Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report

Hydrochloric acid

Product-type 2
(Private area and public health area disinfectant and other biocidal products)

9 December 2011

Annex I - Latvia

CONTENTS

1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of hydrochloric acid as product-type 2 (private area and public health area disinfectant and other biocidal products), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market[1], with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Hydrochloric acid (EC No. 231-595-7) was notified as an existing active substance, by Exponent International Ltd on behalf of Reckitt Benckiser Healthcare (UK) Ltd, hereafter referred to as the applicant, in product-type 2.

Commission Regulation (EC) No 1451/2007 of 4 November 2003[2] lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, Latvia was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for hydrochloric acid as an active substance in Product Type 02 was 31 July 2007, in accordance with Annex V of Regulation (EC) No 1451/2007.

On 27 July 2007, Latvian competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 26 October 2007. On 30th of June 2008 the time period was suspended and the evaluation taken up again on 27th March 2009 after the applicant had submitted the necessary data.

On 16 October 2009 the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 16 November 2009. The competent authority report included a recommendation for the inclusion of hydrochloric acid in Annex I to the Directive for product-type 2.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 29 October 2010. This

---

[1] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing biocidal products on the market. OJ L 123, 24.4.98, p.1

[2] Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of hydrochloric acid in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 9 December 2011.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 9 December 2011.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include hydrochloric acid in Annex I to Directive 98/8/EC for product-type 2. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 2 that contain hydrochloric acid. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website[3], shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing hydrochloric acid for the product-type 2, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

i. compliance with the particular requirements in the following sections of this assessment report,

ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and

---

[3] http://ec.europa.eu/comm/environment/biocides/index.htm

iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see Appendix II). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

2. OVERALL SUMMARY AND CONCLUSIONS

2.1 Presentation of the Active Substance

2.1.1 Identity,Physico-Chemical Properties & Methods of Analysis

CAS-No.	N/A
EINECS-No.	231-595-7
IUPAC Name	Hydrochloric acid…%
Common name, synonyms	Hydrogen chloride aquatic, Muriatic acid
Molecular formula	HCl (aq)
Structural formula	H-Cl
Molecular weight (g/mol)	36.46 g/mol
Minimal purity g/kg	999

Hydrochloric acid is a strong acid that is very soluble in water and dissociates completely (Cl^- is a very weak conjugate base, therefore the reaction goes to completion), to form chloride ion and hydronium ions[4].

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

Hydrogen Chloride (gas) is highly soluble in water (823 g/L at 0°C), however solubility in water is not considered a relevant parameter to be measured for the hydrochloric acid concentrate, as by definition hydrochloric acid is an aqueous solution of hydrogen chloride. 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 $-\log_{10}[H^+]$, where the units of hydrogen ion concentration are moles/litre (molarity).

Hydrochloric acid is a liquid at room temperature with a freezing point of $< -20^{o}C$ and a boiling point ranging from $56.1 - 97.7^{o}C$ (36% and 28% respectively). Gaseous hydrogen chloride has a boiling point of $-85.05^{o}C$. The density of hydrochloric acid varies according to the hydrogen chloride content from 1.1782 g/mL for a 34.1% concentration to 1.1716 g/mL for a 36.2% concentration. The viscosity of hydrochloric acid is $1.7 \times 10^{-6}\ m^2/s$ at $20^{o}C$ and $1.3 \times 10^{-6}\ m^2/s$ at $40^{o}C$. Vapour pressure is 3.1333×10^3 Pa for a 32 % HCl at 20 ^0C. It is not possible to calculate

---

[4] The Merck Index, 1976 p628, 632 9th edition, Merck & Co. Inc, NJ

the Henry's Law Constant for the two specific sources of hydrochloric acid detailed above, however there are a range of Henry's Law constants cited in the literature for the gas hydrogen chloride, from $0.01 - 2 \times 10^4$ mol/m^3/Pa.

HCl is a non-flammable, non-oxidising liquid which does not itself pose any explosive risk. On contact with metals hydrochloric acid can emit hydrogen which is potentially explosive.

The quantification of hydrogen chloride in hydrochloric acid as manufactured is performed by either density measurement or titrimetric determinations. Methods of analysis for impurities are described in the confidential section.

Hydrochloric acid, formulated as Harpic Limescale Remover, will be used by non professionals as a surface disinfectant for toilet bowls in private and domestic situations. The active substance will be formulated at a concentration of 6% w/w.

Harpic Limescale Remover is a uniform, opaque clear green liquid with a relative density of 1.0262, a surface tension of 30.5 mN/m and a viscosity of 2.27×10^{-4} m^2/s at 20^{0}C and 45.1×10^{-6} m^2/s at 40^{0}C. The pH of a 1% w/v dilution at 20ºC is 2.0 and its acidity expressed as %H_2SO_4 is 8.546. The diluted formulation had 32 ml persistent foam after 1 minute, and was homogenous for at least 18 hours at 20^{o}C.

Harpic Limescale Remover is not classified as explosive, oxidizing or flammable. The product is stable following accelerated (12 weeks at 35^{o}C) and low temperature storage (7 days at 0^{o}C and at 2 years at ambient temperature). No pack-product interactions were observed in the accelerated storage stability study or over 2 years at ambient temperature and storage in commercial packaging precludes light. The product is not intended to be used in conjunction with any other product, as described on the label.

The analytical method for the determination of hydrochloric acid active substance in Harpic Limescale Remover is titrimetric determination using sodium hydroxide as titrant.

2.1.2. Intended Use and Efficacy

Hydrochloric acid has been evaluated for its use as private area and public health area disinfectants and other biocidal products [products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algaecides].

In accordance with the evaluated use (i.e. indoors) of biocidal products with active substance hydrochloric acid, there will be no direct exposure of the outdoor environment.

Hydrochloric acid is fully dissociated in solution and forms the hydronium ion (H_3O^+) which is highly reactive with organic molecules. In contact with biological material, this reactivity results in cellular injury and/or necrosis (WHO, 1982)[5].

The assessment of the biocidal activity of Harpic Limescale Remover demonstrates that it has a sufficient level of efficacy against the target organisms and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious as a disinfectant with broad spectrum of activity.

Hydrochloric acid present in the product at the concentration of 6 % w/w is fully dissociated in solution and forms the hydronium ion (H_3O^+) which is highly reactive with organic molecules. In contact with biological material, this reactivity results in cellular injury and/or necrosis (WHO, 1982)[5].

The realistic case pH in Sewage Treatment Plant (STP) influent following the proposed use of the product is theoretically calculated to be 6.0. However, 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[6] 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[7].

