu).

([7]) Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 (OJ L 243, 9.7.2021, p. 1).

([8]) European Climate Law (europa.eu).

(10) On 16 November 2021, in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, Denmark made a request to the Commission for the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' not to apply in its territory, based on the grounds provided in Article 37(1), points (a) and (c), of that Regulation, as the presence of halogenated organic compounds such as C(M)IT/MIT in fuel may result in the formation of dioxins during fuel combustion, alternatives for fuel preservation without halogenated compounds are available and preservatives for fuels are not used by refineries or at service stations in Denmark.

(11) On 12 December 2021, Germany requested that the Commission adjusts the conditions of the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' in its territory in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, based on the grounds referred to in Article 37(1) points (a) and (c), of that Regulation so as not to allow its use for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis in line with national legislation as set out in the 10th Federal Emission Control Ordinance ([9]) in combination with the German Road Traffic Act (Straßenverkehrsgesetz) ([10]).

(12) On 15 July 2022, in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012, Belgium made a request to the Commission for the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' not to apply in its territory, based on the grounds provided in Article 37(1), points (a) and (c), of that Regulation, as it considers that the presence of halogenated organic compounds such as C(M)IT/MIT in fuel may result in the formation of dioxins during fuel combustion, that the formation of dioxins should be minimised and, where feasible, fully eliminated in Belgium, and that alternatives for fuel preservation without halogenated compounds are available.

(13) The Commission considers that the requests made by Germany to adjust the conditions and the requests made by Denmark and Belgium not to apply the Union authorisation of the biocidal product family 'CMIT/MIT SOLVENT BASED' in the respective territories of those Member States in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012 can be considered justified on the grounds of the protection of the environment and the protection of health and life of humans pursuant to Article 37(1), points (a) and (c), of that Regulation as the presence of halogenated organic compounds, such as C(M)IT/MIT, in fuel may result in the formation of dioxins during fuel combustion.

(14) Therefore, the biocidal product family 'CMIT/MIT SOLVENT BASED' should not be authorised for use in Denmark and Belgium and should be not be used in Germany for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis.

(15) Therefore, the Commission concurs with the opinion of the Agency and considers it appropriate to grant a Union authorisation for 'CMIT/MIT SOLVENT BASED' with the adjustments for Germany, Denmark and Belgium requested in accordance with Article 44(5), second subparagraph, of Regulation (EU) No 528/2012.

(16) 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-0023657-0000 is granted to Nutrition & Biosciences Netherlands B. V. for the making available on the market and use of the biocidal product family 'CMIT/MIT SOLVENT BASED' in accordance with the summary of the biocidal product characteristics set out in the Annex.

([9]) Zehnte Verordnung zur Durchführung des Bundes-Immissionsschutzgesetzes.
([10]) Straßenverkehrsgesetz.

However, the Union authorisation shall not apply in the territory of the Kingdom of Denmark and in the territory of the Kingdom of Belgium, nor shall it apply in the territory of the Federal Republic of Germany for the preservation of fuels for non-rail bound on-road motor vehicles, except for the purpose of research, development or analysis.

The Union authorisation is valid from 15 March 2023 until 28 February 2033.

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, 22 February 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Summary of product characteristics for a biocidal product family

CMIT/MIT SOLVENT BASED

Product type 6 – Preservatives for products during storage (Preservatives)

Authorisation number: EU-0023657-0000

R4BP asset number: EU-0023657-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. **Family name**

Name	CMIT/MIT SOLVENT BASED

1.2. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

1.3. **Authorisation holder**

Name and address of the authorisation holder	Name	MC (Netherlands) 1 B.V.
	Address	Willem Einthovenstraat 4, 2342BH Oegstgeest Netherlands
Authorisation number	EU-0023657-0000	
R4BP asset number	EU-0023657-0000	
Date of the authorisation	15 March 2023	
Expiry date of the authorisation	28 February 2033	

1.4. **Manufacturer(s) of the biocidal products**

Name of manufacturer	Specialty Electronic Materials Switzerland GmbH
Address of manufacturer	Im Ochsensand, 9470 Buchs Switzerland
Location of manufacturing sites	Im Ochsensand, 9470 Buchs Switzerland

