LATVIJAS VIDES, ĢEOLOĢIJAS UN METEOROLOĢIJAS CENTRS

Draft of Product Assessment Report

Biocidal product family

Hydrochloric Acid Family B

07.04.2015.

(Updated: 03.04.2019.)

Internal registration/file no:	
R4BP3 Ref.-No.`	[redacted]
Authorisation/Registration no:	LV/16/NA/02
Granting date/entry into force of authorisation/ registration:	20 June 2016
Expiry date of authorisation/ registration:	30 April 2024
Active ingredient:	Hydrochloric acid
Product type:	2 (Disinfectants and algaecide not intended for direct application to humans or animals)

Biocidal product assessment report related to product authorisation under Regulation (EU) 528/2012

Contents

1 General information about the product application

1.1 Applicant

Company Name:	Reckitt Benckiser (Brands) Ltd
Address:	103 – 105 Bath Road
City:	Slough
Postal Code:	SL1 3UH
Country:	Great Britain
Telephone:	+ 44 1482 583461
Fax:	+ 44 1482 582532
E-mail address:	[redacted]

1.1.1 Person authorised for communication on behalf of the applicant

[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]
[redacted]	[redacted]

1.2 Current authorisation holder

No applicable.

1.3 Proposed authorisation holder

Company Name:	Reckitt Benckiser Production (Poland) Sp.z o.o.
Address:	Okunin 1
City:	Nowy Dwor Mazowiecki
Postal Code:	05-100
Country:	Poland
Telephone:	+ 44 1482 583461
Fax:	+ 44 1482 582532
E-mail address:	[redacted]
Letter of appointment for the applicant to	No

represent the authorisation holder provided (yes/no):	

1.4 Information about the product application

1.4.1 Product authorisation

Application received:	22.05.2014.
Application reported complete:	21.06.2016.
Type of application:	Product authorisation
Further information:	-

1.4.2 Major changes authorisation

Application received:	**21.12.2016.**
Application reported complete:	**23.03.2018.**
Type of application:	**Major changes authorisation**
Further information:	**All submitted information for major changes are in bold.**

1.5 Information about the biocidal product

1.5.1 General information

Trade name:	1. Limescale Remover Original (further Product 1, Product 2 and Product 5) 3. Limescale Remover Fresh (further Product 3, Product 4 and Product 6)* *These are generic names. Product names may vary in different Member States. Names used in Latvia: 1. Harpic Lime Scale Remover Original tualetes tīrīšanas līdzeklis Delisted* 2. Harpic Lime Scale Remover Original tualetes tīrīšanas līdzeklis Delisted** 3. Harpic Lime Scale Remover Fresh tualetes tīrīšanas līdzeklis Delisted* 4. Harpic Lime Scale Remover Fresh tualetes tīrīšanas

	līdzeklis Delisted** 5. Harpic Lime Scale Remover Original tualetes tīrīšanas līdzeklis 6. Harpic Lime Scale Remover Fresh tualetes tīrīšanas līdzeklis *Manufactured in Poland **Manufactured in UK
Manufacturer's development code number(s), if appropriate:	[redacted] 6.
Product type:	2 (Disinfectants and algaecide not intended for direct application to humans or animals)
Composition of the product (identity and content of active substance(s) and substances of concern; full composition see confidential Annex 1):	Hydrochloric acid 6.75 (% w/w) (CAS No.: not applicable; EC No: 231-595-7).
Formulation type:	Ready to use liquid
Ready to use product (yes/no):	Yes
Is the product the very same (identity and content) to another product already authorised under the regime of directive 98/8/EC (yes/no); If yes: authorisation/registration no. and product name: or Has the product the same identity and composition like the product evaluated in connection with the approval for listing of active substance(s) on to Annex I to directive 98/8/EC (yes/no):	No

1.5.2 Information on the intended use(s)

Overall use pattern (manner and area of use):	Use as a surface disinfectant for toilet bowls.
Target organisms:	Broad spectrum disinfectant with proven efficacy against bacteria, fungi, yeasts, viruses and bacterial spores. *Pseudomonas aeruginosa ATCC 15442;* *Staphylococcus aureus ATCC 6538;* *Escherichia coli ATCC 10536 ;* *Enterococcus hirae ATCC 10541;* *Candida albicans ATCC 10231;* *Aspergillus brasiliensis (niger) ATCC 16404;* *Spores of Bacillus subtilis ATCC 6633;* *Adenovirus type 5 Strain Adenoid 75, ATCC VR-5;* *Poliovirus type 1, Strain Sabin 1 NIBSC 01/528 (LSc-2ab),*

	CDC; ATCC VR-1562. Note*
Category of users:	Trained professional/professional/general public (non-professional).
Directions for use including minimum and maximum application rates, application rates per time unit (e.g. number of treatments per day), typical size of application area:	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. The application rate ~80 ml. Use frequency of product is not restricted, as required. Use undiluted.
Potential for release into the environment (yes/no):	No
Potential for contamination of food/feedingstuff (yes/no)	No
Proposed Label:	The labelling has to be in accordance with the summary of product characteristics of the product and Section 2.9. of this PAR.
Use Restrictions:	Do not use with any bleaches or other cleaning products.

* Reference strains are selected from International collection American Type Culture Collection (ATCC), Manassas, USA and Center for Disease Control and revention (CDC), Atlanta, GA, USA.

1.5.3 Information on active substance(s)

Active substance chemical name:	Hydrochloric acid
CAS No:	-
EC No:	231-595-7
Purity (minimum, g/kg or g/l):	999 g/kg
Inclusion directive:	2012/16/EU, 10 May 2012
Date of inclusion:	1 May 2014
Is the active substance equivalent to the active substance listed in Annex I to 98/8/EC (yes/no):	Yes
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 09/09/2015
Company Name:	Industrial Chemicals Limited
Address:	Stoneness Road, Grays
City:	Essex
Postal Code:	RM175DU
Country:	United Kingdom
Telephone:	+ 44 0137 538900
Fax:	+ 44 1375 389110

E-mail address:	sds@icgl.co.uk
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 14/10/2015
Company Name:	Brenntag Polska Ltd.
Address:	Ul. J. Bema 21
City:	Kędzierzyn-Koźle
Postal Code:	47-224
Country:	Poland
Telephone:	+ 48 7747 21500
Fax:	+ 48 7747 21600
E-mail address:	violetta.panczyk@brenntag.pl
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 14/10/2015
Company Name:	BASF SE
Address:	Carl-Bosch-Str. 38, Ludwigshafen am Rhein, Rheinland-Pfalz
City:	Ludwigshafen
Postal Code:	67056
Country:	Germany
Telephone:	+ 49 6216 040055
Fax:	+ 49 6216 040055
E-mail address:	reach-inorganics@basf.com
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 07/12/2015
Company Name:	Ineos Chlor Limited
Address:	South Parade, PO Box 9
City:	Runcorn, Chesire
Postal Code:	WA7 4JE
Country:	United Kingdom
Telephone:	+ 44 1928 561111
Fax:	+ 44 1928 516636
E-mail address:	msds.chlor@ineos.com
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 07/12/2015
Company Name:	PCC Rokita SA
Address:	Ul Sienkiewicza 4
City:	Brzeg Dolny
Postal Code:	56-120
Country:	Poland
Telephone:	+ 48 7179 42276
Fax:	+ 48 7179 42135
E-mail address:	mariusz.dopierala@pcc.eu
Manufacturer of active substance(s) used in the biocidal product:	Technical equivalence decision – 07/12/2015

Company Name:	Borregaard AS
Address:	PO Box 162
City:	Sarpsborg
Postal Code:	N-1071
Country:	Norway
Telephone:	+ 47 6911 8000
Fax:	+ 47 6911 8770
E-mail address:	msds@borregaard.com

1.5.4 Information on the substance(s) of concern

The biocidal products in Family B contain Ethanol, 2,2'-iminobis-, N-tallow alkyl derivatives (trade name: Bis (2-hydroxyethyl) tallow alkylamine) (1 % < C < 1.5 %).

At the time of evalutation Bis (2-hydroxyethyl) tallow alkylamine was classified as "Dangerous" with the following hazard statement: H302 - Harmful if swallowed, H314 - Causes severe skin burns and eye damage and H400 - Very toxic to aquatic life.

However, already in time of reaching agreement on the summaries of biocidal products characteristic on 10th of December 2015 the Applicant informed RMS that producer of Bis (2-hydroxyethyl) tallow alkylamine submitted the updated safety data sheet (SDS) - revision date 27.11.2015.

On 14th of December 2015 the Applicant submitted updated SDS to RMS. In accordance the new version of SDS Bis (2-hydroxyethyl) tallow alkylamine is classified as H302, H314 and **H410**. Based on new submitted information it can be concluded that Bis (2-hydroxyethyl) tallow alkylamine is substance of concern as leading the additional classification of Family B - H412 Harmful to aquatic life with long lasting effects.

After the identification of Bis (2-hydroxyethyl) tallow alkylamine as substance of concern, the Applicant submitted also updated SDS of Tallow trimethylammonium chlorideto RMS on 2016. In accordance the new version of SDS Tallow trimethylammonium chlorideis classified as H225, H302, H312, H314, H336, H400 and **H410**. Based on new submitted information it can be concluded that Tallow trimethylammonium chlorideis also substance of concern as contributing to the additional classification of Family A - H412 Harmful to aquatic life with long lasting effects.

The new information that co-formulants could be considered as substances of concern was not available at the time of evaluation of the national application, and circulation of the SPC for agreement had already started. Therefore, a condition of the product authorisation was specified that the application for change should be submitted within a given deadline.At the time of national application evaluation, it was confirmed, that all biocidal products in Family B containing 6.750% w/w of HCl were classified as "Dangerous" and "Corrosive" with hazard statement "H314 - Causes severe skin burns and eye damage" based on the very low pH level (pH ~1.5) and *in vitro* skin corrosion tests. This overall classification covered corrosive properties resulting both from properties of the active substance HCl and Bis (2-hydroxyethyl) tallow alkylamine. Due to relatively low content of Bis (2-hydroxyethyl) tallow alkylamine in the biocidal products in Family B additional classification resulting from Bis (2-hydroxyethyl) tallow alkylamine toxicological profile is not triggered and it is not considered as a substance of concern.

The products in Family B also are classified as Met.Corr.1 "H290 May be corrosive to metals". However, the classification is based on the corrosive nature of active substance - HCl acid.

Conclusion: it is confirmed that the products contain the substance of concern Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridewith respect for the

environment/ecotoxicological endpoints. After evaluation of submitted changes it has been confirmed that reclassification is not appropriate.

1.6 Documentation

1.6.1 Data submitted in relation to product application

No new data was provided for active substance.

1.6.2 Access to documentation

Not applicable.

2 Summary of the product assessment

2.1 Identity related issues

No new data was provided for active substance. For properties of the active substance, please refer to the List of Endpoints in the Competent Authority Report of Hydrochloric acid as published upon inclusion of in Annex I of Directive 98/8/EC.

The decisions on technical equivalence of active substance manufactured by *Industrial Chemicals Limited, Brenntag Polska Ltd.* and *BASF SE* were received from European Chemical Agency on 9th of September 2015 and 14th of October 2015. Hydrochloric acid of the alternative source was considered technically equivalent when compared to hydrochloric acid of the reference source.

At the time of restarting the circulation the three applications for technical equivalence (TE) were in evaluation stage in ECHA.

On 7th of December 2015 RMS received the final TE decisions also for following manufacturers:

- Ineos Chlor Limited
- PCC Rokita SA
- Borregaard AS.

RMS asked CMS to accept those TE decisions also in this stage as the part of circulation documentation.

The biocidal products within the Hydrochloric acid Family B (further Family B) contains the active substance hydrochloric acid (EINECS No. 231-595-7) (further HCl). Please find the composition of biocidal product Family B is described in the confidential Annex 1.

The biocidal product is similar to the representative biocidal product accompanying the Annex I inclusion in Directive 98/8/EC.

2.2 Classification, labelling and packaging

2.2.1 Harmonised classification of the biocidal product

The following classification of the biocidal product Family B according to Regulation (EC) 1272/2008 is proposed by the RMS (Table 1).

Table 1. Classification of the Family B.

Hazard classification	Skin Corr. 1 Met.Corr.1 Aquatic Chronic 3
Hazard pictogram	
Signal word	Danger
Hazard statements	H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals H412 Harmful to aquatic life with long lasting effects
Precautionary Statements including preventions, response, storage and disposal	P102 Keep out of reach of children (for non-professional users) P103 Read label before use (for non-professional users) P234 Keep only in original container. P260 Do not breathe vapours. P264 Wash hands thoroughly after handling P273 Avoid release to the environment. P280 Wear protective gloves (only for professional users) P303 + P361 + P353IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing. P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do not induce vomiting. P310 Immediately call a POISON Center or doctor. P101 If medical advice is needed have product container or label at hand. P363 Wash contaminated clothing before reuse. P390 Absorb spillage to prevent material damage. P405 Store locked up. P406 Store in corrosive resistant/… container with a resistant inner liner. P501 Dispose of contents/container in accordance with local/regional regulations.
Child-resistant fastening obligatory?	Yes
Tactile warning of danger obligatory?	Yes
	Do not use with any bleaches or other cleaning products

The reclassification of the two components used in the products of the Family B, namely, Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorideas Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects leads to classification of the products as Aquatic Chronic 3, H412 Harmful to aquatic life with long lasting effects. This classification of the products is based on the CLP regulation, Table 4.1.2 "Classification of a mixture for long-term hazards, based on summation of the concentrations of classified components". The concentration of Bis (2-hydroxyethyl) tallow alkylamine is 1.337% and the concentration of Tallow trimethylammonium chlorideis in the range 0.473-0.475 %Bis (2-hydroxyethyl) tallow alkylamineTallow trimethylammonium chloride.

2.2.2 Labelling of the biocidal product

The following labelling of the biocidal product Family B according to Regulation (EC) 1272/2008 is proposed by the RMS (Table 2).

Table 2. Labelling of the Family B.

Hazard classification	Skin Corr. 1 Met.Corr.1 Aquatic Chronic 3
Hazard pictogram	
Signal word	Danger
Hazard statements	H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals H412 Harmful to aquatic life with long lasting effects
Precautionary Statements including preventions, response, storage and disposal	P102 Keep out of reach of children. *(only for non-professional users)* P103 Read label before use. *(only for non-professional users)* P405+P234 Store locked up. Keep only in original container. P264 Wash hands thoroughly after handling. P280 Wear protective gloves. *(only for professional users)* 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.
Child-resistant fastening obligatory?	Yes
Tactile warnig of danger obligatory?	Yes
	Do not use with any bleaches or other cleaning products

2.2.3 Packaging of the biocidal product

Opaque high density polyethylene (HDPE) bottle 500 ml, 750 ml, 900 ml, 1 L. The plug of packaging should be only in accordance with technical drawing (Annex 2). Taking into account that the plug of packaging is considered as risk mitigation measure - no any deviation can be acceptable without re-evaluating the risk profile of the product. Particular packaging and plug has been described and evaluated in product assessment process.

2.3 Physico/chemical properties and analytical methods

No new data was provided for active substance. For the physical and chemical properties of the active substance, please refer to the List of Endpoints in the Competent Authority Report of Hydrochloric acid as published upon inclusion of in Annex I of Directive 98/8/EC.

Table 3. Physico-chemical properties of the Family B

	Method	**Purity/Specification**	**Results**	**Reference**
Physical state (at 20°C and 101.3 kPa)	Visual inspection GLP (*Products 1 - 2)*	6.75% w/w HCl		
		Initial	Uniform, clear, mobile solution	[redacted]
		12 weeks at 35ºC	Uniform, clear, mobile solution	
		12 months at ambient conditions	Uniform, clear, mobile solution	
		18 months at ambient conditions	Uniform, clear, mobile solution	
		24 months at ambient conditions	Uniform, clear, mobile solution	
		Initial	Uniform, clear, mobile solution	[redacted]
		12 weeks at 35ºC	Uniform, clear, mobile solution	
		6.75% w/w HCl		
	Visual inspection GLP *(Products 3 - 4)*	Initial	Uniform, clear, blue solution	[redacted]
		12 weeks at 35ºC	Uniform, clear, blue solution	
		12 months at ambient conditions	Uniform, clear, blue solution	
		18 months at ambient conditions	Uniform, clear, mobile solution	
		24 months at ambient conditions	Uniform, clear, mobile solution	
Colour (at 20°C and 101.3 kPa)	Visual inspection GLP (*Products 1 - 2)*	6.75% w/w HCl		
		Initial	Blue	[redacted]
		12 weeks at 35ºC	Blue	
		12 months at ambient conditions	Blue	
		18 months at ambient conditions	Blue	
		24 months at ambient conditions	Blue	
		Initial	Blue	[redacted]
		12 weeks at 35ºC	Blue	
		12 months at ambient conditions	Blue	
		18 months at ambient conditions	Blue	
		24 months at ambient conditions	Blue	
	(Products 3 - 4)	6.75% w/w HCl		
		Initial	Green	[redacted]
		12 weeks at 35ºC	Green	
		12 months at ambient conditions	Green	

	Method	Purity/Specification	Results	Reference
		18 months at ambient conditions	Green	
		24 months at ambient conditions	Green	
Odour (at 20°C and 101.3 kPa)	Olfactory inspection GLP	*Products 1-2 (*6.75% w/w HCl)		
		Initial	Pine	[redacted]
		12 weeks at 35ºC	Pine	
		12 months at ambient conditions	Pine	
		18 months at ambient conditions	Pine	
		24 months at ambient conditions	Pine	
		*Products 1-2 (*6.75% w/w HCl)		
		Initial	Pine	[redacted]
		12 weeks at 35ºC	Pine	
	Olfactory inspection GLP	*Products 3-4 (*6.75% w/w HCl)		
		Initial	Pine	[redacted]
		12 weeks at 35ºC	Pine	
		12 months at ambient conditions	Pine	
		18 months at ambient conditions	Pine	
		24 months at ambient conditions	Pine	
Explosive properties	EEC Method A14 GLP	6.1% HCl* (Representative biocidal product data included in the original dossier for HCl inclusion in Annex I of Directive 98/8/EC.)	Thermal sensitivity: Negative Mechanical sensitivity: Negative	[redacted]
Oxidizing properties	EEC Method A21 GLP	6.1% HCl** Batch: 5 (Representative biocidal product data included in the original dossier for HCl inclusion in Annex I of Directive 98/8/EC.)	The sample did not reach a pressure of 2070 kPa in any of the five tests. The sample is therefore not considered to be an oxidising liquid.	[redacted]
Flash point Autoflammability Other indications of flammability	Waiver		The active substance is an aqueous solution of hydrogen chloride and as such is not considered to have any flammable properties. A minimum of 64% of the technical material is water. In addition one component is classified as flammable, all other components are not classified as flammable. The single co-formulant that is classified as flammable is present at <1%. It is a single constituent of this co-formulant mixture that results in the flammability classification. In the product this single constituent is present at <0.5%. Therefore the product should not be classified as flammable.	[redacted]
Acidity / Alkalinity	*Products 1-2 (*6.75% w/w HCl)			
	CIPAC MT 75.3 GLP	Initial	pH 1 % dilution: 1.61	[redacted]
		12 weeks at 35ºC	pH 1 % dilution: 1.66	
		12 month at ambient conditions	pH 1 % dilution: 1.70	
		18 months at ambient conditions	pH 1 % dilution: 1.73	

