Product Authorisation

Domestos Zero Limescale

Biocidal product family containing Hydrogen chloride for use in Product Type 2

From Unilever UK Limited

UK-2016-1052

UK Competent Authority Product Assessment Report

Health and Safety Executive
5S.1 Redgrave Court, Merton Road, Bootle, Merseyside, L20 7HS, UK
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www.hse.gov.uk/biocides/index.htm

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1. APPLICANT, ACTIVE SUBSTANCE MANUFACTURER AND PRODUCT FORMULATOR

1.1 Applicant

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Country	Netherlands
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1.2 Authorisation Holder

Contact name	Rhian Eckley
Company Name	Unilever UK Limited
Address	Unilever House Springfield Drive Leatherhead Surrey KT22 7GR
Country	United Kingdom
Telephone	+44 1372 945196
E-mail address	Rhian.Eckley@unilever.com

1.3 Active substances

The biocidal product contains the following active substance:

Common name	Hydrochloric acid
IUPAC name	Hydrogen chloride
EC no	231-595-7
Content	8% (w/w)
Purity	999 g/kg (99.9% w/w)

1.3.1 Active substance manufacturer

Contact name	[redacted]
Company Name	Borsodchem Zrt.
Address	Bolyai tér 1 H-3700 Kazincbarcika
Country	Hungary
Telephone	[redacted]
Fax	[redacted]
E-mail address	[redacted]

1.3.2 Statement of technical equivalence

The notified source of hydrochloric acid (Borsodchem Zrt.) is considered technically equivalent compared to the reference source in respect of which the initial risk assessment was carried out. This decision of technical equivalence was made by the European Chemicals Agency and is documented on R4BP3 (Asset no. EU-0005282-0000).

1.3.3 Access to documentation

1.3.3.1 Active substance data

Reckitt Benckiser PLC owns or has access to the hydrochloric acid active substance (Annex II) dossier and has provided the applicant (Unilever Nederland Services BV) with a letter of access to these data and therefore no further consideration is required.

1.4 Manufacturer/formulator of the product

Company Name	Unilever Magyarorszag KFT
Address	Nyriba Tancsics Milhaly u 2-4 H-4300 Nyirbator
Country	Hungary

1.5 Date of authorisation and authorisation numbers

Product authorisation granted on 12th December 2016

Product authorisation expires on 30th April March 2024

Authorisation Number: UK-2016-1052 (Domestos Zero Limescale)

UK-2016-1052-1-0001 (Domestos Zero Limescale Lime)

UK-2016-1052-1-0002 (Domestos Zero Limescale Pink)

UK-2016-1052-1-0003 (Domestos Zero Limescale Aquamarine)

1.6 Amendment to the authorisation

25th May 2017

The evaluating competent authority and concerned competent authorities have discussed the environmental classification for this product since authorisation. These discussions have resulted in a change to the classification and labelling of the product.

The following changes have been made to the existing authorisation:

The classification and labelling of this authorisation has been amended as follows:

- Aquatic chronic 3 replaced by Aquatic chronic 2.
- H411 Toxic to aquatic life with long lasting effects will be amended to H412 Harmful for aquatic life with long lasting effects.
- The precautionary phrase P391 Collect spillage has been removed as it is no longer required according to Regulation (EC) No 1272/2008.

The following sections of the PAR have been amended to reflect these changes:

- 2.5.2 Classification and labelling of the biocidal product
- 8.2 Necessary issues accounted for in the product label

2. GENERAL PRODUCT INFORMATION

2.1 Identity of the biocidal product

Product name: Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine

Product codes: 8314328; 8314329; 8639901

Formulation type: Any other liquid (AL)

Active substance	Minimum purity (% w/w)	EC No.	Content, pure (% w/w)
Hydrochloric acid	99.9	231-595-7	8

Tolerance limits: ± 5 % (actual nominal concentration range in product 7.6 – 8.4 % w/w)

Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine are any other liquid (AL) formulations which are part of the Domestos Zero Limescale biocidal product family name (see Confidential Annex of this document for formulation comparison). The physical/chemical properties and storage stability data submitted to support these formulations are conducted on Domestos Zero Limescale Lime, the results of which can be extrapolated to all the variants.

2.2 Product type

PT-2 (Disinfectants and algaecides not intended for direct application to humans or animals)

2.3 Procedure for evaluation

Product authorisation (NA-APP)

2.4 Composition of the formulation and substances of concern

The full composition of the biocidal products, including the non-active ingredients, are provided in the Member State Confidential Annex to this PAR. Three co-formulants, present at 6%, 1.52 – 1.55%, and 0.77 – 0.88% were identified as a SOCs and are addressed in Section 5.3.7.

2.5 Classification and labelling

2.5.1 Classification and labelling of the active substance

According to Annex VI of the CLP Regulation, as updated with the 1st ATP, the agreed classification of the active substance in accordance with Regulation (EC) No 1272/2008 is:

Signal word	Warning
Hazard statement class and category	Skin Corr. 1B Acute tox. 3 STOT SE 3
Hazard statement	H314 – Causes severe skin burns and eye damage H331 – Toxic if inhaled H335 – May cause respiratory irritation (C≥10%)

2.5.2 Classification and labelling of the biocidal product

No related studies were provided on Domestos Zero Limescale and classification is based on the levels of components in the formulation and their classifications. The proposed classification of the biocidal product in accordance with Regulation (EC) No 1272/2008 is:

GHS Pictograms	Corrosive
Signal word	Danger
Hazard statement class and category	Skin Corr. 1 Corrosive to metals Eye dam. 1 Aquatic Chronic 3
Hazard statement	H314 – Causes severe skin burns and eye damage H290 – May be corrosive to metals H412 – Harmful for aquatic life with long lasting effects
Precautionary statements	P101 – If medical advice is needed, have product container or label at hand. P102 – Keep out of reach of children. P103 – Read label before use. P234 – Keep only in original container P260 – Do not breathe dust/fume/gas/mist/vapours/spray. P264 – Wash … thoroughly after handling. P273 – Avoid release to the environment. P280 – Wear protective gloves (professional only). P310 – Immediately call a POISON CENTER or doctor/physician. P390 – Absorb spillage to prevent material damage. P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

	P363 – Wash contaminated clothing before reuse. P304+P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position 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. P405 – Store locked up. P406 – Store in corrosive resistant/…container with a resistant inner liner. P501 – Dispose of contents/container to…

This classification is based on the product pH below 2.

NB: According to Article 4 of Regulation (EC) 1272/2008 of the 16th December 2008, it is the responsibility of manufacturers, importers and downstream users to meet the obligation to classify substances or mixtures in accordance with the provisions of Title II of the same Regulation before placing them on the market.

In accordance with Regulation (EC) 1272/2008 the biocidal product Domestos Zero Limescale is classified for skin corrosion (Skin Corr. 1). The human health risk assessment presented herein does not necessitate the use of personal protective equipment (PPE) and the provisions of Article 19 of Regulation (EU) 528/2012 do not preclude the use of products classified Skin Corr. 1 by the general public. Consequently, UK CA considers it acceptable to authorise this corrosive product for use by the general public.

2.6 Packaging

The proposed packaging is detailed below:

750 mL HDPE bottle

The packaging is fitted with a child-resistant fastening and a tactile warning.

3. PHYSICOCHEMICAL PROPERTIES, STORAGE STABILITY AND ANALYTICAL METHODS

3.1 Physicochemical properties and storage stability

Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine are any other liquid (AL) formulations which are part of the Domestos Zero Limescale biocidal product family (see Confidential Annex of this document for formulation details). These were not the representative formulations considered for active substance approval. The physical/chemical properties and storage stability data submitted to support these formulations are summarised in Table 3.1. Due to formulation comparability (see Confidential Annex) the data conducted on the lead product Domestos Zero Limescale Lime supports the other variants, but appearance and density are reported for each product.

Table 3.1: A summary of the physical/chemical properties of Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine.

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Reference	GLP (Y/N)	UKCA comments
3.1 Appearance	visual	Domestos Zero Limescale – Lime, Batch 3355 dd 21-12-2013 – Pink, Batch 3354 dd 20-12-2013 – Aqua, Batch 3356 dd 22-12-2013	Lime: Clear green liquid, characteristic odour. Pink: Clear pink liquid, characteristic odour. Aquamarine: Clear blue liquid, characteristic odour.	U. Selditz, Project 504891; I. van Doormalen-Schaap, Projects 504893, 504894	Y	Acceptable
3.1.1 Physical state and nature	-	-	See 3.1	-	-	Acceptable
3.1.2 Colour	-	-	See 3.1	-	-	Acceptable
3.1.3 Odour	-	-	See 3.1	-	-	Acceptable

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Reference	GLP (Y/N)	UKCA comments
3.2 Explosive properties	EC A.14 / case	Domestos Zero Limescale original – Lime Batch 3355 dd 21-12-2013	None of the components of the test substance does contain chemical groups which are associated with explosive properties. The molecular structures of components at ≤ 1% were not taken into account. In conclusion, Domestos Zerolimescale Original - Lime has no explosive properties.	U. Selditz, Project 504889	Y	Acceptable. None of the co-formulants are considered explosive therefore formulation is not explosive.
3.3 Oxidising properties	EC A.21 / case	Domestos Zero Limescale original – Lime Batch 3355 dd 21-12-2013	None of the components of the test substance does contain groups that act as an oxidizing agent. The molecular structures of components at ≤ 1% were not taken into account. In conclusion, Domestos Zerolimescale Original - Lime has no oxidizing properties.	U. Selditz, Project 504889	Y	Acceptable. None of the co-formulants are oxidising therefore the formulation is not considered oxidising.

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Reference	GLP (Y/N)	UKCA comments
3.4 Flash-point and other indications of flammability or spontaneous ignition Flash point	EC A.9	Domestos Zero Limescale original – Lime, Batch 3355 dd 21-12-2013	It was visually observed that the test substance has a boiling temperature of approximately 102°C. A flammable vapour/air mixture was not produced at temperatures below the boiling temperature of the test substance. From this, it was concluded that the test substance has no flash point. During boiling, test substance boiled out of the test cup which is typical for test substances which have a boiling point in the tested range. Therefore a second test was not performed.	U. Selditz, Project 504889	Y	Acceptable. No flash point observed below the boiling temperature of the formulation.
Auto-ignition temperature	EC A.15		No ignition of test substance observed <650°C			Acceptable.
Pyrophoric properties	EC A.13/case		Not pyrophoric. None of the components of the test substance contain groups that might lead to ignition in contact with air. Moreover the test substance was handled under normal laboratory conditions during this project. It demonstrated that the test substance does not ignite in contact with air at room temperature.			Acceptable. Formulation not considered pyrophoric.
3.5 Acidity/Alkalinity	CIPAC MT 75.3 and CIPAC MT 191	Domestos Zero Limescale original – Lime, Batch 3355 dd 21-12-2013	pH of 1% (w/v) mixture: 1.6 pH of neat test substance: -0.5 Acidity, as H_2SO_4 : 13.6%(m/m)	U. Selditz, Project 504891	Y	Acceptable. Acidity determined as pH<4. Additionally, on the draft product label the formulation is classified as corrosive.

<table>
<tr><th>Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Reference</th><th>GLP (Y/N)</th><th>UKCA comments</th></tr>
<tr><td>3.6 Relative density/bulk density</td><td>OECD 109 / EC A.3</td><td>Domestos Zero Limescale

– Lime, Batch 3355 dd 21-12-2013

– Pink, Batch 3354 dd 20-12-2013

– Aqua, Batch 3356 dd 22-12-2013</td><td>Lime: 1.07 g/cm^3 at 20°C

Pink: 1.07 g/cm^3 at 20°C

Aquamarine: 1.07 g/cm^3 at 20°C</td><td>U. Selditz, Project 504891; I. van Doormalen-Schaap, Projects 504893, 504894</td><td></td><td>Acceptable.</td></tr>
<tr><td>3.7 Storage stability - stability and shelf life

Accelerated storage data
2 weeks at 54°C in 100 mL glass bottle with screw cap and PE insert.</td><td>CIPAC MT 46.3

Visual

FAO 2006 SANCO/3030/99

CIPAC MT 75.3

CIPAC MT 191</td><td>Domestos Zero Limescale original

– Lime,
Batch 3355 dd 21-12-2013</td><td>Accelerated storage data:
<table><tr><th>Test</th><th>Prior to storage</th><th>After storage for (temp and time)</th></tr><tr><td>Appearance</td><td>Clear green liquid, characteristic odour.</td><td>Clear green liquid, characteristic odour.</td></tr><tr><td>Active content %w/w</td><td>7.73</td><td>7.91</td></tr><tr><td>pH of 1% (w/v) mixture</td><td>1.6</td><td>1.6</td></tr><tr><td>Acidity, as H_2SO_4</td><td>13.6 % (m/m)</td><td>13.7 % (m/m)</td></tr></table></td><td>U. Selditz, 504891</td><td>Y</td><td>Acceptable. No significant change in formulation appearance following storage.

Acceptable. No degradation of active content.