Name of manufacturer	AD Productions BV
Address of manufacturer	Markweg Zuid 27, 4794 SN Heijningen Netherlands
Location of manufacturing sites	Markweg Zuid 27, 4794 SN Heijningen Netherlands

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

Active substance	Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)
Name of manufacturer	Jiangsu FOPIA Chemicals Co., Ltd (Specialty Electronic Materials Switzerland GmbH)
Address of manufacturer	Touzeng Village, Binhuai Town, 224555 Binhai County, Yancheng City, Jiangsu China
Location of manufacturing sites	Touzeng Village, Binhuai Town, 224555 Binhai County, Yancheng City, Jiangsu China

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1
Butyl carbitol	2-(2-butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	0,0	89,2

2.2. **Type(s) of formulation**

Formulation(s)	AL – Any other liquid

PART II

SECOND INFORMATION LEVEL – META SPC(S)

META SPC 1

1. META SPC 1 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 1 identifier**

Identifier	Meta SPC KATHON FP

1.2. **Suffix to the authorisation number**

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

2. META SPC 1 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1

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

Formulation(s)	AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	Causes severe skin burns and eye damage. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe vapours. Contaminated work clothing should not be allowed out of the workplace. Avoid release to the environment. Wear protective gloves/protective clothing/eye protection. Specific treatment (see supplemental first aid instructions on this label). IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN: Wash with plenty of water. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing.

	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Take off contaminated clothing. And wash it before reuse. Collect spillage. If skin irritation or rash occurs: Get medical advice. Store locked up. Dispose of contents to an approved facility in accordance with local, regional, national and international regulations.

4. AUTHORISED USE(S) OF THE META SPC 1

4.1. **Use description**

Table 1. Use # 1 – Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Product type	PT06 – Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %
Target organism(s) (including development stage)	Scientific name: Fungi/moulds Common name: mould Development stage: vegetative cells and spores Scientific name: Fungi/Yeast Common name: yeast Development stage: vegetative cells Scientific name: Bacteria Common name: bacteria Development stage: vegetative cells
Field(s) of use	Indoor The biocidal product family is recommended to control microorganisms in de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %. The biocidal product family is not to be used for the preservation of aviation fuels, naphthas, alkenes/olefins and aromatics (simple and more complex structures).
Application method(s)	Method: Loading of biocidal product into the blend tank containing de-watered crude oils or refined products (middle and light distillate fuels) Detailed description: The biocidal product is added as a single dose at the time of manufacture, storage or shipment. Dose the biocidal product to the end use fluid at a point to ensure adequate mixing using automated metering or by manual pouring using a safe measuring dosing system. The biocidal product should not be dispensed as supplied into an empty fuel tank. Fuel tanks being treated with the biocidal product should be at least 10 % full in order to ensure good homogenisation of the biocidal product, which aids effectiveness of the treatment.

	Fuel tanks and sumps should be drained of water regularly. Following treatment, drain off dead microorganisms and other debris from the treated fuel which have accumulated at the bottom of the tank. Filters should also be checked frequently and examined for the build-up of suspended solids. Whenever periodic maintenance is carried out, tanks should be checked for microbial growth.
Application rate(s) and frequency	Application Rate: Preservation for mid and long term storage and curative treatment 50-100 ppm v/v of biocidal product as supplied. Refined products (middle and light distillate fuels) and de-watered crude oils – Mid/long term preservation: 50 to 150 ppm v/v of biocidal product as supplied – Curative treatment: 200 to 400 ppm v/v of biocidal product as supplied Dilution (%): - Number and timing of application: **De-watered crude oils:** Mid/long-term preservation: — 50 to 150 ppm v/v of biocidal product as supplied (0,75 – 2,25 ppm v/v CMIT/MIT), contact time needs to be 1 to 4 weeks, depending on the dose used. Curative treatment:: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Refined products (middle and light distillate fuels): Mid/long-term preservation: — 50 to 150 ppm v/v of biocidal product as supplied (0,75 – 2,25 ppm v/v CMIT/MIT), contact time needs to be 1 to 4 weeks, depending on the dose used. Curative treatment:: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Repeat as necessary when contamination is detected.
Category(ies) of users	Professional
Pack sizes and packaging material	Flasks: 5 l nominal, material of construction is high density polyethylene (HDPE) Pails: 20 l nominal, material of construction is HDPE Pails: 25 l nominal, material of construction is HDPE Drums: 215 l nominal, material of construction is HDPE Drums: 220 l nominal, material of construction is HDPE Intermediate bulk container (IBC): 1000 l nominal, material of construction is HDPE

