Summary of product characteristics for a biocidal product family

Family name: HCl Family B

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

Authorisation number: 2019-11-26-B01

R4BP 3 asset reference number: MT-0021914-0000

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Part I.- First information level

1. Administrative information

1.1. Family name

HCI Family B	HCl Family B					
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1.2. 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 holder

Citywoot Pusiness Campus 7 Divervally DE24 H2CE Dublin 24	Name	RB Ireland Hygiene Home Commercial Ltd
Address Campus / Riverwalk DE24 H2CE Dubin 24 Ireland	Address	Citywest Business Campus 7 Riverwalk DE24 H2CE Dublin 24 Ireland

Authorisation number

2019-11-26-B01

R4BP 3 asset reference number

MT-0021914-0000

Date of the authorisation

30/06/2016

Expiry date of the authorisation

21/06/2026

1.4. Manufacturer(s) of the biocidal products

Name of the manufacturer

Reckitt Benckiser (UK) Ltd

Address of the manufacturer

Sinfin Lane DE24 9GG Derby United Kingdom

Location of manufacturing sites

Sinfin Lane DE24 9GG Derby United Kingdom

Name of the manufacturer	P.P.H.U. TRANS-CHEM
Address of the manufacturer	ul. Przemysłowa 5 05-100 Nowy Dwor Mazowiecki Poland
Location of manufacturing sites	ul. Przemysłowa 5 05-100 Nowy Dwor Mazowiecki Poland
Name of the manufacturer	Reckitt Benckiser Production (Poland) sp z.o.o.,
Address of the manufacturer	UI Okunin 1 05-100 Nowy Dwor Mazowiecki Poland

UI Okunin 1 05-100 Nowy Dwor Mazowiecki Poland

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

Location of manufacturing sites

Active substance	36 - Hydrochloric acid
Name of the manufacturer	Ineos Chlor Limited
Address of the manufacturer	South Parade, PO Box 9 WA7 4JE Runcorn United Kingdom
Location of manufacturing sites	South Parade, PO Box 9 WA7 4JE Runcorn United Kingdom
Active substance	36 - Hydrochloric acid
Name of the manufacturer	BASF SE
Address of the manufacturer	Carl-Bosch-Str. 38, Ludwigshafen am Rhein, Rheinland-Pfalz 67056 Ludwigshafen Germany
Location of manufacturing sites	Carl-Bosch-Str. 38, Ludwigshafen am Rhein, Rheinland-Pfalz 67056 Ludwigshafen Germany

Active substance	36 - Hydrochloric acid
Name of the manufacturer	PCC Rokita SA
Address of the manufacturer	ul. Sienkiewicza 4 56-120 Brzeg Dolny Poland
Location of manufacturing sites	ul. Sienkiewicza 4 56-120 Brzeg Dolny Poland
Active substance	36 - Hydrochloric acid
Name of the manufacturer	Brenntag Polska Sp. z.o.o.
Address of the manufacturer	ul. J. Bema 21 47-224 Kędzierzyn-Koźle Poland
Location of manufacturing sites	ul. J. Bema 21 47-224 Kędzierzyn-Koźle Poland
Activo substanco	26. Hydrochloric acid
Active substance	36 - Hydrochloric acid
Active substance Name of the manufacturer	36 - Hydrochloric acid Industrial Chemicals Limited
Name of the manufacturer	Industrial Chemicals Limited
Name of the manufacturer Address of the manufacturer	Industrial Chemicals Limited Hogg Lane, Grays, Essex RM17 5DU Grays United Kingdom
Name of the manufacturer Address of the manufacturer	Industrial Chemicals Limited Hogg Lane, Grays, Essex RM17 5DU Grays United Kingdom
Name of the manufacturer Address of the manufacturer Location of manufacturing sites	Industrial Chemicals Limited Hogg Lane, Grays, Essex RM17 5DU Grays United Kingdom Stoneness Road, West Thurrock, Grays, Essex RM20 3AG Grays United Kingdom
Name of the manufacturer Address of the manufacturer Location of manufacturing sites Active substance	Industrial Chemicals Limited Hogg Lane, Grays, Essex RM17 5DU Grays United Kingdom Stoneness Road, West Thurrock, Grays, Essex RM20 3AG Grays United Kingdom 36 - Hydrochloric acid

