

2023/2200

COMMISSION IMPLEMENTING REGULATION (EU) 2023/2200

of 19 October 2023

granting a Union authorisation for the biocidal product family 'HCl Disinfecting Toilet Bowl Cleaner' 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 2 May 2018, SC Johnson Europe SARL submitted to the European Chemicals Agency ('the Agency') an application in accordance with Article 43(1) of Regulation (EU) No 528/2012 for Union authorisation of a biocidal product family named 'HCl Disinfecting Toilet Bowl Cleaner' of product-type 2, as described in Annex V to that Regulation, providing written confirmation that the competent authority of the Netherlands had agreed to evaluate the application. The application was recorded under case number BC-LA039435-53 in the Register for Biocidal Products.
- (2) 'HCl Disinfecting Toilet Bowl Cleaner' contains hydrochloric acid as the active substance, included in the Union list of approved active substances referred to in Article 9(2) of Regulation (EU) No 528/2012 for product-type 2.
- (3) On 25 May 2022, the evaluating competent authority submitted, in accordance with Article 44(1) of Regulation (EU) No 528/2012, an assessment report and the conclusions of its evaluation to the Agency.
- (4) On 15 December 2022, the Agency submitted to the Commission its opinion (²), the draft summary of the biocidal product characteristics ('SPC') of 'HCl Disinfecting Toilet Bowl Cleaner' and the final assessment report on the biocidal product family, in accordance with Article 44(3) of Regulation (EU) No 528/2012.
- (5) The opinion concludes that 'HCl Disinfecting Toilet Bowl Cleaner' 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.
- (6) On 10 January 2023, the Agency transmitted to the Commission the draft SPC in all the official languages of the Union in accordance with Article 44(4) of Regulation (EU) No 528/2012.
- (7) The Commission concurs with the opinion of the Agency and considers it therefore appropriate to grant a Union authorisation for 'HCl Disinfecting Toilet Bowl Cleaner'.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

^{(&}lt;sup>2</sup>) ECHA opinion of 24 November 2022 on the Union authorisation of 'HCl Disinfecting Toilet Bowl Cleaner' (ECHA/BPC/370/2022), https://echa.europa.eu/opinions-on-union-authorisation

HAS ADOPTED THIS REGULATION:

Article 1

A Union authorisation with authorisation number EU-0030299-0000 is granted to SC Johnson Europe SARL for the making available on the market and use of the biocidal product family 'HCl Disinfecting Toilet Bowl Cleaner' in accordance with the summary of the biocidal product characteristics set out in the Annex.

The Union authorisation is valid from 9 November 2023 to 31 October 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, 19 October 2023.

For the Commission The President Ursula VON DER LEYEN

ANNEX

SUMMARY OF PRODUCT CHARACTERISTICS FOR A BIOCIDAL PRODUCT FAMILY

HCl Disinfecting Toilet Bowl Cleaner

Product type 2 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Authorisation number: EU-0030299-0000

R4BP asset number: EU-0030299-0000

PART I

FIRST INFORMATION LEVEL

1. ADMINISTRATIVE INFORMATION

1.1. Family name

Name	HCl Disinfecting Toilet Bowl Cleaner

1.2. Product type(s)

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct
	application to humans or animals (Disinfectants)

1.3. Authorisation holder

Name and address of the authorisation	Name SC Johnson Europe Sàrl		
holder	Address	Z.A. la Piece 8, 1180 Rolle, Switzerland	
Authorisation number	EU-003029	9-0000	
R4BP asset number	EU-0030299-0000		
Date of the authorisation	9 November 2023		
Expiry date of the authorisation	31 October 2033		

1.4. Manufacturer(s) of the biocidal products

Name of manufacturer	SC Johnson Europlant BV
Address of manufacturer	PO Box 38, 3640 AA Mijdrecht, Netherlands
Location of manufacturing sites	Groot Mijdrechtstraat 81, 3641 RV Mijdrecht, Netherlands

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

Active substance	Hydrochloric acid
Name of manufacturer	SC Johnson Europe Sàrl
Address of manufacturer	Z.A. la Piece 8, 1180 Rolle, Switzerland
Location of manufacturing sites	Ludwigstraße 12, D-47495 Rheinberg, Germany

2. PRODUCT FAMILY COMPOSITION AND FORMULATION

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

Commence		E	CAS number	EC number	Cont	ent (%)
Common name	IUPAC name	Function	CAS number	EC number	Min	Max
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,0	6,0
2,2'-(octadec- 9-enylimino) bisethanol	2-[(2-hydro- xyethyl)[(9E)- octadec-9-en- 1-yl]amino] ethan-1-ol	Non-active substance	25307-17-9	246-807-3	2,14	2,14
Alcohols, C1 3-1 5-branched and linear, ethoxylated	Alcohols, C1 3-1 5-bran- ched and linear, ethoxylated (1-2,5 mol EO)	Non-active substance	157627-86-6		1,0	1,0
Diphenyl ether	1,1'-Oxybis- benzene	Non-active substance	101-84-8	202-981-2	0,0	0,0045