4.1.1. *Use-specific instructions for use*

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [1] OF THE META SPC 1

5.1. **Instructions for use**

— Always read the label or leaflet before use and follow all the instructions provided.

— Respect the conditions of use of the biocidal product (concentration, contact time, temperature, pH, etc.)

— For preservation during mid/long-term storage, contact time needs to be 1 to 4 weeks, depending on the dose used. For curative treatment, the biocidal effect is achieved after 1-3 days.

— Products are to be used only for mid or long-term storage or for curative treatment. Do not use in case of high turnover systems.

— Check regularly the residual concentration of the active substance (both in the fuel and aqueous phases) between fuel transfers in order to ensure lack of contamination between treatments. The choice of intervals between treatments is based on the check of the residual active substance concentrations.

— Microbiological tests to prove adequacy of preservation have to be undertaken (both in the fuel and aqueous phases) by the user of the product in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

Not authorised for use in the Kingdom of Denmark and in the Kingdom of Belgium.

Applicable in the Federal Republic of Germany only: Do not use the products for the preservation of fuels for non rail bound on road motor vehicles, except for the purpose of research, development or analysis.

5.2. **Risk mitigation measures**

— For preservation up to the dose of 6 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 15 000 m^3.

— For preservation up to the dose of 3 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 35 000 m^3.

When handling the biocidal product:

— Wear protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least type 6 EN13034), during product handling phase.

[1] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 1.

— Wear chemical goggles meeting the requirements of the European Standard EN 166 during product handling phase.

— The following technical and organisational measures should be implemented:

  — regular cleaning of the equipment and work area;.

  — the use of a dosing pump for manual loading;

  — minimisation of manual phases;

  — adequate ventilation during application of product.

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

— IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

— IF ON SKIN: Rinse skin with water (or shower). Take off immediately all contaminated clothing and wash it before reuse.

— IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

— IF INHALED: Remove person to fresh air and keep comfortable for breathing.

— If skin irritation or rash occurs: Get medical advice/attention.

— Keep the container or label available.

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

— Release only to an industrial sewage treatment plant (STP).

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

— Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets) nor down the drain.

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

Shelf-life: 24 months

6. OTHER INFORMATION

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

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

Trade name(s)	KATHON FP 1.5 Biocide	Market area: EU
	BLUECIDE 832	Market area: EU
	BIOCIDA CARBURANTE DIESEL-BIODIESEL	Market area: EU
	T2642	Market area: EU
	XC85957	Market area: EU
	BIOSTOP 15 GL	Market area: EU
	C 412 GP 10	Market area: EU
	SPEC-AID 8Q700	Market area: EU
	Predator 9015	Market area: EU

	FuelClear M15	Market area: EU			
	MIRECIDE-KW/615	Market area: EU			
	BIOC41770A	Market area: EU			
	Bactron B1770	Market area: EU			
Authorisation number	EU-0023657-0001 1-1				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		11,3

META SPC 2

1. META SPC 2 ADMINISTRATIVE INFORMATION

1.1. **Meta SPC 2 identifier**

Identifier	Meta SPC KATHON HP

1.2. **Suffix to the authorisation number**

Number	1-2

1.3. **Product type(s)**

Product type(s)	PT06 – Preservatives for products during storage (Preservatives)

2. META SPC 2 COMPOSITION

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)	
					Min	Max
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		10,8	12,1

Butyl carbitol	2-(2-butoxye-thoxy)ethanol	Non-active substance	112-34-5	203-961-6	87,9	89,2