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 (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75 - 6,75

Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0 - 0,475
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	0 - 1,337

2.2. Type(s) of formulation

Ready to use liquid

Part II.- Second information level - meta SPC(s)

1. Meta SPC administrative information

1.1. Meta SPC identifier

Toilet disinfection

1.2. Suffix to the authorisation number

1-1

1.3 Product type(s)

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

2. Meta SPC composition

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

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75 - 6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0 - 0,475

Bis (2-hydroxyethyl) Ethanol, 2,2'-iminobis-, N- Non-active tallow alkyl derivatives substance 61791-44-4 263-177-5 0 - 1,337

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

Formulation(s)

Ready to use liquid

3. Hazard and precautionary statements of the meta SPC

Hazard statements

Causes severe skin burns and eye damage.

May be corrosive to metals.

Harmful to aquatic life with long lasting effects.

Precautionary statements

Keep out of reach of children.

Read carefully and follow all instructions.

Store locked up.

Keep only in original packaging.

Wash hands thoroughly after handling.

Wear protective gloves.

IF SWALLOWED:Rinse mouth.Do NOT induce vomiting.

Immediately call a POISON CENTER.

 $\label{lem:lemove} \mbox{IF INHALED:Remove person to fresh air and keep comfortable for breathing.}$

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

Avoid release to the environment.

Dispose of contents to local regulations.

4. Authorised use(s) of the meta SPC

4.1 Use description

Use 1 - Surface disinfectant for toilet bowls in private and domestic situations

Product type

PT02 - Disinfectants and algaecides not intended for direct application to humans or animals (Disinfectants)

Where relevant, an exact description of the authorised

Used as surface disinfectant for toilet bowls

Target organism(s) (including development stage)

Scientific name: Pseudomonas aeruginosa Common name: Pseudomonas aeruginosa, bacteria Development stage: Vegetative cells (exponential phase)

Scientific name: Staphylococcus aureus Common name: Staphylococcus aureus, bacteria Development stage: Vegetative cells (exponential phase)

Scientific name: Escherichia coli Common name: Escherichia coli, bacteria Development stage: Vegetative cells (exponential phase)

Scientific name: Enterococcus hirae Common name: Enterococcus hirae, bacteria Development stage: Vegetative cells (exponential phase)

Scientific name: Bacillus subtilis Common name: Bacillus subtilis, bacterial spore Development stage: Spore

Scientific name: Candida albicans Common name: Candida albicans, fungi (yeast) Development stage: Spore and spore producing structures

Scientific name: Aspergillus brasiliensis Common name: Aspergillus brasiliensis (niger), fungi (mould) Development stage: Spore and spore producing structures

Scientific name: Adenovirus type 5, Strain Adenoid 75 Common name: Adenovirus type 5, virus Development stage: Viral particles

Scientific name: Poliovirus type 1, Strain Sabin NIBSC 01/528 Common name: Poliovirus type 1 , virus Development stage: Viral particles

Field(s) of use

Indoor

Toilet bowl disinfectant cleaner

Application method(s)

Method: Pouring

Detailed description:

Product to be applied by the user by directing the nozzle under the rim of the toilet bowl. Instructions are provided to the user to apply enough product to cover the toilet bowl

completely.

Application rate(s) and frequencies

Application Rate: ~80 mL as per label instructions

Dilution (%): 0

Number and timing of application:

Not restricted. As required

Category(ies) of users

Trained professional

Professional

General public (non-professional)

Pack sizes and packaging material

Bottle, Plastic: HDPE, 500 mL Bottle, Plastic: HDPE, 750 mL Bottle, Plastic: HDPE, 900 mL Bottle, Plastic: HDPE, 1000 mL

Opaque high density polyethylene (HDPE) bottle. The plug of packaging should <u>only</u> be in accordance with the technical drawing defined in PAR

The plug of packaging should <u>only</u> be in accordance with the technical drawing defined in PAR

4.1.1 Use-specific instructions for use

We recommend you wear gloves while you disinfect and clean your toilet.