No resistance to HCl has been reported for any of the likely target species and development of resistance is considered unlikely due to the non-specific mode of action.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in Appendix II.

2.1.3. Classification and Labelling

Classification of HCl in accordance with Directive 67/548/EEC:

---

[5] WHO Environmental Health Criteria 21 (1982) Chlorine and Hydrogen Chloride. International Programme on Chemical Safety

[6] UK DEFRA web site: http://www.defra.gov.uk/Environment/water/quality/uwwtd/report02/01 htm

7 Pescod, M.B. Wastewater treatment and use in agriculture - FAO irrigation and drainage paper 47. Food And Agriculture Organization Of The United Nations. Rome, 1992.

Identification of danger:	C [corrosive] Xi [irritant]
Risk phrases:	R34 [Causes burns] R37 [Irritating to respiratory system]

Specific concentration limits:

Concentration	Classification
$C \geq 25\%$	C; R34 [Causes burns] R37 [Irritating to respiratory system]
$10\% \leq C < 25\%$	Xi; R36/37/38 [Irritating to eyes, respiratory system and skin]

Labelling of HCl in accordance with Directive 67/548/EEC:

Symbol and identification of danger:	 **Corrosive**
Risk phrases:	R34 [Causes burns] R37 [Irritating to respiratory system]
Safety phrases:	S1/2 [Keep locked up and out of the reach of children] S26 [In case of contact with eyes, rinse immediately with plenty of water and seek medical advice] S45 [In case of accident or if you feel unwell seek medical advice immediately (show the label where possible)]

Classification and labelling of HCl in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006:

Classification:

Hazard Class and Category Codes:	Skin Corr. 1B STOT SE 3
Hazard statement codes:	H314 [Causes severe skin burns and eye damage] H335 [May cause respiratory irritation]

Specific concentration limits:

Concentration	Classification
C ≥ 25%	Skin Corr. 1B; H314 [Causes severe skin burns and eye damage]
10% ≤ C < 25%	Skin Irrit. 2; H315 [Causes skin irritation]
10% ≤ C < 25%	Eye Irrit. 2; H319 [Causes serious eye irritation]
C ≥ 10%	STOT SE 3, H335 [May cause respiratory irritation]

Labelling:

Pictogram, Signal Word Codes:	  **Danger**
Hazard statement codes:	H314 [Causes severe skin burns and eye damage] H335 [May cause respiratory irritation]
Precautionary statements Prevention:	P260 [Do not breathe dust/fume/gas/mist/vapours/spray] P264 [Wash ... thoroughly after handling] P280 [Wear protective gloves/protective clothing/eye protection/face protection]
Precautionary statements Response:	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] P310 [Immediately call a POISON CENTER or doctor/physician] P321 [Specific treatment (see ... on this label)] P305+P351+P338 [IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.]
Precautionary statements Storage:	P405 [Store locked up.]
Precautionary statements Disposal:	P501 [Dispose of contents/container to ...]

Proposed classification, labeling and packaging of representative product – Harpic Limescale Remover - in accordance with Directive 88/379/EEC, as amended by 1999/45/EC as amended by 2006/8/EC:

Classification:

Symbol and identification of danger:	**C [Corrosive]**
Risk phrases:	R34 [Causes burns.*]

* on the basis of its very low pH (< 2), also confirmed by the results of a Transcutaneous Resistance Assay.

Labelling:

Hazardous components which must be listed on the label:	Hydrochloric acid
Symbol and identification of danger:	 **C [Corrosive]**
Risk phrases:	R34 [Causes burns]
Safety phrases:	S1/2 [Keep locked up and out of reach of children.] S13 [Keep away from food, drink and animal feeding stuffs.] S24/25 [Avoid contact with skin and eyes.] S26 [In case of contact with eyes rinse immediately with plenty of water and seek medical advice.]

	S28 [After contact with skin rinse immediately with plenty of water.] S45 [In case of accident or if you feel unwell, seek medical advice immediately.] S64 [If swallowed, rinse mouth with water (only if person is conscious).]
Precautionary phrases	Keep in original container. Do not use with any liquid bleaches or powder cleaners. Do not allow to come into contact with any surfaces other than the toilet bowl.

Packaging	Child – resistant packaging. Tactile warning of danger. Opaque high density polyethylene (HDPE) bottle. Metal containers must be avoided.

Classification indicates that S37 (Wear suitable gloves) is required for representative product. However, in accordance with Directive 1999/45/EC Article 10, point 2.6. states “As a general rule, a maximum of six S phrases shall suffice to formulate the most appropriate safety advice; for this purpose the combined phrases listed in Annex IV to Directive 67/548/EEC shall be regarded as single phrases. However, in some cases more than six S phrases may be necessary.” and taking into consideration that the representative product risk assessment illustrated that gloves are not necessary to mitigate the risk for the representative product; the S37 phrase is not necessary.

2.2. Summary of the Risk Assessment

The risks associated with the physico-chemical properties of both the active substance and the product such as flammability, explosivity and thermal stability are low. The key property that drives the risk associated with use of this product is corrosivity.

2.2.1. Human health risk assessment

2.2.1.1. Hazard identification

Hydrochloric acid toxicity is related to its site-of-contact corrosive/irritating properties, depending on concentrations and this mode of action is confirmed by acute, short-term or long-term studies in animals as well as observations in humans.

Due to the low concentration of hydrochloric acid (6 % w/w) present in the Harpic Limescale Remover as well as due to the existence of protective mechanisms at the skin surface and very limited duration of possible dermal as well as real inhalation contact, Harpic Limescale Remover is not hazardous neither in relation to dermal exposure route nor for inhalation exposure.

Harpic Limescale Remover does require classification with respect to corrosive properties to skin on the basis of its very low pH (< 2).

2.2.1.2 Effects assessment

Most significant dangerous effects of hydrochloric acid are associated with its site-of-contact corrosive/irritating properties through dermal and inhalation routes and depending on its concentrations.

The primary toxic effect of hydrochloric acid is likely to be contact irritation/corrosion with no significant penetration being expected from dermal exposure to sub-irritant concentrations. Exposure to an irritant concentration would be reversible in time, and a few droplets spread over the skin surface, although temporarily altering the local skin pH, would be expected to rapidly return to within physiological limits because of the diluting effect of sweat and the buffering capacity of the acidic mantle.

Insignificant dermal penetration of hydrochloric acid is expected, the acidic mantle at the skin surface being protective, immediately diluting hydrochloric acid leading again to hydronium and chlorine ions.