	Method	Purity/Specification	Results	Reference
		24 months at ambient conditions	pH 1 % dilution: 1.82	
	CIPAC MT 191 GLP (% w/w as H_2SO_4)	Initial	8.90%	[redacted]
		12 weeks at 35ºC	9.14%	
		12 month at ambient conditions	9.30%	
		18 months at ambient conditions	8.95%	
		24 months at ambient conditions	8.98%	
	*Products 1-2 (*6.75% w/w HCl)			
	CIPAC MT 75.3 GLP	Initial	pH 1 % dilution: 1.64	[redacted]
		12 weeks at 35ºC	pH 1 % dilution: 1.64	
	CIPAC MT 191 GLP (% w/w as H_2SO_4)	Initial	8.82%	
		12 weeks at 35ºC	9.17%	
	*Products 3-4 (*6.75% w/w HCl)			
	CIPAC MT 75.3 GLP	Initial	pH 1 % dilution: 1.62	[redacted]
		12 weeks at 35ºC	pH 1 % dilution: 1.63	
		12 month at ambient conditions	pH 1 % dilution: 1.67	
		18 months at ambient conditions	pH 1 % dilution: 1.76	
		24 months at ambient conditions	pH 1 % dilution: 1.69	
	CIPAC MT 191 GLP (% w/w as H_2SO_4)	Initial	9.07%	
		12 weeks at 35ºC	9.26%	
		12 month at ambient conditions	9.28 %	
		18 months at ambient conditions	9.04%	
		24 months at ambient conditions	9.06%	
Relative density / bulk density	EEC Method A3 GLP	6.75% w/w HCl		
		Product 1-2 *Product 1-2* *Product 3-4*	1.0285 1.0282 1.0286	[redacted]
Storage stability – stability and shelf life (performed in commercial packaging)	Croplife International Monograph 17 GLP 24 months at ambient conditions	*Product 1-2* *Product 3-4*	Weight loss (initial concentration (%) of active substance – concentration (%) after 24 month storage): 0.18% (6.62-6.64) 0.16% (6.72-6.72) No loss of active substance content was observed. Conclusion: The products are considered to be stable at ambient conditions for 24 months. No significant changes in other properties were observed. Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance, Acidity/Alkalinity, Reactivity towards container materials	[redacted]
Effects of temperature (performed in commercial packaging)	Accelerated storage test CIPAC MT 46.3 GLP 12 weeks at 35ºC	6.75% w/w HCl		
		Product 1-2 *Product 1-2* *Product 3-4*	Weight loss: 0.07% 0.11% 0.07% No loss of active substance content was observed. The products are considered to be stable at 35°C for 12 weeks.	[redacted]

	Method	Purity/Specification	Results	Reference
			Conclusion: products can be considered stable at 35°C for 12 weeks. No significant changes in other properties were observed. Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance, Acidity/Alkalinity, Reactivity towards container materials	
Effects of temperature Storage stability test (performed in commercial packaging)	Croplife International Monograph 17 GLP 12 months at ambient conditions	6.75% w/w HCl		
		Product 1-2 *Product 3-4*	Weight loss: 0.08% 0.29% Conclusions: no loss of active substance content was observed. The products are considered to be stable at ambient conditions for 12 months. Conclusion: products can be considered stable at ambient conditions for 12 months. No significant changes in other properties were observed. Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance, Acidity/Alkalinity, Reactivity towards container materials	[redacted]
	18 months at ambient conditions	*Product 1-2* *Product 3-4*	Weight loss: 0.16% 0.14% Conclusions: no loss of active substance content was observed. The products are considered to be stable at ambient conditions for 18 months. Conclusion: products can be considered stable at ambient conditions for 18 months. No significant changes in other properties were observed. Further effects of temperature on the following technical characteristics are given at the individual endpoints: Appearance, Acidity/Alkalinity, Reactivity towards container materials	[redacted]
Effects of temperature Low temperature stability tests (liquids) (performed in commercial packaging)	CIPAC MT 39.3 GLP 7 days at 0°C (*Product 1-4)*	6.75% w/w HCl	No separation observed following storage at 0°C for 7 days. Conclusion: products can be considered stable at 0°C for 7 days.	[redacted]
Effects of light	Waiver		Effects of light were not examined. The packaging is an lightproof.	
Reactivity towards container material	(*Product 1-4*)	6.75% w/w HCl	The product/pack interaction was not observed on the initial, 12 weeks (at 35°C) and and 12, 18 and 24 months (ambien conditions) storage test items.	[redacted]

	Method	Purity/Specification	Results	Reference
Technical characteristics in dependence of the formulation type	Waiver (*Product 1-4*)		Ready-to-use liquid formulations intended for use as toilet bowl cleaner. Therefore the technical Characteristics are waived (not applicable) except persistent foaming (see below).	
	Products 1-4 (6.75% w/w HCl)			
Persistent foaming	CIPAC MT47.2 GLP	Initial	CIPAC water D, 3.8% 10 sec.:> 100 ml 1 min.: > 100 ml 3 min.: > 100 ml 12 min.: > 100 ml	[redacted]
		12 weeks at 35°C	CIPAC water D, 3.8% 10 sec.:> 100 ml 1 min.: > 100 ml 3 min.: > 100 ml 12 min.: > 100 ml	
		12 months at ambient conditions	CIPAC water D, 3.8% 10 sec.:> 100 ml 1 min.: > 100 ml 3 min.: > 100 ml 12 min.: > 100 ml	
		18 months at ambient conditions	CIPAC water D, 3.8% 10 sec.:> 100 ml 1 min.: > 100 ml 3 min.: > 100 ml 12 min.: > 100 ml	
		24 months at ambient conditions	CIPAC water D, 3.8% 10 sec.:> 100 ml 1 min.: > 100 ml 3 min.: > 100 ml 12 min.: > 100 ml	
			Conclusion: the level of foam generated under the conditions of CIPAC method MT47.2 should not exceed 60 ml after 1 minute. However, taking into account the large volume of the toilet bowl cavity and the large volume of water present, the product does not produce excessive amounts of foam. Therefore, there is no adverse risk to users	
Compability with other products	Waiver (*Product 1-4)*		Not required as products are not intended to co-apply with other substances or mixtures.	
Surface tension	EEC Method A 5 GLP	6.75% w/w HCl		
		Product 1-2 *Product 1-2* *Product 3-4*	33.29 mN/m at 20°C 31.96 mN/m at 20°C 32.29 mN/m at 20°C	[redacted]
Viscosity***	*Products 1-2*			
	OECD 114 GLP	6.75% w/w HCl	Viscosity (mPa.s) at 20°C (mean of two): 20 rpm: 347.9 40 rpm: 334.1 60 rpm: 325.7 80 rpm: 311.8 100 rpm: 293.6 Viscosity (mPa.s) at 40°C (mean of two): 20 rpm: 53.3 40 rpm: 52.5 60 rpm: 54.0	[redacted]

	Method	Purity/Specification	Results	Reference
			80 rpm: 54.4 100 rpm: 56.1 120 rpm: 57.8 The product displays non-Newtonian flow behaviour.	
			Products 1-2	
	OECD 114 GLP	6.75% w/w HCl	Viscosity (mPa.s) at 20°C (mean of two): 20 rpm: 313.4 40 rpm: 309.7 60 rpm: 300.9 80 rpm: 290.6 100 rpm: 279.1 Viscosity (mPa.s) at 40°C (mean of two): 20 rpm: 46.5 40 rpm: 47.2 60 rpm: 51.0 80 rpm: 54.2 100 rpm: 57.8 120 rpm: 61.1 The product displays non-Newtonian flow behaviour.	[redacted]
			Products 3-4	
	OECD 114 GLP	6.75% w/w HCl	Viscosity (mPa.s) at 20°C (mean of two): 20 rpm: 381.7 40 rpm: 360.0 60 rpm: 349.9 80 rpm: 336.3 100 rpm: 327.4 Viscosity (mPa.s) at 40°C (mean of two): 20 rpm: 59.3 40 rpm: 59.6 60 rpm: 60.8 80 rpm: 61.3 100 rpm: 64.1 120 rpm: 64.5 The product displays non-Newtonian flow behaviour.	[redacted]
Particle size distribution	Waiver (*Product 1-4*)		Ready-to-use liquid formulations intended for use as toilet bowl cleaner. Therefore the particle size distribution are waived (not applicable).	
Dilution stability	CIPAC MT 41 GLP (*Product 1 - 2*)	6.75% w/w HCl		
		Initial	Uniform, clear, blue solution	[redacted]
		12 weeks at 35ºC	Uniform, clear, blue solution	
		12 months at ambient conditions	Uniform, clear, blue solution	
		18 months at ambient conditions	Uniform, clear, blue solution	
		24 months at ambient conditions	Uniform, clear, blue solution	
	CIPAC MT 41 GLP (*Product 3 - 4*)	6.75% w/w HCl		
		Initial	Uniform, clear, green solution	[redacted]
		12 weeks at 35ºC	Uniform, clear, green solution	
		12 months at ambient conditions	Uniform, clear, green solution	
		18 months at ambient conditions	Uniform, clear, green solution	

	Method	Purity/Specification	Results	Reference
		24 months at ambient conditions	Uniform, clear, green solution	

*The tested product comprises of a series of surfactants, fragrances and dyes, which are chemically identical or very similar to those in biocidal product Family B. In addition, none of the components of biocidal product Family B are classified as explosive, indicating that the product does not possess explosive properties.
** The tested product is comprised of a series of surfactants, fragrances and dyes, which are chemically identical or very similar to those in biocidal product Family B. In addition, none of the components of biocidal product Family B are classified as oxidising, indicating that the product does not possess oxidising properties.
*** Biocidal product family contains hydrocarbons. According to CLP regulation In Annex I, Section 3.10. the mixture shall be classified in hazard category for aspiration toxicity if "A mixture which contains a total of 10 % or more of a substance or substances classified in Category 1, and has a kinematic viscosity of 20.5 mm^2/s or less, measured at 40°C, shall be classified in Category 1." In Family A the maximum amount of substances with classification H304 in products are less than 0.5% and the lowest value of kinematic viscosity is above 20.5 mm^2/s (the calculated kinematic viscosity lowest value is ~ 43 mm^2/s). No classification criteria are fulfilled.

2.3.1 Analytical methods

2.3.1.1 Analytical methods for active substance

The information regarding ***analysis of active substance as manufactured*** is taken from the application (including also Competent Authority Report) for Hydrochloric Acid inclusion in Annex I of Directive 98/8/EC.

Two analytical methods are given for the determination of hydrogen chloride in hydrochloric acid in accordance with the Polish standard PN-91/C-84046. As these methods are appropriate/consistent with the ISO standards 905-1976, 904-1976 and hence it is not necessary to provide any additional validation data as these are internationally accepted standard methods. One method is based on determination of hydrogen chloride content by density measurement; another is based on determination of hydrogen chloride content by titration.

Determination of hydrogen chloride content by density measurement

The density of sample of industrial hydrochloric acid is measured at 20±0.5°C using a hydrometer. The concentration (%w/w) of hydrogen chloride corresponding to the measured density is then established by comparison. Intermediate values are determined by interpolation of the data.

Determination of hydrogen chloride content by titration

The total acidity of a sample of industrial hydrochloric acid is determined by titration with a sodium hydroxide solution in the presence of an indicator (bromocresol green). To use this method a correction has to be made for sulphuric acid content (a method for determination of sulphuric acid content is given in the standard).

The information regarding about impurities for active substance is taken from the application (including also Competent Authority Report) for Hydrochloric Acid inclusion in Annex I of Directive 98/8/EC.

Hydrochloric acid potentially contains trace metals (e.g. arsenic etc.) and organic compounds (carbon tetrachloride) that are classified for toxicological or ecotoxicological effects. However, these are present at quantities <0.1ppm (equivalent to $<1 \times 10^{-5}$ %w/w) and are not considered relevant for risk assessment. There are also other non-classified impurities at levels <0.01%.

Therefore it is not considered scientifically justified to provide methods for the determination of such compounds in the active substance as manufactured.

Table 4. ***Analytical methods for active substance in the formulation***

Principle of method:	*Goncalves, J. (2012), Verification of Test Method GLP-V15-1541-HCL-08 for the determination of Hydrochloric Acid in Harpic Powerplus (PP) and Limescale Remover (LSR) Products, Reckitt Benckiser Analytical Laboratory, New Jersey, USA. 12 September 2012. In accordance with guideline SANCO/3030/99 rev 4.* Samples of Hydrochloric Acid Family B are titrated against 1M sodium hydroxide, in the presence of phenolphthalein indicator.
Active substance in the formulation:	In the products from Family B the RSD is 0.19-2.95%. Titrations were performed using blank formulation to demonstrate specificity of the method. The maximum value obtained from blank formulation titration was 1.41%; consequently no correction to sample titrations was applied. Titration is well-known method for determining acid content therefore full additional validation is not necessary.

The confirmatory methods for consideration of residues of the active substance in soil, air, water, body fluids and tissues, food of plant and animal origin are not provided, since it is considered as scientifically unjustified unjustified based on the considerations described below.

- Hydrochloric acid dissociates completely in water to form chloride ions and hydronium ions. The same in the presence of moisture in air, hydrogen chloride is dissolved into moisture and exists in the dissociated form. Therefore any effects observed are due to the ion concentrations; the major effect being the resultant pH. Exposures in aqueous compartments have been assessed considering pH changes due to the addition of HCl to water. Predicted emissions of chloride and hydronium ions are expected to have minimal impact on the aquatic environment as hydrochloric acid enters the sewage system in a dissociated form and will not cause a significant change in the pH levels due to the high level of dilution and the well buffered environment of the STP. Furthermore, both hydrogen and chlorine are ubiquitous in the environment from natural and man-made sources making it impossible to determine the exact source. Analytical methods to monitor residues of hydrochloric acid in air, water, soil are therefore considered to be scientifically unjustified.
- Regarding to residues in animal and human body fluids and tissues, in accordance with Guidance on the Biocidal Products regulation Volume I, Part A, Section 5.2. “where an active substance is classified as toxic or very toxic, validated analytical methods must be submitted which allows determination of the active substance at the NOAEC” The Family B is not classified as toxic or very toxic, consequently analytical methods to monitor levels in body fluids and tissues are scientifically unjustified.
- Regarding to residues in/on food of plant and animal origin or feeding stuffs in accordance with point 5.3. of Annex III to the BPR and taking into account the Guidance on the Biocidal Products regulation Volume I, Part A Section 5.3. “Analytical methods [..] not necessary if neither the active substance not the material treated with it come into contact with food-producing animals, food of plant and animal origin or feeding staff”. Therefore, the need to conduct studies on residues of the biocidal product in food and feedstuffs are unjustified.

2.3.1.2 Analytical method for substances of concern

Determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine in Cilit Bang Limescale Removal Original test item

The fully validated analytical method for the determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine surfactant content in toilet bowl cleaner

formulations is provided. The analytical method [redacted] for the determination of surfactants in Limescale Removal (Products 1 and 2) formulations employs an LC-MS/MS technique to measure the summed response from five selected ion transitions for each analyte. The validation of the method was performed according to the criteria of Guideline SANCO/3030/99 rev.4, 11 July 2000.

Nominal concentrations of surfactants in the formulations are 0.473% w/w for Tallow trimethylammonium chlorideand 1.337% w/w for Bis (2-hydroxyethyl) tallow alkylamine.

Since both Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine contain a mixture of compounds, this analytical method is not typical and the summed responses of five ions for each surfactant for the calculation were used. The retention time windows were determined for Tallow trimethylammonium chloridefrom 0.6-6 min and for Bis (2-hydroxyethyl) tallow alkylamine from 1.5-9 min.

The instrumentation (Agilent 1100 series HPLC system coupled to an AB Sciex 4000 MS system) used in the method for the determination is regarded as "commonly available".

Table 4[1]. Analytical method for substances of concern in the formulation

Principle of method:	**The dilution of test item in acetonitrile with further dilution in acetonitrile/water, 60:40% v/v and detection by liquid chromatography – tandem mass spectrometry. The determination of response factor for each substances of concern using summed response of five ions in each channel.**
Substances of concern in the formulation:	**Tallow trimethylammonium chloride(CAS No 8030-78-2): 0.473% w/w;** **Bis (2-hydroxyethyl) tallow alkylamine (CAS No 61791-44-4): 1.337% w/w.**
Validation parameters and data.	
Specificity	***The response of interference peaks should be < 3% of the response for the target analyte.*** **No interfering peaks in the analyte retention time windows in the reagent of formulation blank samples.** **Interfering peaks of Bis (2-hydroxyethyl) tallow alkylamine in an Tallow trimethylammonium chloridestandard solution – 0% and interfering peaks of Tallow trimethylammonium chloridein an Bis (2-hydroxyethyl) tallow alkylamine standard solution – 1.49%.** **Fully labelled chromatograms from the analysis of reference standards in test items and blank formulation are provided.**
Linearity	**Eight matrix-matched standard solutions (2 replicates for each) were prepared over the range of 80 to 120% of the nominal concentrations of active substances in test items.** **Concentration range for Tallow trimethylammonium chlorideare 0.22-0.86 % w/w and for Bis (2-hydroxyethyl) tallow alkylamine are 0.49-3.00 % w/w.** **Linearity plots, peaks areas and the equations of the calibrations are provided, correlation coefficients are higher than 0.99.**

Precision (Repeatability)	***The acceptability of results based upon the modified Horwitz equation:*** ***$RSDr < 2^{(1-0.5\log C)} \times 0.67$*** **The precision of the method was assessed by the analysis of six replicate determinations at the nominal concentration.** **%RSD values are lower compared to Horwitz Value with the exception of Bis (2-hydroxyethyl) tallow alkylamine where %RSD at nominal concentration is 2.59 (Horwitz value – 2.52).** **The determination of Bis (2-hydroxyethyl) tallow alkylamine is not a typical analysis as the substance of concern consists of a complex mixture and there are multi-component analytes.**
Recovery (Accuracy)	***Recovery rates should be 97-103% for concentration range from 1-10% w/w, and 95-105% for concentration <1% w/w.*** **Recovery was assessed by the analysis of six replicate determinations of sample prepared by the fortification of blank formulation with active ingredient equivalent to 80% and 100% of the nominal active ingredients.** **Recovery rates meet criteria with exception of recovery of Tallow trimethylammonium chlorideat nominal concentration which is 107.1%.** **The determination of Tallow trimethylammonium chlorideis not a typical analysis as the substance of concern consists of a complex mixture and there are multi-component analytes.'**
Stability test	**An assessment of the standard stability indicated that Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine are stable in standard solutions in acetonitrile/water (60/40, v/v) when stored between 2 – 8 ºC for a period of at least 18 days.**

Linearity, precision, accuracy and specificity were evaluated in the validation study and compared to the criteria specified in SANCO 3030/99 revision 4. The data presented in this study shows that the conditions described in the method [redacted] are suitable for the determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine in Product 1 and Product 2 formulations. The determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine is not a typical analysis as the substances of concern consist of a complex mixture and are multi-component analytes.