- 1. Lift up the toilet seat and carefully direct the nozzle under the toilet rim.
- 2. Squeeze and apply slowly all around the inside of the bowl, allowing enough liquid to cover the bowl completely.
- 3. For [optimum] cleaning results leave for [1/5/10/30] minutes, flush and brush
- 4. To disinfect, leave for 60 minutes, flush and brush.

4.1.2 Use-specific risk mitigation measures

The plug of packaging should only be in accordance with the technical drawing defined in PAR

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

HUMAN HEALTH

Severe skin burns or eye damage. Chemical burns must be treated promptly by a physician.

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a Poison Center or doctor if adverse health effects persist or are severe.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

Call a Poison Center or doctor if adverse health effects persist or are severe.

Wash contaminated clothing before reuse.

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 or doctor

IF SWALLOWED: Rinse mouth. Do not induce vomiting

Immediately call a POISON Center or doctor

Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately.

Recommends to users - Wash hands and exposed skin before meals and after use.

ENVIRONMENTAL PART

Harmful to aquatic life with long lasting effects

Avoid release to the environment.

Dispose of contents/container in accordance with local/regional regulations.

Spill control:

Small spills: Dilute with water and mop up,or absorb with inert material. Any contaminated materials must be disposed of as hazardous waste.

Large spills: Contain and collect for disposal. Disposal of this product should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Product:

Methods of disposal: Any contaminated materials must be disposed of as hazardous waste. This material and its container must be disposed of in a safe way. Disposal of this product should at all times comply with the waste disposal legislation and any regional local authority requirements.

European waste catalogue (EWC) Waste code 20 01 29*: detergents containing dangerous substances

Packaging

Methods of disposal: The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

European waste catalogue (EWC) Waste code 15 01 10*: packaging containing residues of or contaminated by dangerous substances

Special precautions: Any disposal must comply with the waste disposal legislation and any regional local authority requirements. Packaging and containers to be recycled only if emptied completely.

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

Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials and food and drink.

Separate from alkalis. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright.

Do not store in unlabelled containers.

The shelf life of the product is 24 months.

5. General directions for use of the meta SPC

5.1. Instructions for use

We recommend you wear gloves while you disinfect and clean your toilet.

- 1. Lift up the toilet seat and carefully direct the nozzle under the toilet rim.
- 2. Squeeze and apply slowly all around the inside of the bowl, allowing enough liquid to cover the bowl completely.
- 3. For [optimum] cleaning results leave for [1/5/10/30] minutes, flush and brush
- 4. To disinfect, leave for 60 minutes, flush and brush

5.2. Risk mitigation measures

The plug of packaging should only be in accordance with the technical drawing defined in PAR

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

HUMAN HEALTH

Severe skin burns or eye damage. Chemical burns must be treated promptly by a physician.

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

Call a Poison Center or doctor if adverse health effects persist or are severe.

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

Call a Poison Center or doctor if adverse health effects persist or are severe.

Wash contaminated clothing before reuse.

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 or doctor

IF SWALLOWED: Rinse mouth. Do not induce vomiting

Immediately call a POISON Center or doctor

Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately.

Recommends to users - Wash hands and exposed skin before meals and after use.

ENVIRONMENTAL PART

Harmful to aquatic life with long lasting effects

Avoid release to the environment.

Dispose of contents/container in accordance with local/regional regulations.

Spill control:

Small spills: Dilute with water and mop up,or absorb with inert material. Any contaminated materials must be disposed of as hazardous waste.

Large spills: Contain and collect for disposal. Disposal of this product should at all times comply with the waste disposal legislation and any regional local authority requirements.

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

Product:

Methods of disposal: Any contaminated materials must be disposed of as hazardous waste. This material and its container must be disposed of in a safe way. Disposal of this product should at all times comply with the waste disposal legislation and any regional local authority requirements.