No systemic effects are expected for any of the possible routes of exposure, since hydrochloric acid completely dissociates into hydrogen and chlorine ions, both of which are physiological electrolytes, on contact with water. Lack of systemic effects due to complete dissociation to physiological electrolytes precludes any possible site-of-contact toxicity to the reproductive system.

The blood chlorine pool is large, approx. 100 mEq/L (equivalent to 3.5 g/L based on a chlorine molecular weight of 35.45) in humans, and it is eliminated in urine at 140-250 mEq/L (i.e. 5-8.5 g/L). Considering a 60 kg person producing 1 litre of urine per day, this value corresponds to 83-142 mg/kg bw/day.

Hydrogen ion concentration is critical to enzyme function and the body has sophisticated mechanisms for ensuring that pH remains within the normal range. Hydrogen ions are actively secreted in the proximal and distal tubules and are eliminated at amounts as high as 30-40 mmol/day *via* the kidneys. In terms of a corresponding hydrochloric acid value this would be equivalent to 1.09-1.4 g per day, i.e. 18-24 mg/kg bw/day.

These figures are derived from using normal physiological values for these electrolytes, the main intake of which is likely to be *via* the diet, and without considering that additional chlorine and hydrogen ions are also eliminated by sweat. Taken together they suggest that normal human physiological capacity can safely handle 20 mg/kg bw/day of hydrochloric acid, when delivered at non-irritant concentrations.

The uptake of hydronium ions from exposure to hydrochloric acid under normal conditions of use is not expected to affect the pH in the blood or body fluids as this is regulated within a narrow range to maintain homeostasis. The pH will be maintained *via* urinary excretion and exhalation of carbon dioxide.

Hydrochloric acid was not genotoxic in *in vitro* tests using bacterial or simple eukaryotic cells, while its effects on the pH of the medium precludes the possibility of testing in other *in vitro* non-bacterial systems. No metabolite of concern is generated from hydrochloric acid, and no evidence of any mutagenic potential is expected, because of the buffering capabilities within the organism.

No increased incidence in any kind of tumours were detected in a group of 100 life-span exposed rats to 10 ppm (14,91 mg/m^3 – RMS recalculations*[8]) by inhalation, and IARC (1992)[9] concluded that the epidemiologic studies reviewed provide no adequate evidence of the carcinogenicity of hydrogen chloride to humans. It shall be underlined that the IARC classification is not fully coinciding with classification adopted according to the Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (CLP regulation). According to CLP, hydrochloric acid and the representative product "Harpic Limescale Remover"is not included in any group or category at all.
Hydrochloric acid is not sensitizing.

2.2.1.3. Exposure assessment

The main exposure routes of hydrochloric acid are dermal and inhalation, as the primary toxic effect is considered to be contact irritation/corrosion. There is no appropriate study on experimental animals investigating appropriate NOAELs for hydrochloric acid. Human data are available, and these prevail over animal data. It appears unlikely that hydrochloric acid is dermally absorbed to a significant extent, and hence a systemic NOAEL is irrelevant.

Due to the large uses in many different industries, occupational exposure to hydrochloric acid has long been controlled in each country by the establishment of standard concentrations at the work place, these have tended to be reduced with time, with an increase in awareness of the general population for a higher degree of protection and control of health related matters being an additional factor.
Within Europe, the Commission Directive 2000/39/EC[10] established 5 ppm (8 mg/m^3) for 8-hrs exposure (measured or calculated in relation to a reference period of eight hours time weighed average) and a short-term value of 10 ppm (15 mg/m^3) for 15-min exposure (as a limit value above which exposure should not occur).

---

[8] Here and forward: concentration from ppm to mg/m^3 are recalculated using following formula: Y mg/m^3 = (X ppm)(molecular weight = 36.46 mol)/24.45 L/mol at temperature 25°C and 1 atmosphere.

[9] International Agency for Research on Cancer. IARC monographs on the Evaluation of Carcinogenic Risks to Humans, Vol. 54, Occupational Exposures to mists and Vapours from strong Inorganic acids, and Other Industrial Chemicals, pp189-211, Lyon, France

[10] European Commission Directive 2000/39/EC establishing a First List of Indicative Occupational Exposure Limit Values at European Community level in implementation of council directive 98/24/EC on the protection of the health and safety of workers from the risk related to chemical agents at work.

In accordance with the guidance document: *Risk Characterization of local effects* (Ispra, 05/03/2010) (RCLE) and *TNsG on Annex I Inclusion Revision of Chapter 4.1.: Quantitative Human Health Risk Characterization* (16-17 September 2009) (TnsG 4.1.); NOAEC 30 mg/m^3, AEC 3.75 mg/m^3. NOAEC and derived AEC are considered appropriate for risk assessment for acute and prolonged inhalation exposure of workers and prolonged inhalation exposure for non-professional users.

Based on experimental results, the very conservative assumption is that the maximum potential exposure concentration of hydrochloric acid by using the Harpic Limescale Remover in a bathroom will not exceed 3.0 ppm (4.47 mg/m^3 – RMS recalculations) when a full container of Harpic Limescale Remover has been applied to a toilet and left to sit for 8 hours. In actual practice, exposure concentrations are anticipated to be lower than 3.0 ppm (4.47 mg/m^3– RMS recalculations) because consumers will not use an entire product container and will not allow the product to sit in the toilet bowl for 8 hours. Once the toilet is flushed, the "source" hydrochloric acid is removed, and so exposure concentrations will diminish as air circulates within the house. The realistic scenario gave average results from the five toilets ranging from 0.02 ppm (0.03 mg/m^3 – RMS recalculations) HCl at the 1 min sampling time point to 1.2 ppm (1.79 mg/m^3 – RMS recalculations) HCl at 8 hrs.

The label of the representative product "Harpic Limescale Remover" recommends "After contact with skin rinse immediately with plenty of water" and also the scenario in CONSEXPO for toilet cleaners recommends washing the hands immediately after use: possible local irritating effects are therefore unlikely to occur, because of the very limited time of dermal contact. Further testing is not considered necessary nor considered appropriate to set any reference value for acute and prolonged dermal exposure.