Acidity determined as pH <4. Additionally, on the draft product label the formulation is classified as corrosive.</td></tr>
</table>

Subsection (Annex Point/TNsG)	Method	Purity/ Specification	Results	Reference	GLP (Y/N)	UKCA comments
	OECD 114 CIPAC MT 41 Case		Kinematic viscosity, mm^2/s: 20°C: 1637, 40°C: 235; 20°C: 2248, 40°C: 247 Dilution stability, 5, 15, 50 mL test substance.: No separated material; No separated material Effect of light: The potential effect of light is not studied as the container is designed to exclude light.			Acceptable. Formulation does not contain hydrocarbons therefore not an aspiration hazard. Acceptable. Acceptable.
3.7 Storage stability - stability and shelf life **Ambient storage data**	-	-	Ambient storage data: Study planned Feb 2014 – March 2016. Data available for evaluation April 2016.	-	-	Data not provided, but it is noted that a 2 year ambient storage study is ongoing. This will be set as a data requirement for continuing authorisation. Meanwhile, the accelerated storage data can support the claimed shelf life of 2 years.

<table>
<tr><th>Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Reference</th><th>GLP (Y/N)</th><th>UKCA comments</th></tr>
<tr><td>3.7 Storage stability - stability and shelf life

Cold temperature storage data:
7 days at 0.0 ± 0.2 °C</td><td>CIPAC MT 39.3</td><td>Domestos Zero Limescale original

– Lime,
Batch 3355 dd 21-12-2013</td><td>Cold temperature storage:<table><tr><td>Test</td><td>Prior to storage</td><td>After storage (temp and length)</td></tr><tr><td>Appearance</td><td>Clear green liquid</td><td>Clear green liquid</td></tr></table>There was no change to consistency observed.</td><td>I.van Doormalen-Schaap, 504890</td><td>Y</td><td>Acceptable. No significant change to appearance or consistency occurred following low temperature storage.</td></tr>
<tr><td>3.8 Technical characteristics</td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>3.9 Compatibility with other products</td><td>Case provided</td><td>Domestos Zero Limescale original

– Lime,
Batch 3355 dd 21-12-2013</td><td>The following reasoned case/justification for data waiving has been provided:

Mixing of Domestos Zero Limescale with other products (like bleach or other toilet cleaners) must be avoided. Due to large differences in acidity, vigorous reactions may occur. Also, when mixing with NaOCl based bleaches Cl_2 is released. Therefore, the product label contains the warning: "Do not mix with other products (like bleach or other toilet cleaners)."</td><td>-</td><td>-</td><td>Acceptable. No product mixes are recommended. The label should state ‘“Do not mix with bleach or other cleaner as it may result in the formation of toxic chlorine gas or heat.”</td></tr>
<tr><td>3.10 Surface tension</td><td>AC A.5</td><td>Domestos Zero Limescale original

– Lime,
Batch 3355 dd 21-12-2013</td><td>46.1 mN/m at 20°C</td><td>U. Selditz, Project 504889</td><td>Y</td><td>Acceptable. Formulation does not contain hydrocarbons therefore not an aspiration hazard</td></tr>
<tr><td>3.11 Vapour pressure</td><td>EC A.4</td><td>Domestos Zero Limescale original

– Lime,
Batch 3355 dd 21-12-2013</td><td>20°C: 9.1 × 102 Pa = 6.8 mm Hg

25°C: 1.2 × 103 Pa = 9.3 mm Hg</td><td>U. Selditz, Project 504889</td><td>Y</td><td>Acceptable.</td></tr>
</table>

<table>
<tr><th>Subsection (Annex Point/TNsG)</th><th>Method</th><th>Purity/ Specification</th><th>Results</th><th>Reference</th><th>GLP (Y/N)</th><th>UKCA comments</th></tr>
<tr><td>3.12 Persistent foam</td><td>CIPAC MT 47.2</td><td>Domestos Zero Limescale original – Lime,
Batch 3355 dd 21-12-2013</td><td>In standard water C, persistent foam after 1 minute:
<table>
<tr><th>Concentration (% w/v)</th><th>Extra volume suspension (including foam) (ml)</th><th>Volume foam (ml)</th></tr>
<tr><td>5</td><td>≥ 103</td><td>≥ 106</td></tr>
<tr><td>15</td><td>≥ 108</td><td>≥ 110</td></tr>
<tr><td>50</td><td>10</td><td>10</td></tr>
</table></td><td>U. Selditz, Project 504889</td><td>Y</td><td>Acceptable. Even though at low concentrations significant foam was formed and persisted after 1 minute (>60 mL). Considering the expected use of the product (i.e undiluted), this is not expected to cause concern.</td></tr>
</table>

3.2 Methods of analysis

3.2.1 Analytical method for the active and impurities in the technical material

The notified source of hydrochloric acid (Borsodchem Zrt.) is technically equivalent to that previously considered for approval of the reference source in respect of which the initial risk assessment was carried out. This decision of technical equivalence was made by the European Chemicals Agency and is documented on R4BP3 (Asset no. EU-0005282-0000).

The authorisation holder has a letter of access to these data and therefore no further consideration is required.

3.2.2 Analytical method for the active substance in the biocidal product

Report: Determination of the accelerated storage stability of Domestos Zero Limescale original – Lime by storage for 2 weeks at 54 °C' U. Selditz, Project no. 504891.

The chloride content is determined in the biocidal product family Domestos Zero Limescale by potentiometric titration (Titrino 716 DMS with Pt-electrode). The test item (*ca.* 230 mg) was diluted with water (100 mL) to give a solution of concentration 2.3 mg/mL. The electrode was immersed in the solution and it was titrated with silver nitrate solution 0.1N until the endpoint was reached. For accuracy samples, two accurately weighed samples of approximately 115 mg were taken from the test substance and spiked with 9 ml of chloride analytical standard (equivalent to 9.05 mg chlorine). Water was added to an approximate total volume of 100 ml and the solution was mixed well. The electrode was immersed in the solution and the solution was titrated with silver nitrate solution 0.1N until endpoint had reached. During titration, the solution was stirred.
A summary of the validation data are outlined in Table 3.2.

Table 3.2 Analytical validation data for the determination of chloride in Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine

Analyte	Supported LOQ (%w/w)	Recovery levels of added analyte (mg/100 mL)	Recovery %	Repeatability % RSD (n)	Linearity	Specificity
Chloride	0.0905 mg/mL (7.88 % w/w)	9.05 mg	105, 104 SANCO acceptable range = 97 – 103 %	1.6 (5) Acceptable Horwitz $\%RSD_r$ = 1.97	-	Method is specific.

Recovery (accuracy) – An assessment of the accuracy of the analytical method was determined by spiking a test sample with 9 mg of chloride analytical standard and analysing for the spiked

content. This was tested in duplicate. Although the recoveries lie marginally outside the range specified in SANCO/3030/99 rev. 4, they are considered acceptable for a titration method.

Precision (repeatability) – An assessment of the precision of the analytical method was made by determining the active substance content in five (n = 5) individual samples of Domestos Zero Limescale - Lime. The associated %RSD value is less than the proposed acceptable Horwitz $\%RSD_r$ value, which is a good indication of analytical precision.

Linearity – Was not determined as the method was a titration method.

Specificity – To reach the chloride endpoint for the blank sample, a volume of 0.067 mL silver nitrate solution was required. Since this was <3% of the volume needed for the test sample, the method is considered specific for chloride. Additionally, titration with silver nitrate is a well established method for determination of chloride in solution.

The method is satisfactorily validated in accordance with the EU guidance document SANCO/3030/99 rev. 4, as a titration method involves a greater degree of variation.

According to the agreed list of end points there are no relevant impurities associated with hydrochloric acid and therefore no further consideration is required.

3.2.3 Analytical methods for the monitoring of residues (soil, water, air, body fluids and tissues and food)

Methods of analysis for the determination of hydrochloric acid in soil, water, air, body fluids and tissues, and food/feed of plant and animal origin have previously been considered at EU level and accepted in the approval of the active substance. The authorisation holder has access to these active substance data by means of a letter of access and therefore no further consideration is required.

3.3 Risk assessment for physico-chemical properties of the product

The Domestos Zero Limescale product family are coloured liquid (AL) formulations containing 8% w/w hydrochloric acid. They have a pH of 1.6 and acidity of 13.6% and are classified as corrosive. The formulations are not explosive, flammable or oxidising and are not classified as an aspiration hazard. Following accelerated temperature storage (2 weeks at 54°C) there was an acceptable retention of active substance and the physical and chemistry data support a shelf life of 2 years. Ambient storage stability data (2 years in the commercial packaging) is required for continuing authorisation and must be completed within 3 years of product authorisation.

Sufficient Annex III (formulation) data have been provided to recommend authorisation under BPR.

4. HUMAN HEALTH RISK ASSESSMENT

4.1 Effects assessment

No toxicological studies have been performed with the products. The classification and labelling of the products has been prepared based information on the active ingredient,the classification of the co-formulants, the pH of the formulation and on the classification criteria for mixtures as described in Annex I of the CLP Regulation and ECHA Guidance documents.

Please see the "Assessment Report on Hydrochloric Acid" (Latvia, 2011)[1] for the available information on the active substance and the agreed list of endpoints.
The main exposure routes are dermal and inhalation. Systemic NOAELs have not been set for HCl because it dissociates into hydrogen and chlorine ions on contact with water, and both of these compounds are physiological electrolytes.
AEC (inhalation) of 3.75 mg/m^3 has been set for acute and prolonged inhalation exposure of workers and prolonged inhalation exposure for non-professional users (AR for hydrochloric acid, December 2011).

Acute toxicity

Domestos Zero Limescale contains the active substance hydrochloric acid (HCl) at 8% (w/w in water). There are no substances of concern (SoC) to human health in this product. Acute toxicity data for Domestos Zero Limescale have not been submitted. Therefore classification for acute toxicity has been based on the pH and on classification by the calculation method.

Classification and Labelling for human health effects

The active substance hydrochloric acid solution is listed on Annex VI of EU 1272/2008
Skin Corr. 1B H314 Causes severe burns and eye damage
with specific concentration limits of :
Skin Corr. 1B; H314: C ≥ 25 %
Skin Irrit. 2; H315: 10 % ≤ C < 25 %
Eye irrit. 2 H319 10% ≤ C < 25%
STOT SE 3; H335 May cause respiratory irritation (C ≥ 10%)

[1] Latvia, 2011; Assessment Report on the 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); 9 December 2011.

The product Domestos Zero Limescale should be classified:

Skin Corrosion 1 H314

Eye damage 1 H314

This classification is based on the product pH below 2.

Dermal absorption

No dermal absorption data for this product has been submitted. It is considered unlikely that HCl is absorbed dermally to a significant extent, and as no systemic AELs have been set for HCl dermal absorption data is not required.

4.2 Exposure assessment

4.2.1 General aspects and intended uses

The products are toilet disinfectants plus limescale removers. Domestos Zero Limescale is applied neat under the toilet rim and is left there for approximately 30 minutes. Thereafter, brushing may take place (a flush) and a re-application, if considered necessary. The active substance is used for its disinfectant and limescale removal properties. The product is intended for use by professionals (i.e. professional cleaners) and non professionals alike.

A summary of the use is given in Table 4.2.1.

Table 4.2-1 Summary of the use

Product type	Field of use for the a.s.	Concentration at which a.s. is used
EU BPR Product type 2: Disinfectants and algaecides not intended for direct application to humans or animals	Disinfection of the inside of toilet bowls	8% w/w HCl (in water)

4.2.2 Human exposure assessment

Given that the modelling of exposures and subsequent risk characterisation during production and formulation of Domestos Zero Lime scale is addressed under other EU legislation (e.g. Directive 98/24/EC) and not repeated under Regulation 528/2012 (this principle was agreed at Biocides Technical Meeting TMI06) the UK CA has not considered exposure from production of the product.

4.2.2.1 Primary exposure

In the absence of a systemic AEL no consideration of chronic exposure is necessary (dermal or inhalation). Product pH is < 2 therefore classification confirmed by calculation as skin corrosion 1 H314 ‘Causes severe skin burns and eye damage’. The product is applied as a liquid directly from the 750ml container in a squeezing action. The neck of the container is angled so that the hand is not directly underneath the aperture when squeezing the product into the rim of the toilet. Because of the packaging design and the viscous nature of the fluidthe risk of direct dermal

contact to the product during application is considered to be very low. Furthermore the user is directed to leave the product for at least 30 minutes before brushing/flushing during which time HCL ions would rapidly disassociate in water such that subsequent brushing action which might result in some dermal contamination is unlikely to present a significant risk of adverse local effects. Given the product is a toilet disinfectant it is expected that individuals will wash hands immediately after use minimising prolonged dermal exposure. The product label should carry the phrase 'WASH HANDS AND EXPOSED SKIN before meals and after use'..

A requirement to wear gloves (not an option for non-professional use) to mitigate the risk is not necessary. That said, professionals in particular would be expected to wear some form of glove during the course of their work for hygiene reasons which would afford some additional protection to the product. To enforce this assumption the P280 phrase 'Wear protective gloves (professionals only)' will appear in the CLP section of the label and the phrase 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)' will be included in the professional section of the summary product characteristics.