Analytical method for monitoring of residues of substances of concern in surface water

The fully validated analytical method for the determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine surfactant content in surface water is provided. The analytical method [redacted] for the determination of surfactants in surface water includes an extraction of analytes by solid phase extraction, reconstitution of samples in acetonitrile and water solution, and detection by LC-MS/MS technique. The validation of the method was performed according to the criteria of Guideline SANCO/3030/99 rev.4, 11 July 2000.

Since both Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine contain a mixture of compounds, this analytical method is not typical and the summed responses

of five ions for each surfactant for the calculation were used. The retention time windows were determined for Tallow trimethylammonium chloridefrom 2 - 5.1 min and for Bis (2-hydroxyethyl) tallow alkylamine from 1.5 - 7.8 min.

The instrumentation (Agilent 1100 series HPLC system coupled to an AB Sciex 4000 MS system) used in the method for the determination is regarded as "commonly available".

Table 4[2]. Analytical method for substances of concern in surface water

Principle of method:	**The solid phase extraction of 50 mL surface water followed by reconstitution of sample in acetonitrile/water, 60:40%, v/v and detection by liquid chromatography – tandem mass spectrometry. The determination of response factor for each active substance using summed response of five ions in each channel.**
Reference item:	**Tallow trimethylammonium chloride (CAS No 8030-78-2, purity 51.7%.** **Bis (2-hydroxyethyl) tallow alkylamine (CAS No 61791-44-4), purity 100%.**
Test Item:	**Surface water, River Meon, UK (Sample reference: CCON/116/010)**
Validation parameters and data.	
Specificity	***The response of interference peaks should be not higher than 30% of the LOQ.*** **The assessment found average interference contribution of 39.46% of the LOQ for Tallow trimethylammonium chlorideand 29.56% of the LOQ for Bis (2-hydroxyethyl) tallow alkylamine. The majority of the interference is considered to be baseline noise integrated in the retention time window for each analyte.** **The average contribution of Bis (2-hydroxyethyl) tallow alkylamine present in an Tallow trimethylammonium chloridestandard solution was found to be 0.01% while the average contribution of** **Tallow trimethylammonium chloridepresent in an Bis (2-hydroxyethyl) tallow alkylamine standard solution was found to be 12.40%.** **Fully labelled chromatograms from the analysis of reference standards in test items and blank formulation are provided.**
LOQ	***The LOQ must be below the PNEC (predicted no effect concentration) in water.*** **According to regulation (EC) No. 1907/2006, PNEC in fresh water is 0.68 µg/L for Tallow trimethylammonium chlorideand 0.214 µg/L for Bis (2-hydroxyethyl) tallow alkylamine.** **The LOQ of the method is established as 0.1 µg/L for both analytes.**
Linearity	**Eight matrix-matched standard solutions (2 replicates for each) were prepared over the range of 8 to 284 µg/L for Tallow trimethylammonium chlorideand 7 to 248 µg/L for Bis (2-hydroxyethyl) tallow alkylamine. As the regression plot appeared to be non-linear for both analytes, the highest calibration levels were disregarded.** **The response of the LC-MS/MS was found to be linear in calibration range of 8 to 227 µg/L for Tallow trimethylammonium chlorideand 7 to 199 µg/L for Bis (2-hydroxyethyl) tallow alkylamine.** **Linearity plots, peaks areas and the equations of the calibrations are**

	provided, correlation coefficients are higher than 0.99. **As no significant matrix interferences were observed between matrix matched calibration and non-matrix-matched calibration, the last one was used for quantification of recovery and precision data.**
Precision (Repeatability)	***RSD should be ≤ 20% per level.*** **The precision of the method was assessed by the analysis of six replicate determinations of sample prepared by the fortification of surface water at the LOQ (0.1 µg/L) and at 10 x LOQ (1.1 µg/L Tallow trimethylammonium chlorideand 1.0 µg/L Bis (2-hydroxyethyl) tallow alkylamine) levels.** **%RSD values are <20% for both analytes and both levels in case of calculation based upon a non-matrix-matched calibration.**
Recovery (Accuracy)	***Recovery rates should be in the range of 70-110%.*** **Recovery was assessed by the analysis of six replicate determinations of sample prepared by the fortification of surface water at the LOQ (0.1 µg/L) and at 10 x LOQ (1.1 µg/L Tallow trimethylammonium chlorideand 1.0 µg/L Bis (2-hydroxyethyl) tallow alkylamine) levels.** **Recovery rates do not meet criteria, however the determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine are not typical analysis as substances of concern consist of a complex mixture and are multi-component analytes.**
Stability test	**An assessment of the standard stability indicated that Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine are stable in standard solutions in acetonitrile/water (60/40, v/v) when stored between 2 – 8 ºC for a period of at least 18 days.**

Linearity, precision, accuracy and specificity were evaluated in the validation study and compared to the criteria specified in SANCO 3030/99 revision 4. The data presented in this study shows that the conditions described in the method [redacted] **are enable the determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine in surface water at appropriate LOQ values. Although the accuracy data does not meet the criteria, the precision of the method is <20% and therefore validation data can be considered as acceptable. The determination of Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine is not a typical analysis as the substances of concern consist of a complex mixture and are multi-component analytes.**

2.4 Risk assessment for Physico-chemical properties

In accordance with Regulation (EC) 1272/2008 products within Family B are not considered as explosive, oxidising, flammable or autoflamable. It is concluded that there are no identified risks associated with physico-chemical properties of the products of Family B.

However, the products in Family B are classified as Met.Corr.1 "H290 May be corrosive to metals". The classification is based on the corrosive nature of active substance - HCl acid.

Products are considered to be stable for two years when stored in the commercial container at ambient temperatures.

2.5 Effectiveness against target organisms

Information on effectiveness against target organisms submitted for the products in Family B (active substance HCl at 6.75% w/w) is evaluated and the results are summarised.

The proposed function for products in Family B is claimed as *bactericide, sporicide, fungicide, yeasticide and virucide* (broad spectrum disinfectants). Products are effective against a range of Gram positive and Gram negative bacteria and spore forming bacteria, fungi incl. moulds and yeasts and viral types as Poliovirus and Adenovirus.

The efficacy testing of products Family B is provided by using EN test methodology (EN 14885:2006 - Chemical disinfectants and antiseptics – Application of European Standards for chemical disinfectants and antiseptics). The used Standards based on quantitative suspension test (phase 2/step1) or quantitative surface test (phase 2/step 2) both simulate practical conditions appropriate to its intended use (temperature, soiling, contact time, concentrations, etc) to support claims for evaluation of antimicrobial activity and label claims for Family B.

The following Standards were used:

- PN-EN 1276:2000/Ap1:2001 ‘Evaluation of bactericidal activity in quantitative suspension test’.
- PN-EN 1650:2002 ‘Evaluation of fungicidal activity in quantitative suspension test’
- PN-EN 1650:2008 ‘Evaluation of fungicidal activity in quantitative suspension test ‘
- PN-EN 13697:2002/Ap1:2003 ‘Evaluation of activity in the nonporous surfaces test’
- PN-EN 13704:2004 ‘Evaluation of sporicidal activity in quantitative suspension test’
- EN 14476 ‘Chemical disinfectants and antiseptics - Virucidal suspension test for chemical disinfectants and antiseptics used in human medicine - Test method and requirements (phase 2, step 1).

For all intended uses and reference target organisms, efficacy has been successfully demonstrated for products in Family B.

The antimicrobial activity tests are performed against the claimed target micro-organism strains and fulfilled the basic requirement for product type PT2. Microbial reference strains actual used in efficacy tests are selected from International collections (see 1.5.2.) and preserved in the Testing Laboratories collections:

- *Pseudomonas aeruginosa ATCC 15442;*
- *Staphylococcus aureus ATCC 6538;*
- *Escherichia coli ATCC 10536;*
- *Enterococcus hirae ATCC 10541;*
- *Candida albicans ATCC 10231;*
- *Aspergillus brasiliensis (niger) ATCC 16404;*
- *Spores of Bacillus subtilis ATCC 6633;*
- *Adenovirus type 5 Strain Adenoid 75, ATCC VR-5;*
- *Poliovirus type 1, Strain Sabin 1 NIBSC 01/528 (LSc-2ab), CDC; ATCC VR-1562.*

The validation tests on microbial suspension, test conditions, filtration procedure and filtration validation test are performed with all target strains as appropriate according to Standard method. Uncertainty = mean intra-laboratory standard deviation for testing chemical disinfectants; extension factor k = 2 for confidence interval 95%. All validity criteria are met. Tabulated data of validation tests included in Test Protocols.

The test procedures are performed under Quality Management System according to ISO/IEC 17025 General Requirements for the competence of testing and calibration laboratories and under Good Laboratory Practice (GLP) regulation set documents. Respectively, the Accreditation Certificates with GLP regulation statement n documents are submitted.

2.5.1 Effects on target organisms and efficacy

The efficacy on target organisms for Family B (active substance HCl at 6.75% w/w) is evaluated based on the Laboratory studies data (Table 5-16).

Efficacy evaluation demonstrates that the products in Family B meet agreed acceptability criteria for reduction (R log) in infectivity of bacteria, bacterial spores, fungi and viruses under in appropriate effective concentrations and under defined standard test conditions. Accordingly, a detailed scheme of testing efficacy tests were carried out on Product 1 as representative product in Family B.

Based on the information below (Table 5-16), it can be demonstrated that product within Family B are sufficient efficacious to achieve the intended biocidal effect, and support the label claims for the products within Family B.

Summary:

*For **Product 1:** Suspension tests* demonstrated that Product 1 is a sufficiently effective bactericide, fungicide and yeasticide passing the defined reduction criteria (R log) in number of CFU as follows:

1) *bactericide* at concentrations 1.5 % and 80% ($R \geq 5$ log) against *Escherichia coli*, *Pseudomonas aeruginosa, Escherichia coli*, *Pseudomonas aeruginosa, Enterococcus hirae* and *Staphlococcus aureus;*

under dirty test conditions (BSA 3g/l) with contact times 5 minutes and temperature $20^0C \pm 1^0C$.

2) *fungicide* at concentration 80% ($R \geq 4$ log) against mould *Aspergillus brasiliensis (niger);*
3) *yeasticide* at concentrations 2%, 3% and 80% ($R \geq 4$ log) against *Candida albicans*;

under dirty test conditions (BSA 3g/l) with contact times 15 minutes and temperature $20^0C \pm 1^0C$.

4) *sporicide* at concentration 80% against *Bacillus subtilis spores* under dirty test conditions (BSA 3g/l) with contact times 60 minutes and temperature $20^0C \pm 1^0C$;

5) *virucide* at concentration 12.5% and 50% against target *Adenovirus* and *Poliovirus* types in both "clean" (0.3% BSA) and "dirty" (3% BSA + 3% erythrocytes) conditions at 60 minute contact time and temperature $20^0C \pm 1^0C$.

Non-porous surface tests has demonstrated that the Product 1 is a sufficiently effective bactericide, fungicide and yeasticide passing the defined reduction criteria (R log) in number of CFU as follows:

1) *bactericide* as undiluted (100%) ($R \geq 4$ log) against four bacterial strains; for each species highest dilutions were as for *Pseudomonas aeruginosa (0.3%), Escherichia coli and Enterococcus hirae (1%). Staphylococcus aureus (2%)* ($R \geq 4$ log) under dirty test conditions (BSA 3g/l) with contact times 5 minutes and temperature $20^0C \pm 1^0C$.

2) fungicide as undiluted (100%) ($R \geq 3$ log) against two fungal strains; for each species highest dilutions were as for mould *Aspergillus brasiliensis (niger)* undiluted (100%) and yeast *Candida albicans at concentrations 3% and 4%* under dirty test conditions (BSA 3g/l) with contact times 15 minutes and temperature $20^0C \pm 1^0C$.

The proposed efficacy specification of Family B Product 1 are bactericide (sporicide), fungicide (including yeasticide) and virucide at effective test concentrations against reference test organisms and under defined test conditions according to EN Standard Methods that have been appropriate for claimed intended use - toilet disinfectant.

Summary results on the efficacy data of the biocidal products Family B (active substance at 6.75 % w/w) against the target organisms see below (Tables 5-16).

2.5.1.1 Detailed test results for Family B Product 1

- *Family B Product 1 (Table 5-6)* **in quantitative suspension test** at concentrations 0.2 -1.5% (v/v) demonstrated a different efficacy against *Pseudomonas aeruginosa* (0.3%), *Staphylococcus aureus* (1.0%), *Escherichia coli* (1.5%), and *Enterococcus hirae* (1.0%) under dirty conditions (BSA 3 g/l) and 5 minutes contact period. Respectively, Product 1 is a high effective against all bacterial strains at relatively low concentration 1.5% (v/v) and up to concentration 80% (undiluted as is).

It can be accepted that Product1 in Family B is an **sufficiently effective bactericide** at concentration 1.5% (and above) under standard dirty conditions in contact time of 5 minutes and has reached a necessary reduction criteria (R ≥5 log). (Tables 5-6).

Table 5. Reduction factor for viable counts of colony forming units (R, CFU/ml)

Test Organism (Strain)	**Contact Times And Product Concentrations Tested (% v/v)**			
	5 minutes			
	0.2	**0.3**	**0.5**	**80**
Pseudomonas aeruginosa ATCC 15442	<3.92 ± 0.15	**>5.22 ± 0.15**	**>5.22 ± 0.15**	**>5.22 ± 0.15**
	0.5	**1.0**	**1.5**	**80**
Escherichia coli ATCC 10536	<4.10 ± 0.15	4.71 ± 0.15	**>5.40 ± 0.15**	**>5.40 ± 0.15**
Enterococcus hirae ATCC 10541	<4.19 ± 0.15	**5.33 ± 0.15**	**>5.50 ± 0.15**	**>5.50 ± 0.15**
	0.5	**0.7**	**1.0**	**80**
Staphylococcus aureus ATCC 6538	<4.19 ± 0.15	4.86 ± 0.15	**>5.49 ± 0.15**	**>5.49 ± 0.15**

Bold values = passes (> 5 log reduction)

Table 6. Tabulated test results of bactericidal activity (EN 1276:2000/Ap1:2001)

Test Strain	**Microbial Suspension in the Test**		**Test Procedure at Product Concentration v/v (%)**			
			0.5	**0.3**	**0.2**	**80***
Pseudomonas aeruginosa	10^{-6}: 233;265	Vc	0;0	0;0	>300;>300	0;0
	10^{-7}: 22;29	Na	<1.5 x 10^2	<1.5 x 10^2	>3.0 x 10^3	<1.5 x 10^2
	N: 2.5 x 10^8	R	**>5.22 ± 0.15**	**>5.22 ± 0.15**	<3.92 ± 0.15	**>5.22 ± 0.15**
			Test Procedure at Product Concentration v/v (%)			
			1.0	**0.7**	**0.5**	**80***
Staphylococcus aureus	10^{-6}: >300;>300	Vc	0;0	59;67	>300;>300	0;0
	10^{-7}: 43;48	Na	<1.5 x 10^2	6.3 x 10^2	>3.0 x 10^3	<1.5 x 10^2
	N: 4.6 x 10^8	R	**>5.49 ± 0.15**	4.86 ± 0.15	<4.19 ± 0.15	**>5.49 ± 0.15**
			Test Procedure at Product Concentration v/v (%)			
			1.5	**1.0**	**0.5**	**80***
Escherichia coli	10^{-6}: >300;>300	Vc	0;0	76;71	>300;>300	0;0
	10^{-7}: 36;39	Na	<1.5 x 10^2	7.4 x 10^2	>3.0 x 10^3	<1.5 x 10^2

	N: 3.8 x 10^8	R	**>5.40 ± 0.15**	4.71 ± 0.15	<4.10 ± 0.15	**>5.40 ± 0.15**
Enterococcus hirae	10^{-6}: >300;>300	Vc	0;0	20;23	>300;>300	0;0
	10^{-7}: 41;52	Na	<1.5 x 10^2	2.2 x 10^2	>3.0 x 10^3	<1.5 x 10^2
	N: 4.7 x 10^8	R	**>5.50 ± 0.15**	**5.33 ± 0.15**	<4.19 ± 0.15	**>5.50 ± 0.15**

* - tested for the product as is
Vc – viable count; N – CFU/ml in the bacterial test suspension
R – reduction factor of viable counts [values in bold = passes (≥5 Log reduction)]
Na - CFU/ml in the test mixture
The validation tests on bacterial suspension, test conditions, filtration procedure and filtration validation test are performed with all four bacterial strains as appropriate according to Standard method. Uncertainty = mean intra-laboratory standard deviation for testing chemical disinfectants / antiseptics; extension factor k = 2 for confidence interval 95%.

- *Family B Product 1* (Table 7-8) **in quantitative suspension test** was sufficiently effective in reducing of yeast strain *Candida albicans* at concentrations of 2% and 80% and mould strain *Aspergillus brasiliensis (niger)* at a concentration of 80% under dirty condition (BSA 3 g/l) following a 15 minute contact period. The product demonstrated the necessary fungicidal action with a reduction in CFU of R ≥4 log.

It was shown, that the efficacy of Product 1 against strains *Candida albicans* and *Aspergillus brasiliensis (niger)* considerably differs in fungal infectivity reducing. The results of microscopic and cultural study of test organisms in culture explains the reasons for these a differences.

Candida albicans: yeast, vegetative cells. Colonies were small to medium, white, circular, convex, dull. *Aspergillus brasiliensis (niger):* mould, vegetative cells and spores. From microscopic inspection at least 75 % were a spiny spores, absence of germination and mycelia fragments. White colonies, reverse becoming pale yellow.

It is known, that spores are relatively more resistant than vegetative cells to chemicals or others toxic substances and environmental unfavourable factors. Therefore to destroy spores need higher concentration of disinfectant as well as longer contact/exposure time than to vegetative cells.

Respectively, it is acceptable that efficacy specification for Product 1 is an sufficiently ***effective fungicide*** at concentrations of 2% and above for yeast strain *Candida albicans* and only undiluted (80%) for mould strain *Aspergillus brasiliensis (niger)* under standard dirty conditions using a contact time of 15 minutes (Tables 7-8).