2.2.1.4. Risk characterisation

Hydrochloric acid (HCl), is a HPV chemical widely used for different applications and only in very limited amount as biocidal active substance. HCl dissociates rapidly in the water forming hydrogen and chlorine, ubiquitous elements in the environment and in the body fluids and organs of all living organisms. Because, it is justified that HCl does not have such properties within the toxicological profile as genotoxicity, carcinogenicity, reproductive (developmental) toxicity and neurotoxicity. HCl does not have sensitizing properties, as well. The primary toxic effect of HCl is contact irritation/corrosion both through inhalation and dermal routes due to very low pH of the substance. The oral route plays role only in cases of exceptional intentional misuse by humans – in suicide cases

It can be proposed that LC_{50} for acute 5 min. inhalation for rats is 50-66 mg/L and for acute 30 min. inhalation – 8-9 mg/L (or 50000 – 66000 mg/m^3 and 8000-9000 mg/m^3 accordingly).
It has been concluded that concentrations of HCl above 3.3% cause dermal irritation and concentrations above 17% cause dermal corrosion in animal studies. Concentrated HCl can cause

severe eye damage, as well. Irritating/corrosive properties of HCl are showing pronounced dose-effect relationships: more is the concentration of the substance more is the influence on endpoints.

It has been reported that short-term exposure to airborne concentration up to 1.8 ppm (2.89 mg/m^3) did not cause irritation to the respiratory tract of sensitive asthmatic volunteers but in accordance with the guidance document: *Risk Characterization of local effects* (Ispra, 05/03/2010) (RCLE) and *TNsG on Annex I Inclusion Revision of Chapter 4.1.: Quantitative Human Health Risk Characterization* (16-17 September 2009) (TnsG 4.1.); NOAEC 30 mg/m^3, AEC is 3.75 mg/m^3. NOAEC and derived AEC is considered appropriate for risk assessment for acute and prolonged inhalation exposure of workers and prolonged inhalation exposure for non-professional users.

Very restricted investigations with respect to dermal acute LD_{50} value for rabbits have set it at > 5,010 mg/kg but human data concerning any reference values with regard to acute and prolonged dermal exposure are not available. The label of the representative product recommends "After contact with skin rinse immediately with plenty of water" therefore possible local irritating effects are unlikely to occur, because of the very limited time of dermal contact. On this basis it is not considered appropriate to set any reference value for acute and prolonged dermal exposure within the particular risk assessment.

Considering professional users in a production/formulation phase of the biocidal product following critical endpoint has been detected:

For inhalation (acute and prolonged exposure), in accordance with the guidance document: *Risk Characterization of local effects* (Ispra, 05/03/2010) (RCLE) and *TNsG on Annex I Inclusion Revision of Chapter 4.1.: Quantitative Human Health Risk Characterization* (16-17 September 2009) (TnsG 4.1.); NOAEC 30 mg/m^3, AEC is 3.75 mg/m^3. NOAEC is considered appropriate for risk assessment for acute and prolonged inhalation exposure of workers.

What regards non-professional users, their critical endpoint is following:

Inhalation (both acute and prolonged), in accordance with the guidance document: *Risk Characterization of local effects* (Ispra, 05/03/2010) (RCLE) and *TNsG on Annex I Inclusion Revision of Chapter 4.1.: Quantitative Human Health Risk Characterization* (16-17 September 2009) (TnsG 4.1.); NOAEC 30 mg/m^3.

The product is specifically designed to remove the build up of limescale, and therefore it is not anticipated that the product would be used on a daily basis, as would be the case for conventional toilet cleaners.

During use of the product by non-professionals, potential exposure may occur *via* the inhalation route (through exposure to hydrogen chloride vapours) or *via* dermal contact with the cleaning solution during the brushing of the toilet.

Hence, AEC concentration of 3.75 mg/m^3 has been established both for acute and chronic inhalation exposure scenario. The typical exposure scenario predicts much lower airborne concentration (0.33 mg/m^3), but the „worst case scenario" - a bit higher concentration (4.9

mg/m^3), but it can be neglected as unbelievable because a number of unrealistic usage conditions have to coincide.

There is no cause for concern for inhalation exposures experienced in either the formulating facility or in the home. Therefore, it is considered that the cumulative exposure from both environments is also below the level of concern.

Dermal exposures associated with the formulation and use of Harpic Limescale Remover are considered to be low. Additional risk mitigation measures in place at the formulating facility and recommended on the label ensure that the risk associated with formulating and use of the product is considered to be acceptable.

In addition, as another method for exposure reduction has been used - the special design bottle for the representative product, which excludes splashes and spillages of the product.

Harpic Limescale Remover does require classification as R34 (corrosive to the skin) on the basis of its very low pH (< 2), also confirmed by the results of a Transcutaneous Resistance Assay[11]. Since the preparation is classified as R34 then risk of severe damage to eyes is considered implicit so classification as R41 (risk of serious damage to eye) is not required.

Harpic Limescale Remover is not classified for acute dermal or inhalation toxicity as well as for oral toxicity.

Harpic Limescale Remover is not sensitizing.

IARC considered hydrochloric acid to be not classifiable (group 3) for carcinogenicity to humans, the same considerations apply to the representative product “Harpic Limescale Remover”.

2.2.2. Environmental risk assessment

2.2.2.1. Fate and distribution in the environment

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 ^{0}C) 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.

---

[11] Dreher, D. (2005) Harpic LSR: Transcutaneous Electrical Resistance Assay Covance Laboratories Ltd., UK Report No. 1864/031

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

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. 3×10^{-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.

2.2.2.2. Effects assessment

The formulation Harpic Limescale Remover is very simple in nature consisting of 6% w/w of the active substance HCl in water (91%) plus very small amounts of other co-formulants (total 3%).

The co-formulants are not expected to significantly affect the toxicity of the formulation which is driven primarily by the low pH of the active substance.

The environmental exposure assessment for Harpic Limescale Remover concludes that no significant perturbation of pH will occur in either the sewage treatment plant or receiving surface waters following the proposed formulation and use of the product as a surface disinfectant for toilet bowls in private and domestic situations. Emission of HCl to air as a result of the proposed use is predicted to be insignificant. Finally, no significant perturbation of soil pH is expected from the proposed use.

Given that predictions indicate negligible perturbations of environmental pH levels the need to conduct studies on the effects of the formulation on other specific, non-target organisms is considered to be scientifically unjustified. The available ecotoxicity data for the active substance HCl are sufficient to assess the toxicity/classification of the product by extrapolation. The product is not classified as Dangerous for the Environment.

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)[12] which states that the buffer capacity, pH and fluctuation of the pH are specific to each aquatic ecosystem.

No atmospheric or terrestrial biotic effects data for hydrochloric acid are available. However, given that these data are not specified for the indoor use of a PT2 product (TNsG on Data Requirements)[13] and since the environmental exposure assessment confirms low exposure of these compartments with insignificant perturbation of environmental pH, it is considered that such data are not required.

2.2.2.3. PBT assessment

Hydrochloric acid does not fulfil the PBT criteria.