An AEC of 3.75 mg/m^3 for acute and prolonged inhalation exposure is appropriate. The risk of inhalation of droplets during brushing is considered to be low but a consideration of vapour inhalation using ConsExpo is provided. Professional use (e.g. full time cleaner) over 8 hours is considered a reasonable worst case (and precautionary with regard to non-professional use). Whilst the toilet cleaning operation itself may only take a few minutes it is possible that the professional cleaner may stay in the same area for longer as they clean the rest of the bathroom during which time they continue to be exposed to the vapour and for this reason a 30 minute duration per operation is assumed. From this 16 operations per day is derived. The cleaner will move from one bathroom to the next and therefore the mean air concentration encountered throughout the working day will be the same as that during one 30 minute exposure event. Room volume and ventilation rate parameters are taken from the default values in the ConsExpo General Fact sheet. The vapour pressure is a key parameter and for an 8% hydrochloric acid solution at 20^{o}C the applicant has proposed 0.237 Pa based on a paper by Evans (1993)[2]. This figure has been independently confirmed from an alternative source (Table 2-10, Section 2 of Perry's Chemical Engineers Handbook) for which the stated value at the same concentration and temperature is 0.00178 mmHg equivalent to 0.237 Pa. The input parameters are specified in Table 4.2.2.1-1 below.

[2] Evans, M. (1993) Modeling Hydrochloric Acid Evaporation in ALOHA, Report No. HAZMAT 93-3, published on the internet: http://docs.lib.noaa.gov/noaa_documents/NOS/HMRA/HAZMAT_report_93-3.pdf

Table 4.2.2.1-1 Input parameters and settings for calculating potential inhalation exposure estimates during professional use using the ConsExpo tool.

Input parameter	Value	Remarks
Application temperature	20°C	
Molecular weight	36.5 g/mol	For the conversion from ppm to mg/m^3. The tool provides an estimate in ppm based on the other provided input parameters. The tool uses 22 L as the molar volume of gas at room temperature and pressure.
Vapour pressure	0.237 Pa (at 20°C)	The vapour pressure of the major part of the products was experimentally determined to be 9.1E02 Pa at 20°C. But as this value corresponds to the water fraction of the products, the measured partial pressure of an 8% HCl solution in water as published in a report was considered to be more suitable.
Exposure frequency	16 per day	A maximum of 16 applications per day is assumed.
Weight fraction compound	8%	
Exposure duration	30 minutes	Time between the application and a flush.
Applied amount	75 g	70 mL is recommended to be applied. With a density of 1.07 g/mL this corresponds to 75 g.
ConsExpo Factsheet used for the other needed parameters	Product database: Cleaning and washing; Product category: Sanitary products; Default product: Toilet cleaner, acid	*Other parameters:* - Room volume: 2.5 m^3 - Ventilation rate: 2 air exchanges per hour

The instantaneous release model in ConsExpo derives a mean event concentration of 3.56 mg/m^3 of pure HCl which is 95% of the inhalation AEC of 3.75 mg/m^3 and is therefore acceptable for both professional and non-professional use.

4.2.2.2 Secondary exposure

Secondary exposure to children and adults alike is only likely to occur via inhalation when entering toilet areas that have been cleaned. Given the frequency and duration of exposure is unlikely to exceed that considered for professional operators inhalation exposure is expected to be acceptable. The packaging includes a child resistant closure which is a requirement for products classified as corrosive under Regulation (EC) No 1272/2008.

4.2.2.3 Conclusion

The risk to professional and non-professional users is acceptable, as well as those re-entering treated areas. The phrase 'WASH HANDS AND EXPOSED SKIN before meals and after use.' should appear on the product label.

In accordance with Regulation (EC) 1272/2008 the biocidal product Domestos Zero Limescale is classified for skin corrosion (Skin Corr. 1). The human health risk assessment presented herein does not necessitate the use of personal protective equipment (PPE) and the provisions of Article

19 of Regulation (EU) 528/2012 do not preclude the use of products classified Skin Corr. 1 by the general public. Consequently, UK CA considers it acceptable to authorise this corrosive product for use by the general public particularly when considered against the public health benefits arising from the use of the product (see Table 26, p250 of the Human Health Expsure Guidance Document[3]: Guidance for concluding qualitatively on the acceptability of the risk for general public). According to Regulation (EC) No 1272/2008 the packaging of formulations classified for skin corrosion and supplied to the general public has to be fitted with a child-resistant fastening and a tactile warning which must be stated in the SPC.

For professional users the frequency of use and therefore the likelihood of exposure will be greater than for non professional users. Professional cleaners are expected to wear gloves for hygiene purposes that will afford some additional protection. To reinforce the assumption the P280 phrase 'Wear suitable protective gloves (professionals only)' will appear in the CLP section of the label and the phrase 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information)' will be included in the professional section of the summary product characteristics of the authorisation.

[3] Guidance on the Biocidal Products Regulation Volume III Human Health - Part B Risk Assessment Version 2.0 October 2015

5. ENVIRONMENTAL RISK ASSESSMENT

5.1 Effects assessment

The IUCLID dossier contains further information per endpoint as well as on the PNEC derivation and discusses the classification and labelling for Domestos Zero Limescale.

Aquatic compartment

The available aquatic effect studies on the active substance taken from the Assessment Report on Hydrochloric Acid (Latvia, 2011)[1] show toxicity endpoints for the three trophic levels fish, invertebrates and algae, as well as for activated sludge microorganisms. This Assessment Report concludes:

> *"It is accepted that hydrochloric acid effects on aquatic organisms are due to H^+ (H_3O^+) ions and their resultant effect on pH rather than the presence of the Cl^- ion. Sodium chloride LC_{50} for fish and Daphnia are reported as 7846 and 3310 mg/L respectively. Available acute fish toxicity data for hydrochloric acid show that the 96 h LC_{50} is between pH 3 and 4 (RMS recalculation[4] 36.46 to 3.65 mg/L). The 48 hour EC_{50} was shown to be at pH 4.92 (RMS recalculation 0.439 mg/L) for the aquatic invertebrate Daphnia magna using hydrochloric acid. The 72 hour EC_{50} for the green algal species C. vulgaris was shown to be at pH 4.82 (RMS recalculation 0.552 mg/L) using hydrochloric acid. Aquatic microbial data showed that the 3 hour EC_{50} for inhibition of respiration of activated sludge was between pH 5.0 and 5.5 (RMS recalculation 0.365 to 0.115 mg/L) using hydrochloric acid."*

There are no further environmental effect studies available on hydrochloric acid. As negligible pH effect is calculated for all of the environmental compartments, further studies on the active ingredient are not warranted. The available ecotoxicity data are concluded to be sufficient to assess the toxicity and classification of the product by extrapolation.

Atmosphere

No atmospheric effect studies were deemed necessary on hydrochloric acid (Assessment Report on Hydrochloric Acid (Latvia, 2011))[1]. Furthermore, the Assessment Report concludes:

> "*The standard estimation of phototransformation is not suitable for inorganic compounds which contain no nitrogen groups, hydroxide groups, double bonds, triple bonds or aromatic rings. Particulate associated HCl desorbs rapidly. Hydrogen chloride will be dissolved into atmospheric moisture and exist in its dissociated form. Hydrogen chloride*

[4] The pH is converted to H^+ concentrations by $[H^+]$ = 10-pH mol/L. Subsequently, this is converted to equivalents of HCl (in mg/L) by multiplying by 36500. This is a theoretical concentration and does not account for the innate buffering capacity of the test system and thus does not represent the concentration of HCl required to maintain pH at which the EC_{50} was measured. Added concentrations were much higher, for example in the Daphnia study the solution at pH 4.5 was calculated to be a 0.69 mM solution equivalent to 25.2 mg/L. The figures included as mg/L are therefore included for illustrative purposes only.

can react with hydroxyl radicals in air to form free chloride radicals. Hydrogen chloride in its gaseous form is not persistent in air. Interaction and neutralisation with gases such as ammonia (NH_3) can also occur. As a result of these removal processes, long range transport from the source area is thought to be of limited importance".

Terrestrial compartment (incl. groundwater)

Given that no perturbation of the soil and water pH is expected from the proposed indoor use of Domestos Zero Limescale, no acute or long-term risk to terrestrial organisms is anticipated. It is therefore considered that there is no justification for the generation of acute and/or long-term data on the toxicity of hydrochloric acid to terrestrial organisms.

5.2 Environmental exposure assessment

5.2.1 Life cycle analysis

Manufacture of the active ingredient

Hydrochloric acid is not exclusively manufactured for biocidal purposes within the EU. Potential human or environmental risks are taken into account by other legislation (Regulation (EC) No 1907/2006; REACH Regulation). Therefore the manufacturing processes do not have to be taken into account in the environmental exposure assessment.

Formulation of the biocidal product

Domestos Zero Limescale is formulated in Nyírbátor, Hungary. Any waste is treated on site in an effluent treatment plant and subsequently directed to a municipal sewage treatment plant. Emissions of hydrochloric acid are considered to be very limited (personal communication Unilever) as all the wash water, wastes and spillages are collected into a separate washwater tank and reworked into the final product during packaging (applying a Pulsa reblend pump head). Following the limited emissions and the subsequent onsite and offsite treatment, a quantitative environmental assessment is not considered necessary and hence no risk to the environment is to be expected from the formulation of Domestos Zero Limescale.

Non-professional use

Domestos Zero Limescale, containing 8% (w/w) HCl, is formulated in a ready-to-use (RTU) surface disinfectant and limescale remover for toilet bowls to be used by non-professionals.

The label recommendation is to apply 70 mL of product per application. The instructions for use state that the product should be applied to cover the entire toilet bowl and that 30 minutes should elapse before the toilet is flushed. If needed, a single re-application may then be made. Mixing with other products should be avoided. Current product use data are available from the UK market

and indicate that in 2012 the total market penetration of the two variants of the Domestos Zero Limescale product is [redacted]% (Unilever, market research data).

The anticipated average frequency of use of the product is two times per month. Based on 70 mL product per application, the annual use per household applying this product in the UK is [redacted]L. This is in line with data reported by EuroPanel (Unilever, market research data) that on average [redacted] L of toilet bowl disinfectant is used annually per household. In a realistic worst-case scenario it is anticipated that one use per month will include a re-application. Following this, 210 mL product is used per month, corresponding with 2.5 L per year and a mean use of 7 mL/day.

Based on the use pattern, the realistic worst case scenario is defined as two monthly 70 mL applications plus one 70 mL re-application

Professional use

In addition to the non-professional use described above, professional cleaning staff can also apply the ready-to-use product. This use is comparable to the use by non-professionals. Available sales data show that in the UK [redacted] litres of the (total of the two) products are put on the market (2012 sales data Unilever). As [redacted]% of the 26.4 million UK households (Office of National Statistics; http://www.ons.gov.uk/ons/rel/family-demography/families-and-households/2012/stb-families-households.html) is using the (total of the two) products, the annual consumption following the realistic worst case assumptions for non-professional use is: [redacted] L. As the calculated annual consumption following the non-professional use exceeds the total annual sales volume ([redacted] L), it is concluded that the environmental emission due to professional use is covered by the environmental emission due to non-professional use. A separate scenario for professional use is therefore not required.

Disposal

Used product containers may contain residues of the product and are assumed to enter the municipal solid waste (MSW) disposal pathway. Since the release of chemicals from MSW treatment processes (e.g. landfill, incineration) is controlled through other legislative mechanisms[5], the potential environmental releases of biocides from MSW do not require further consideration (JRC-IHCP, 2011).

Emission scenario

Following the above life cycle assessment, the environmental emissions which occur during consumer use need to be assessed. Therefore, the environmental Emission Scenario Document (ESD) for PT2 private and public health area disinfectants and other biocidal products (JRC-IHCP, 2011) was consulted to address this specific product residential use. However, the subtypes for

[5] Including the Waste Incineration Directive 2000/76/EC, and Landfill of Waste Directive 99/31/EC.

PT2 as discussed in this ESD do not cover the use of Domestos Zero Limescale. Therefore, the exposure assessments outlined below follow the principles and relevant algorithms proposed by ECHA (ECHA 2012).

5.2.2 Fate and distribution in the environment

Active ingredient

For the assessment of the environmental fate and behaviour of hydrochloric acid contained in Domestos Zero Limescale, reference is made to the Assessment Report on Hydrochloric Acid (Latvia, 2011[1]; Product-type 2 (Private area and public health area disinfectant and other biocidal products)). The below summary is taken from this Assessment Report on Hydrochloric Acid.

"A full suite of standard core environmental fate studies with hydrochloric acid are not available. However there is much information about the behaviour of hydrochloric acid in water, air and soil.

Based on physicochemical properties (vapour pressure: 3.1333 x 10^3 Pa for a 32 % HCl at 20 ^oC) and extreme water solubility and the proposed use HCl will be mainly distributed between air and water compartments and is not expected to reach the terrestrial compartment.

As an inorganic compound, hydrochloric acid is not biologically degradable. The active substance is a strong acid that is very soluble in water and dissociates completely to form chloride ion and hydronium ions.

$HCl + H_2O \rightarrow H_3O^+ + Cl^-$

The resulting hydronium ion is very acidic and is solvated by water molecules. As a result of the complete dissociation of HCl in water, the concentration of the resultant hydronium ions is equal to the concentration of the HCl introduced to the solution and for the purpose of calculating the resultant pH the reaction may be written as:

$HCl\ (aq) \rightarrow H^+ + Cl^-$

pH is calculated as $-log_{10}[H^+]$. This statement is valid for added concentrations > approx. 3 x 10^{-7} mol/L. As hydrochloric acid dissociates in water, effects are due to hydronium and chloride ion concentrations and the major result of dissolution of HCl in water is the resulting pH.