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

Formulation(s)	AL – Any other liquid

3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 2

Hazard statements	Causes severe skin burns and eye damage. May cause an allergic skin reaction. Very toxic to aquatic life with long lasting effects. Corrosive to the respiratory tract.
Precautionary statements	Do not breathe vapours. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves meeting the requirements of the European Standard EN 374/protective clothing of at least type 6 EN13034/Wear chemical goggles meeting the requirements of the European Standard EN 166. Specific treatment (see supplemental first aid instructions on this label). IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. IF ON SKIN: Wash with plenty of water. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. IF INHALED: Remove person to fresh air and keep comfortable for breathing. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. Take off contaminated clothing. And wash it before reuse. Wash contaminated clothing before reuse. If skin irritation or rash occurs: Get medical advice. Store locked up. Dispose of contents to an approved facility in accordance with local, regional, national and international regulations. Avoid release to the environment. Collect spillage.

4. AUTHORISED USE(S) OF THE META SPC 2

4.1. **Use description**

Table 2. Use # 1 – Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Product type	PT06 – Preservatives for products during storage (Preservatives)
Where relevant, an exact description of the authorised use	Preservation of de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %

Target organism(s) (including development stage)	Scientific name: Bacteria Common name: bacteria Development stage: vegetative cells Scientific name: Fungi/Yeast Common name: yeast Development stage: vegetative cells Scientific name: Fungi/moulds Common name: mould Development stage: vegetative cells
Field(s) of use	Indoor The biocidal product family is recommended to control microorganisms in de-watered crude oil and refined products (middle and light distillate fuels) with a maximum water content of 2 %. The biocidal product family is not to be used for the preservation of aviation fuels, naphthas, alkenes/olefins and aromatics (simple and more complex structures).
Application method(s)	Method: Loading of biocidal product into the blend tank containing de-watered crude oils or refined products (middle and light distillate fuels) Detailed description: The biocidal product is added as a single dose at the time of manufacture, storage or shipment. Dose the biocidal product to the end use fluid at a point to ensure adequate mixing using automated metering or by manual pouring using a safe measuring dosing system. The biocidal product should not be dispensed as supplied into an empty fuel tank. Fuel tanks being treated with the biocidal product should be at least 10 % full in order to ensure good homogenisation of the biocidal product, which aids effectiveness of the treatment. Fuel tanks and sumps should be drained of water regularly. Following treatment, drain off dead microorganisms and other debris from the treated fuel which have accumulated at the bottom of the tank. Filters should also be checked frequently and examined for the build-up of suspended solids. Whenever periodic maintenance is carried out, tanks should be checked for microbial growth.
Application rate(s) and frequency	Application Rate: Refined products (middle and light distillate fuels) and de-watered crude oils – Mid/long term preservation: 50 to 150 ppm v/v of biocidal product as supplied – Curative treatment: 200 to 400 ppm v/v of biocidal product as supplied Dilution (%): Number and timing of application: **De-watered crude oils** Mid/long-term preservation: — Bacteria: 33 to 200 ppm v/v of biocidal product as supplied (0,5 – 3 ppm v/v CMIT/MIT), — Fungi (Yeasts/Moulds): 50 to 200 ppm v/v of biocidal product as supplied (0,75 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used.

	Curative treatment: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. **Refined products (middle and light distillate fuels)** Mid/long-term preservation: — Bacteria: 33 to 200 ppm v/v of biocidal product as supplied (0,5 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used. — Fungi (Yeasts/Moulds): 50 to 200 ppm v/v of biocidal product as supplied (0,75 – 3 ppm v/v CMIT/MIT), contact time needs to be 1-4 weeks, depending on the dose used. Curative treatment: — Bacteria: 200 to 400 ppm v/v of biocidal product as supplied (3 – 6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. — Fungi (Yeasts/Moulds): 400 ppm v/v of biocidal product as supplied (6 ppm v/v CMIT/MIT), contact time needs to be 1 to 3 days, depending on the dose used. Repeat as necessary when contamination is detected.
Category(ies) of users	Professional
Pack sizes and packaging material	Flasks: 5 l nominal, material of construction is high density polyethylene (HDPE) Pails: 20 l and 25 l nominal, material of construction is HDPE Drums: 215 l and 220 l nominal, material of construction is HDPE Intermediate bulk container (IBC): 1000 l nominal, material of construction is HDPE

4.1.1. Use-specific instructions for use

See general directions for use.