2.2.2.4. Exposure assessment

HCl is a HPV chemical with numerous and diverse uses both in the manufacturing industry and synthetic chemistry. Both hydrogen and chlorine are commonly found in the environment as a result of natural and man-made sources. It is considered that the tonnage of HCl released into the

---

[12] SIDS Initial Assessment Report for SIAM 15. UNEP Publications, October 2002

[13] Technical Guidance Document in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. EUR 20418 EN/2. Italy, April 2003

environment as a result of the use of Harpic Limescale Remover is significantly less than that available from these other sources and that consequently the environmental impact will be negligible.

Specifically, HCl released from liquid lavatory disinfectant cleaners, when used as a non-professional biocidal cleaning product, enters the sewage system in its dissociated form and will not cause significant change to the pH levels in a standard sewage treatment plant due to the high level of dilution and the well buffered environment of the STP. As a result of the buffering capacity of wastewater and natural water/sediment systems and also of EU water quality legislation governing quality of discharges, predicted emissions of chloride and hydronium ions as a result of the proposed use of Harpic Limescale Remover are expected to have minimal impact on the receiving aquatic environment. Emission to air as a result of the proposed use is predicted to be insignificant. As a result of the buffering capacity of soils and also of EU legislation governing application of sewage sludge to land, any emissions of chloride and hydronium ions as a result of the proposed use of Harpic Limescale Remover are expected to have minimal impact on the terrestrial environment.

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. Exposure from Harpic Limescale Remover is not expected to lead to any significant perturbation of environmental levels. Due to insignificant exposure and since HCl cannot bioaccumulate there is no risk of secondary poisoning in either the aquatic or terrestrial compartments.

2.2.2.5. Risk characterisation

The aquatic toxicity of the formulation is driven by the active substance content as the other minor components have no significant effect on the toxicity to aquatic organisms. Therefore the toxicity of the product may be extrapolated from the available data for the active substance hydrochloric acid.

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 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.

(Note: 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 EC50 was measured. Added concentrations were much higher, for example in the Daphnia study the solution at pH 4.5 was calculated to be a

0.69mM solution equivalent to 25.2 mg/L. The figures included as mg/L are therefore included for illustrative purposes only.)

The formulation and use of the product Harpic Limescale Remover is not expected to lead to significant exposure of the atmosphere. It is noted that the contribution of hydrochloric acid to the atmosphere from the proposed use of Harpic Limescale Remover is considered to be insignificant compared to that from other natural and man-made sources. Lack of exposure from this type of domestic product is backed up by the Defra e-digest Statistics about air quality figures for 2005 (latest figures) in UK[14] which show that the total estimated emissions of hydrogen chloride were 21 thousand tonnes of which 12 thousand tonnes were from energy industries, 6 thousand tonnes from manufacturing industries and construction but notably none from household and gardening (mobile).

Hydrochloric acid is not expected to contribute to global warming or ozone depletion in the stratosphere on the basis of its physical and chemical properties. Although hydrochloric acid can lead to acidification, the outdoor exposure from the formulation of the product Harpic Limescale Remover and its proposed indoor uses are considered to be negligible.

The formulation and domestic indoor use of the product Harpic Limescale Remover is not expected to lead to significant perturbations of terrestrial levels of chloride or pH. This conclusion is based on the lack of significant direct exposure of soil, natural buffering capacity of soils and EU legislation controlling the application of sewage sludge to land. Given the lack of significant pH lowering effects in soil from formulation, use and disposal, no risk to soil dwelling organisms is anticipated.

As hydrochloric acid completely dissociates in water no bioconcentration in aquatic organisms is possible. Negligible exposure of the terrestrial environment is expected from the formulation and proposed use of hydrochloric acid as a surface disinfectant for toilet bowls in private and domestic situations. Additionally, given that upon exposure to moisture hydrochloric acid becomes completely dissociated, it will not therefore be subject to bioaccumulation in terrestrial organisms.

Conclusion of the PBT criteria application to hydrochloric acid is that it is not considered as PBT substance.

2.2.3. List of endpoints

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in Appendix I.

3 DECISION

---

[14] www.defra.gov.uk/environment/statistics/airqual/aqhydrogen htm

3.1 Background to the decision

Hydrochloric acid has been evaluated for indoors use as a surface disinfectant for toilet bowls in private and domestic situations. The target organisms are bacteria, fungi and viruses.

Based on the assessment of data on the active substance hydrochloric acid and the representative product Harpic Limescale Remover health risks for the users of the biocidal product are at an acceptable level if use instructions and recommendations on the label of the product are respected. In addition, the criteria for approval given in Article 5(1) of Directive 98/8/EC concerning efficacy, physical and chemical properties and analytical methods are fulfilled.

Harpic Limescal Remover is effective against a range of Gram positive and Gram negative bacteria, common fungal species and common viral types. No resistance to HCl has been reported for any of the likely target species and development of resistance is considered unlikely due to the non-specific mode of action. Harpic Limescale Remover reduces the numbers of individuals capable of causing infection thus resulting in a reduction in infectivity of bacteria, fungi and viruses. The benefits to humans are therefore substantial.

In accordance with the evaluated use of biocidal products with active substance hydrochloric acid, there will be no direct exposure of the outdoor environment. Hydrochloric acid is very soluble in water and dissociates completely forming chloride ion and hydronium ions and hence negligible exposure of the terrestrial and aquatic environments is expected. The environmental risk assessments indicate low risk to the atmosphere, aquatic and soil organisms, and very low risk of primary and secondary poisoning of non-target vertebrates from the uses of hydrochloric acid.

Generally, it may be expected, that the use of hydrochloric acid in Product type 2 (private areas and public health disinfectants and other biocidal products) will fulfil the conditions laid down in Article 10(1) of Directive 98/8/EC and therefore the inclusion into Annex I of Directive 98/8/EC can be recommended.

3.2 Decision regarding inclusion in Annex I

Hydrochloric acid with a minimum purity of 999 g/kg shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 2 (private area and public health area disinfectants and other biocidal products).

Not all potential uses have been evaluated at the Community level. It is therefore appropriate that Member States assess those risks to the compartments and populations that have been representatively addressed in the Community level risk assessment, when granting product authorisations, ensure that appropriate measures are taken or specific conditions imposed in order to mitigate the identified risks to acceptable levels.

3.3 Elements to be taken into account by member states when authorising products

All the effects of the hydrochloric acid, as an active substance within the meaning of the Biocidal Products Directive 98/8/EC terminology, are inseparably linked with high concentration of hydrogen (hydroxonium) ions (strong acid). However any changes to the use pattern will require exposure to other environmental compartments to be taken into account.