Ions formed as a result of the dissociation of hydrochloric acid in water (the primary environmental compartment for emission) will be buffered. The equilibrium between CO_2, HCO_3^- and CO_3^{2-} in the aquatic ecosystem is reported to be mainly responsible for the buffer capacity of receiving water. In the soil, ion-exchange processes will also result in a buffering of pH.

In the air, hydrogen chloride can react with hydroxyl radicals to form free chloride radicals:

$HCl + OH\bullet \rightarrow H_2O + Cl\bullet$

However, this reaction cannot occur in the presence of moisture because hydrogen chloride is dissolved into moisture and exists in its dissociated form. Therefore, hydrogen chloride in its gaseous form is not persistent in air. Hydrogen chloride will be dissolved into atmospheric moisture and exist in its dissociated form as chloride and hydronium or hydrogen ions. Any reaction with hydroxyl radicals in air will lead to the formation of free chloride radicals which are not expected to persist in air.

The half-life of hydrogen chloride in air through the reaction with 10^6 molecule/cm^3 of hydroxyl radicals is calculated to be 11 days. Because of its high solubility in water, hygroscopic nature, strong reactivity and complete ionisation in solution, the form of HCl in the atmosphere will depend on factors such as humidity and the presence of other constituents. A proportion of the anthropogenic releases of hydrogen chloride become rapidly associated with particles. However, as a result of its high solubility, HCl will rapidly dissolve in cloud water or rain and both wet and dry deposition of HCl is rapid, although dry deposition is stated to be limited by physical processes in the atmosphere. Particulate associated HCl desorbs rapidly and is unlikely to be associated with particulates when it reaches the ground. Due to its reactivity, it can interact with gases such as ammonia (NH_3) and be neutralised. As a result of these removal processes, long range transport from the source area is thought to be of limited importance."

Product ingredients

An assessment on the environmental relevance of the ingredients used in Domestos Zero Limescale is reported separately (Unilever, 2014: "Classification and labelling proposal and Substance of concern", confidential business information). Following that assessment none of the product ingredients should be regarded as substances of concern (also see Section 5.3.7).

The environmental relevant effect of the active ingredient is a reduction in pH (see section 5.2.3). The product composition data (see IUCLID section 1.2) shows that one ingredient also has acidic

properties and hence this compound is concluded to be relevant for the environmental assessment, in addition to the active ingredient hydrochloric acid.

This acidic compound is a phase-in substance under the REACH Regulation (Regulation (EC) No 1907/2006) and a high volume REACH dossier (10,000 to 100,000 tonnes per annum) is available (http://apps.echa.europa.eu/registered/data/dossiers/). This compound, being an inorganic acid, completely dissociates in water to form hydronium ions and the related anions. The available physicochemical and environmental fate data as included in the REACH dossier are considered sufficient to characterize the behavior of this acid in the environment: vapour pressure = 0.78 Pa; logPow not defined (inorganic substance); very water soluble (181.4 g/L); pKa = 1 (25^{o}C); Koc very low due to ionic character; not biologically degradable (inorganic substance). Based on these data it is concluded that this acid will be mainly distributed between air and water compartments and is not expected to reach the terrestrial compartment. Furthermore, based on the calculated Henry's Law Constant (1.76 x 10^{-7} at 12^{o}C) it is concluded that this acid will stay predominantly in the water phase.

5.2.3 PEC in STP, surface water, ground water and sediment

Based on the physicochemical properties of hydrochloric acid (vapour pressure: 3.1333 x 10^{3} Pa for a 32 % aqueous HCl solution, at 20 ^{o}C; and high water solubility, up to 40% (Latvia, 2011))[1] and the proposed use of the product, HCl will mainly be distributed between the air and water compartment (see section 5.2.2). Domestos Zero Limescale has a relatively high viscosity (1637 mm^{2}/s at 20 ^{o}C; see IUCLID dossier, point 4.22) and this property will reduce the partitioning of the active substance into air. For the environmental releases it is assumed that 100% of hydrochloric acid applied to the toilet bowl is flushed into the sewage system, representing a worst case situation.

As indicated by ECHA, the releases to fresh water for wide dispersive use are by default via the municipal STP (ECHA, 2012). Therefore, direct discharge to the surface water is not addressed.

Hydrochloric acid dissociates in water and hence any environmental effects are due to hydronium and/or chloride ions, the major effect being a decrease in pH resulting from an increase in H^{+} concentration. The following is concluded in the Assessment Report on Hydrochloric Acid (Latvia, 2011)[1]:

> *"It is accepted that the toxic effects of hydrochloric acid result from the presence of the H^{+} ion and the resultant lowered pH at high concentrations. A full suite of standard core aquatic toxicity studies showing the effects of lowered pH with hydrochloric acid are available. These aquatic toxicity data show that extremely low pH is detrimental to aquatic organisms (pH 3-5). Since the resultant pH in the environment will be dependent on the buffering capacity of*

the water body, it is considered that toxicity end-points in terms of mg/L hydrochloric acid are meaningless. Similarly it is considered that there is no merit in determining aquatic PNEC values. This approach is endorsed in the OECD SIDS document for Hydrogen chloride (UNEP publications)[6] which states that the buffer capacity, pH and fluctuation of the pH are specific to each aquatic ecosystem."

Following the above concept, exposure to aquatic compartments is estimated by considering pH changes due to the environmental releases of Domestos Zero Limescale. Besides hydrochloric acid, other acidic/alkaline compounds in the formulated product can contribute to pH changes. Based on the composition of Domestos Zero Limescale (see IUCLID section 1.2), it is concluded that a further, moderately strong, acid (calculated pKa = -1.14[7]; pKa from the REACH database is 1) is present in a significant concentration (6% (w/w)) and hence needs to be taken into consideration in the exposure and risk assessment. Following its pKa, this acid will be completely dissociated under environmentally relevant pH conditions. The publically available information from the REACH (Regulation (EC) No 1907/2006) dossier on this acid (http://echa.europa.eu/information-on-chemicals/registered-substances) shows a high water solubility (181.4 g/L and a relatively low vapour pressure (0.78 Pa)) for this substance; the calculated Henry's Law Constant (1.76 x 10^{-7} at 12°C, see section 5.2.2) indicates that this acid will predominantly stay in the water phase. For the environmental releases it is therefore assumed that 100% of this acid applied on the toilet bowl is flushed into the sewage system, representing a worst case situation.

To enable calculation of pH changes due to releases of Domestos Zero Limescale, the concentration of both acids in the product is recalculated to H^+ concentration ($[H^+]$). The calculations take into account a product density of 1.07 kg/L (see IUCLID, point 4.4) and molecular weights of 36.46 g/mol and 97.10 g/mol for hydrochloric acid and the second acidic ingredient (sulphamic acid), respectively.

Table 5.2.3-1 Acidic Species present in the Domestos Zero Limescale products

Concentration in product	Substance	
	Hydrochloric acid	**Sulphamic acid**
w/w	8% ; 80 g/kg	6%; 60 g/kg
g/L	85.6	64.2
mol/L	2.35 (=$[H^+]$)	0.66 (=$[H^+]$)
Total $[H^+]$ in product	3.01 mol/L	

A total hydronium concentration $[H^+]$ of 3.01 mol/L in Domestos Zero Limescale is used in further PEC calculations. The counter ion in hydrochloric acid (Cl^-) is anticipated to be not relevant in

[6] SIDS Initial Assessment Report for SIAM 15. UNEP Publications, October 2002
[7] calculated using the Perrin calculation method (pKalc 5.0, module in Pallas 3.0, CompuDrug International)

terms of environmental risk assessment considering the amount of hydrochloric acid released into the environment and the relatively low toxicity of Cl^- (see also section 5.3).

PEC in STP

Although the primary use for these products (elimination of limescale in private lavatories) is not covered on any available ESD, such products are nevertheless routinely used for disinfection purposes given the inherent bactericidal nature of the active substance. Therefore, calculation of emissions to STP using an approach based on the PT2 ESD 'for the calculation of the release of disinfectants used for sanitary purposes based on average consumption' (OECD, 2011) has been undertaken as a 1st Tier approach. As a result, a market penetration factor of 50% has been applied in the first instance.

Furthermore, since the product authorisation covers both "variants" as part of a product family, where both exhibit identical active substance concentrations and use patterns but differ in colour/fragrance materials, it is only appropriate to use a cumulative market penetration ([redacted] %) as refinement. Therefore, recalculation of emissions to STP has also been undertaken using company market share data as a 2nd Tier approach.

According to ECHA (ECHA 2012), the average amount of wastewater generated per inhabitant is 200 litres per day and the default local sewage treatment plant (STP) receives this waste water flow from 10,000 inhabitants. Based on statistical data, the number of people per household was estimated around 2.47 (HEIMTSA 2011). It can thus be assumed that 4,049 households are connected to a STP which has a 10,000 equivalent habitant capacity. Using the realistic worst case assumption that 7 mL product is used per day, the quantity of product reaching local STP per day should be considered as 14.0 l (based upon 50% share) and [redacted] l (based upon [redacted]% share) of Domestos Zero Limescale per local STP. These calculations are shown below on Table 3-10 assuming 100% of both acids applied are flushed into the sewerage system:

Table 5.2.3-2 Emissions to STP from sanitary uses of the Domestos Zero Limescale products.

Parameters	**Symbol**	**Tier 1 F_{market} 0.5**	**Tier 2 F_{market} [redacted]**	**Units**	
Active substance in product	C_a	8	8	$\%_{ww}$	Input
$[H^+]_{Total}$ from all acidic species in product	$[C]_1$	3.011	3.011	moles l^{-1}	Input
Frequency of use per house each month	-	3	3	-	Input
Amount of product per use	-	70	70	ml	Input
Maximum application per 30 d (month)	-	210	210	ml	Input
Mean dosage per day	D	7	7	ml day^{-1}	Input
Fraction released to waste water (-)	F	1	1	[-]	Default
No. of houses in STP catchment corrected for market share	N_{local}	2000	[redacted]	Houses	Input
Mean volume of product discharging to local STP	V	14.0	[redacted]	l day^{-1}	Output

The above calculated pH values in STP influent is based on a theoretical calculation assuming the addition of both acids to pure water without consideration of the high buffering capacity of wastewater.

The Assessment Report on Hydrochloric Acid (Latvia, 2011)[1] concludes the following:

> "……..*this theoretical calculation assumes the addition of hydrochloric acid to pure water without consideration of the high buffering capacity of wastewater. Municipal wastewater (sewage), is generally a mixture of domestic waste water from baths, sinks, washing machines and toilets, waste water from industry and rainwater run-off from roads and other surface areas[8] and comprises mainly water (99.9%) together with small concentrations of suspended and dissolved organic and inorganic solids. Among the organic substances present in sewage are carbohydrates, lignin, fats, soaps, synthetic detergents, proteins and their decomposition products, as well as various natural and synthetic organic chemicals from the process industries (Pescod, 1992)[9]."*

Based on this buffering capacity of wastewater, it cannot be assessed to which extend the pH of wastewater will be decreased. The theoretical pH calculated (5.9) however is just below the normal pH range for wastewater (6.5 – 8.5; TDEC, 2014) and of raw wastewater and primary effluent from selected treatment plants as reported by FAO (6.8 to 7.8) (Pescod, 1992)[9]. Results of aquatic toxicity data in the Assessment Report on Hydrochloric Acid (Latvia, 2011)[1] are expressed as pH. In addition, the RMS concluded that due to the buffering capacity of the test media, the amounts of hydrochloric acid do not correspond to the expected pH decrease which could be calculated based on a non-buffered system: "….*Added concentrations were much higher, for example in the Daphnia study the solution at pH 4.5 was calculated to be a 0.69 mM solution equivalent to 25.2 mg/L*." As a pH of 4.5 corresponds to a hydrochloric acid concentration of 1.15 mg/L in a non-buffered system, a 22-fold excess of hydrochloric acid is required to obtain the pH decrease to 4.5.

The referenced FAO document (Pescod, 1992)[9] shows the levels of the major constituents of domestic wastewaters indicating chloride concentrations to be in the range of 30 to 200 mg/L. As indicated above, the [H^+] in the STP is calculated to be 1.28E-06 mol/L of which 2.35/3.01 part results from hydrochloric acid and hence the chloride concentration will be (1.28E-06 x (2.35/3.01)

[8] UK DEFRA web site: http://www.defra.gov.uk/Environment/water/quality/uwwtd/report02/01.htm
[9] 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. Report available at http://www.fao.org/docrep/T0551E/T0551E00.htm#Contents

x 35.5 x 1000=) 0.035 mg/L. This is negligible compared to the background levels in domestic wastewater (30 to 200 mg/L).

Based upon market penetration of 50% (Tier 1 assumption) and [redacted]% (Tier 2 refinement using market survey data), the following pH values of wastewater arriving at STP can be determined:

Table 5.2.3-3 pH determination of wastewater from sanitary uses of the Domestos Zero Limescale products.