Table 7. Reduction factor for viable counts of colony forming units (R, CFU/ml)

Test Organism (Strain)	**Contact Times And Product Concentrations Tested (% v/v)**			
	15 minutes			
	1	**2**	**3**	**80**
Candida albicans ATCC 10231	<3.37 ± 0.15	**>4.37 ± 0.15**	**>4.37 ± 0.15**	**>4.37 ± 0.15**
	-	**20**	**50**	**80**
Aspergillus brasiliensis (niger) ATCC 16404	**-**	<3.39 ± 0.15	<3.39 ± 0.15	**>4.39 ± 0.15**

Bold values = passes (> 4 log reduction)

Table 8. Tabulated test results of fungicidal activity in suspension test (EN 1650: 2008)

Test Strain	**Microbial Suspension in the Test**		**Test Procedure at Product Concentration v/v (%)**			
			3	**2**	**1**	**80***
Candida albicans	10^{-5}: >150;>150	Vc	0;0	0;0	>150	0;0

	10^{-6}: 31;38	Na	<1.5 x 10^2	<1.5 x 10^2	>1.5 x 10^3	<1.5 x 10^2
	N: 3.5 x 10^7	**R**	**>4.37 ± 0.15**	**>4.37 ± 0.15**	<3.37 ± 0.15	**>4.37 ± 0.15**
			Test Procedure at Product Concentration v/v (%)			
			80	**50**	**20**	**-**
Aspergillus brasiliensis (niger)	10^{-5}: >150;>150	Vc	0;0	>150	>150	-
	10^{-6}: 33;41	Na	<1.5 x 10^2	>1.5 x 10^3	>1.5 x 10^3	-
	N: 3.7 x 10^7	**R**	**>4.39 ± 0.15**	<3.39 ± 0.15	<3.39 ± 0.15	-

* - tested for the product as is
Vc – viable count; N – CFU/ml in the test suspension
R – reduction factor of viable counts [values in bold = passes (≥4 Log reduction)]
Na - CFU/ml in the test mixture
The validation tests on bacterial suspension, test conditions, filtration procedure and filtration validation test are performd with all four bacterial strains as appropriate according to Standard method. Uncertainty = mean intra-laboratory standard deviation for testing chemical disinfectants / antiseptics; extension factor k = 2 for confidence interval 95%.

- *Family B Product 1* (Table 9 -10) ***in non-porous surface test*** demonstrated a sufficient *bactericidal* activity at concentrations 1% and undiluted against test organisms *Escherichia coli and Enterococcus hirae;* 0.3% , 0.5% and undiluted against *Pseudomonas aeruginosa; 2%, 3%* and undiluted against *Staphylococcus aureus* in dirty conditions (BSA 3 g/l), in 5 minute contact time and at $20^0C \pm 1^0C$ temperature.

Family B Product 1 ***in non-porous surface test*** was also sufficiently effective in reducing yeast infectivity of *Candida albicans* at concentrations at 3%, 4% and above and mould strain *Aspergillus brasiliensis (niger)* undiluted (80%) in a standard non-porous surface test, under dirty conditions (BSA 3 g/l) and 15 minutes contact time.

Respectively, Product 1 is an sufficiently ***effective bactericide*** at concentrations of 2% or above under defined standard test conditions using contact time 5 minutes (pass R = ≥ 4 log); as well as sufficiently ***effective fungicide*** if product applied as undiluted and sufficiently ***effective yeasticide*** at concentration of 3% or above under defined standard test conditions using contact time 15 minutes (pass R = ≥ 3 log). (Tables 9-10).

Table 9. Reduction factor for viable counts of colony forming units (R, CFU/ml)

Test Organism (Strain)	**Contact Times And Product Concentrations Tested (% v/v)**			
	5 minutes			
	1.0	**0.7**	**0.5**	**100**
Escherichia coli ATCC 10536	**>5.81 ±0.15**	3.52 ±0.15	2.62 ±0.15	**>5.81 ±0.15**
Enterococcus hirae ATCC 10541	**>6.11 ±0.15**	3.45 ±0.15	2.63 ±0.15	**>6.11 ±0.15**
	0.5	**0.3**	**0.2**	**100**
Pseudomonas aeruginosa ATCC 15442	**>5.78 ±0.15**	**4.18 ±0.15**	2.62 ±0.15	**>5.78 ±0.15**
	3.0	2.0	1.0	100
Staphylococcus aureus ATCC 6538	**>6.71 ±0.15**	**4.07 ±0.15**	2.48 ±0.15	**>6.71 ±0.15**
	15 minutes			
	4.0	3.0	**2.0**	**100**
Candida albicans ATCC 10231	**>4.92 ±0.15**	**3.21 ±0.15**	1.66 ±0.15	**>4.92 ±0.15**
	-	20	50	100
Aspergillus brasiliensis (niger) ATCC 16404	-	2.03 ±0.15	2.52 ±0.15	**>5.97 ±0.15**

Bold values = passes (>4 log reduction for bacteria and >3 log reduction for fungi).

Table 10. Tabulated results for *bactericidal and fungicidal activity* in the non-porous surfaces test (EN 13697:2002/ Ap1:2003)

Test Strain	**Test Suspension N**	**Control With Water Nc**		**Test Procedure at Product Concentration v/v (%)**			
				0.5	**0.3**	**0.2**	**100***
P. aeruginosa	10^{-6}: >300;>300	10^{-3}: 72;79	**10^{0}**	0;0	5;5	134;158	0;0
		10^{-4}: 9;9	10^{-1}	0;0	1;1	14;20	0;0
	10^{-7}: 38;45	Nc: 5.88	Nd	<0.1	1.70	3.16	<0.1
	N: 7.02		Nts	0	0	0	0
		Nts: 42	**ME**	**>5.78±0.15**	**4.18±0.15**	2.62±0.15	**>5.78±0.15**
				Test Procedure at Product Concentration v/v (%)			
				3	**2**	**1**	**100***
S. aureus	10^{-6}: >300;>300	10^{-3}: >300;>300	**10^{0}**	0;0	51;58	>300;>300	0;0
		10^{-4}: 61;67	10^{-1}	0;0	4;7	203;234	0;0
	10^{-7}: 44;50	Nc: 6.81	Nd	<0.1	2.74	4.33	<0.1
	N: 7.07		Nts	0	0	18	0
		Nts: 96	**ME**	**>6.71±0.15**	**4.07±0.15**	2.48±0.15	**>6.71±0.15**
				Test Procedure at Product Concentration v/v (%)			
				1	**0.7**	**0.5**	**100***
E. coli	10^{-6}: 254;279	10^{-3}: 78;86	**10^{0}**	0;0	22;27	183;208	0;0
		10^{-4}: 8;8	10^{-1}	0;0	3;4	15;18	0;0
	10^{-7}: 26;31	Nc: 5.91	Nd	<0.1	2.39	3.29	<0.1
	N: 6.82		Nts	0	0	5	0
		Nts: 55	**ME**	**>5.81±0.15**	3.52±0.15	2.62±0.15	**>5.81±0.15**
E. hirae	10^{-6}: >300;>300	10^{-3}: 172;149	**10^{0}**	0;0	54;61	>300;>300	0;0
		10^{-4}: 14;21	10^{-1}	0;0	6;9	42;35	0;0
	10^{-7}: 42;47	Nc: 6.21	Nd	<0.1	2.76	3.58	<0.1
	N: 7.05		Nts	0	2	12	0

Test Strain	Test Suspension N	Control With Water Nc		Test Procedure at Product Concentration v/v (%)			
				0.5	**0.3**	**0.2**	**100***
		Nts: 34	**ME**	**>6.11±0.15**	3.45±0.15	2.63±0.15	**>6.11±0.15**
				Test Procedure at Product Concentration v/v (%)			
				4	**3**	**2**	**100***
C. albicans	10^{-5}: >300;>300	10^{-2}: 98;113	10^{0}	0;0	8;5	218;235	0;0
		10^{-3}: 8;11	10^{-1}	0;0	3;3	22;24	0;0
	10^{-6}: 34;39	Nc: 5.02	Nd	<0.1	1.81	3.36	<0.1
	N: 5.96		Nts	0	0	9	0
		Nts: 57	**ME**	**>4.92±0.15**	**3.21±0.15**	1.66±0.15	**>4.92±0.15**
				Test Procedure at Product Concentration v/v (%)			
				100*	**50**	**20**	**-**
A. brasiliensis (niger)	10^{-5}: >150;>150	10^{-2}: >150;>150	10^{0}	0;0	>150;>150	>150;>150	-
		10^{-3}: 109;124	10^{-1}	0;0	32;39	117;102	-
	10^{-6}: 42;49	Nc: 6.07	Nd	<0.1	3.55	4.04	-
	N: 6.06		Nts	0	11	4	-
		Nts: 23	**ME**	**>5.97±0.15**	2.52±0.15	2.03±0.15	-

* - tested for the product as is
N - log $_{10}$ of CFU in 0.025 ml of microbial suspension in the test
Nc - log $_{10}$ of CFU on the tested surface in test procedure with water
Nts – number of residual CFU
Nd - log $_{10}$ of CFU on the tested surface in test procedure with product
ME – microbicidal action [values in bold = passes (≥3 Log reduction)];
Uncertainty = mean intralaboratory standard deviation for testing chemical disinfectants / antiseptics; extension factor k = 2 for confidence interval 95%.

- *Family B Product 1* (Table 11-12) ***in a standard quantitative suspension test*** at concentration 80% was sufficiently effective in reducing *infectivity* of *Bacillus subtilis* spores in following 60 minute contact period. The tests showed that at a concentration of 80 %, the Product 1 demonstrated the necessary sporicidal action with a reduction in CFU of ≥3 log.

Respectively, Product 1 is an ***effective sporicide*** undiluted (80 %) under standard dirty conditions using a contact time of 60 minutes (Tables 11-12).

Table 11. Reduction factor for viable counts of colony forming units (R, CFU/ml)

Test Organism (Strain)	Contact Times And Product Concentrations Tested (% v/v)			
	60 minutes			
	-	30	50	80
Bacillus subtilis ATCC 6633	-	<2.16	2.24	**>3.46**

Bold values = passes (>3 log reduction)

Table 12. Tabulated test results of ***sporicidal activity*** in suspension test (EN 13704:2004)

Test Strain	Microbial Suspension in the Test		Test Procedure at Product Concentration v/v (%)		
			80*	**50**	**30**
Bacillus subtilis	10^{-4}: >300;>300	Vc	0;0	242;267	>300
	10^{-5}: 39;47	Na	<1.5 x 10^2	2.5 x 10^3	>3.0 x 10^3
	N: 4.3 x 10^6	**R**	**>3.46**	2.24	<2.16

* - tested for the product as is
Vc – viable count
N – CFU/ml in the test suspension
R – reduction factor of viable counts [values in bold = passes (≥3 Log reduction)]
Na - CFU/ml in the test mixture
Uncertainty = mean intralaboratory standard deviation for testing chemical disinfectants / antiseptics; extension factor k = 2 for confidence interval 95%.

- *Family B Product 1* (Table 13-14) ***in a standard suspension test*** was sufficiently effective in reducing ***virus infectivity*** of *Adenovirus* type 5, at concentrations of 12.5% and above in following 60 minute contact period in both 'clean'(0.3% BSA) and 'dirty' (3%BSA + 3% erythrocytes) conditions.

Also Product 1 demonstrated a virucidal activity at 50% and undiluted (100%) under clean and dirty conditions.

Respectively, Product 1 is an ***effective virucide*** (R ≥4 log) at concentrations of 12.5% and above against Adenovirus type 5 (Adenoid 75) under standard 'clean conditions' and 'dirty conditions' using a contact time of 60 minutes (Table 13-14).

Table 13. Reduction factor for viral activity ($TCID_{50}$/ml)

Test Organism (Strain)	Contact Times And Product Concentrations Tested (% v/v)		
	60 minutes (clean conditions)		
	12.5	**50**	**100**
Adenovirus type 5 (adenoid 75)	**4.2 ±0.52**	≥3.94	≥3.94
	60 minutes (dirty conditions)		
	12.5	**50**	**100**
Adenovirus type 5 (adenoid 75)	**4,46±0.50**	**≥4.64**	≥3.94

Table 14. Tabulated test results of virucidal activity against adenovirus (EN 14476)

Product Concentration: 100%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	≤1.75	≤1.75
Residual virus detectable	No	No
Virus Reduction* (lg ID_{50})	≥3.94	≥3.94
Virucidal activity given with respect to EN 14476**	Yes	Yes
Product Concentration: 50%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	≤1.75	≤1.05
Residual virus detectable	No	No
Virus Reduction* (lg ID_{50})	≥3.94	≥4.64
Virucidal activity given with respect to EN 14476**	Yes	Yes
Product Concentration: 12.5%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	1.49±0.37	1.23±0.33
Residual virus detectable	Yes	Yes
Virus Reduction* (lg ID_{50})	**4.2±0.52**	**4.46±0.50**
Virucidal activity given with respect to EN 14476**	Yes	Yes

*Titre of residual virus (lg ID_{50}); with respect to cytotoxicity (if applicable)
**Virus titre of virus control (lg ID_{50}) minus virus titre of sample (lg ID_{50})
Virucidal activity applies as given, whether RF ≥ 4.0 log
Bold values = passes (≥4 log reduction)

- *Family B Product 1* (Table 15-16) ***in a standard suspension test*** was sufficiently effective in reducing ***virus infectivity*** of *Poliovirus type 1 (LSc-2ab*) at concentrations of 12.5% and above in following 60 minute contact period in both 'clean' and 'dirty' conditions. The test showed that Product 1 has a virucidal activity also at concentration 50% and undiluted (100%) when tested under clean conditions and dirty conditions and 14 minutes contact time.

Product 1 is a sufficient ***effective virucide*** at concentrations of 12.5% and above for Poliovirus type 1 (LSc-2ab) under standard 'clean conditions' and 'dirty conditions' using a contact time of 60 minutes (Table 15-16).

Table 15. Reduction factor for viral activity (TCID50/ml)

Test Organism (Strain)	**Contact Times And Product Concentrations Tested (% v/v)**		
	60 minutes (*clean conditions*)		
	12.5	**50**	**100**
Poliovirus type 1 (LSc-2ab)	**≥6.05**	**≥6.05**	**≥5.35**
	60 minutes (*dirty conditions*)		
	12.5	**50**	**100**
Poliovirus type 1 (LSc-2ab)	**≥5.52**	**≥4.82**	**≥4.12**

Bold values = passes (≥ 4 log reduction)

Table 16. Tabulated test results of virucidal activity against poliovirus (EN 14476)

Product Concentration: 100%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	≤1.05	≤1.75
Residual virus detectable	No	No
Virus Reduction* (lg ID_{50})	≥5.35	≥4.12
Virucidal activity given with respect to EN 14476**	Yes	Yes
Product Concentration: 50%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	≤0.35	≤1.05
Residual virus detectable	No	No
Virus Reduction* (lg ID_{50})	≥6.05	≥4.82
Virucidal activity given with respect to EN 14476**	Yes	Yes
Product Concentration: 12.5%		
Protein Load	**Clean Conditions**	**Dirty Conditions**
Ø Titre/test volume (lg ID_{50})	≤0.35	≤0.35
Residual virus detectable	No	No
Virus Reduction* (lg ID_{50})	≥6.05	≥5.52
Virucidal activity given with respect to EN 14476**	Yes	Yes

*Titre of residual virus (lg ID_{50}); with respect to cytotoxicity (if applicable)
**Virus titre of virus control (lg ID_{50}) minus virus titre of sample (lg ID_{50})
Virucidal activity applies as given, whether RF ≥ 4.0 log
Bold values = passes (≥4 log reduction)

2.5.1.2 Evaluation of the label claims

The product is intended to use as toilet bowl disinfectant and cleaner. The evaluation of efficacy demonstrates that the products in Family B meet agreed acceptability criteria for reduction of bacteria, bacterial spores, yeasts, fungi and viruses in suspended test and also meet agreed acceptability criteria for reduction of bacteria, yeasts and fungi in non-porous surface test in the defined test conditions according to EN Standard methods.

The indicated mode of action: cellular injury and/or necrosis in contact with biological material (e.g. microorganisms) due to action of highly reactive ions, that results as "killing" and reduction in bacteria, bacterial spores, fungi, yeasts and viruses.

Therefore, products in Family B are considered as broad spectrum disinfectants with proven efficacy specification bactericide, fungicide, yeasticide, virucide and bacterial sporicide.

General label claim is: bactericide, fungicide, yeasticide, virucide and bacterial sporicide.

The target organisms in the submitted efficacy studies for confirmation of label claim are:

Pseudomonas aeruginosa ATCC 15442;
Staphylococcus aureus ATCC 6538;
Escherichia coli ATCC 10536;
Enterococcus hirae ATCC 10541;
Candida albicans ATCC 10231;
Aspergillus brasiliensis (niger) ATCC 16404;
Spores of Bacillus subtilis ATCC 6633;
Adenovirus type 5, Strain Adenoid 75, ATCC VR-5;
Poliovirus type 1, Strain Sabin 1 NIBSC 01/528 (LSc-2ab), CDC; ATCC VR-1562.

FOR LATVIA:

The Latvian CA also considers that the following label claims provided by the applicant are suitable on products label for trained professionals, professionals and general public (non-professionals):

- Kills 99.9%* microbes**/microorganisms**/bacteria/fungi/viruses
- Antimicrobial*
- Antibacterial*
- Disinfects*
- Disinfectant*
- Bactericide*
- Fungicide*
- Virucide *
- Yeasticide *
- Sporicide *

*pass microbial reduction criteria (lg R), ref. EN 1276, EN 1650, EN 13697, EN 13704, EN 14476 [1]
** bacteria, bacterial spores, fungi, viruses.

The above mentioned label claims are acceptable to use in Latvia. The applicant has to agree with concerned Member States for the use of terminology and translation of label claim for trained professionals, professionals and general public (non-professionals) users in each language.

2.5.2 Dose / mode of action / known limitations / resistance

The biocide product should ideally be tested at a variety of application rates (minimum three concentrations) including rates below those suggested for commercial use. The dose should be in order to assess if the recommended dose is the minimum necessary to achieve the desired effect. The products of Family B were tested at a variety of rates including untreated control and a dose which achieved the claimed effect. The dose rates data for Product 1 (2.5.1.1.) are shown in tabular presentations for each efficacy test (Tables 5-20).

The Latvian CA considers that the application rate ~80 ml proposed by the applicant as per label instructions would achieve the claimed effect. Use frequency of product is not restricted, as required.

The results of the efficacy tests conclusively demonstrate that the products in Family B at concentration 80% (used as is / undiluted) for a 60 min contact time reached a sufficient effectiveness and passed the microbial reduction criteria (R log) and achieved the claimed effect proposed by the applicant for intended use of products in Family B as toilet bowl disinfectants and cleaner.