Authorisation shall be subject to appropriate risk mitigation measures, taking into account product classification and labelling. In particular, if the wearing of personal protective equipment would be the only possible method for reducing the exposure, products shall not normally be authorised for non-professional use, unless it can be demonstrated in the application that risk to non-professional users can be reduced to an acceptable level by others means for example, child-resistant package, ready for use product.

In consideration of risk assessment of Harpic Limescale Remover and taking into account additional risk mitigation measures - special design bottle and high viscosity - the use of protective gloves shall be seen as an additional and precautionary measure only.

3.4 Requirements for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of hydrochloric acid for use in product-type PT 2 (private area and public health area disinfectants and other biocidal products) in Annex I to Directive 98/8/EC.

3.5 Updating this assessment report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of hydrochloric acid in Annex I to the Directive.

Appendix I: List of endpoints

Chapter 1: Identity, Physical and Chemical Properties, Details of Uses, Further Information, and Proposed Classification and Labelling

Active substance (ISO Common Name)	Hydrochloric acid…%
Product-type	2 (Private area and public area disinfectants and other biocidal products)

Identity

Chemical name (IUPAC)	Hydrochloric acid…%
Chemical name (CA)	Hydrogen chloride aquatic, Muriatic acid
CAS No	N/A
EC No	231-595-7
Other substance No.	Not available
Minimum purity of the active substance as manufactured (g/kg or g/l)	Minimal purity 999 g/kg
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	None
Molecular formula	HCl
Molecular mass	36.46 g/mol
Structural formula	**H - Cl**

Physical and chemical properties

Melting point (state purity)	Freezing temperature <-20^{o}C (34.1%)
Boiling point (state purity)	Has no meaning
Temperature of decomposition	Not applicable
Appearance (state purity)	Clear, colourless, uniform liquid (34.1%)
Relative density (state purity)	1.1782 (34.1%) at 20^{0}C
Surface tension	It is not technically possible to conduct this test.
Vapour pressure (in Pa, state temperature)	3.1333×10^{3} Pa (32%) at 20 ^{0}C
Henry's law constant (Pa m^{3} mol^{-1})	It is not possible to calculate the Henry's Law Constant.
Solubility in water (g/l or mg/l, state temperature)	HCl is fully soluble in water up to concentrations of about

	40%.
Solubility in organic solvents (in g/l or mg/l, state temperature)	Not relevant.
Stability in organic solvents used in biocidal products including relevant breakdown products	Not relevant.
Partition coefficient (log P_{OW}) (state temperature)	It is not technically possible to conduct this test.
Hydrolytic stability (DT_{50}) (state pH and temperature)	It is not technically possible to conduct this test.
Dissociation constant	HCl will fully dissociate in water in the environmentally relevant pH range.
UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)	Not applicable.
Photostability (DT_{50}) (aqueous, sunlight, state pH)	It is not technically possible to conduct this test.
Quantum yield of direct phototransformation in water at Σ > 290 nm	It is not technically possible to conduct this test.
Flammability	Not flammable, not auto-flammable
Explosive properties	Not explosive providing instructions for safe use are followed. On contact with a majority of metals hydrogen is emitted and this can pose a risk of explosion.

Classification and proposed labelling

With regard to physical/chemical data	None
With regard to toxicological data	R34, R37 or H314, H335
With regard to fate and behaviour data	None
With regard to ecotoxicological data	None

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)	Titrimetric or density measurements
Impurities in technical active substance (principle of method)	Confidential information

Analytical methods for residues

Soil (principle of method and LOQ)	Due to negligible exposure to the terrestrial environmental compartment and the fact that both hydrogen and chlorine are ubiquitous in the environment from natural and man made sources making it impossible to determine the exact source, the need for an analytical method to determine residues in soil is considered to be scientifically unjustified.

Air (principle of method and LOQ)	Due to both hydrogen and chlorine being ubiquitous in the environment from natural and man made sources making it impossible to determine the exact source as well as the contribution of HCl to the atmosphere from the proposed use being considered insignificant when compared to that from other natural and man-made sources, the need for an analytical method to monitor residues in air is considered to be scientifically unjustified.
Water (principle of method and LOQ)	Due to hydrochloric acid dissociating completely in water to form chloride ions and hydronium ions any effects observed are due to the ion concentrations. Both hydrogen and chlorine are ubiquitous in the environment from natural and man made sources making it impossible to determine the exact source the need for an analytical method to determine residues in water is considered to be scientifically unjustified.
Body fluids and tissues (principle of method and LOQ)	Hydrochloric acid is not classified as toxic nor highly toxic, therefore analytical methods to monitor levels in body fluids and tissues are scientifically unjustified.
Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes)	Hydrochloric acid is not used in a manner that would cause it to come in to contact with food or feedstuffs, therefore the need for an analytical method to determine residues in food of plant origin is considered to be scientifically unjustified.
Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes)	Hydrochloric acid is not used in a manner that would cause it to come in to contact with food or feedstuffs, therefore the need for an analytical method to determine residues in food of animal origin is considered to be scientifically unjustified.

Chapter 3: Impact on Human Health

Absorption, distribution, excretion and metabolism in mammals

Rate and extent of absorption:	Due to its high solubility and immediate dissociation properties, an aqueous solution of hydrochloric acid is not expected to be systematically available in living organisms.
Distribution:	Due to its high solubility and immediate dissociation properties, an aqueous solution of hydrochloric acid is not expected to be systematically available in living organisms and therefore not available for distribution.
Potential for accumulation:	Due to its high solubility and immediate dissociation properties, an aqueous solution of hydrochloric acid is not expected to be systematically available, and no accumulation of hydrogen chloride *per se* is expected in living organisms.
Rate and extent of excretion:	Due to its high solubility and immediate dissociation properties, an aqueous solution of hydrochloric acid is not expected to be systematically available in living organisms, and if not absorbed can not be excreted.
Toxicologically significant compounds (animals, plants and environment)	Parent.