Parameters	**Symbol**	**Tier 1 F_{market} 0.5**	**Tier 2 F_{market}** [redacted]	**Units**	
Mean volume of product discharging to local STP	V	14.0	[redacted]	l day^{-1}	Output
Effluent discharge rate of STP	$EFFLUENT_{stp}$	2000000	2000000	l	Default
$[H^+]_{Total}$ discharging to the STP	$[C]_2$	2.11E-05	[redacted]	moles l^{-1}	Output
pH in untreated wastewater	**$pH_{localinf}$**	**4.68**	**5.64**	**[-]**	Output

A Tier 1 approach suggests an extreme worst case pH in influent wastewater of 4.68, whilst a Tier 2 realistic worst case approach suggests a value (based on market penetration for the branded product) of pH 5.64. However, as indicated by the applicant, even the pH value of 5.64 based on actual market penetration represents over-estimation of acidity. Firstly, it assumes no reaction with limescale (calcium carbonate) in the toilet bowl – the main reason for application of the product. In addition, the resultant solution travelling to STP is assumed to consist of biocidal product in only pure water but this does not reflect the effect of a complex matrix such as wastewater, where suspended solids, various types of organic waste as well as species in solution could interact with the free hydrogen ion present in the influent. Furthermore, the large dilution factor which currently applies to local sewers prevents significant drops in the pH of the influent discharging to the STP. It should be noted that any decrease in pH of the receiving wastewater will strongly depend on the system's alkalinity or buffering capacity. On this basis, the use of any form of chemically-aided precipitation at the primary treatment stage such as flocculation with $Al(OH)_3$ or $Ca(OH)_2$ would further boost the capacity of the system to withstand decreases in pH induced by daily discharge of large amounts of acid. Overall, it is accepted that the Tier 2 calculated value of pH 5.64 represents the lowest possible pH of wastewater containing Domestos Zero Limescale and true pH will be significantly nearer pH 7.

In summary, estimated releases of an acidic load due to the non-professional use of the toilet disinfectant and limescale remover product, Domestos Zero Limescale, entering the sewage system, will not cause significant change of the pH levels in a standard sewage treatment plant due to the high level of dilution and the well-buffered environment of the STP.

PEC in surface water

A default dilution factor of 10 can be applied to the effluent concentration of an STP in order to estimate the concentration in the receiving compartment (PECsurfacewater) as proposed by ECHA (ECHA, 2012). In a theoretical calculation, assuming the addition of both acids to pure water, this would increase the pH calculated for the STP by one unit to 6.9. This pH is considered to be “neutral” for pure water and hence it can be concluded that the pH of surface water will not be influenced by the calculated releases of Domestos Zero Limescale. Moreover, taking account of the buffering capacity of the wastewater and the STP as explained above, any (limited) pH variations would not influence the actual pH in the STP and of the effluent. In addition, natural receiving water/sediment systems also have the capacity to buffer pH. The equilibrium between CO_2, HCO_3^- and CO_3^{2-} in the aquatic ecosystem is reported to be mainly responsible for the buffering capacity of receiving water. Furthermore, the EU Urban Waste Water Treatment Directive (Council Directive 91/271/EEC, 1991) protects the water environment from the adverse effects of discharges of urban waste water and from certain industrial discharges. This Directive has requirements for monitoring treatment plants and receiving waters and sets standards for sewage treatment. Likewise, in the UK, consents to discharge effluent are subject to conditions such as biological oxygen demand, pH, temperature, concentration of suspended solids and toxicity, and are governed by the Water Resources Act 1991[10]. Although there is no statutory limit for pH values of discharges, stringent water quality and effluent standards have been developed that require control of pH as well as reduction of a variety of physical and chemical constituents (Directive 2000/60/EC, 2000). The pH of effluents is frequently measured to maintain the water quality because the pH is a key parameter in water quality (WHO, 1998), and can be adapted easily to the aquatic ecosystem. The normal pH range for effluent used for agricultural irrigation water is from 6.5 to 8.4; pH values outside this range are a good warning that the water is abnormal in quality (FAO, 1992). Normally, pH is a routine measurement in irrigation water quality assessment and the pH of most raw water lies within the range 6.5-8.5 (WHO, 1998). Significant decrease of the pH of the receiving water, therefore, is not expected.

Applying a default dilution factor of 10 and taking the buffering capacity of the receiving compartment into consideration as well as the fact that the pH is monitored in STPs and precautionary measures are taken to avoid pH values outside the acceptable range for the effluent, the pH of the receiving surface water is concluded not to be affected by the predicted releases of Domestos Zero Limescale.

PEC in groundwater

[10] http://www.environment-agency.gov.uk/

The terrestrial exposure assessment (see section 5.2.5) concludes that emissions of chloride and hydronium ions to soil as a result of the proposed use of Domestos Zero Limescale is negligible. Therefore, pH in ground water is not expected to be impacted and no environmentally relevant concentrations of chloride are to be expected in groundwater.

PEC in sediment

As the pH of surface water will not be influenced, the sediment pH will subsequently also not be influenced. In addition, potential changes in acidic load can be buffered by the cation exchange capacity (CEC) of sediment following the same rationale as provided for soil in section 5.2.5.
Chloride anions are not expected to adsorb to the negatively charged sediment and hence no significant exposure of the sediment compartment is anticipated.

5.2.4 PEC in air

Emission of hydrochloric acid to air due to the use of Domestos Zero Limescale will predominantly occur during application and during retention in the STP. In the OECD SIDS on Hydrogen Chloride (OECD, 2002) the half-life of hydrogen chloride in air through the reaction with 10^6 molecule/cm^3 of hydroxyl radicals was reported to be 11 days following the reaction:

$HCl + OH\bullet \rightarrow H_2O + Cl\bullet$ (rate constant; 7×10^{-13} cm^3/molecule/s)

Hydrochloric acid dissolves and immediately dissociates in water, and hence the above reaction with hydroxyl radicals might be of less importance since the route of entry into the environment is via the water compartment. It can be concluded that hydrochloric acid is not persistent in air as it either will dissociate or react with hydroxyl radicals. This is in line with the conclusions in the Assessment Report on Hydrochloric Acid (Latvia, 2011)[1]:

"The half-life of hydrogen chloride in air through the reaction with 10^6 molecule/cm^3 of hydroxyl radicals is calculated to be 11 days. Because of its high solubility in water, hygroscopic nature, strong reactivity and complete ionisation in solution, the form of HCl in the atmosphere will depend on factors such as humidity and the presence of other constituents. A proportion of the anthropogenic releases of hydrogen chloride become rapidly associated with particles. However, as a result of its high solubility, HCl will rapidly dissolve in cloud water or rain and both wet and dry deposition of HCl is rapid, although dry deposition is stated to be limited by physical processes in the atmosphere. Particulate associated HCl desorbs rapidly and is unlikely to be associated with particulates when it reaches the ground. Due to its reactivity, it can interact with gases such as ammonia (NH_3) and be neutralised. As a result of these removal processes, long range transport from the source area is thought to be of limited importance."

It is recognized that a significant amount of hydrochloric acid is released into the environment (air) from natural and anthropogenic sources as stipulated in the OECD SIDS on Hydrogen Chloride (OECD 2002):

> "*Hydrogen and chlorine, which is the source of formation for hydrogen chloride, are commonly found in the environment. Thus, hydrogen chloride occurs in nature through the reaction of sea salt aerosol with acidic sulphate in the ocean surface and through the atmospheric or aquatic (hydrolysis or biodegradation) degradation of organo-halogens etc. (European Commission- European Chemical Bureau 2000, WHO 1982). Also, volcano eruption injects approximately 400,000- 11,000,000 tonnes/year of hydrogen chloride into the atmosphere. Hydrogen chloride may be released into air from artificial sources such as production and user sites. Unwanted hydrogen chloride generated at garbage incineration plants and by open burning or fire is released into the environment*."

UK hydrogen chloride monitoring data, produced between 1999 and 2002, show that annual average concentrations in air ranged between 0.12 and 0.41 µg/m^3 (2002 data) (Coleman et al., 2005).

A worst case PEC in air can be calculated assuming all hydrochloric acid released due to the use of Domestos Zero Limescale is evaporated from the STP. This is considered a worst case point source compared to the individual point sources per residence (when applying the biocidal product), especially as the release of hydrogen chloride from the product will significantly be reduced due to the physical/chemical properties (especially the high viscosity of the product (1637 mm^2/s at 20 ^{o}C; see IUCLID dossier, point 4.22). Although the Henry's Law Constant cannot be calculated for hydrochloric acid (list of endpoints; Assessment Report on Hydrochloric Acid (Latvia, 2011))[1], the high water solubility indicates that HCl will have an affinity to stay in the water phase.

Based on the amount of product released to a default STP (850 mL/day), the release rate to the STP is calculated to be 0.073 kg HCl/day (= $Elocal_{water}$). Following the calculations as provided by ECHA (ECHA, 2012), the worst case concentration in air at a distance of 100 meters from the point source is estimated (= $Clocal_{air}$ = $Elocal_{water}$*$Cstd_{air}$)[11] to be 0.020 µg/m^3. This worst case calculated concentration at a point source (STP) does not take any dissipation of hydrochloric acid from the air compartment into consideration. Although only UK measured environmental concentrations are taken as a reference, it can be concluded that the calculated worst case concentration of hydrochloric acid in air due to the use of Domestos Zero Limescale is far below the background concentrations in air.

[11] $Cstd_{air}$ = concentration in air at source strength of 1 kg/day = 2.78.10^{-4} mg/m^3

5.2.5 PEC in soil

Following the prescribed use of Domestos Zero Limescale there is no direct emission to the terrestrial compartment. Indirect exposure of the terrestrial compartment can be a result of deposition from air and/or application of sewage sludge to agricultural soil.

Deposition from air is not further assessed as concentrations in air due to the use of Domestos Zero Limescale are low and considered insignificant. Furthermore, calculated worst case PECs for hydrochloric acid at point sources (STP) are concluded to be far below measured background concentrations as presented for the UK (see section 5.2.4).

As described in section 5.2.3, the pH in the STP is not expected to decrease and hence the [H^+] will not increase as a result of the calculated emissions due to the use of Domestos Zero Limescale. Although this refers to the aqueous phase, it can be concluded that as a result the amount of H^+ ions available for exchange does not increase and hence also the pH of the sludge will not decrease.

As the pH of sewage sludge will not be influenced, the soil pH after application of sewage sludge will also not be influenced. In addition, potential changes in acidic load can be buffered by the cation exchange capacity (CEC) of soil. Soils have a CEC primarily because clay particles and organic matter in the soil tends to be negatively charged. Organic matter can have a 4 to 50 times higher CEC per given weight than clay (Ketterings *et al*., 2007). The source of negative charge in organic matter is the dissociation of organic acids which can exert a buffering capacity.

The chloride anion is not expected to adsorb to the negatively charged sewage sludge and hence no significant exposure of the soil compartment is anticipated.

5.2.6 Non-compartment specific exposure relevant to the food chain (secondary poisoning)

The first step in the assessment strategy is to consider whether there are indications for bioaccumulation potential. The Assessment Report on Hydrochloric Acid (Latvia, 2011)[1] concludes:

> "*Hydrochloric acid dissociates completely in water and as such it is not possible for bioaccumulation of HCl in organisms. Both H^+ and Cl^- occur naturally in the environment."*

For substances without bioaccumulation potential, a further assessment for predators needs not to be conducted (ECHA, 2012). In addition, the environmental exposure assessment as described in section 5.2 concludes that exposure from Domestos Zero Limescale is not expected to lead to a significant increase of environmental concentration levels of the hydronium ion and chlorine ion. Hence, there is no risk of secondary poisoning in either the aquatic or terrestrial compartment.

5.2.7 Humans exposed indirectly via the environment

Indirect exposure of humans can potentially occur via air, water and food. The environmental exposure assessment as described in section 5.2 concludes that exposure from Domestos Zero Limescale is not expected to lead to any significant perturbation of environmental concentration levels. Hence, indirect exposure of humans via the environment is not considered to be relevant.

5.3 Risk characterisation for the environment

Domestos Zero Limescale consists of 8% (w/w) of the active substance hydrochloric acid in water ([redacted]% (w/w)) plus small amounts of other ingredients (total <3% (w/w)) as well as 6% (w/w) of a second acidic substance which is considered in the risk assessment as it can contribute to the environmentally relevant effect of the active substance (decrease of pH). The other product ingredients are not expected to significantly affect the toxicity of the formulation which is driven primarily by the low pH of the acids present; details are reported separately (Unilever, 2014: "Classification and labelling proposal and substance of concern", confidential business information).

5.3.1 Aquatic compartment (including STP)

The environmental exposure assessment for Domestos Zero Limescale (see Effects and Exposure Assessment document) concludes that no significant perturbation of pH will occur in either the sewage treatment plant or receiving surface waters following the proposed use of the product as a surface disinfectant and limescale remover for toilet bowls in private, domestic and professional situations. The acidic load due to the release of both acids contained in the biocidal product is taken into account in calculating the relevant PEC values. The PEC for STP microorganisms was pH 6.1 and just above the effect concentration established in an activated sludge inhibition of respiration study (3 hour EC_{50}: pH 5.0 to 5.5). This is considered acceptable as the PEC of pH 5.9 does not account for the buffering capacity of the STP. The calculation in section 5 of the Effects and Exposure Assessment document shows that for instance for obtaining a pH of 4.5 in the Daphnia study did require 25.5 mg HCl/L while in pure water a concentration of 2.0 mg HCl/L will already result in a pH of 4.5. Hence the buffering capacity of the medium used for the Daphnia study requires more than a 10-fold excess of the acid to be added for obtaining the pH as calculated for pure water.

Therefore, the use of Domestos Zero Limescale will not have any direct or indirect adverse effects on the STP and the receiving water compartment, including sediment.