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	100 % Limescale
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1.2. Suffix to the authorisation number

Number	1-1

1.3. **Product type(s)**

Product type(s)	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2. META SPC 1 COMPOSITION

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

Common nomo	IUPAC name	Function	CAS number	EC number	Cont	ent (%)
Common name	IOPAC name	Function	CAS number	EC number	Min	Max
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,0	6,0
2,2'-(octadec- 9-enylimino) bisethanol	2-[(2-hydro- xyethyl)[(9E)- octadec-9-en- 1-yl]amino] ethan-1-ol	Non-active substance	25307-17-9	246-807-3	2,14	2,14
Alcohols, C13-15-branched and linear, ethoxylated	Alcohols, C1 3-1 5-bran- ched and linear, ethoxylated (1-2,5 mol EO)	Non-active substance	157627-86-6		1,0	1,0
Diphenyl ether	1,1'-Oxybis- benzene	Non-active substance	101-84-8	202-981-2	0,0	0,0045

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

Formulation(s)	AL – Any other liquid
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3. HAZARD AND PRECAUTIONARY STATEMENTS OF THE META SPC 1

Hazard statements	May be corrosive to metals. Causes severe skin burns and eye damage. Harmful to aquatic life with long lasting effects.
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Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Do not breathe vapours. Wash hands thoroughly after handling. Immediately call a POISON CENTER or doctor/physician.
	IF ON SKIN (or hair):Take off immediately all contaminated clothing.Rinse skin with water. IF IN EYES:Rinse cautiously with water for several minutes.Remove contact lenses, if present and easy to do. Continue rinsing. IF SWALLOWED:Rinse mouth.Do NOT induce vomiting. IF INHALED:Remove person to fresh air and keep comfortable for breathing.
	Wash contaminated clothing before reuse. Keep only in original packaging. Store locked up. Avoid release to the environment. Dispose of contents to hazardous or special waste collection point in accordance with local regulations.

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

4.1. Use description

Table 1

Product type	PT02 – Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)		
Where relevant, an exact description of the authorised use	_		
Target organism(s) (including development stage)	Common name: Bacteria Development stage: not applicable		
Field(s) of use	Indoor Toilet bowl disinfectant		
Application method(s)	Method: Pouring Detailed description: Apply product under the toilet bowl rim to cover the surface (above the waterline) completely.		
Application rate(s) and frequency	Application Rate: 60 ml for one use in the toilet bowl. Dilution (%): The product is ready-to-use. Number and timing of application: Daily use. Contact time: minimum 5 minutes.		

Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	BOTTLE: High-density polyethylene, 750 ml, opaque. CAP: Polypropylene. INSERT: Linear low-density polyethylene. Child resistant fastening.

4.1.1. Use-specific instructions for use

See general instructions for use.

4.1.2. Use-specific risk mitigation measures

See general risk mitigation measures.

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 instructions for use.

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

See general instructions 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 instructions for use.

5. GENERAL DIRECTIONS FOR USE (1) OF THE META SPC 1

5.1. Instructions for use

Lift the toilet seat. To remove the cap, squeeze the two textured side surfaces and unscrew completely. Tip bottle to fill neck. To disinfect above the water line, squeeze evenly to coat entire bowl direct (60 ml) of liquid gel under the rim and allow to sit for at least 5 minutes. Brush the entire bowl and flush. Replace cap and close tightly until an audible click is heard. Daily use. Comply with the instructions for use.

5.2. Risk mitigation measures

The packaging is designed to minimise consumer exposure. The product has a swan neck with a nozzle that targets the product accurately when squeezed under the rim of the toilet.

Usage instructions contain the additional warnings: Store locked up. Avoid contact with skin and eyes. Apply only into the rim of the toilet to avoid skin contact. Avoid splashing. Wash hands thoroughly after handling. Keep only in original container.

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

If medical advice is needed, have product container or label at hand.

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

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

⁽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.

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

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

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

At the end of the treatment, dispose unused product and the packaging in accordance with local requirements.

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

Shelf-life is 4 years at room temperature.

Keep out of reach of children and non-target animals/pets.

6. OTHER INFORMATION

Additional labelling: -

Do not mix with bleach or any other household cleaners.

For use in toilet bowls only.

< 5 % non-ionic surfactants, disinfectants, perfume.