Acute toxicity

Rat LD_{50} oral	238 - 277 mg/kg	
Rat LD_{50} dermal	Not available from primary source. There is available data from OECD - > 5.010 mg/kg - rabbits However the likely route of exposure is inhalation. A study is considered not appropriate because of the known corrosive properties of hydrochloric acid.	
Rat LC_{50} inhalation	8,3 mg/L (30 min, aerosol)	Classified R37 Irritating to respiratory system (H335 May cause respiratory irritation)
Skin irritation	Corrosive	Classified R34 - Causes burns (H314 Causes severe skin burns and eye damage)
Eye irritation	Corrosive	Classified R34 - Causes burns (H314 Causes severe skin burns and eye damage)
Skin sensitization (test method used and result)	No skin sensitising potential. (Mouse ear swelling test and maximisation test)	Not classified

Repeated dose toxicity

Species/ target / critical effect	Respiratory tract pathological changes
Lowest relevant oral NOAEL / NOEL	The likely route of exposure is inhalation. A study is not required, nor considered an appropriate use of animals because of the known effects of presence of hydrogen chloride in the GI tract.
Lowest relevant dermal NOAEL / NOEL	Concentrated hydrogen chloride is corrosive to skin. A study is not required, nor considered an appropriate use of animals because of the known corrosive properties.
Lowest relevant inhalation NOAEL / NOEL	NOAEL: 20 ppm (Rat, Mouse) 90-d inhalation study NOEL: 10 ppm (Rat) 90-d inhalation study

Genotoxicity	No evidence of Genotoxicity in *in vitro* tests using bacterial or simple eukaryotic cells. Instances of false positive results in mammalian cell gene mutation and chromosomal aberration tests, due to the acidic pH conditions of the medium. No *in vivo* test required.

Long term toxicity and carcinogenicity

Target/critical effect	Hyperplasia of the larynx and trachea
Lowest relevant NOAEL / NOEL	NOAEL: < 10 ppm
Carcinogenicity	Hydrochloric acid did not evoke a carcinogenic response in treated rats following daily exposure of rats to gaseous hydrochloric acid at the concentrations of 10 ppm, 6 hours a day, 5 days per week up to 128 weeks.

Reproductive toxicity

Species/ Reproduction target / critical effect	Lack of systemic availability due to complete dissociation to physiological electrolytes preclude any possible site-of-contact toxicity to the reproductive system.
Lowest relevant reproductive NOAEL / NOEL	Not relevant
Species/ Developmental target / critical effect	Due to complete dissociation the possible exposure of the organism under development would be to physiological electrolytes. Possible adverse effects on foetus due to excess of hydrogen ions inseparable from maternal toxicity.
Developmental toxicity	
Lowest relevant developmental NOAEL / NOEL	Not relevant

Neurotoxicity / Delayed neurotoxicity

Species/ target/critical effect	Requirement for specific neurotoxicity testing is not triggered. Standard systemic toxicity studies have demonstrated no evidence of neurotoxicity. In addition, the mode of action of hydrochloric acid (site-of-contact toxicity) infers neurotoxicity is not a concern, since neurological tissues would not be exposed.
Lowest relevant developmental NOAEL / LOAEL.	Not relevant

Other toxicological studies

None

Medical data

A nested case-control study to evaluate the possible human carcinogenicity of hydrochloric acid showed no evidence of a relationship between occupational exposure to hydrochloric acid and lung cancer.

Limited evidence of a moderate increase in risk was obtained when comparing men who had worked for at least 5 years in jobs entailing exposures to hydrochloric acids in excess of 1 mg/m^3 to controls, however, results indicate that any risk from exposures to hydrochloric acid below 1 mg/m^3 is small.

90% of workers from a galvanising plant exhibited dental erosion, but it was unclear if this was mainly caused by hydrochloric acid exposure.

Summary	**Value**	**Study**	**Safety factor**
Non-professional user			
ADI (acceptable daily intake, external long-term reference dose)	Not applicable		
AOEL-S (Operator Exposure)			
ARfD (acute reference dose)	Not applicable		
Professional user			
Reference value for inhalation (proposed OEL)			
Reference value for dermal absorption			
AEC (inhalation)	3.75 mg/m^3		

Acceptable exposure scenarios (including method of calculation)

Professional users	
Production of active substance:	
Formulation of biocidal product	
Intended uses	
Secondary exposure	
Non-professional users	
Indirect exposure as a result of use	

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water

Hydrolysis of active substance and relevant metabolites (DT_{50}) (state pH and temperature)	pHs 4, 7 and 9: hr @ 40 ^{o}C, day @ 25 ^{o}C : Not determined. Due to the intrinsic properties of hydrochloric acid (complete dissociation in water), it is scientifically impossible to perform the hydrolysis test.
	pH 7: hr @ 40 ^{o}C, day @ 25 ^{o}C: Not determined. Due to the intrinsic properties of hydrochloric acid (complete dissociation in water), it is scientifically impossible to perform the hydrolysis test in accordance with the test method.
	pH 9: hr @ 40 ^{o}C, day @ 25 ^{o}C: Not determined. Due to the intrinsic properties of hydrochloric acid (complete dissociation in water), it is scientifically impossible to perform the hydrolysis test.
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	Due to the intrinsic properties of hydrochloric acid (complete dissociation in water), it is scientifically impossible to perform the phototransformation in water test in accordance with the test method.
Readily biodegradable (yes/no)	Not relevant. Hydrochloric acid, is an inorganic compound, therefore is not biologically degradable.
Biodegradation in seawater	Not relevant. Hydrochloric acid, is an inorganic compound, therefore is not biologically degradable
Non-extractable residues	Not determined. Not relevant.
Distribution in water / sediment systems (active substance)	Hydrochloric acid, is an inorganic compound, which is not biologically degradable and dissociates completely in water to form chloride ion and hydronium ions.
Distribution in water / sediment systems (metabolites)	Hydrochloric acid dissociates completely in water to form chloride ion and hydronium ions ($H_3O^+ + Cl^-$). The hydronium ion is solvated by water molecules.

Route and rate of degradation in soil

Mineralization (aerobic)	Not relevant. Negligible exposure to the terrestrial environmental compartment. Hydrochloric acid, is an inorganic compound, which is not biologically degradable and dissociates completely in (soil) water to form chloride ion and hydronium ions.
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT_{50lab} (20°C, aerobic): Not relevant (see above).
	DT_{90lab} (20°C, aerobic): Not relevant (see above).
	DT_{50lab} (10°C, aerobic): Not relevant (see above).
	DT_{50lab} (20°C, anaerobic): Not relevant (see above).

	degradation in the saturated zone: Not relevant (see above).
Field studies (state location, range or median with number of measurements)	Not relevant. Negligible exposure to the terrestrial environmental compartment. Hydrochloric acid, is an inorganic compound, which is not biologically degradable and dissociates completely in (soil) water to form chloride ion and hydronium ions.
	DT_{50f}: Not relevant (see above). DT_{90f}: Not relevant (see above).
Anaerobic degradation	Not relevant. Negligible exposure to the terrestrial environmental compartment. Hydrochloric acid, is an inorganic compound, which is not biologically degradable and dissociates completely in (soil) water to form chloride ion and hydronium ions.
Soil photolysis	Not relevant. Negligible exposure to the terrestrial environmental compartment. Hydrochloric acid, is an inorganic compound, which is not biologically degradable and dissociates completely in (soil) water to form chloride ion and hydronium ions.
Non-extractable residues	Not relevant (see above).
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	Not relevant (see above).
Soil accumulation and plateau concentration	Negligible exposure to the terrestrial environmental compartment.