2.5.2.1 Mode of action

Active substance HCl of Family B fully dissociates in solution and forms the hydronium ion (H_3O^+) which is highly reactive with organic molecules. In contact with biological material, such as micro-organisms, this reactivity results in cellular injury and/or necrosis (WHO, 1982). Therefore the mode of action for this product Family B is “killing”. Finally products in Family B cause a reduction in number of micro-organisms including individuals capable of causing infection.

[1] The reference for apporpriate standard must be used for the each label claim on the label

2.5.2.2 Known limitations

The limiting factors which may influence the efficacy testing procedure process (e.g. temperature, pH, humidity, nutrient media, equipment or other interfering factors) have not been recorded in Test Reports. The efficacy studies of products Family B have been performed in Laboratories which have a Good Laboratory Practice (GLP) statement as well as in accordance with standard test procedures and conditions claimed in EN Standard Method protocols.

2.5.2.3 Resistance

No clear scientific evidence exists that the target organisms have developed resistance against the active substance HCl. Development of resistance is considered unlikely due to the non-specific mode of action (cellular injury and necrosis due to highly reactive ions) and lack of bioaccumulation. As the risk of resistance developing to HCl is low, no specific management strategies have been required.

2.6 Exposure assessment

2.6.1 Description of the intended use(s)

All products in Family B are ready-to-use surface disinfectants for toilet bowls to be used by professionals and non-professionals. In general, they belong to the biocidal product type PT2: *disinfectants and algaecides not intended for direct application to humans or animals; products used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs.*

It is understood that professionally the products are primarily used in small hotels and restaurants for disinfection and cleaning purposes. The products are used approximately 10–20 times per day by professional cleaners in such a setting. In contrast, in the household by the general population the products are used on average approximately 3 times every 28 days. This is equivalent to a use frequency of 39 times/year.

The label recommendation is to apply up to 80 ml of product per application. The label instructions for use state that the product should be carefully applied only under the rim of the toilet bowl and that up to 10 minutes should elapse before the toilet is flushed. Additional instructions are given for the purpose of achieving the intended biocidal effect, whereby one hour should be allowed to elapse before the toilet is flushed. The toilet should not be used while the product is applied and no other cleaning agents should be used in conjunction with the product since the product is not intended to be mixed with any other substances or products. The product is incompatible with bleaches and other cleaning products. Therefore, a statement is included under the 'Precautions' section of the product label; 'Do not use with any bleaches or other cleaning products'.

2.6.2 Assessment of exposure to humans and the environment

The active substance Hydrochloric Acid (HCl) is a High Production Volume (HPV) chemical and therefore is not exclusively manufactured for biocidal purposes within the EU. It is therefore considered that the manufacture of the active substance and formulation of biocidal products is assessed by other EU legislation. Therefore, the manufacturing and formulation processes do not have to be taken into account in the exposure assessments for human health and the environment.

All products in Family B are ready-to-use products, therefore, exposure to humans only occurs by direct application of the products indoors to the toilets only. The products are not used in a manner that would cause them to come into contact with food or feedstuffs.

HCl dissociates rapidly in water forming protons (H^+ ions) and chloride ions which are ubiquitous chemical species in the environment and in the body fluids and organs of all living organisms. HCl is

not genotoxic, carcinogenic, toxic to reproduction and development or neurotoxic; the substance has not sensitizing properties. The products in Family B are merely classified as corrosive (Skin. Corr. 1B H314: Causes severe skin burns and eye damage). The primary toxic effect of HCl is contact irritation/corrosion both through inhalation and dermal routes due to the very low pH of the substance. Exposure and risk assessment needs to address only the local site-of-contact irritancy, since at lower non-irritant concentrations HCl only contributes to the physiological electrolyte pool.

During use of the product both by professionals and non-professionals (general public), potential exposure may occur *via* the inhalation route (through exposure to hydrogen chloride vapours) or *via* the dermal contact with the cleaning solution during the brushing of the toilet. Therefore, the flushing is recommended before the brushing of the toilet, as after application the product is removed from the toilet system by flushing, which eliminates any further potential exposure to humans. Possible exposure of residues through environment is considered irrelevant as the product is diluted significantly by wastewater. Besides, the active substance HCl is dissociated easily into chloride ions and protons (H^+ ions) being highly abundant endogenous ions in human tissue fluids and blood plasma as well as in the human sweat.

With respect to **inhalation exposure**, in order to determine the concentration of gaseous hydrochloric acid or hydrogen chloride in the headspace of a toilet bowl when products of Family B are applied, a special experiment was carried out by Reckitt Benckiser [redacted]. The test material Harpic Power Plus Original with content of HCl 9 % w/w was used belonging to the Family A with a higher HCl content in comparison to products of Family B which contain 6.75 % w/w HCl. So, the results obtained constitute some overestimation of exposure in relation to products of Family B.

All toilet bowls were thoroughly cleaned with a 12% HCl solution prior to the experiment and left to air out over night to prevent interference from the cleaning product. It should be remarked that there are no approved guidelines for performance of such kind of studies but they have been carried out acc. to GLP.

The "worst case scenario" applying the whole bottle of the product (1000 ml or ~1018-~1038 g) and the "realistic scenario" applying 80 $\pm$ 25 g of the product according to the instruction for use were studied. In addition, the "blank test" was performed in the conditions similar to "scenarios" studies but without the product`s application. In each case 5 toilets were used and all results of measurements were given as arithmetical means at respective point in time: 1, 10 minutes, 1, 2, 4 and 8 hours following the initial product application (Tables 17 and 18). A fragrance box was placed over each toilet to confine the headspace area, and the air was sampled using a Gastec Hydrogen Chloride Detector Tube with a Gastec GV-100 piston pump.

The concentration of gaseous hydrochloric acid in the headspace of toilet bowls was on average 9.3 ppm HCl when measured 8 hrs following application of a whole bottle of the test material and 1.6 ppm HCl when following the label instructions, which is the more "realistic scenario". The highest average HCl value within the "realistic scenario" was determined after 4 hours (3.9 ppm).

Regarding the suggested application time given in the label instruction, after 10 minutes the concentration was **1.10 ppm** both for the "worst case scenario" and the "realistic scenario" but after 1 hour – **1.80 ppm** and **1.60 ppm**, respectively.

The blank test system recorded zero values throughout.

Table 17. Average HCl readings from 5 toilets after application of Harpic Power Plus Original (HCl 9 % w/w) – the "worst case scenario"

Time Point	HCl, ppm
1 min	0.75
10 mins	1.10
1 hr	1.80
2 hr	3.90
4 hr	4.80
8 hr	9.30

Table 18. Average HCl readings from 5 toilets after application of Harpic Power Plus Original (HCl 9 % w/w) – the "realistic scenario"

Time Point	HCl, ppm
1 min	0.47
10 mins	1.10
1 hr	1.60
2 hr	3.00
4 hr	3.90
8 hr	3.00

Dermal exposures due to contact with the cleaning solution were estimated using the scenario for use of "Toilet cleaners" as described in the "Cleaning Products Fact Sheet" by RIVM and integrated into the residential exposure model, ConsExpo 4.1. The external dermal exposure dose per day was estimated to **0.206 mg/kg bw**. A systemic internal dose (by applying a factor for dermal absorption) was not calculated, as localised, rather than systemic effects would occur. Reabsorption of H^+ and chloride ions, dissociation products of HCl, which are present in the human sweat also, are not observed. It should be noted that dermal exposures predicted by ConsExpo model do not take into consideration the use of specific personal protection equipment (PPE), namely, gloves.

2.7 Risk assessment for human health

Risk assessment for human health is based on evaluation of the toxicological properties and hazard potential of the active substance in question, namely, HCl and the products of Family B. Exposure estimation stemming from "field" experiment in relation to released HCl vapour in the air after application of the product as well as modelled dermal exposure data (modelled by *ConsExpo 4.1*) is the core for risk assessment carried out.

2.7.1 Hazard potential

2.7.1.1 Toxicology of the active substance

The active substance Hydrochloric Acid (HCl) is classified as "Dangerous" acc. to Regulation 1272/2008: H290 - May be corrosive to metals; H314 - Causes severe skin burns and eye damage and H335 - May cause respiratory irritation. All biocidal products in Family B containing ~6.75 % w/w of HCl are classified as "Dangerous" and "Corrosive" with hazard statement "H314- Causes severe skin burns and eye damage" based on the very low pH level (pH ~1.5) and in vitro skin corrosion tests.

HCl dissociates rapidly in water forming protons (H^+ ions) and chloride ions which are ubiquitous chemical species in the environment and in the body fluids and organs of all living organisms. HCl is

not genotoxic, carcinogenic, toxic to reproduction and development or neurotoxic; the substance has no sensitizing properties. The primary toxic effect of HCl is contact irritation/corrosion both through inhalation and dermal routes due to the very low pH of the substance. Lower non-irritant concentrations of HCl only contributes to the physiological electrolyte pool. Dermal absorbtion or reobsorption of HCl dissociation products which are present in the human sweat is not occurring.

2.7.1.2 Toxicology of the substance(s) of concern

Not applicable.

2.7.1.3 Toxicology of the biocidal product

All biocidal products in Family B containing ~6.75 % w/w of HCl are classified as "Dangerous" and "Skin. Corr. 1" with hazard statement "H314 - Causes severe skin burns and eye damage" based on the very low pH level (pH ~1.5) and *in vitro* skin corrosion tests. A transcutaneous electrical resistance (TER) measurements` test is performed on behalf of the applicant by the [redacted] in order to determine the skin corrosivity potential of the products [redacted]. Corrosive substances are producing an irreversible loss of normal stratum corneum integrity and functions which can be measured as a reduction in the TER below a corrosive threshold level (5 kohm). By application of 0.15 ml of the test product identified as Harpic LSR (HCl 6 %, pH < 2) on the rat skin discs in vitro for 24 hours the TER value was 0.934 kohm (the average value from 3 skin discs).

Two other co-formulants (Tallow trimethylammonium chlorideand Bis (2-hydroxyethyl) tallow alkylamine) are classified as H314: Causes severe skin burns and eye damage as well, constituting less than 2 % of the products together. Additionally applying CLP criteria for skin corrosion of mixtures (Table 3.2.3), the proper classification for the product family shall be Skin Corr. 1, H314 (Causes severe skin burns and eye damage).

However the active substance HCl is classified as STOT SE 3 with hazard statement H335 - May cause respiratory irritation as well, the products of Family B are not classified for respiratory irritation due to HCl concentration being below the specific concentration limit of 10 % triggering the classification in question.

Other constituents in biocidal products

Additionally, the products contain 6.75 % w/w Hydrochloric Acid and ~91 % w/w water with surfactants, dyes, fragrance making up the rest of the ingredients. Under CLP in the absence of data for a mixture, the resulting classification of the product may be derived using the additivity formula (Part 3, 3.1.3.6.1) according to which the products shall not be classified as acute oral toxic (all ingredients classified as acute oral toxic are taken into account), acute toxic if inhaled (none of the components present in any of the products is classified for acute inhalation toxicity) or acute toxic in dermal contact. Concerning respiratory irritancy, only Hydrochloric Acid is classified as STOT SE 3, but the content of it is below the SCL=10 % for this effect. In addition, none of the products contain substances classified for skin sensitisation or other toxicological end points. Classification for skin and eye irritation is not applicable as the products are classified as Skin Corr. 1, H314.

2.7.2 Exposure

The biocidal product contains the active substance HCl (pure: ~90 g/kg).

2.7.2.1 Exposure of professional users

Inhalation route

Information on HCl conservative concentrations in the toilets` headspace after application of the biocidal products of Family B containing 6.75 % w/w of HCl are summarized in the Table 1 ("worst case scenario") and Table 2 ("realistic scenario") above. It must be stressed that all field experiments are performed using a biocidal product of Family A containing 9 % w/w of HCl and therefore giving higher values as it would be expected by application of a product containing 6.75 % w/w HCl.

Following the suggested application time given in the label instruction, after 10 minutes the concentration was **1.10 ppm** (1 ppm HCl = 1.5 mg/m^3 HCl) both for the "worst case scenario" and the "realistic scenario" but after 1 hour – **1.80 ppm** and **1.60 ppm**, respectively. These values are obtained as average concentrations from 5 toilets used in the field experiment. Converting the HCl concentrations expressed as ppm to mg/m^3 we can get the following values: concentration after 10 minutes for both scenarios **1.65 mg/m^3**, concentration after 1 hour for the "worst case scenario" **2.7 mg/m^3** and **2.4 mg/m^3** after 1 hour following the application of the biocidal products of Family A within the "realistic scenario" which supposes taking into consideration the label instruction and applying ~80 ml of the product to the toilet rim.

*The derived **Acceptable effect concentration** (AEC) for HCl vapors through inhalation route determined in the process of assessment of biocidal active substance HCl is **3.75 mg/m^3**. (Inclusion of active substances in Annex I or IA to Directive 98/8/EC. Hydrochloric acid. Product-type 2 (Private area and public health area disinfectant and other biocidal products). (Final CAR, November 2011).*

During up to one hour of the maximal application time, as suggested by the label instruction and even in the case of misuse when the whole bottle (~ 1 L) of the biocidal product is applied, no detrimental effects on the health of professional users are expected.

In addition to explanations already outlined above, the conditions of the field experiment carried out by Reckitt Benckiser are more conservative in comparison to real life situations - a fragrance box was placed over each toilet to confine the headspace area and not to allow for the formed HCl fumes to be diluted with the adjacent air, especially when appropriate ventilation systems are in place.

Furthermore, the general protection measures for bulk handling and use state that if a risk assessment indicates this is necessary, a properly fitted, air-purifying or air-fed respirator shall be used. However, this seems to be more relevant for the production/formulation process of the biocidal products, as, according to the information submitted by the applicant, the products in question are primarily used in small hotels, restaurants and offices for disinfection and cleaning purposes approximately only 10–20 times per day by professional cleaners.

Dermal route

The external dermal exposure dose per day for professional users was estimated to be **0.206 mg/kg bw** by means of residential exposure model ConsExpo 4.1 based on assumption of dilution of the applied cleaning solution (see description of usage patterns below) and the usage scenario outlined in the "Cleaning Products Fact Sheet" elaborated by RIVM. The input parameters for ConsExpo 4.1 are the following: frequency of use: 20 times/day; exposed area : 215 cm^2; product amount: 2.2 g; weight fraction of the solution based on RIVM default value : 0.0056; bodyweight : 60 kg; dermal absorption: 100 %.

A reference value for acute and prolonged dermal exposure has not been derived as the primary toxic effect is considered to be contact irritation/corrosion with no penetration being expected from dermal exposure to sub-irritant concentrations as the dissociation products of HCl (H^+ and chlorine ions) are widely present physiological electrolytes. If a few droplets of the concentrated formulation come into contact with the skin, it will dilute rapidly in human sweat, on the one hand, and due to its irritating properties the skin will be washed immediately, on the other hand. Assumption that no chronic, repeated and systemic dermal exposure is expected to occur is reasonable and justified.

Very minor experimental data obtained on rabbits state that **LD_{50}** from dermal exposure makes up **>5010 mg/kg** (Draft OECD SIDS on hydrogen chloride).

During use of the products by professionals potential dermal exposure may occur via the contact with the cleaning solution during the brushing of the toilet, as the opportunity for direct dermal contact to the undiluted product is minimised due to special construction of products` bottle (Annex 2) and prescribed application patterns. The product is applied directly from the product container by squeezing the bottle (equipped with a non-drip nozzle) and directing the application under the rim of the toilet.

The summary on both inhalation and dermal exposure assessment in relation to professional users is provided in the Table 19.

Table 19. Summary of exposures associated with application of products of Family B (HCl = 6.75 % w/w) by professional users

* Conservative conditions applied using a product containing 9 % w/w of HCl
** Acceptable effect concentration

Exposure route	**Exposure concentration**			**Reference value**
	After 10 min.	**After 1 hour**	**Day**	
Inhalation*	1.10 ppm = **1.65** mg/m³ "*Worst case scenario*" and "*realistic scenario*"	1.80 ppm = **2.7** mg/m³ "*Worst case scenario*" 1.60 ppm = **2.4** mg/m³ "*Realistic scenario*"		AEC** = **3.75** mg/m³
Dermal			**0.206** mg/kg bw	LD_{50} = **>5010** mg/kg (rabbits)

2.7.2.2 Exposure of non-professional users and the general public

Inhalation route

Information on HCl conservative concentrations in the toilets` headspace after application of the biocidal products of Family B containing 6.75 % w/w of HCl are summarized in the Table 21 ("worst case scenario") and Table 18("realistic scenario") above. It must be stressed that all field experiments

are performed using a biocidal product of Family A containing 9 % w/w of HCl and therefore giving higher values as it would be expected by application of a product containing 6.75 % w/w HCl.

Besides, it should be remarked that both non-professional and professional users are subject to the same HCl concentrations in the air by the single application of the biocidal product. It is considered that only adult users are taken into account as children will not have access to the product, as recommended on the label. No exposure during application is assumed to occur for children.

Following the suggested application time given in the label instruction, after 10 minutes the concentration was **1.10 ppm** both for the "worst case scenario" and the "realistic scenario" but after 1 hour – **1.80 ppm** and **1.60 ppm**, respectively. These values are obtained as average concentrations from 5 toilets used in the field experiment. Converting the HCl concentrations expressed as ppm to mg/m^3 we can get the following values: concentration after 10 minutes for both scenarios **1.65 mg/m^3**, concentration after 1 hour for the "worst case scenario" **2.7 mg/m^3** and **2.4 mg/m^3** after 1 hour following the application of the biocidal products of Family A within the "realistic scenario" which supposes taking into consideration the label instruction and applying ~80 ml of the product to the toilet rim.

The derived **Acceptable effect concentration** (AEC) for HCl vapors through inhalation route determined in the process of assessment of biocidal active substance HCl is **3.75 mg/m^3**. *Inclusion of active substances in Annex I or IA to Directive 98/8/EC. Hydrochloric acid. Product-type 2 (Private area and public health area disinfectant and other biocidal products). (Final CAR, November 2011).*

During up to one hour of the maximal application time as suggested by the label instruction and even in the case of misuse when the whole bottle (~ 1 L) of the biocidal product is applied, there are no detrimental effects on health of non-professional users expected.

In addition to explanations already outlined above, the conditions of the field experiment carried out by Reckitt Benckiser are more conservative in comparison to real life situations - a fragrance box was placed over each toilet to confine the headspace area and not to allow for the formed HCl fumes to be diluted with the adjacent air.

Dermal route

The external dermal exposure dose per day for non-professional users was estimated to be **0.206 mg/kg bw** by means of residential exposure model ConsExpo 4.1 based on assumption of dilution of the applied cleaning solution and the usage scenario outlined in the "Cleaning Products Fact Sheet" elaborated by RIVM. The input parameters for ConsExpo 4.1 are the following: frequency of use: 39 times/year; exposed area: 215 cm^2; product amount: 2. 2 g; weight fraction of the solution based on RIVM default value: 0. 0056; bodyweight: 60 kg; dermal absorption: 100 %.