As the calculated concentration of chloride in the STP (0.035 mg/L, see section 5.2.3) is significantly below the levels of chloride in domestic wastewaters (30 to 200 mg/L (Pescod, 1992))[9], the use of Domestos Zero Limescale does not significantly add to the chloride concentrations in the environment.

5.3.2 Atmosphere

Emission of both acids to air as a result of the proposed use of the biocidal product is predicted to be insignificant. Therefore, no further assessment is deemed necessary.

5.3.3 Terrestrial compartment (including groundwater)

Given that no perturbation of the soil and water pH is expected from the proposed indoor use of Domestos Zero Limescale, no acute or long-term risk to terrestrial organisms is anticipated. It is therefore considered that there is no need for a justification for the generation of acute and/or long-term data on the toxicity of hydrochloric acid to terrestrial organisms.

5.3.4 Non-compartmental specific effects relevant to the food chain (secondary poisoning)

A further assessment is not required as there is no potential for bioaccumulation (see section 5.2.6).

5.3.5 Humans exposed indirectly via the environment

The exposure assessment shows that the indirect exposure of humans via the environment is not considered to be relevant (see section 5.2.7) and hence a further assessment is considered not required.

In terms of risk characterisation of the Domestos Zero Limescale product family, it is accepted that the approach proposed by the applicant follows that taken in the biocidal review of hydrochloric acid for PT 2 uses and that assessment at local STP (consumption approach) represents a worst case approach. Although the product has a starting pH of approximately -0.5, significant dilution has been demonstrated during transit to local STP, such that emissions to all relevant environmental compartments will not be expected to give rise to unacceptable risks based upon acidic pH (due to presence of H^+ ion).

Such conclusions have been reached on the assumption that the product will be used in a manner consistent with the manufacturer's recommendations presented within this Product Authorisation Report and that the specific pattern of use (in terms of application rate and re-treatment interval) will be reflected on product labels.

5.3.6 PBT assessment

Domestos Zero Limescale does not contain any ingredients at a concentration level of 0.1% or higher which are considered to have PBT or vPvB properties; composition details of the biocidal product are reported separately (Unilever, 2014: "Classification and labelling proposal and substance of concern", confidential business information).

5.3.7 Substances of concern

Three co-formulants were identified as SOCs. The information is summarised below.

Component	SOCs %w/w	Classification
Sulphamic acid	6.0%	H412
Bis (2-hydroxyethyl) oleyl amine	1.52 – 1.55%	H410
Cetrimonium Chloride	0.77 – 0.88%	H410

Sulphamic acid

It is noted that one component (sulphamic acid) in Domestos Zero Limescale can be considered to fall within the classification of "Substance of Concern". As the formulation will be marketed as RTU, then no consideration of in-use concentration would be relevant. Therefore, the following section provides background on the contribution to emissions and risk posed solely by this additional SoC in the environment.

Sulphamic acid is present in the product as an inhibitor of free chlorine gas, at a concentration of 6.0 % (w/w). This additional acid will contribute to the total acidity of the effluent discharging to the local STP. The emissions discharging to STP have been calculated using the ESD market penetration factor value as first Tier (worst case scenario F_{market}=0.5); which assumes half houses in UK are using the product. The second tier value used is claimed by the applicant to be based on actual market data. Physicochemical parameters have been used to calculate distribution at the STP using Simple Treat. Sulphamic acid is non-readily biodegradable.

Local Emissions calculated for Sulphamic Acid present in Domestos Zero Limescale at 6%

Parameters	Symbol	Tier 1 F_{market} 0.5	Tier 2 F_{market} [redacted]	Units	
% Active substance in product	%	6	6	$\%_{ww}$	I
Conc. Sulphamic acid in product	C	0.0642	0.0642	kg l^{-1}	I
Fraction released to waste water	F	1	1	[-]	D
Number of inhabitants per STP	N_{local}	10000	10000	[-]	D
Consumption per capita (limescale removal)	V_{form}	0.0018	0.0018	[-]	D
Market penetration factor	F_{market}	0.5	[redacted]	ml	D/I
Emission rate to wastewater: Elocal=Nlocal*Q*C*F*F_{market}	E_{local}	[redacted]	[redacted]	kg d^{-1}	O
No. of houses in STP catchment corrected for market share F_{market}=0.5	N_{local}	2000	[redacted]	Houses	I
Effluent discharge rate of STP	$Effluent_{STP}$	2 x 10^{+6}	2 x 10^{+6}	l	I
Concentration in untreated wastewater	Clocalinf	[redacted]	[redacted]	mg l^{-1}	O
Fraction directed to water by STP (Simpletreat)	$Fstp_{water}$	0.999	0.999	[-]	D

Conc. in STP effluent	Clocaleff	[redacted]	[redacted]	mg l^{-1}	O
Weight fraction organic carbon in suspended solids	FOC_{susp}	0.1	0.1	[-]	D
Partition coefficient organic carbon - water	Koc	6.124	6.124	l kg^{-1}	I
Partition coefficient solid – water in suspended matter	Kp_{susp}	0.6124	0.6124		O
Concentration of suspended matter	$SUSP_{water}$	15	15	mg l^{-1}	D
Dilution for direct discharge to surface water	DILUTION	10	10		D
$PEC_{surface\ water}$	**$Clocal_{water}$**	[redacted]	[redacted]	mg l^{-1}	O

The following concentration directed onto surface waters can be determined:

Concentration and pH of wastewater discharging to surface waters from sanitary uses of sulphamic acid at 6% in Domestos Zero Limescale

Parameters	Symbol	Tier 1 F_{market} 0.5	Tier 2 F_{market} [redacted]	Units	
Concentration of active in surface water	**$Clocal_{water}$**	[redacted]	[redacted]	mg l^{-1}	Output
Product density	**Density**	1.07	1.07	kg l^{-1}	I
Concentration of active in effluent discharging to surface water	**%**	[redacted]	[redacted]	%	Default
pH in untreated wastewater	**$pH_{localwater}$**	**5.54**	**7.57**	**[-]**	Output

A Tier 1 approach suggests an extreme worst case pH in STP effluent to surface waters of 5.54, as a result of the presence of sulphamic acid alone. A Tier 2 realistic worst case approach suggests a value (based on market penetration for the branded product) of pH 7.57. However, both pH values represent an over-estimation of acidity arising from sulphamic acid as they take no account of any other neutralising factors.

It is clear that the SoC, sulphamic acid, contributes to acidity of the overall product and therefore it must be incorporated into a cumulative environmental risk assessment. This will address risks posed by both the active (HCl) and SoC (H_3NSO_3) (see Section 5.3).

Bis (2-hydroxyethyl) oleyl amine

Bis (2-hydroxyethyl) oleyl amine with CAS 25307-17-9 supplied as [redacted] from [redacted] and is present in biocidal product family formulation at 1.52 – 1.55%. This substance is classified as H410 (Aquatic Chronic 1) and also has an alternative CAS number: 26635-93-8.

The PNECs identified for this substance are as follows, and are consistent with those identified in the harmonised REACH registration dossier:

$PNEC_{aquatic}$	2.14E-4 mg/l
$PNEC_{soil}$	5 mg/kg dry weight (4.41 mg/kg wwt)
$PNEC_{stp}$	1.5 mg/l
$PNEC_{sed}$	1.692E+0 mg/kg dwt (3.68E-1 mg/kg wwt)

The MSDS for the substance states a vapour pressure of 7.3E-6 hPa (or 7.3E-4 Pa) at 20 °C, a log Kow of 3.4 (2511.9) at 25 °C, and that the substance is insoluble in water. The molecular weight for the compound is 355.6 g/mol and the Persistence and Degradability section of the MSDS states that compound is readily biodegradable (>60 %) in a 28-d OECD 301D study; assumed to indicate that 10-d window has been passed.

It is noted that a second MSDS for this substance is provided by the applicant ([redacted] from [redacted]). However, whilst this appears to be a duplicate source of compound to that supplied as [redacted] there is a discrepancy in that the $PNEC_{sed}$ for [redacted] does not correspond with the value stated in the harmonised REACH dossier for the substance. As such, UK CA has assessed the substance of concern based upon the values presented for [redacted], which parallels those in the harmonised dossier. This information has been fed back to the applicant for them to take up with the substance supplier as appropriate.

Behaviour at STP modelled in SimpleTreat v3.1 using stated phys-chem data and biodegradability (passing and failing 10-d window):

Fraction	Ready Biodegradable (passing 10-d)
Degraded at STP	0.210
Directed to air (Fstp_air)	2.09E-5
Directed to waterbody (Fstp_water)	6.67E-2
Directed to sludge (Fstp_sludge)	0.724

A default soil DT50 could be taken as 30 d in Table 8 (as Log Kow is 3.4). However, Kp soil calculated via Koc would be 90520 x 0.02 = 1810 and this would suggest a DT50 of 300 – 3000 d.

Searching of ECHA REACH dossier for the compound uncovered a modern soil degradation study at 20 °C where degradation was investigated in 3 soil types (DT50 values of 8.7 – 9.9 d were observed). Normalisation of slowest degradation would give rise to approximate value of 18.8 d at 12 °C.
As it is not clear if this study has been appraised at EU level, it would support use of the default 30-d DT50 value as a realistic way forward for emissions assessment.

Any subsequent risk assessment with regard to mixture toxicity will solely focus on alkylamine component (SoC) at 1.55% maximum because HCl (active) and sulphamic acid (another SoC) were already assessed based upon pH and dilution factors before reaching STP.

The product is applied in toilet bowls and all losses are discharged to drains and reach STP.
Based upon information already supplied in UK PAR, Tier 1 assumes 50% market penetration (generic default) but the applicant provided argumentation to support a Tier 2 approach based on [redacted]% market penetration for the Domestos product family.

Emissions to STP from sanitary uses of the Domestos Zero Limescale products: input values.

Parameters	**Symbol**	**Tier 1 F_{market} 0.5**	**Tier 2 F_{market}** [redacted]	**Units**	
SoC (alkylamine) in product	-	1.55	1.55	%ww	Input
Frequency of use per house each month	-	3	3	-	Input
Amount of product per use	-	70	70	ml	Input
Maximum application per 30 d (month)	-	210	210	ml	Input
Mean dosage per day	D	7	7	ml day^{-1}	Input
Fraction released to waste water (-)	F	1	1	[-]	Default
No. of houses (4000) in STP catchment corrected for market share	N_{local}	2000	[redacted]	Houses	Input
Mean volume of product discharging to local STP	V	14.0	[redacted]	l day^{-1}	Output

As a result, the quantity of product reaching local STP per day should be considered as 14.0 l (based upon 50% share) and [redacted] l (based upon [redacted]% share). Assuming that the alkylamine SoC makes up 1.55% of product and that formulation density is 1.07 g/cm^3 (taken from phys-chem section of PAR), this results in SoC $Elocal_{water}$ of [redacted] kg/d (50% penetration) and [redacted] kg/d ([redacted]% penetration).

Parameter	*50% market penetration*	[redacted]% *market penetration*
$Elocal_{water}$ (kg/d)	[redacted]	[redacted]
$Clocal_{inf}$ (mg/l)	[redacted]	[redacted]
$Clocal_{eff}$ (mg/l) **PECstp**	[redacted]	[redacted]
$Clocal_{water}$ (mg/l) **PECwater**	[redacted]	[redacted]
PECsediment (mg/kg wwt)	[redacted]	[redacted]
Csludge (mg/kg dwt)	[redacted]	[redacted]
Clocal soil (mg/kg wwt) **PECsoil**	[redacted]	[redacted]
PECporewater (µg/l)	[redacted]	[redacted]

Compartment	PEC ([redacted]% penetration)	PNEC	Risk Quotient
STP (mg/l)	[redacted]	1.50	5.67E-4
Water (mg/l)	[redacted]	2.14E-4	0.350
Sediment (mg/kg wwt)	[redacted]	0.368	0.399
Soil (mg/kg wwt)	[redacted]	4.41	6.26E-3
Groundwater (µg/l)	[redacted]	0.1	5.67E-2

When considering [redacted]% market penetration such that [redacted] homes per STP can reasonably be expected to use Domestos Zero Limescale on the same day, risks to STP, surface water, ground water and soil are considered acceptable for discharges of the Bis (2-hydroxyethyl) oleyl amine SoC.

The issues posed by HCl and sulphamic acid relate to pH (presence of H+) so it would not be possible, or appropriate, to undertake mixture toxicity in combination with Bis (2-hydroxyethyl) oleyl amine.

Conclusion: using reported OECD study information that reports that the Bis (2-hydroxyethyl) oleyl amine is readily biodegradable (passing the 10-d window) and using market penetration to argue that only [redacted]% of houses will discharge any variation of Domestos Zero Limescale to local STP on the same day, then acceptable risks are shown for this component.

Cetrimonium chloride

It has been identified that Domestos Zero Limescale contains a further SoC, namely cetrimonium chloride (CAS of 112-02-7) at 0.77 – 0.88 % in the biocidal product family. The material is stated as being supplied as [redacted] from [redacted].