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)	Duck® 100 % Anti-Limescale	Market area: EU
	Duck® 100 % Limescale Marine	Market area: EU
	Duck® 100 % Limescale Remover Marine	Market area: EU
	Duck® 100 % Anticalcar – detergent lichid pentru toaletă	Market area: EU
	Duck® 100 % Anticalcare Marine	Market area: EU
	Duck® 100 % Disincrostante	Market area: EU
	Duck® 100 % Kalkfri – Marine	Market area: EU
	Duck® 100 % Kalkfjerner – Marine	Market area: EU
	Duck® 100 % Κατά των Αλάτων	Market area: EU
	Duck® 100 % κατά των αλάτων – Marine	Market area: EU
	Duck® 100 % против котлен камък	Market area: EU
	Duck® 100 % Odstraňovač vodného kameňa	Market area: EU

	Duck® 100 % od vodného kameňa		Market area: EU		
	Duck® 100 % od vodního kamene	straňovač	Market area: EU		
	Duck® 100 % od vodního kamene			Market area: EU	
	Duck® 100 % przeciw kamieniowi Marine – żel do czyszczenia i dezynfekcji toalet			Market area: EU	
	Duck® 100 %-tn kamenca Marine	i uništavač	Market area: EU		
	Duck® 100 % víz tisztító folyadék	vkőoldó – WC	Market area: EU		
	Duck® 100 % víz WC tisztító fertőt			Market area: EU	
	Canard® 100 % A	Anti-tartre		Market area: EU	
	Canard® 100 % I	Détartrant Marine		Market area: EU	
Canard® 100 % Détartrant Marine/Canard® 100 % Kalkaanslagvernietiger Marine		Market area: EU			
	WC-Ente® 100 %	6 Anti-Kalk	Market area: EU		
	WC Ente® 100 % ANTI-KALK Marine		Market area: EU		
	WC-EEND® Nr. 1 toiletreiniger Mar		Market area: EU		
	Pato® 100 % Ant	i-cal	Market area: EU		
	Pato® 100 % Ant	ti-cal Marine	Market area: EU		
	Pato® 100 % Ant	ticalcário	Market area: EU		
	Pato® 100 % Ant	icalcário Marine	Market area: EU		
	00 null null® Uri	nstein & Kalklöser	Market area: EU		
	00 null null® Urinstein & Kalklöser – Marine		Market area: EU		
Authorisation number	EU-0030299-000	J-0030299-0001 1-1			
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,0

2,2'-(octadec- 9-enylimino) bisethanol	2-[(2-hydroxye- thyl)[(9E)- octadec-9-en- 1-yl]amino] ethan-1-ol	Non-active substance	25307-17-9	246-807-3	2,14
Alcohols, C13-15-branched and linear, ethoxylated	Alcohols, C13-15-bran- ched and linear, ethoxylated (1-2,5 mol EO)	Non-active substance	157627-86-6		1,0
Diphenyl ether	1,1'-Oxybis- benzene	Non-active substance	101-84-8	202-981-2	0,0045

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

Trade name(s)	Duck® 100 % Limescale Citrus	Market area: EU
	Duck® 100 % Limescale Remover Citrus	Market area: EU
	Duck® 100 % Anticalcare Citrus	Market area: EU
	Duck® 100 % Anticalcar Citrus – detergent lichid pentru toaletă	Market area: EU
	Duck® 100 % Kalkfri – Citrus	Market area: EU
	Duck® 100 % Kalkfjerner – Citrus	Market area: EU
	Duck® 100 % κατά των αλάτων – Citrus	Market area: EU
	Duck® 100 % против котлен камък – Цитрус	Market area: EU
	Duck® 100 % odstraňovač vodného kameňa – Citrus	Market area: EU
	Duck® 100 % odstraňovač vodního kamene – Citrus	Market area: EU
	Duck® 100 % przeciw kamieniowi Citrus – żel do czyszczenia i dezynfekcji toalet	Market area: EU

	Duck® 100 %-tn kamenca Citrus	i uništavač	Market area: EU		
	Duck® 100 % víz WC tisztító fertőt			Market area: EU	
	Canard® 100 % Anti-tartre Citrus Canard® 100 % Détartrant Citrus Canard® 100 % anti-tartre – Fraîcheur Citron Canard® 100 % Détartrant Citrus/Canard® 100 % Kalkaanslagvernietiger Citrus WC Ente® 100 % ANTI-KALK Citrus WC-EEND® Nr. 1 Ontkalker toiletreiniger Citrus Pato® 100 % Anti-cal Citrus Pato® 100 % Anticalcário Citrus 00 null null® Urinstein & Kalklöser – Citrus		Market area: EU		
			Market area: EU		
				Market area: EU	
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			Market area: EU		
			Market area: EU		
			Market area: EU		
Authorisation number		E	U-0030299-0002	1-1	
Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,0
2,2'-(octadec- 9-enylimino) bisethanol	2-[(2-hydroxye- thyl)[(9E)- octadec-9-en- 1-yl]amino] ethan-1-ol	Non-active substance	25307-17-9	246-807-3	2,14
Alcohols, C13-15-branched and linear, ethoxylated	Alcohols, C13-15-bran- ched and linear, ethoxylated (1-2,5 mol EO)	Non-active substance	157627-86-6		1,0