A reference value for acute and prolonged dermal exposure has not been derived as the primary toxic effect is considered to be contact irritation/corrosion with no penetration being expected from dermal exposure to sub-irritant concentrations as the dissociation products of HCl (H^+ and chlorine ions) are widely present physiological electrolytes. If a few droplets of the concentrated formulation will come into contact with the skin, it will dilute rapidly in human sweat, on the one hand, and due to its irritating properties the skin will be washed up immediately, on the other hand. Assumption that no chronic, repeated and systemic dermal exposure is expected to occur is reasonable and justified.

Assumption that children will not have access to the product, as recommended on the label, is again in place.

Very minor experimental data obtained on rabbits state that **LD_{50}** from dermal exposure makes up **>5010 mg/kg** (Draft OECD SIDS on hydrogen chloride).

During use of the products by non-professionals potential dermal exposure may occur via contact with the cleaning solution during the brushing of the toilet, as the opportunity for direct dermal contact to the undiluted product is minimised due to special construction of products` bottle and prescribed application patterns. The product is applied directly from the product container by squeezing the bottle (equipped with a non-drip nozzle) and directing the application under the rim of the toilet.

Owing to the special construction of the product`s bottles and suggested application rules as well as taking into account the fact that general users will apply the products only occasionally for domestic usage (one toilet per day, ~3 times per month, up to 39 times per year) it is not expected that the non-professional users will be significantly exposed. Such assumption is valid even if it is unlikely that non-professional users will use any personal protection equipment, probably with the exception of protective gloves.

The summary on both inhalation and dermal exposure assessment in relation to non-professional users is provided in the Table 20.

Table 20. Summary of exposures associated with application of products of Family B (HCl = 6.75 % w/w) by non-professional users

Exposure route	**Exposure concentration**			**Reference value**
	After 10 min.	**After 1 hour**	**Day**	
Inhalation*	1.10 ppm = **1.65** mg/m³ "*Worst case scenario*" and "*realistic scenario*"	1.80 ppm = **2.7** mg/m³ "*Worst case scenario*" 1.60 ppm = **2.4** mg/m³ "*Realistic scenario*"		AEC** = **3.75** mg/m³
Dermal			**0.206** mg/kg bw	LD_{50} = **>5010** mg/kg (rabbits)

* Conservative conditions applied using a product containing 9 % w/w of HCl
** Acceptable effect concentration

2.7.2.3 Exposure to residues in food

The products of Family B are ready-to-use products intended to be only applied indoors (in toilets). The products are not used in a manner that would cause them to come into contact with food or feedstuffs. Possible exposure of residues through environment possibly taken up by food plants is also considered irrelevant because the active substance HCl discociates rapidly in the water forming H^+ and chloride ions which naturally occur in the environment.

2.7.3 Risk Characterisation

Risk characterisation for professional and non-professional users is based on a "field" experiment in relation to released HCl vapour in the air after application of the product as well as modelled dermal exposure data and comparison with the derived AEC.

2.7.3.1 Risk for Professional Users

Risk Characterization Ratios (RCRs) for professional users are given in the Table 21.

Table 21. Summary of RCRs associated with application of products of Family B (HCl = 6.75 % w/w) by professional users and non-professional users

Exposure route	**RCR**			**Remarks**
	After 10 min.	**After 1 hour**	**Day**	

Inhalation	**1.65** mg/m³/**3.75** mg/m³= = **0.44** "*Worst case scenario*" and "*realistic scenario*"	**2.7** mg/m³/**3.75** mg/m³= = **0.72** "*Worst case scenario*" **2.4** mg/m³/**3.75** mg/m³= = **0.64** "*Realistic scenario*"		RCR = exposure concentration /AEC*
Dermal			Not applicable**	

* Acceptable effect concentration

**A reference value for acute and prolonged dermal exposure has not been derived as the primary toxic effect is considered to be contact irritation/corrosion with no penetration being expected from dermal exposure to sub-irritant concentrations.

Based on the risk assessment of the active substance, a risk for professional users resulting from the intended use of products of Family B is unlikely because the RCRs values in relation to inhalation exposure are below "1" both 10 min. after application and 1 hour after application irrespective of "worst case scenario" or "realistic scenario".

With respect to dermal exposure, the primary toxic effect is considered to be contact irritation/corrosion. It is supposed that the professional users will apply relevant personal protective equipment, for example, protective gloves. Even without gloves, if a few droplets of the concentrated formulation come into contact with the skin, it will dilute rapidly in human sweat, on the one hand, and due to its irritating properties the skin will be washed immediately, on the other hand, however, it is quite unlikely to occur due to special construction of products` bottle and prescribed application patterns. The product is applied directly from the product container by squeezing the bottle (equipped with a non-drip nozzle) and directing the application under the rim of the toilet.

Table 22. Qualitative risk assessment matrix for local skin effects caused by application of products of Family B

Hazard Category	Effects in terms of C&L	Additional relevant hazard information	PT	Who is exposed?	Tasks, uses, processes	Potential exposure route	Frequency and duration of potential exposure	Potential degree of exposure	Relevant RMM & PPE	Conclusion on risk	Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)
Medium taking into account relatively small concentration of substances with corrosive properties	Skin Corr. 1, H314	-	2	Professional users	Direct application from the product container by squeezing the bottle (equipped with a non-drip nozzle) and directing the application under the rim of the toilet	Skin	10–20 times per day; few minutes per application	Irrelevant	Hazard labelling, label instructions for use including indication to brush the toilet bowl after the toilet with applied product is flushed, ready to use product in specially constructed bottle excluding possibility for spillage or splashing and with child proof closure, washing of hands after use and when signs of skin irritation are occurring, suggestion for professionals to use protective glows.	Acceptable since: -low duration and irrelevant degree of potential exposure for both users` groups -low frequency for general public - professionals suggested to use protective glows - special packaging - users shall follow instructions for use	Instructions for use might not be followed (↑)
				General public: adults			39 times/year; few minutes per application				

Regarding occupational safety, there are no objections against the intended use.

2.7.3.2 Risk for non-professional users and the general public

RCRs for non-professional users are given in the Table 5. It must be noted that both professional and non-professional users (general public) are subject to the same inhalation exposure values by single application of the biocidal product.

Based on the risk assessment of the active substance, a risk for non-professional users (general public) resulting from the intended use of products of Family B is unlikely because the RCRs values in relation to inhalation exposure are below "1" both 10 min. after application and 1 hour after application irrespective of "worst case scenario" or "realistic scenario".

With respect to dermal exposure, the primary toxic effect is considered to be contact irritation/corrosion. It is thought that the professional users will apply at least protective gloves. Even without gloves, if a few droplets of the concentrated formulation come into contact with the skin, it will dilute rapidly in human sweat, on the one hand, and due to its irritating properties the skin will be washed immediately, on the other hand, however, it is quite unlikely to occur due to special construction of products` bottle and prescribed application patterns. The product is applied directly from the product container by squeezing the bottle (equipped with a non-drip nozzle) and directing the application under the rim of the toilet (please see Table 37).

Direct exposure via the environment or to other residues resulting from the intended use is unlikely to cause any unacceptable acute or chronic risk to consumers (non-professionals, bystanders and residents). Regarding consumer health protection, there are no objections against the intended uses.

2.7.3.3 Risk for consumers via residues

The acute or chronic exposure to residues in food resulting from the intended uses is not in place, therefore, risk to consumers will not occur. Regarding consumer health protection, there are no objections against the intended uses.

2.8 Risk assessment for the environment

The formulation process involves primarily automated mixing of raw materials in a closed system. There is no direct release of formulation to water or soil. Potential release of HCl fumes to air is controlled through scrubbers, in which NaOH solution is used to absorb any HCl. There is no periodic monitoring of HCl residual fumes as quantities are not detectable. The NaOH solution is periodically replaced and effluent is pH-adjusted in an on-site treatment plant, or is collected and treated at another waste water treatment plant. The pH and chloride concentration are monitored at the output of the waste-water treatment plants and are within allowable limits (pH 5 to 11); maximum 4700 mg Cal-/l). There are special Directives and EU water quality legislation governing quality of discharges, predicted emissions of chloride and hydronium ions exist.

As HCl dissociates in water, any effects are due to hydronium and chloride ion concentrations and the major effect is the resulting pH. HCl released from liquid lavatory disinfectant cleaners, when used as a biocidal cleaning product, enters the sewage system in its dissociated form and will not cause significant change to the pH levels in a standard sewage treatment plant due to the high level of dilution and the well buffered environment of the Sewage Treatment Plant (STP). Therefore it will not have any direct or indirect adverse effects on aquatic biota. Chlorine is widely used in the purification of water intended for drinking. It is also used as a disinfectant to treat sewage effluent.

Hydrochloric acid is not directly released to the terrestrial compartment under normal conditions of use. As a result of the low concentrations entering the STP, buffering capacity of natural

water/sediment systems and also of EU water quality legislation governing quality of discharges, predicted emissions of chloride and hydronium ions as a result of the proposed use are expected to have negligible impact on the receiving aquatic environment (freshwater and marine).

Potential indirect routes considered are application of sewage sludge and deposition from air immediately outside the dwelling where the product is used. Concentrations from both routes are predicted to be negligible. As a result of the buffering capacity of soils and also of EU legislation governing application of sewage sludge to land, any emissions of chloride and hydronium ions as a result of the proposed use are expected to have negligible impact on the terrestrial environment.

The exposure of HCl to the atmosphere from the proposed use indoors in toilet bowls is considered to be insignificant compared to that from other natural and man-made sources.

According to the TNsG and the ECHA Guidance on information requirements (V1.0, July 2013) tests on leaching behaviour are not required for formulations used indoors including a disinfectant cleaner as any leaching is not expected.

As regards the reclassification of the two components used in the products of the Family B, namely, Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorideas Aquatic Chronic 1, H410 Very toxic to aquatic life with long lasting effects, the substances (mixtures) are not exclusively manufactured for use in biocidal products within the EU. Accordingly, it has been stated that in such cases, similar to Hydrochloric acid, detailed manufacturing information is not required in order to address potential environment risk. The manufacturing processes are covered by other legislation and therefore do not have to be taken into account in the exposure assessment for the product. The formulation process involves primarily automated mixing of raw materials in a closed system. There is no direct release to air, water or soil. As liquid waste is directed via on-site treatment plants and effluent is controlled, there is no exposure to any environmental compartment during formulation process. The following risk characterisation of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride for the environment is solely based on exposure assessment from usage of the products of the Family A having higher amount of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridecompared to products of the Family B. This risk characterisation as a conservative worst case assessment is pertinent for environment exposure assessment from usage of the products of the Family B as well.

2.8.1 Risk characterisation for the environment

The products in Family B containing 6.75% w/w HCl, are formulated as ready-to-use household products to be applied by professionals and non-professionals, indoors only. Both hydrogen and chlorine are commonly found in the environment as a result of both natural and manmade sources.

Information regarding the substances of concern please refer to Section 1.5.4 of this document.

The use of liquid disinfectant cleaners as a disinfectant (PT2) indicates that the standard sewage treatment plant is considered as the point source and the release to wastewater by default is 100%. Therefore it is not expected that hydrochloric acid will reach the terrestrial compartment, under normal conditions of use.

Taking these points into consideration, it is not justified to conduct additional fate and behaviour studies on the products as a consequence of either the method of application or the product formulation. Neither the application technique nor the product composition, are expected to influence the fate and behaviour of the active substance in the environment.

The risk characterisation of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridefor the environment is based on a number of considerations. The

products are formulated for use as ready-to-use surface disinfectant cleaners for toilets. According to the label recommendation ~80 ml of the product is used per application. The product is mainly used by non-professional users but professional use is also expected for these products in some Member States [redacted]. It is assumed that the exposure assessment for non-professional use also covers the professional use of the products. [redacted]

It is still assumed that 100 % of the product will be released to wastewater and that wastewater will pass through the STP before being discharged into the environment. EUSES 2.1.2 model is applied for the estimation of the distribution of components of the product in the STP and the PECs (Predicted environmental concentration) in aquatic systems and soil.

The exposure assessments take into account the properties and behaviour of Bis (2-hydroxyethyl) tallow alkylamine (2,2'-(C16-18 (evennumbered, C18 unsaturated) alkyl imino) diethanol) and the components of Tallow trimethylammonium chloride(60 %w/w tallow trimethyl ammonium chloride and 40 %w/w 2-propanol). The physico-chemical input data for EUSES model are taken from respective REACH registration dossiers[2] for substances in question and/or from Safety Data Sheets. Default assumptions in accordance with the Emission Scenarios Document (ESD)[3] for Product Type 2 are used in the model as well.

In line with the Technical Guidance Document (EC 2003)[4], it is assumed that the typical local STP serves 10000 inhabitants (person equivalents) representing 4000 households (according to statistics the average number of people per household in the EU is 2.5[5]).

According to calculations 4869 ml of product per day enter the STP ([3 applications x 80 ml product x 4000 households/100 x 14.2 % of households applying the product]/ 28 days).

The maximum concentration of Bis (2-hydroxyethyl) tallow alkylamine in the products of the Family B is 1.337 %. Based on the assumption of a product density of 1.04 g/ml it was calculated that a maximum of 67.7 g Bis (2-hydroxyethyl) tallow alkylamine per day is released to the STP ([4869 x 1.04]/100 x 1.337).

The maximum concentration of Tallow trimethylammonium chloridein the products of the Family B is 0.475%. Based on the assumption of a product density of 1.04 g/ml it was calculated

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[2] 2,2'-(C16-18 (evennumbered, C18 unsaturated) alkyl imino) diethanol– https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/14180/1
Tallow trimethyl ammonium chloride - https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/12749
2-propanol - https://echa.europa.eu/lv/registration-dossier/-/registered-dossier/15339/1

[3] EUBEES Emission Scenarios Document (ESD) for Product Type 2: Private and public area disinfectants and other biocidal products (sanitary and medical sector) (RVIM report 601450 008, 2001)

[4] Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on risk assessment for new notified substances, Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part II. European Communities, 2003.

[5] European Environment Agency figures published in 2001, from EuroStat/NewCronos (24/03/2000) and Euro Monitor – European Marketing data and statistics, 1997, 32nd Edition. http://www.eea.europa.eu/data-and-maps/indicators/household-number-and-size

that a maximum of 24.1 g Tallow trimethylammonium chlorideper day is released to the STP ([4869 x 1.04]/100 x 0.475). This amount consists of 14.4 g of tallow trimethyl ammonium chloride and 9.6 g of 2-propanol taking into account the respective percentage of these components in the mixture.

The input values for EUSES modelling are summarised in the Table 23.

Table 23. Input values used for calculation of PECs by EUSES model

Parameter	General input values	Bis (2-hydroxyethyl) tallow alkylamine	Tallow trimethyl ammonium chloride	
			tallow trimethyl ammonium chloride	2-propanol
Number of emission days per year	365	-	-	-
Fraction released to wastewater	1 (100 %)	-	-	-
Number of inhabitants served by local STP	10000	-	-	-
Number of households served by local STP	4000	-	-	-
Market penetration factor of disinfectant	[redacted]	-	-	-
Emission rate per day	-	0.0677 kg	0.0144 kg	0.0096 kg
Log Kow	-	3.6	3.38	0.05
Vapour pressure at 25°C	-	0.0012 Pa	2.9 x 10^{-6} Pa	0.00602 Pa
Solubility	-	0.0035 g/L	0.14 g/L	Totally miscible (assumed 1000 g/L)
Koc	-	225333 ml/g	1640329 ml/g	-
Readily biodegradable	-	YES (based on the weight of evidence from a number of tests)	YES	YES

Kow - Octanol-water partition coefficient; Koc – Organic carbon-water partition coefficient

2.8.1.1 Aquatic compartment (incl. sediment)

First of all the toxicity of the formulation Family B is driven by the active substance (HCl) content.

Therefore the toxicity of the product Family B may be extrapolated mainly from the available data for the active substance HCl.

There is no direct release of the formulation Family B to the environment (freshwater, marine water, air or soil). As HCl dissociates in water, any effects are due to hydronium and chloride ion concentrations and the major effect is the resulting pH rather than the presence of the chloride ion. Therefore the aquatic compartment has been accessed exactly by considering pH changes due to the addition of HCl to water.

Based on the ecotoxicological studies, organisms in natural waters have a different optimum pH conditions, ranging from poorly buffered waters with a pH 5 to very hard waters with pH values of up to 9.

Very little experimental data on the toxicity of HCl on aquatic organisms is available. According to the available data acute fish toxicity for hydrochloric acid at the 96 h LC_{50} is between pH 3 and 4. However critical swimming speed is significantly depressed earlier below 4.4 in hard water and below 4.6 in soft water. The relationship between HCl and water hardness is found to be complicated as a variety of natural and anthropogenic factors occurred in water bodies.

The toxicity of the active substance to aquatic invertebrate and algae are relatively similar. The EC_{50} for the *Daphnia magna* using hydrochloric acid was shown to be at pH 4.92; for the green algal species *C. vulgaris* was shown to be at pH 4.82 at the 48 and 72 h, respectively. The buffering capacity of the receiving water body is one of the decisive factors in determining toxicity from hydrochloric acid.

The microbiological data showed that the 3 hour EC_{50} for inhibition of respiration of activated sludge (most sensitive component of the treatment process) was between pH 5.0 and 5.5 using hydrochloric acid that is an essential factor to the normal operation of Sewage Treatment Plant (STP). For comparison, the growth of *Escherichia coli* that is one of most common inhabitants and typical saprophyte in wastewater to be inhibited only at pH 3.7 using hydrochloric acid. If the pH of raw waste water and primary effluent from selected STPs usually demonstrate pH at 7.3-7.7 and based on data below it is considered that the influent pH to some extent did not provoke any perturbation of pH in the treatment process as well as ensures the stability of activated sludge.

There are studies that reported on the toxicity associated with acid precipitation (pH below 5.6) that has a detrimental effect on aquatic ecosystems since acidity in a solution such as rain is synonymous with the presence of hydrogen ions.

The anion released upon acid dissociation has little or no effect. Sodium chloride LC_{50} for fish and Daphnia are reported as 7846 and 3310 mg/L respectively.

Standard risk assessments are usually based on a comparison of effects data and estimated exposure levels given in units of mg/L (PEC/PNEC). It is not possible to determine quantitative mg/L values for either the effects (PNEC) or the exposure data (PEC) for Hydrochloric acid due to the dissociation, variation in buffering capacity inherent in the different test media and a variety of fluctuated natural factors in environmental compartments. The final pH in different environmental locations will not result from the same influx of acid. It is also of note that H+ increases from sources other than HCl will not be distinguishable in the environment. The buffer capacity, pH and fluctuation of the pH are very specific for specific water ecosystems and it is really not possible to assess the source of issue on fluctuations in pH since it may be a as a result of both natural and anthropogenic (e.g. industrial, pollutions) origin.