Limited information is available on the material from SDS but vapour pressure reported as 3 kPa at 25 °C, the compound is reported as soluble in water and log Kow is reported as being “not applicable”. It is reported as being readily biodegradable (passing 10-d window) with 95% degradation after 28-d in an OECD 301B study. The molecular weight of the substance is 320.0 g/mol. However, a REACH registration dossier for cetrimonium chloride is available and indicates the vapour pressure to be <0.006 Pa at 25 °C, water solubility to be 240 mg/l at 25 °C (in a micelle study) and log Kow to be 3.08 (Kow of 1208.3). Mean arithmetic Koc from 4 results was reported as 2658607.8 (log Koc of 6.425).

Behaviour at STP modelled in SimpleTreat v3.1 using stated phys-chem data and biodegradability (passing 10-d window:

Fraction	Ready Biodegradable (passing 10-d)
Degraded at STP	1.56E-2
Directed to air (Fstp_air)	1.86E-7
Directed to waterbody (Fstp_water)	7.86E-2
Directed to sludge (Fstp_sludge)	0.906

A default soil DT50 could be taken as 30 d in Table 8 (as Log Kow is 3.08). However, Kp soil calculated via Koc would be 2658607.8 x 0.02 = >50,000 and this would suggest a DT50 of > 3000 d.

Pre-2000 soil degradation data (from related compound) are available in the REACH registration dossier and indicates a DT50 of 40 d at 22 °C which is equivalent to 89 d at 12 °C. As a precaution, this value will be used instead of default value taken from ECHA Guidance on ERA, Vol IV, Part B.

As a result of emissions assessment presented in UK PAR, the quantity of product reaching local STP per day should be considered as 14.0 l (based upon 50% share) and [redacted] l (based upon [redacted]% share). Assuming that the quaternary ammonium compound makes up 0.88% of product and that formulation density is 1.07 g/cm^3 (taken from phys-chem section of PAR), this results in SoC $Elocal_{water}$ of [redacted] kg/d (50% penetration) and [redacted] kg/d ([redacted]% penetration).

Parameter	*50% market penetration*	[redacted]*% market penetration*
$Elocal_{water}$ (kg/d)	[redacted]	[redacted]
$Clocal_{inf}$ (mg/l)	[redacted]	[redacted]
$Clocal_{eff}$ (mg/l) **PECstp**	[redacted]	[redacted]
$Clocal_{water}$ (mg/l) **PECwater**	[redacted]	[redacted]
PECsediment (mg/kg wwt)	[redacted]	[redacted]
Csludge (mg/kg dwt)	[redacted]	[redacted]
Clocal soil (mg/kg wwt) **PECsoil**	[redacted]	[redacted]
PECporewater (µg/l)	[redacted]	[redacted]

PNEC (aquatic) for Cetrimonium Chloride
Toxicity data

Result	Species	Exposure	Test
Acute EC50 0,18 mg/L	Algae	72 hours	OECD 201 Alga, Growth Inhibition Test
Acute EC50 0,09 mg/L	Daphnia	48 hours	OECD 202 *Daphnia* sp. Acute Immobilization Test and Reproduction Test
Acute LC50 0,71 mg/L	Fish	96 hours	OECD 203 Fish, Acute Toxicity Test

Assessment Factor = 1000
$PNEC_{aquatic}$ = 0.09 mg/L / 1000 = 0.00009 mg/L (9.0E-5 mg/l)

In the absence of reliable PNECs, then EPM is used to calculate PNEC in soil and sediment (equations 70 & 72 of ERA guidance, Volume IV, Part B) from the value given above in surface water (PNECaquatic of 9.0E-5 mg/L). Information provided in ECHA registration dossier 14219/1 indicates that cetrimonium chloride has a mean Koc of 2.66E+6 L/Kg, so that predicted K_{soil_water} and K_{susp_water} values of 79758 L/Kg and 66466 L/kg respectively can be calculated.
This gives rise to a $PNEC_{sediment}$ of 5.202 mg/kg wwt and $PNEC_{soil}$ of 42.234 mg/kg wwt.

Although there is no obvious way to predict/calculate PNECstp, the SDS does report bacterial toxicity results against *P. putida* where an EC_{50} of 3.2 mg/l was noted in a DIN 38412 T.8 study; although non-standard, these results are used to derive a pseudo-$PNEC_{stp}$ of 3.2 / 100 = 3.2E-2 mg/l.

Compartment	PNEC*
STP (mg/l)	3.20E-2
Water (mg/l)	9.00E-5
Sediment (mg/kg)	5.202 (wet)
Soil (mg/kg)	42.234 (wet)
Groundwater (µg/l)	0.1

*derived by eCA using data and/or EPM

Compartment	PEC ([redacted]% penetration)	PNEC	Risk Quotient
STP (mg/l)	[redacted]	3.20E-2	1.78E-2
Water (mg/l)	[redacted]	9.00E-5	0.127
Sediment (mg/kg wwt)	[redacted]	5.202	0.127
Soil (mg/kg wwt)	[redacted]	42.234	6.11E-4
Groundwater (µg/l)	[redacted]	0.1	3..30E-3

Conclusion: using reported OECD study information that reports that the cetrimonium chloride is readily biodegradable (passing the 10-d window) and using market penetration to argue that only [redacted]% of houses will discharge any variation of Domestos Zero Limescale to local STP on the same day, then acceptable risks are shown for this component.

Overall consideration of mixture toxicity

HCl and sulphamic acid give rise to adverse effects based upon pH: cumulative risks have already been considered in the UK CA PAR and found to be acceptable.

Two further SoCs (cetrimonium chloride and Bis (2-hydroxyethyl) oleyl amine) have been identified in the formulation and individual risks have been presented above. The cumulative risks posed by cetrimonium chloride and Bis (2-hydroxyethyl) oleyl amine are as follows:

Compartment	Hydroxyethyl oleylamine PEC/PNEC	Cetrimonium chloride PEC/PNEC	Combined Risk
STP	5.67E-4	1.78E-2	1.84E-2
Water	0.350	0.127	0.477

Sediment	0.399	0.127	0.526
Soil	6.26E-3	6.11E-4	6.87E-3
Groundwater	5.67E-2	3.30E-3	6.00E-2

The presence of HCl, sulphamic acid, cetrimonium chloride and Bis (2-hydroxyethyl) oleyl amine in the product family formulation does not give rise to unacceptable risks in any environmental compartment.

6. EFFICACY

Please note Domestos Zero Limescale refers to a family of 3 products, however for simplicity this assessment has been written for one product within the family, the differences between the 3 products is noted in the discussion section below.

6.1 Function

This product is a disinfectant (PT 2).

6.2 Organism(s) to be controlled and products, organisms or objects to be protected.

The product is a liquid that is applied undiluted to toilet bowls to kill bacteria, bacterial spores, yeast, fungi and viruses. It is for domestic and professional use.

Domestos Zero Limescale contains 8g per 100g (8% w/w) hydrochloric acid.
The product is supplied as a ready to use liquid in a 750ml bottle.

The application rate is approximately 70 ml per toilet (enough to cover the entire toilet bowl). The product should be left for 30 minutes (with brushing if required). Reapplication is recommended as necessary.

6.3 Evaluation of the label claims

The following label claims were submitted for evaluation by the applicant:

[redacted]

6.4 New data

Eight studies have been provided in support of the efficacy of Domestos Zero Limescale.

6.4.1 Efficacy against Fungi, Bacteria and Bacterial Spores

All of the studies provided refer to the test substance as HSK or HELSINKI (except where stated otherwise). The applicant confirmed that the test products used in the efficacy tests were 'identical to the commercial products indicated in the dossier as Domestos Zero Limescale – Lime variant'.

1. EN 13697 (Fungi) – Lonati 2006

This study was conducted following the standard EN 13697 protocol using the obligatory conditions. The product was tested neat (i.e. undiluted) under high soil conditions.

Tests were conducted for both the required test organisms, *Candida albicans* and *Aspergillus niger* with an additional contact time of 30 minutes (in addition to the 15 minute contact time required by the standard).

The standard requires a 3 log reduction in organism viability to demonstrate fungicidal activity. This was achieved in all the tests performed.

The controls in this study were acceptable by the criteria in the standard protocol.

2. EN 13697 (Bacteria) – Brambilla 2014

This study was conducted following the standard EN 13697 protocol using the obligatory conditions. The product was tested neat under high soil conditions.

Tests were conducted using the required test organisms, *Pseudomonas aeruginosa*, *Eschericia coli*, *Staphylococcus aureus* and *Enterococcus hirae* for an additional contact time of 15 minutes (in addition to the 5 minute contact time required by the standard).

The standard requires a 4 log reduction in viability to demonstrate bactericidal activity. This was achieved in all the tests performed for the neat and 95% concentrated product.

The controls in this study were acceptable by the criteria in the standard protocol.

3. EN 1650 (Fungi) – Lonati 2006

This study was conducted following the standard EN 1650 protocol using the obligatory conditions. The product was tested at 80% of its neat concentration under high soil conditions.

Tests were conducted for both the required test organisms, *C. albicans* and *A. niger* with an additional contact time of 30 minutes (in addition to the 15 minute contact time required by the standard).

The standard requires a 4 log reduction in viability to demonstrate fungicidal activity. This was achieved in all the tests performed.

The controls in this study were acceptable by the criteria in the standard protocol.

4. EN 13704 (Bacterial Spores) – Lonati 2009

This study was conducted following the standard EN 13704 protocol using the obligatory conditions. The product was tested neat under high soil conditions.

The test was conducted using the required test organism, *Bacillus subtillis* (spores) for an additional contact time of 30 minutes (in addition to the 60 minute contact time required by the standard).

The standard requires a 3 log reduction in viability to demonstrate sporicidal activity. This was achieved in all the tests performed.

The controls in this study were acceptable by the criteria in the standard protocol.

5. EN 1276 (Bacteria) – Brambilla 2014

This study was conducted following the standard EN 1276 protocol using the obligatory conditions. The obligatory tests conditions include a 5 minute contact time under high soil conditions.

The product was tested at 76, 3.0, 2.5, 2.0, 1.5, 1.0 and 0.5% of its neat concentration under high soil conditions with a contact time of 5 and 30 minutes. All four required test organisms, *P. aeruginosa*, *E. coli*, *S. aureus* and *E. hirae* were tested at each concentration and for each contact time.

The standard requires a 5 log reduction in viability to demonstrate bactericidal activity. This was achieved in all the tests performed at concentrations of 1.5% and above with a 5 minute contact time and 1.0% and above for the 15 minute contact time.

The controls in this study were acceptable by the criteria in the standard protocol.

6. EN 14476 (Viruses) – Brambilla 2014

This study was conducted following the standard EN 14476 protocol using the obligatory conditions. The product was tested at 50.0, 20.0 and 3.0% of its neat concentration under high soil conditions (0.3% bovine serum albumin with sheep erythrocytes).

Tests were conducted for all the required test organisms, Adenovirus Type 5, Poliovirus Type 1 and Murine norovirus (S99) with contact times of 15, 30 and 60 minutes.

The standard requires a 4 log reduction in viability to demonstrate virucidal activity. This was achieved in the tests performed using a 20% solution at all contact times.

The controls in this study were acceptable by the criteria in the standard protocol.

7. EN 1650 (Fungi) – Annese 2015

The test product used in this study was Domestos Zero Limescale Lime variant, with sulphamic acid, ethoxylated amine and centrimonium chloride removed and water added in their place.

This study was conducted following the standard EN 1650 protocol using the obligatory conditions. The product was tested at 80% of its neat concentration under high soil conditions.

Tests were conducted for both of the required test organisms, *C. albicans* and *A. niger* with a contact time of 15 minutes.

The standard requires a 4 log reduction in viability to demonstrate fungicidal activity. This was achieved in all the tests performed.

The controls in this study were acceptable by the criteria in the standard protocol.

8. EN 1276 (Bacteria) – Annese 2015

The test product used in this study was Domestos Zero Limescale Lime variant, with sulphamic acid, ethoxylated amine and centrimonium chloride removed and water added in their place.

This study was conducted following the standard EN 1276 protocol using the obligatory conditions. The obligatory tests conditions include a 5 minute contact time under high soil conditions.

The product was tested at 80% of its neat concentration under high soil conditions with a contact time of 5 minutes. All four required test organisms, *P. aeruginosa*, *E. coli*, *S. aureus* and *E. hirae* were tested.

The standard requires a 5 log reduction in viability to demonstrate bactericidal activity. This was achieved in all the tests performed.

The controls in this study were acceptable by the criteria in the standard protocol.

6.5 Discussion

It has been agreed between Member States that the criteria set out in new guidance documents will only be applied by Competent Authorities once the document has been available to applicants etc. for 2 years. At the time of the submission of the data package for this product the Technical Notes for Guidance (TNsG) for PT2 had not been available for 2 years. For this reason the UK CA has not applied the guidance in the TNsG to this product. The UK CA does, however, consider that the principles of ‘good science’ should apply, and where available and appropriate it is preferable for testing to be conducted using recognised standards.

The testing requirements for surface disinfectants for use against bacteria, bacterial spores, fungi and yeast in food, industrial, domestic and institutional areas set out in EN 14885 are given in Table 6.5-1 below:

Table 6.5-1: The testing requirements set out in EN 14885 for a surface disinfectant for use against bacteria, bacterial spores, fungi and yeast.