4.1.2. *Use-specific risk mitigation measures*

See general directions for use.

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 general directions for use.

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

See general directions for use.

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

See general directions for use.

5. GENERAL DIRECTIONS FOR USE [2] OF THE META SPC 2

5.1. **Instructions for use**

— Always read the label or leaflet before use and follow all the instructions provided.

— Respect the conditions of use of the biocidal product (concentration, contact time, temperature, pH, etc.)

— For preservation during mid/long-term storage, contact time needs to be 1 to 4 weeks, depending on the dose used. For curative treatment, the biocidal effect is achieved after 1-3 days.

— Products are to be used only for mid or long-term storage or for curative treatment. Do not use in case of high turnover systems.

— Check regularly the residual concentration of the active substance (both in the fuel and aqueous phases) between fuel transfers in order to ensure lack of contamination between treatments. The choice of intervals between treatments is based on the check of the residual active substance concentrations.

— Microbiological tests to prove adequacy of preservation have to be undertaken (both in the fuel and aqueous phases) by the user of the product in order to determine the effective dose of the preservative for the specific matrix/location/system. If needed, consult the manufacturer of the preservative product.

Not authorised for use in the Kingdom of Denmark and in the Kingdom of Belgium.

Applicable in the Federal Republic of Germany only: Do not use the products for the preservation of fuels for non rail bound on road motor vehicles, except for the purpose of research, development or analysis.

5.2. **Risk mitigation measures**

— For preservation up to the dose of 6 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 15 000 m^3.

— For preservation up to the dose of 3 ppm, the maximum amount of treated de-watered crude oil or refined products emptied daily per site is 35 000 m^3.

When handling the biocidal product:

— Wear protective chemical resistant gloves meeting the requirements of the European Standard EN 374 (glove material to be specified by the authorisation holder within the product information) and a protective coverall (at least type 6 EN13034), during product handling phase.

— Wear chemical goggles meeting the requirements of the European Standard EN 166 during product handling phase.

— The following technical and organisational measures should be implemented:

  — regular cleaning of the equipment and work area;.

  — the use of a dosing pump for manual loading;

  — minimisation of manual phases;

  — adequate ventilation during application of product.

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

— IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Call a POISON CENTER or doctor/physician if you feel unwell.

— IF ON SKIN: Rinse skin with water (or shower). Take off immediately all contaminated clothing and wash it before reuse.

— IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

— IF INHALED: Remove person to fresh air and keep comfortable for breathing.

[2] Instructions for use, risk mitigation measures and other directions for use under this section are valid for any authorised uses within the meta SPC 2.

— If skin irritation or rash occurs: Get medical advice/attention.

— Keep the container or label available.

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

— Release only to an industrial sewage treatment plant (STP).

— Dispose of unused product, its packaging and all other waste, in accordance with local regulations.

— Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets) nor down the drain.

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

Shelf-life: 3 months

6. OTHER INFORMATION

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

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

Trade name(s)	KATHON HP 120 Biocide			Market area: EU	
	BLUECIDE 833			Market area: EU	
	Predator 9000			Market area: EU	
	FuelClear M68 Pro			Market area: EU	
	MIRECIDE-KW/615.C			Market area: EU	
Authorisation number	EU-0023657-0002 1-2				
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Mixture of 5-chloro-2-methyl-2H- isothiazol-3-one (Einecs 247-500-7) and 2-methyl-2H-isothiazol-3-one (Einecs 220-239-6) (Mixture of CMIT/MIT)		Active Substance	55965-84-9		11,3
Butyl carbitol	2-(2-butoxyethoxy)ethanol	Non-active substance	112-34-5	203-961-6	88,7