Exposure to surface water sediment only occurs indirectly via the sewage treatment plant and surface water. As a result of the low concentrations entering the STP, buffering capacity of natural water/sediment systems and also of EU water quality legislation governing quality of discharges, predicted emissions of chloride and hydronium ions as a result of the proposed use are expected to have negligible impact on the receiving aquatic environment (freshwater and marine). Therefore no risk to Sewage Treatment Plant (STP) micro-organisms and activated sludge or surface water and sediment organisms are expected as a result of the formulation of the product. As no significant lowering of environmental pH in either surface water or sediment compartments is expected from effluents of around pH 7, no risk to organisms in either of these compartments is expected as a result of the proposed use of Family B.

It is therefore considered that the risk assessment for Family B (HCl) will be based on a qualitative assessment of its potential effects on environmental pH and justified from scientific point of view and evidence. This approach is endorsed by the OECD SIDS document for hydrogen chloride which states

that it would not be useful to derive an aquatic PNEC value for HCl because the buffer capacity, pH and fluctuation of the pH are very specific for specific ecosystems.

The influence of the two components reclassified with respect to aquatic toxicity and used in the products of the Family B, namely, Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorideis assessed by means of comparison of effects data for substances in question given in the REACH registration dossiers[2] and Safety Data Sheets and exposure levels estimated by EUSES model (Predicted environmental concentration/Predicted no effect concentration (PEC/PNEC) given in units of mg/L). As a conservative worst case the exposure characterisation for maximum content of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridein products of the Family A in comparison to products of the Family B is applied.

2.8.1.1.1 Aquatic risk assessment

Formulation

The formulation process of the product Family B involves primarily automated mixing of raw materials in a *closed system.* There is no direct release the product Family B to water bodies (freshwater, marine), air or soil from the formulation of Family B.

As claimed by manufacturers, potential release of hydrochloric acid fumes to air is controlled through scrubbers, in which NaOH solution is used to absorb any HCl. There is no monitoring of residual hydrochloric acid fumes as quantities are not detectable. The NaOH solution is periodically replaced and effluent is pH-adjusted in an on-site treatment plant, or is collected and treated at another waste water treatment plant.

Neither Bis (2-hydroxyethyl) tallow alkylamine and tallow trimethyl ammonium chloride nor 2-propanol are considered volatile and would not be expected to volatilise to air in significant quantities with respective vapour pressures of 0.0012 Pa, 2.9 x 10^{-6} Pa and 0.00602 Pa.

Effluent, if present, is diluted with water and then sent to the on-site waste water treatment plant where the pH is adjusted. The pH and chloride concentration are monitored at the output of the waste-water treatment plants and are within allowable limits (pH 5 to 11); maximum 4700 mg Cl-/l. Therefore no risk to STP micro-organisms and activated sludge are expected as a result of the formulation Family B.

Use of products within Family B

The basic tool used in the decision making is the PEC/PNEC ratio or, if this not available, a *qualitative* estimation, that scientifically demonstrate (justified) that there are no risks for the environment. The environmental risk assessment for ionising substances states that the STP is a well buffered environment, and recommends that a default pH of 7 can be used for exposure calculations. The realistic case scenario pH in STP influent following the proposed use of the product is theoretically calculated to be 5.2 at conditions of HCl to pure water. As municipal waste water contains high levels of organic matter which are known to have high buffering capacity, the raw waste water and primary effluent from selected STPs pH can be 7.3-7.7. Given that pH in the range 3-5 had significant effects on aquatic organisms. On the basis of this evidence and ecotoxicity studies data it is considered that the raw waste water influent pH did not provoke any perturbation of pH in the treatment process as well as to some extent does not affect the stability of activated sludge.

It is therefore concluded that the proposed use of Products of Family B will not cause any significant change to the pH levels in standard STPs due to the high level of dilution and well buffered environment.

It is considered the buffering capacity of the waste water system plus that of the natural water/sediment system plus the stringent EU water quality legislation for discharges to surface water, no significant pH effects on surface water are expected.

As no significant lowering of environmental pH in either surface water or sediment compartments is expected from effluents of around pH 7, no risk to organisms in either of these compartments is expected as a result of the proposed use of Family B.

As reported the chloride content of these raw wastewaters was 120 – 397 mg/l. As sodium chloride LC_{50} for fish and *Daphnia* are reported as 7846 and 3310 mg/L. The approximate LC_{50} values for the chloride ion is estimated to be 4759 and 2008 mg chloride/L respectively (Cl is 60.67% of NaCl based on molecular weight).

Based on the realistic worst case environmental exposure assessment, only a small fraction 0.78 mg chloride/L (for realistic case 0.23 mg chloride/L) is expected in wastewater as a result of the proposed use of Family B. These evidences conclusively demonstrate that the levels of chloride seen in wastewater are of insignificant toxicity to aquatic organisms.

With regards to the two components reclassified for aquatic toxicity – Bis (2-hydroxyethyl) tallow alkylamine and Tallowtrimethylammonium chloride, Bis (2-hydroxyethyl) tallow alkylamine is expected to partition to water (vapour pressure of 0.0012 Pa; Log Kow 3.6). Constituent parts of Tallow trimethylammonium chloride- tallow trimethyl ammonium chloride is expected to partition to soil/sludge (vapour pressure of 2.9 x 10^{-6} Pa; Log Kow 3.38), but the 2-propanol would be expected to predominantly remain in the water phase (vapour pressure 0.00602 Pa; Log Kow 0.05). All three substances are considered to be readily biodegradable. Based on read across study to Bis (2-hydroxyethyl) tallow alkylamine - STP simulation biodegradation test (according to OECD 303A guideline) carried out with oleyl bis(2-hydroxyethyl)amine (another substance from the Primary Fatty Amine Ethoxylated (PFAEO) category) it was demonstrated that 99 % removal from the water phase of the STP can be assumed and only 1 % adsorption to sludge is considered. The Simple Treat model was not used for this assessment as experimental data if they are in place should be always preferred.

It is assumed that 100 % of the products are released to STP which is considered as the point source in relation to wastewater discharges to surface water. The products are not directly released to surface water. Predicted environmental concentrations in the STP, surface water and sediment as well as predicted no effect concentrations and their ratios are given in the Table 24.

Table 24. PEC/PNEC ratios for Bis (2-hydroxyethyl) tallow alkylamine, tallow trimethyl ammonium chloride and 2-propanol in the STP, freshwater and sediment

Compartment	PEC	PNEC	PEC/PNEC ratio
Bis (2-hydroxyethyl) tallow alkylamine			
STP	**3.76 x 10^{-4} mg/L**	**1.5 mg/L**	**2.51 x 10^{-4}**
Freshwater	**2.81 x 10^{-5} mg/L**	**2.14 x 10^{-4} mg/L**	**0.13**
Sediment	**0.633 mg/kg dwt**	**1.692 mg/kg dwt**	**0.37**
Tallow trimethyl ammonium chloride (Arquad T50)			
STP	**5.6 x 10^{-4} mg/L**	**1.1 mg/L**	**5.09 x 10^{-4}**
Freshwater	**1.62 x 10^{-5} mg/L**	**0.00068 mg/L**	**0.02**
Sediment	**2.66 mg/kg dwt**	**111.54 mg/kg dwt ***	**0.02**
2- propanol (Arquad T50)			
STP	**6.07 x 10^{-4} mg/L**	**2251 mg/L**	**2.70 x 10^{-7}**

Freshwater	**6.07 x 10^{-5} mg/L**	**140.9 mg/L**	**4.31 x 10^{-7}**
Sediment	**2.86 x 10^{-4} mg/kg dwt**	**552 mg/kg dwt**	**5.18 x 10^{-7}**

*** A PNEC for sediment of 0.201 mg/kg dwt is given in the REACH[1] registration dossier and Safety Data Sheet for the substance; however, this appears to be an error. No toxicity data are available in sediment and therefore this PNEC will have been calculated using the equilibrium partitioning method. The derivation of a PNEC in sediment of 0.201 mg/kg dwt from a PNEC water of 0.00068 mg/L requires a Koc of ~3000 ml/g which is significantly below the actual Koc range of 18251 to 6171657 ml/g given for the substance. The PNEC for sediment was therefore recalculated using the mean Koc of 1640329 ml/g, which was also used in the exposure assessment.**

In addition, with respect to Bis (2-hydroxyethyl) tallow alkylamine the alternative EUSES modelling was performed according to request of German CA, applying the following changed initial data concerning the fate of the Ethomeen T/12 in the STP:

- **Fraction of emission directed to water by STP: 1 %;**
- **Fraction of emission directed to sludge by STP: 22.9 %;**
- **Fraction of emission degraded in STP: 76.1 %.**

The recalculated PEC values in STP, freshwater and sediment as well as the following PEC/PNEC ratios are the same as given in the Table 24.

The PEC/PNEC ratios are below 1 for all single components as well as for the sum of them in each aquatic compartment. The PEC/PNEC ratios show no concern for the aquatic environment from the use of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride in the Hydrochloric Acid Family B products. A quantitative risk assessment was not performed for HCl in the environmental compartments as the risk was concluded to be negligible both for the single substance and for the mixture containing HCl, Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride.

Disposal of product packaging

The environmental exposure assessment considers the fate of any residual HCl in spent bottles reaching a landfill site. Due to the high levels of organic material and thus high buffering available in the landfill site no significant alteration of pH is expected in either the landfill solids or leachate. It should be noted in any case that landfill leachate is collected and treated before disposal under the responsibility of special laws and EU waste legislation standards to ensure sufficient protection of the environment. It can be accepted that there will be no significant risk to organisms in the aquatic or terrestrial environment. **The same conclusion is true with respect to Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridein the products. Based on data on the amount of product remaining in spent packaging, it is known that approximately 17.43 g of product is left in a 1 L bottle (originally containing ca.1040 g product). A used bottle contains about 18 g (17.43 g) product (or 0.23 g Bis (2-hydroxyethyl) tallow alkylamine [17.43/100 x 1.337] and 0.083 g Tallow trimethylammonium chloride[17.43/100 x 0.475]) as a worse case estimation. Therefore, it is concluded that the disposal of the product will not contribute significantly to the environmental exposure in comparison to the emissions from the in-use phases of the life cycle.**

Marine exposure

No standard guideline data on the toxicity of hydrochloric acid to marine organisms are available. Therefore the published study data with accepted scientific principles have been used. For example, acute toxicity test on survival, growth and osmoregulation of the seawater invertebrate (prawn *Penaeus monodon*) showed that the 96 hour EC50 of hydrochloric acid to the marine water prawn is at pH 3.7.

There is no direct release of the formulation Family B to the marine waters, which primarily enters the sewage system (via STP). Moreover as a result of the low concentrations entering, high level of dilution and quite neutral raw waste water effluent pH at 7.3-7.7, predicted pH changes are expected to be negligible in the receiving marine environment. Since the environmental exposure assessment concludes that there will be no significant perturbation of pH in the marine environment from the formulation, use and disposal of Family B, no risk to any specific marine organisms or non-target organisms (flora and fauna) is expected. The justification for non-submission of data on marine exposure is accepted. **The same conclusion is valid concerning Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorideused in the products. As there is no direct release of the products to the marine environment and they are primarily entering STPs as well as taking into account high dilution rates and readily biodegradability of the co-formulants in question, it is not expected that the use of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloridein the Hydrochloric Acid Family B products will cause significant risk to the marine environment.**

Groundwater contamination

Since the environmental exposure assessment concludes that there will be no significant perturbation or lowering of pH in the aquatic compartment incl. sediment as well as the terrestrial environment from the formulation, use and disposal, no effects on pH in ground water are expected. In addition, as hydrochloric acid completely dissociates in water no bioaccumulation in organisms is possible. It can therefore be concluded that there will be no risk to ground water organisms. The need to conduct studies on the effects on groundwater contamination is considered to be scientifically unjustified. The justification for non-submission of data regarding groundwater contamination by hydrochloric acid is accepted.

With regard to Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorideused in the products, the disinfectant is not directly released to groundwater. The substances could potentially reach the groundwater compartment due to application of sewage sludge on soil. PEC in groundwater for Bis (2-hydroxyethyl) tallow alkylamine is 2.43 x 10^{-6} mg/L, but for the components of Tallow trimethylammonium chloride- tallow trimethyl ammonium chloride 7.99 x 10^{-6} mg/L and 2-propanol - 1.19 x 10^{-5} mg/L. As the directive 2006/118/EC[6] sets the maximum permissible concentration of pesticides in groundwater less than 1 x 10^{-4} mg/L (< 0.1 µg/L), it can be concluded that the risk to the groundwater environment from the use of Family B biocide products is acceptable both for the single components and the sum of them. Calculations were done by EUSES 2.1.2 model.

The recalculated PEC in groundwater for Bis (2-hydroxyethyl) tallow alkylamine according the the request of German CA (see chapter 2.8.1.1.1) is 5.54 x 10^{-5} mg/L causing no concern.

2.8.1.2 Atmosphere

The formulation and use of products in Family B is not expected to lead to significant exposure of the atmosphere. HCl is not expected to contribute to global warming or ozone depletion in the stratosphere on the basis of its physical and chemical properties. Although HCl can lead to acidification from outdoor exposure, its proposed indoor use exposure is considered to be negligible.

It is considered that no acute or long-term risk on birds including respiratory tract and reproduction would be expected. In addition, the generation of such data with a substance known to be corrosive would contravene animal welfare considerations. The exposure of HCl to the atmosphere from the proposed use indoors in toilet bowls is considered to be insignificant compared to that from other

[6] DIRECTIVE 2006/118/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 December 2006 on the protection of groundwater against pollution and deterioration

natural and man-made sources. The justification for non-submission of data with respect to hydrochloric acid is accepted.

With regards to Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride, they are notconsidered to be volatile with the following vapour pressures - 0.0012 Pa for Bis (2-hydroxyethyl) tallow alkylamine, 2.9 x 10^{-6} Pa for tallow trimethyl ammonium chloride and 0.00602 Pa for 2-propanol. Therefore, it would not be expected that the co-formulants in question will volatilise to air in significant quantities during all phases of the life cycle. This conclusion is supported by the PECs in air calculated for uses of the products: 7.12 x10^{-12} mg/m^3, 4.17 x 10^{-18} mg/m^3 and 5.51 x 10^{-17} mg/m^3 for Bis (2-hydroxyethyl) tallow alkylamine, tallow trimethyl ammonium chloride and 2-propanol, respectively. Calculations were done by EUSES 2.1.2 model.

The recalculated PEC in air for Bis (2-hydroxyethyl) tallow alkylamine according the the request of German CA (see chapter 2.8.1.1.1) is 1.89 x10^{-12} mg/m^3 causing no concern.

2.8.1.3 Terrestrial compartment risk assesment

There are no standard guideline data available on the biotic effects of HCl in the terrestrial environment; however, no such requirements are specified in the TNsG on Data Requirements for a PT2 active substance based on the lack of exposure expected (i.e. not for use as a soil/solid waste disinfectant).

The product of Family B is not directly released to the terrestrial compartment, under normal conditions of use. Potential indirect routes considered are application of sewage sludge and deposition from air immediately outside the dwelling where the product is used. As a result of the buffering capacity of soil and also of EU legislation governing application of sewage sludge to land, any emission of chloride and hydronium ions as a result of the proposed use of products Family B are expected to have negligible impact on the terrestrial environment.

The formulation and domestic indoor use of products in Family B are not expected to lead to significant perturbations of terrestrial levels of chloride or pH. The product is not directly released to the terrestrial compartment, under normal conditions of use. This conclusion is based on the lack of significant direct exposure to soil, natural buffering capacity of soils and EU legislation controlling the application of sewage sludge to land. It is considered that there is no need to conduct studies on the acute toxicity to soil non-target micro- or macro-organisms and plants. Given the lack of significant pH lowering effects in soil from formulation, use and disposal, no risk to soil dwelling organisms is anticipated. The justification for non-submission of data regarding terrestrial contamination by hydrochloric acid is accepted.

With regards to Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride, the substances could potentially reach the terrestrial compartment due to application of sewage sludge on soil, as it is assumed that 100 % of the used product enters STP. Predicted environmental concentration in the soil (over 30 days) as well as predicted no effect concentration and their ratio are given in the Table 25.

Table 25 PEC/PNEC ratio for Bis (2-hydroxyethyl) tallow alkylamine, tallow trimethyl ammonium chloride and 2-propanol in the soil

Compartment	PEC	PNEC	PEC/PNEC ratio
Bis (2-hydroxyethyl) tallow alkylamine			
Soil	**0.0111 mg/kg dwt**	**5 mg/kg dwt**	**2×10^{-3}**
Tallow trimethyl ammonium chloride			
Soil	**0.263 mg/kg dwt**	**7 mg/kg dwt**	**0.04**
2- propanol			
Soil	**1.44×10^{-5} mg/kg dwt**	**28 mg/kg dwt**	**5.14×10^{-7}**

The recalculated PEC in soil for Bis (2-hydroxyethyl) tallow alkylamine according the the request of German CA (see chapter 2.8.1.1.1) is 0.254 mg/kg dwt and the PEC/PNEC ratio is $0.254/5 = 5.08 \times 10^{-2}$.

The PEC/PNEC ratio in the soil is below 1 for all single components as well as for the sum of them. No concern for the soil and terrestrial compartment as a whole from the use of Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride in the Hydrochloric Acid Family B products is justified. A quantitative risk assessment was not performed for HCl in the environmental compartments as the risk was concluded to be negligible both for the single substance and for the mixture containing HCl, Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride.

2.8.1.4 Non compartment specific effects relevant to the food chain (secondary poisoning)

Negligible exposure of the terrestrial environment is expected from the formulation and proposed use of HCl as a surface disinfectant for toilet bowls. As HCl completely dissociates in water no bio-concentration in aquatic environment is possible. Additionally, given that upon exposure to moisture HCl becomes completely dissociated, it will not therefore be subject to bioaccumulation or developing resistance in terrestrial macro- or micro-organisms. Both H^+ and Cl- occur naturally in the environment. Exposure from Family B is not expected to lead to any significant perturbation of environmental levels. Due to insignificant exposure and since HCl cannot bio-accumulate there is no risk of secondary poisoning in either the aquatic or terrestrial compartments. **This conclusion is true for both Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chlorid edue to insignificant exposure to all environmental compartments, biodegradability properties of these components and absence of bio-accumulation.**

2.8.1.5 PBT assesment

The PBT criteria are indicated in Regulation (EC) No 1907/2006 Annex XIII.

HCl is an inorganic compound, which is not biologically degradable. HCl is a strong acid that is very soluble in water and dissociates completely, to form chloride ion and hydronium ions.

Based on the property to dissociate in water, HCl will not bio-concentrate in aquatic organisms. Also HCl isn't classified as carcinogenic, mutagenic or toxic to reproduction and there is no data for endocrine disruption. HCl does not meet the criteria in Regulation (EC) No 1907/2006 Annex XIII, and is not considered as PBT substance.