	Claim		
	Bactericidal	Fungicidal/ Yeasticidal	Sporicidal
Testing Requirements	EN 1276 – *S. aureus, P. aeruginosa, E. coli, E. hirae*	EN 1650 – *C. albicans, A. niger*	EN 13704 – Spores, *B. subtilis*
	and/or	and/or	-
	EN 13697 - *S. aureus, P. aeruginosa, E. coli, E. hirae*	EN 13697 – *C. albicans, A. niger*	-

No claim of mycobacterial or tuberculocidal activity is being made in relation to this product, therefore there are no additional requirements for use in medical areas.

The applicant has provided studies conducted following all of the standards in Table 6.5-1. A study has also been conducted to EN14476 to support the virucidal activity of the product.

All the test organisms (and strains) and key conditions specified in the relevant standards have been used. All the test results show the reduction in target organisms required by the appropriate standard. The UK CA therefore considers that the data provided supports the claim kills bacteria, viruses, yeast, fungi and bacterial spores.

This product is for use in toilets, this use might reasonably be considered ‘dirty conditions’, as such there is an additional requirement in the test standards for 3 g/l of bovine albumin to be used in the tests as an interfering substance. This has been done in all the studies provided.

The studies provided tested the product neat or in solution. The UK CA considers this supports the requested application rate for the product ‘cover all surfaces’. The data supports the recommended contact time of 30 minutes. All the results reported meet the required standard (as described by the appropriate EN standard) after a 30 minute contact time or less.

In relation to the label claims made for the product, all include the term ‘germ’. The term ‘germ’ although in common usage, lacks a specific scientific definition.

The UK CA considers that ‘germ’ is generally understood to mean microorganisms, especially those which cause disease. In popular usage the term is used to refer to bacteria (and spores), viruses, fungi (including yeast), protozoa and in some instances algae and parasites.

In order to address this lack of specificity the UK CA considers that the use of the word ‘germs’ is acceptable on the basis that: Data have been provided that addresses several groups of microorganism commonly implied by the term germs, and that where the word germ is used in a label claim it is also clarified which organisms are implied. These should only be the organisms for which the product has been authorised for use against.

In relation to individual claims, below are the label claims submitted and the UK CA’s position on their acceptability.

[redacted]

[redacted]

[redacted]

The UK CA notes that Domestos Zero Limescale contains sulphamic acid (6%), ethoxylated amine (1.5%) and centrimonium chloride (0.77-0.88%) which were identified as actives during the Biocidal Products Directive review process but were not subsequently notified. The applicant has provided the following reasoned case for the presence of these chemicals in the product:

The substances sulphamic acid (CAS 5329-14-6), ethoxylated amine (CAS 25307-17-9) and cetrimonium chloride -CITAC (112-02-7) were originally identified as active substances under the Biocidal Product Directive (98/8/EC), but were not subsequently notified, and therefore have not been included in the revision program. It is therefore important to clarify that there ingredients are not used in Helsinki [Domestos Zero Limescale Family products] as biocidal active substances, but they play a different role within the product. The biocidal active substance is in fact hydrochloric acid, which is included in the product at a level of 8% Here below it is described the role played within the product by these three ingredients:

Sulphamic acid (5329-14-6): it is added in the product at a ratio 3:4 (weight/weight) vs hydrochloric acid, hence at a percentage of 6%, in order to avoid the release of hazardous gases (chlorine) in case the product is accidentally mixed with other toilet products containing hypochlorite. This is a further precaution taken in addition to the warning reported on the label, in order to avoid possible risks for the consumers. Sulpamic acid reacts in fact more quickly with hypochlorite, hence preventing hydrochloric acid to release chlorine.

The on-going reactions are:

$NH_2SO_3H + NaOCl \rightarrow ClHNSO3Na + H_2O$
$NH_2SO_3H + 2\ NaOCl \rightarrow Cl_2NSO_3Na + H_2O + NaOH$

Instead of:

$NaOCl + 2HCl \rightarrow NaCl + H_2O + Cl_2$

Ethoxylated amine (25307-17-9) and CITAC (112-02-7): these two ingredients are included in the product as surfactants, and their choice is primarily determined by the fact that, on top of playing the detergent activity, they allow to obtain a high viscosity for the product, which is a key feature in order for it to optimally adhere to the surfaces of the toilet where it needs to act. In particular the ethoxylated amine, which is the main surfactant (ca.

1.5%), is very stable in the extremely acidic condition of Helsinki formulation, and moreover it has a low degree of dissolution in hydrochloric acid, which allows to have the desired high viscosity of the product. Cetrimonium chloride, included at a concentration of 0.77-0.88%, acts as cosurfactant and it contributes in the optimization of several properties of the product such as the viscosity, the dissolution of the fragrance and the cloud point.

In conclusion we declare that the choice of these three ingredients has been made for specific formulative reasons as explained above, and that are not used as biocidal active substances in the product.

Tests conducted using a simplified formulation of Domestos Zero Limescale (Annese 2015) show that without these three co-formulates the product is capable of producing the required biocidal effect. The (declared) active substance (HCL) is sufficiently effective in the formulation in the absence of the 'potentialy active substances' this demonstrates that they do not need to be included in the products formulation to contribute to the products's efficacy.

The UK CA accepts the applicants reasoned case for the inclusion of sulphamic acid (to prevent the release of hazardous gasses in the event of accidental mixing), ethoxylated amine and centrimonium chloride (as detergents). The applicant has explained why these components could not reasonably be substituted for other non-active components and that there are no alternative substances which could be used for this purpose.

The UK CA therefore considers it is not reasonable to reject the authorisation of product as these substances have been demonstrated to have been included for purposes other than to act as biocidal active substances. The UK CA considers that sulphamic acid, ethoxylated amine and centrimonium chloride should not be considered as biocidal active substances in this product.

The products included within the Domestos Zero Limescale family differ only in the minor fragrance and dye components. The UK CA considers that these differences in formulation will not have a significant impact on the efficacy of the products and accepts the use of the Lime variant as a representative test substance.
The evaluation has shown sufficient data have been provided to permit the authorisation of the product Domestos Zero Limescale as a disinfectant at the requested application rate.
The label claims supported by the data are:

[redacted]

[redacted]

7. UNACCEPTABLE EFFECTS OF THE BIOCIDAL PRODUCT

None identified.

8. DECISION

8.1 Summary of decisions and restrictions

It is concluded that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit authorisation of the biocidal product according to the following conditions:

1) Users – Non-professional and professional
2) The concentration of the active substance hydrogen chloride in the biocidal product is 8.0% w/w. The source of hydrogen chloride is Borsodchem Zrt., Hungary. Minimum purity 99.9% w/w.
3) The Domestos Zero Limescale biocidal product family incorporates three variants: Domestos Zero Limescale Lime, Domestos Zero Limescale Pink and Domestos Zero Limescale Aquamarine. The concentration of active substance is identical for all variants.
4) Authorisation is granted for the disinfection of the inside of toilet bowls by the application of the undiluted product. Domestos Zero Limescale should be applied at a rate of 70 ml per toilet (enough to cover the entire toilet bowl). The product should be left for 30 minutes (with brushing if required). Reapplication is recommended as necessary.
5) A shelf life of 2 years is supported.
6) The product is supplied contained within a 750 mL HDPE bottle.
7) The label claims supported by the data are:

[redacted]

The term ‘germ’ is currently widely used and recognised by the UK public however, following discussion with other member states, UK CA requires that each occurrence of ‘germ’ in a label claim must be followed by a suitable symbol (e.g. an asterisk (*)) which links to the phrase ‘*bacteria, yeast, fungi, bacterial spores and viruses’, which must appear on the product label.

8) The product label should carry the phrase 'WASH HANDS AND EXPOSED SKIN before meals and after use.'
9) For professional users the label should carry the phrase 'Wear protective chemical resistant gloves during product handling phase (glove material to be specified by the authorisation holder within the product information).

10) The product label should be amended to include the phrase '"Do not mix with bleach or other cleaner as it may result in the formation of toxic chlorine gas or heat."

8.2 Necessary issues accounted for in the product label

Non-professional and professional users:

GHS Pictograms	Corrosive
Signal word	Danger
Hazard statement class and category	Skin Corr. 1 Corrosive to metals Eye dam. 1 Aquatic Chronic 3
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	P101 – If medical advice is needed, have product container or label at hand. P102 – Keep out of reach of children. P103 – Read label before use. P234 – Keep only in original container P260 – Do not breathe dust/fume/gas/mist/vapours/spray. P264 – Wash … thoroughly after handling. P273 – Avoid release to the environment. P310 – Immediately call a POISON CENTER or doctor/physician. P390 – Absorb spillage to prevent material damage. P301+P330+P331 – IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P303+P361+P353 – IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. P363 – Wash contaminated clothing before reuse. P304+P340 – IF INHALED: Remove victim to fresh air and keep at rest in a position 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. P405 – Store locked up.

	P406 – Store in corrosive resistant/…container with a resistant inner liner. P501 – Dispose of contents/container to…

8.3 Requirement for further information

Ambient storage stability data (2 years in the commercial packaging) is required for continuing authorisation and should be completed within 3 years of product authorisation.

UK Competent Authority

December 2016

Annex A: Exposure calculations

Professional use and non-professional use using the mode "instantaneous release" in ConsExpo [12]:

ConsExpo 4.1 report

file name:
Report date: 1-4-2014

Product

Domestos Zero Limescale

Compound

Compound name :	HCl	
CAS number :		
molecular weight	36,5	g/mol
vapour pressure	0,237	Pascal
KOW		linear

General Exposure Data

exposure frequency	16	1/day
body weight	60	kilogram

Inhalation model: Exposure to vapour : instantaneous release, with limiting the air concentration to the vapour pressure of the pure substance

weight fraction compound	8	%
exposure duration	30	minute
room volume	2,5	m3
ventilation rate	2	1/hr
applied amount	75	gram

Output

Inhalation (point estimates)

inhalation mean event concentration: 3,56 mg/m^3 *(acute exposure during one 30 minute exposure event for non-professionals and for professionals)*

[12] Irrelevant information has been deleted from the report generated by ConsExpo. The exposure frequency does not influence the "inhalation mean event concentration". Therefore this assessment is also applicable for non-professional use.

Annex B: Efficacy data provided in support of the application

Table B.1. Summary

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
HSK	*C. albicans* *A. niger*	EN 13697 using obligatory criteria under high soil conditions. Additional tests were performed with a contact time of 30 minutes for all test organisms.	Results met the requirement of the test standard – all tests gave a ≥ 3 log reduction in viability.	**EN 13697 (Fungi) – Lonati 2006**
HSK	P. aeruginosa E. coli S. aureus E. hirae	EN 13697 using obligatory criteria under high soil conditions. Additional tests were performed with a contact time of 15 minutes for all test organisms.	Results met the requirement of the test standard – all tests gave a ≥ 4 log reduction in viability.	**EN 13697 (Bacteria) - Brambilla 2014**
HSK	*C. albicans* *A. niger*	EN 1650 using obligatory criteria under high soil conditions. The product was tested at 80% of its neat concentration. Additional tests were performed with a contact time of 15 and 30 minutes for all test organisms.	Results met the requirement of the test standard – all tests gave a ≥ 4 log reduction in viability.	**EN 1650 (Fungi) - Lonati 2006**
HSK	*B. subtillis* (spores)	EN 13704 using obligatory criteria under high soil conditions.	Results met the requirement of the test standard – all tests gave a ≥ 3 log reduction in viability.	**EN13704 (Bacterial Spores) - Lonati 2009**

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
		An additional test was performed with a contact time of 30 minutes for the test organism.		
HSK	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276 using obligatory criteria. The product was tested at 76, 3.0, 2.5, 2.0, 1.5, 1.0 and 0.5% of its neat concentration under high soil conditions with a contact time of 5 and 30 minutes for all test organisms.	Results met the requirement of the test standard – the tests performed gave a ≥ 5 log reduction in viability at concentrations of 1.5% and above with a 5 minute contact time and 1.0% and above for the 15 minute contact time.	**EN 1276 (Bacteria) - Brambilla 2014**
HSK	Adenovirus Type 5 Poliovirus Type 1 Murine norovirus (S99)	EN 14476 using obligatory criteria. The product was tested at 50, 20 and 3.0% of its neat concentration under high soil conditions with a contact times of 15, 30 and 60 minutes for all test organisms.	Results met the requirement of the test standard – tests for the 20% solution showed a ≥ 4 log reduction in viability at all contact times.	**EN 14476 (Viruses) – Brambilla 2014**
Domestos Zero Limescale Lime variant, without sulphamic acid, ethoxylated amine and centrimonium chloride	*C. albicans* *A. niger*	EN 1650 using obligatory criteria under high soil conditions. The product was tested at 80% of its neat concentration. Additional tests were performed with a contact time of 15 minutes for all test organisms.	Results met the requirement of the test standard – all tests gave a ≥ 4 log reduction in viability.	**EN 1650 (Fungi) – Annese 2015**

Test substance	Test organism(s)	Test system / concentrations applied / exposure time	Test results: effects, mode of action, resistance	Reference
Domestos Zero Limescale Lime variant, without sulphamic acid, ethoxylated amine and centrimonium chloride	*P. aeruginosa* *E. coli* *S. aureus* *E. hirae*	EN 1276 using obligatory criteria. The product was tested at 80% of its neat concentration under high soil conditions with a contact time of 5 minutes for all test organisms	Results met the requirement of the test standard – the tests performed gave a ≥ 5 log reduction in viability	**EN 1276 (Bacteria) – Annese 2015**