European waste catalogue (EWC) Waste code 20 01 29*: detergents containing dangerous substances

Packaging

Methods of disposal: The generation of waste should be avoided or minimized wherever possible. This material and its container must be disposed of in a safe way. Disposal of this packaging should at all times comply with the waste disposal legislation and any regional local authority requirements.

European waste catalogue (EWC) Waste code 15 01 10*: packaging containing residues of or contaminated by dangerous substances

Special precautions: Any disposal must comply with the waste disposal legislation and any regional local authority requirements. Packaging and containers to be recycled only if emptied completely.

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

Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials and food and drink.

Separate from alkalis. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright.

Do not store in unlabelled containers.

The shelf life of the product is 24 months.

6. Other information

In Malta the following names are authorised:

- 1. Harpic 100% Limescale Remover Original Delisted*
- 2. Harpic 100% Limescale Remover Original Delisted**
- 3. Harpic 100% Limescale Remover Fresh Delisted*
- 4. Harpic 100% Limescale Remover Fresh Delisted**
- 5. HARPIC 100% Limescale Remover Original
- 6. HARPIC 100% Limescale Remover Fresh
- *Manufactured in Poland
- **Manufactured in UK
- 1. All products within this family have the same base product formulation, the only differences being variations in fragrance, dyes and surfactant composition. A detailed breakdown of the formulae may be found in the IUCLID dossier for this Family.
- 2. All products in the family have the same product classification (see below), target organisms, packaging types, use instructions, target areas and dosage.
- 3. The Precautionary statements are given below. Please note that there are additional recommendations included in the language as required by the RMS:

P102 Keep out of reach of children (for non-professional users)

P103 Read label before use.(for non-professional users)

P405+P234 Store locked up. Keep only in original container.

P264 Wash hands thoroughly after handling

P280 Wear protective gloves. (for professional users only)

P301 + P330+ P331+P310 IF SWALLOWED: Rinse mouth. Do not induce vomiting. Immediately call a POISON Center or doctor.

P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305 + P351+ P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P273 Avoid release to the environment.

P501 Dispose of contents/container in accordance with local/regional regulations.

Do not use with any bleaches or other cleaning products.

4. In the time of agreement of SPC it is considered that the products contain substances of concern in relation to environment /ecotoxicological endpoints. After evaluation of submitted changes it is confirmed that the products contain the substances of concern - Bis(2-hydroxyethyl) tallow alkylamine and Tallowtrimethylammonium chloride and reclassification is not appropriate. 5. The correct classification is Skin Corr 1.

7. Third information level: individual products in the meta SPC

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

Trade name(s)	Harpic 100% Limescale Remover Original Delisted*	Market area: MT
Authorisation number	MT-0021914-0001 1-1	
(R4BP 3 asset reference number - National Authorisation)		

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,475
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,337

Trade name(s)

Harpic 100% Limescale Remover Original Delisted**

Market area: MT

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0021914-0002 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,473
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,337

Trade name(s)

Harpic 100% Limescale Remover Fresh Delisted*

Market area: MT

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0021914-0003 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,475
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,337

Trade name(s)

Harpic 100% Limescale Remover Fresh Delisted**

Market area: MT

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0021914-0004 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,473
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,337

Trade name(s)

Harpic 100% Limescale Remover Original

Market area: MT

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0021914-0005 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,345
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,208

Trade name(s)

Harpic 100% Limescale Remover Fresh

Market area: MT

Authorisation number

(R4BP 3 asset reference number - National Authorisation)

MT-0021914-0006 1-1

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Hydrochloric acid	Hydrochloric acid	Active Substance		231-595-7	6,75
Tallow trimethylammonium chloride	Quaternary ammonium compounds, trimethyltallow alkyl, chlorides	Non-active substance	8030-78-2	232-447-4	0,345
Bis (2-hydroxyethyl) tallow alkylamine	Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives	Non-active substance	61791-44-4	263-177-5	1,208