With respect to Bis (2-hydroxyethyl) tallow alkylamine and Tallow trimethylammonium chloride used in the products, the co-formulants in question are readily biodegradable, without

bioaccumulation potential as well as not classified as carcinogenic, mutagenic, toxic to reproduction or as STOT RE. Nevertheless, Bis (2-hydroxyethyl) tallow alkylamine meets the criterion for aquatic toxicity as the NOEC is < 0.01mg/L. Tallow trimethylammonium chloride is not PBT substance.

2.9 Measures to protect man, animals and the environment

The product can only be authorised under specified use conditions which are sumamrised in chapter 2.9.1. The authorisation will be granted for the use indicated in Section 1.5.

2.9.1 Conditions for use

For the protection of man, animals and the environment label and safety data sheet must contain the following indications in addition to the elements already listed Art. 69 (2) of Regulation (EU) 528/2012:

1) **The instructions for use must contain the following indications**

"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."

2) The label information must contain the following hazard and precautionary statements

- Danger;
- Skin Corr. 1
- Met. Corr. 1
- Aquatic Chronic 3
- H314: Causes severe skin burns and eye damage;
- H290 May be corrosive to metals
- H412 Harmful to aquatic life with long lasting effects

- P102 Keep out of reach of children (only for non-professional users)
- P103 Read label before use (only for non-professional users)
- P405+P234 Store locked up. Keep only in original container.
- P264 Wash hands thoroughly after handling.
- P280 Wear protective gloves (only for professional users)
- 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.

In addition, based on exposure assessment, the following statement must be included under the *'Precautions'* section of the product label: Do not use with any bleaches or other cleaning products.

3) Particulars of likely direct or indirect adverse effects and 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.

- **Inhalation:**

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.

- **Skin contact:**

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.

- **Eye contact:**

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Call a Poison Center or doctor if adverse health effects persist or are severe.

- **Ingestion:**

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.

Latvian CA also 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) Waste management measures:

` **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) Storage conditions and stability

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.

2.9.2 Conditions for authorisation

Packaging:

- 500 ml, 750 ml, 900 ml and 1000 ml HDPE bottles.
- The plug of packaging should be only in accordance with technical drawing (Annex 2). Taking into account that the plug of packaging is considered as risk mitigation measure - no any deviation can be acceptable without re-evaluating the risk profile of the product. Particular packaging and plug has been described and evaluated in product assessment process.

The label claims indicated in Section 2.5.4. are acceptable to use in Latvia. The applicant has to agree with concerned Member States for the use of terminology and translation of label claim for trained professionals, professionals and general public (non-professionals) users in each language.

3 Decision

The ready-to-use products within Family B, formulated by Reckitt Benckiser Healthcare (UK) Ltd., with the active substance hydrochloric acid (6.75% w/w) are authorised for use as toilet bowl disinfectants (product type 2) claimed as bactericide, fungicide, yeasticide, virucide and bacterial sporicide. Products are effective against a range of Gram positive and Gram negative bacteria and spore forming bacteria, fungi incl. moulds and yeasts and viral types as Poliovirus and Adenovirus.

The detailed list of target organisms is given in point 1.5.2.

At the same time the Applicant must add the surfactant/co-surfactant indicated within the Family in this level and content to achieve the cleaning function.

For consideration: The plug of packaging should be only in accordance with technical drawing (Annex 2).

The Latvian CA considers that sufficient data have been provided to verify the outcome and conclusions, and permits the authorisation of Family B for professional and non-professional use.

List of Annexes

1. Full composition of Family B.
2. Product packaging
3. List of intended uses (as submitted by the applicant)
4. Toxicology and metabolism –active substance
5. Toxicology – biocidal product
6. Safety for professional operators
7. Safety for non-professional operators and the general public
8. List of studies reviewed
9. List of referencies

Annex 1: Full composition of Family B

Confidencial data

Annex 2: Product packaging

(1 L, 900 ml, 750 ml, 500 ml)

Confidencial data

Annex 3: List of intended uses (as submitted by the applicant)

Use	Target organisms	Function/Mode of action	Field of use	User category	Application method	Packaging size	Application rate	Decision
001	*Pseudomonas aeruginosa ATCC 15442; Staphylococcus aureus ATCC 6538; Escherichia coli ATCC 10536 ; Enterococcus hirae ATCC 10541; Candida albicans ATCC 10231; Aspergillus brasilinies (niger) ATCC 16404; Spores of Bacillus subtilis ATCC 6633; Adenovirus type 5 Strain Adenoid 75, ATCC VR-5; Poliovirus type 1 Sabin 1, LSc-2ab , CDC, ATCC VR-1562*	Bactericide, sporicide, fungicide, yeasticide and virucide. Cellular injury and/or necrosis in contact with biological material (e.g. microorganism) due to action of highly reactive ions, that results as "killing" and reduction in infectivity of bacteria, bacterial spores, fungi, yeasts and viruses.	Toilet bowls disinfectant cleaner.	Trained professional / professional / general public (non-professional).	Product to be applied by the user by directing the nozzle under the rim of the toilet bowl.	Opaque high density polyethylene (HDPE) bottle 500 ml, 750 ml, 900 ml, 1 L. The plug of packaging should be only in accordance with technical drawing defined in Annex 2.	Application rate: ~80 mL as per label instructions. Frequency: Not restricted. As required.	Authorised

Annex 4: Toxicology and metabolism –active substance

HCl

Threshold Limits and other Values for Human Health Risk Assessment

Date: 12.01.2015.

Summary

	Value	Study	SF
AEL long-term	3.75 mg/m^3	[7]	8
AEL medium-term	3.75 mg/m^3	[1]	8
AEL acute	3.75 mg/m^3	[1]	8

Inhalative absorption	NOAEC=30 mg/m^3
	AEL= 3.75 mg/m^3
	SF=8
Oral absorption	NA
Dermal absorption	NA

Classification

with regard to toxicological data (according to the criteria in Dir. 67/548/EEC)	NA
with regard to toxicological data (according to the criteria in Reg. 1272/2008)	Dangerous Skin corr. 1B; H314 - Causes severe skin burns and eye damage (C ≥ 25 %) STOT SE 3; H335 - May cause respiratory irritation (C ≥ 10 %)

[7] Inclusion of active substances in Annex I or IA to Directive 98/8/EC. Hydrochloric acid.
Product-type 2 (Private area and public health area disinfectant and other biocidal products). Final CAR, November 2011

Annex 5: Toxicology – biocidal product

HCl Family B

Date: 12.01.2015

General information	
Formulation Type	Ready to use product
Active substance(s) (incl. content)	HCl (6.75 % w/w)
Category	PT2
Rat LD50 oral (OECD 420)	No acute oral toxicity study was conducted for formulations because of their corrosive properties
Rat LD50 dermal (OECD 402)	No acute dermal toxicity study was conducted for formulations because of their corrosive properties
Rat LC50 inhalation (OECD 403)	No acute inhalation toxicity study was conducted for formulations because of their corrosive properties
Skin irritation (OECD 404)	No skin irritation study was conducted for formulations because of their corrosive properties
Eye irritation (OECD 405)	Since the preparations are classified as corrosive to skin, then risk of severe damage to eyes is considered implicit. No eye irritation study was conducted.
Skin sensitisation (OECD 429; LLNA)	No skin sensitisation study was conducted for formulations because of their corrosive properties.

Short-term toxicity studies	Corrosive to skin, acc. to in vitro transcutaneous electrical resistance assay (TER=0.934 kohm) ([redacted]
Toxicological data on active substance(s) (not tested with the preparation)	NA
Toxicological data on non-active substance(s) (not tested with the preparation)	NA
Further toxicological information	NA

Classification and labelling proposed for the preparation with regard to toxicological properties (Annex IIIB, point 9)	
Directive 1999/45/EC	(NA from June 1, 2015)
Regulation 1272/2008/EC classification	Hazard classification: Skin Corr. 1 Met.Corr.1 Aquatic Chronic Signal word: Danger Hazard statement: H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals H412 Harmful to aquatic life with long lasting effects Precautionary statements: P102 Keep out of reach of children (for non-professional users) P103 Read label before use (for non-professional users) P234 Keep only in original container. P260 Do not breathe vapours. P264 Wash hands thoroughly after handling P273 Avoid release to the environment. P280 Wear protective gloves (only for professional users) P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy

	to do. Continue rinsing. P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do not induce vomiting. P310 Immediately call a POISON Center or doctor. P101 If medical advice is needed have product container or label at hand. P363 Wash contaminated clothing before reuse. P390 Absorb spillage to prevent material damage. P405 Store locked up. P406 Store in corrosive resistant/… container with a resistant inner liner. P501 Dispose of contents/container in accordance with local/regional regulations.
Regulation 1272/2008/EC labelling	**Hazard classification:** Skin Corr. 1 Met.Corr.1 Aquatic Chronic 3 Signal word: Danger Hazard statements: H314 Causes severe skin burns and eye damage. H290 May be corrosive to metals H412 Harmful to aquatic life with long lasting effects Precautionary statements: P102 Keep out of reach of children (only for non-professional users) P103 Read label before use (only for non-professional users) P405+P234 Store locked up. Keep only in original container. P264 Wash hands thoroughly after handling. P280 Wear protective gloves (only for professional users) 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.

Annex 6: Safety for professional operators

HCl Family B

Date: 12.01.2015

Exposure assessment

Exposure scenarios for intended uses (Annex IIIB, point 6.6)

Primary exposure of professionals

Component	**CAS**	**Potential Dermal Total [mg/day]**	**Potential Dermal Total [mg/kg/d]**	**Actual Dermal Total [mg/day]**	**Actual Dermal Total [mg/kg/d]**	**Inhalation Exposure [mg/m³]**	**Model**
HCl	7647-01-0	247.8	4.13	12.36	0.206		ConsExpo 4.1
						2.7 (“worst case scenario”) 2.4 (“realistic scenario”)	[redacted] Headspace Analysis of Harpic Power Plus. Reckitt Benckiser [redacted]

Risk assessment

Component	**CAS**	**AEL [mg/kg/d]**	**Absorption**		**Inhal ext [mg/m3]**			**Derm ext [mg/kg/d]**			**RCR ges**
			inh	derm	Act. Expo	RW	RCR	Act. Expo	RW	RCR	
HCl	7647-01-0	NA	NA	NA	2.7 (worst case) 2.4 (realistic case)	3.75	0.72 (worst case) 0.64 (realis-tic case)	0.206	NA	NA	0.72 (worst case) 0.64 (realis-tic case)

The risk assessment for the substance(s) of concern has to be carried out in almost the same manner.

Annex 7: Safety for non-professional operators and the general public

HCl Family B

Date: 12.01.2015

Exposure assessment

General information	
Formulation Type	Ready to use product
Active substance(s) (incl. content)	HCl (6.75 % w/w)
Category	PT2
Authorisation number	

HCl

Data base for exposure estimation	
according to	Appendix: Toxicology and metabolism – active substance/CAR

Exposure scenarios for intended uses (Annex IIIB, point 6.6)	
Primary exposure	Inhalation exposure: 2.7 mg/m^3 (worst case), 2.4 mg/m^3 (realistic case); Dermal exposure: 0.206 mg/kg bw
Secondary exposure, acute	NA
Secondary exposure, chronic	NA

Conclusion:
Exposure of non-professionals and the general public to the biocidal product containing 6.75 % w/w HCl as active substance is considered acceptable, if the biocidal product is used as intended and all safety advices are followed.

Details for the exposure estimates:

a) Inhalation exposure based on [redacted]. Headspace Analysis of Harpic Power Plus. Reckitt Benckiser [redacted]. Worst case estimate by application of the whole product`s botle after one hour – 2.7 mg/m^3; realistic case estimate by application of ~80 ml of the product after one hour – 2.4 mg/m^3. AEC=3.75. RCR = 0.72 (worst case); RCR = 0.64 (realistic case). The conditions of the field experiment carried out are more conservative in comparison to real life situations as well as the test product contained 9 % w/w HCl instead of 6.75 % w/w HCl giving elevated exposure values.

b) Dermal exposure based on ConsExpo 4.1 modelling - 0.206 mg/kg bw. No AEL derived as as the primary toxic effect is considered to be contact irritation/corrosion with no penetration being expected from dermal exposure to sub-irritant concentrations. Experimental data obtained on rabbits state that LD_{50} from dermal exposure makes up >5010 mg/kg (Draft OECD SIDS on hydrogen chloride).

Annex 8: List of studies reviewed

Confidencial data

Annex 9: List of referencies

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Y/N)	Owner
Anon.	1976	The Merck Index, 1976 p628, 632 9th edition, Merck & Co. Inc, NJ Published	N	NA
Anon.	2001	Family Policy Studies centre figures published in 2001. http://www.spsw.ox.ac.uk/fileadmin/static/fpsc/index.htm Published	N	NA
Anon.	2005	The Water Resources Act http://www.environment-agency.gov.uk/business/142645.aspx Published	N	NA
Anon.	2007	UK Environment Agency and Water UK. Pers. Comm. Unpublished	N	NA
Anon.	-	Saltinsitute: North American based non-profit trade association http://www.saltinstitute.org/ Published	N	NA
Anon.	-	UK Department of Trade and industry. http://www.dti.gov.uk/files/file19171.pdf Published	N	NA
Anon.	-	Ontario Ministry of the Environment, Standard development Branch. Ontario Air Standards for Hydrogen Chloride. Published	N	NA
Anon.	-	National Pollutant Inventory substance profile (NPI). Department of the Environment and Water Resources, Australia. Published	N	NA
Anon.	2006	Edison Electric Institute Toxic Release Inventory Hydrogen Chloride. April 2006 Published	N	NA
Boguslavsky, S.	2000	Organic Sorption and Cation Exchange Capacity of Glacial Sand, Long Island. MSc Thesis. State University of New York Published	N	NA
Brady, N.C.	1984	The Nature and Properties of Soil: Soil Reaction; acidity and alkalinity, page 202-203. Published	N	NA
Chemicals Evaluation and Research Institute (CERI) Japan	2002	International Programme on Chemical Safety (IPCS) (2002). Hydrogen chloride. Screening Information Data Sets (SIDS). Organisation for Economic Co-operation and Development (OECD). WHO. Geneva. Published	N	NA
Coleman, P., Mascarenhas, R., Rumsby, P.	2005	A review of the Toxicity and Environmental Behaviour of Hydrogen Chloride in Air. Published	N	NA
DEFRA	2008	DEFRA ARCHIVE: e-digest Statisticas about air quality http://archive.defra.gov.uk/evidence/statistics/environment/airqual/aqemhydrogen.htm#aqtb23 Published	N	NA
DEFRA	-	UK Defra web site: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/69592/pb13811-waste-water-2012.pdf Published	N	NA
EEA	2001	European Environment Agency figures published in 2001, from EuroStat/NewCronos (24/03/2000) and Euro Monitor – European Marketing data and statistics, 1997, 32nd Edition. http://www.eea.europa.eu/data-and-maps/indicators/household-number-and-size Published	N	NA
EEC	2006	Technical Meeting (TM106GEN), item 8. Human exposure during manufacture. Published	N	NA
EEC	2008	The HEEG opinion on the use of ConsExpo for Exposure Assessment for	N	NA

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Y/N)	Owner
		Professional Users, Ispra (2008), TMII08TOX-item3a-Use of ConsExpo Prof Use. Published		
EEC	2003	Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/1. Italy, April 2003. http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/doc/tgd Published	N	NA
EEC	1991	Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment Published	N	NA
EEC	2006	Regulation (EC) No 1907/2006 of 18 December 2006 concerning PBT criteria Annex XIII. Published http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=oj:l:2006:396:0001:0849:en:pdf Published	N	NA
EEC	1986	Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture Published	N	NA
Goncalves, J.	2012	Verification of Test Method GLP-V15-1541-HCL-08 for the determination of Hydrochloric Acid in Harpic Powerplus (PP) and Limescale Remover (LSR) Products, Reckitt Benckiser Analytical Laboratory, New Jersey, USA. Report No. Not allocated Not GLP Unpublished	N	Reckitt Benckiser
INERIS	2002	Emission scenario document for biocides used as masonry preservatives (product type 10). Published	N	NA
Kamrin, M.A.	1992	Workshop on the Health Effects of HCl in Ambient Air. Reg. Toxicol. Pharmacol. **15**: 73-82 Published	N	NA
Lax, A. *et al.*	1986	A method for determining the cation exchange capacity of organic materials. Plant and Soil. 94. 349-355. Published	N	NA
Marx, D. *et al.*	1999	The nature of the hydrated excess proton in water. Nature. **397** 601 – 604. Published	N	NA
Monsanto	1976	Report YO-76-0404 of Monsanto cited in IUCLID Dataset Hydrochloric acid. European Commission-European Chemical Bureau (2000) Unpublished	N	NA
Perry, T.E. *et. al.*	1986	Buffering capacity of soft-water lake sediments in Florida. ASTM Special technical publication ISSN 0066-0558. Published	N	NA
Pescod, M.B.	1992	Wastewater treatment and use in agriculture - FAO irrigation and drainage paper 47. Food And Agriculture Organization Of The United Nations. Rome, 1992. Published	N	NA
Prud'homme de Lodder *et al.*	2006	"Cleaning Products Fact Sheet – To assess the risks for the consumer" RIVM report 320104003/2006 (Prud'homme de Lodder, Bremmer and Van Engelen; 2006) Published	N	NA
Reckitt Benckiser	2013	Statement provided by Reckitt Benckiser dated 10 July 2013 Supporting monitoring information Unpublished	N	Reckitt Benckiser
Rubino, J.R.	2008	"Kills All Germs" Claim Justification for Chemical Biocides/Disinfectants (20 June 2008) Unpublished	N	NA
Sander, R.	1999	Compilation of Henry's Law Constants for Inorganic and Organic Species of	N	NA

Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Y/N)	Owner
		Potential Importance in Environmental Chemistry (Version 3). http://www.ceset.unicamp.br/~mariaacm/ST405/Lei%2520de%2520Henry.pdf Published		
UK Department of Environment	1993	UK Department of the Environment (1993). Code of Practice For Agricultural Use Of Sewage Sludge. Her Majesty's Stationery Office, London Published	N	NA
UNEP	1995	UNEP (1995) Water quality of world river basins, UNEP Environment Library No.14. Published	N	NA
WHO	1982	World Health Organization Geneva Environmental Health Criteria 21 Chlorine and Hydrogen Chloride, International Programme on Chemical Safety Published	N	NA
WHO	1982	WHO (1982) World Health Organization Environmental Health Criteria 21 Chlorine and Hydrogen chloride – Biermann F.J. (1978) Commodity chemicals. Their role in water treatment. Presented to the Chemical Marketing Research Association. New York. May 9. New Jersey, Water Treatment Chemicals Allied Chemical Corporation. Published	N	NA
Zavitsas, A.A.	2001	Properties of water solutions of electrolytres and nonelectrolytes. J. Phys. Chem.. B. 105 7805 – 7815 Published	N	NA