Adsorption/desorption

Ka , Kd Ka_{oc} , Kd_{oc} pH dependence (yes / no) (if yes type of dependence)	K_{oc}: Not technically possible to perform. Test methods are not applicable to molecules which dissociate. Following dissociation in water, resultant ions are expected to undergo ion exchange within the soil.

Fate and behaviour in air

Direct photolysis in air	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 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.
Quantum yield of direct photolysis	Not determined (see above).

Photo-oxidative degradation in air	Not determined (see above).
Volatilization	Not determined (see above).

Monitoring data, if available

Soil (indicate location and type of study)	No monitoring data available
Surface water (indicate location and type of study)	No monitoring data available
Ground water (indicate location and type of study)	No monitoring data available
Air (indicate location and type of study)	No monitoring data available

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

Species	Time-scale	Endpoint	Toxicity	RMS recalculation* to mg/L
Fish				
Lepomis macrochirus	96 h	LC$_{50}$	pH 3.5 – 3.25	55-31**
Invertebrates				
Daphnia magna	48 h	EC$_{50}$	pH 4.92 .	0.438
Algae				
Chlorella vulgaris	72 h	E$_b$C$_{50}$	pH 4.82	0.552
Microorganisms				
Activated sludge	3 h	EC$_{50}$	pH 5.0-5.5	0.365 – 0.115

* “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 to account for the innate buffering capacity of the test system and thus does not represent the concentration of HCL required to maintain the pH at which the EC50 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”.

** OECD SIDS Initial Assessment Report for SIAM 15. UNEP Publications, October 2002.

Effects on earthworms or other soil non-target organisms

Acute toxicity to …………………………………..	Given that no perturbation of soil pH is expected from the proposed indoor use, no acute risk to earthworms or other soil macro-organisms is anticipated. It is therefore considered that there is no justification for the generation of acute data on the toxicity of hydrochloric acid to earthworms or other soil macro-organisms.
Reproductive toxicity to …………………………	Given that no perturbation of soil pH is expected from the proposed indoor use, no long-term risk to

	earthworms or other soil macro-organisms is anticipated. It is therefore considered that there is no justification for the generation of reproductive data on the toxicity of hydrochloric acid to earthworms or other soil macro-organisms.

Effects on soil micro-organisms

Nitrogen mineralization	Negligible exposure of the outdoor environment including soil is expected from the indoor use proposed therefore these data are not required.
Carbon mineralization	Negligible exposure of the outdoor environment including soil is expected from the indoor use proposed therefore these data are not required.

Effects on terrestrial vertebrates

Acute toxicity to mammals	Acute oral LD_{50} Due to the known corrosive properties of hydrochloric acid and the likely route of exposure being inhalation, the need to conduct studies on the oral toxicity of mammals is scientifically unjustified. In any case, no significant exposure of the terrestrial environment is expected and therefore there is insignificant risk to non-target mammalian wildlife. Acute dermal LD_{50} Due to the known corrosive properties of hydrochloric acid and the likely route of exposure being inhalation, the need to conduct studies on the dermal toxicity of mammals is scientifically unjustified. In any case, no significant exposure of the terrestrial environment is expected and therefore there is insignificant risk to non-target mammalian wildlife. Acute inhalation LD_{50} 8 mg/m^3
Acute toxicity to birds	Given that no significant environmental exposure is expected from the proposed indoor use, no acute risk to birds is anticipated. It is therefore considered that there is no scientific justification for the generation of acute toxicity data on birds.
Dietary toxicity to birds	Given the insignificant exposure of all environmental compartments and therefore insignificant short-term risk to birds it is considered that there is no scientific justification for short-term toxicity studies with birds.
Reproductive toxicity to birds	Given the insignificant exposure of all environmental compartments and therefore insignificant long-term risk

	to birds it is considered that there is no scientific justification for long-term toxicity studies with birds.

Effects on honeybees

Acute oral toxicity	Due to the insignificant exposure *via* either air and/or soil the need to conduct studies on the oral toxicity to honeybees is considered to be scientifically unjustified.
Acute contact toxicity	Due to the insignificant exposure *via* either air and/or soil the need to conduct studies on the contact toxicity to honeybees is considered to be scientifically unjustified.

Effects on other beneficial arthropods

Acute oral toxicity	Due to the insignificant exposure *via* either air and/or soil the need to conduct studies on the oral toxicity to other beneficial arthropods is considered to be scientifically unjustified.
Acute contact toxicity	Due to the insignificant exposure *via* either air and/or soil the need to conduct studies on the contact toxicity to other beneficial arthropods is considered to be scientifically unjustified.

Bioconcentration

Bioconcentration factor (BCF)	Hydrochloric acid dissociates completely in water and as such it is not possible for bioaccumulation in organisms. The need to conduct studies on bioconcentration is considered to be scientifically unjustified.
Depration time (DT_{50}) (DT_{90})	Hydrochloric acid dissociates completely in water and as such it is not possible for bioaccumulation in organisms. The need to conduct studies on bioconcentration is considered to be scientifically unjustified.
Level of metabolites (%) in organisms accounting for > 10 % of residues	Hydrochloric acid dissociates completely in water and as such it is not possible for bioaccumulation in organisms. The need to conduct studies on bioconcentration is considered to be scientifically unjustified.

Chapter 6: Other End Points

None

1. APPENDIX II: LIST OF INTENDED USES

MG/PT	Field of use envisaged	Likely concentr. at which a.s. will be used
PT02	Surface disinfectant for toilet bowls in private and domestic situations	6% w/w HCl

Summary of intended uses[15]

Object and/or situation (a)	Member State or Country	Product name	Organisms controlled (c)	Formulation		Application			Applied amount per treatment			Remarks: (m)
				Type (d-f)	Conc. of as (i)	method kind (f-h)	number min max (k)	interval between applications (min)	g as/L min max	water L/m^2 min max	g as/m^2 min max	
Surface disinfectant for toilet bowls	EU	Harpic Limescale Remover	Range of Gram positive and Gram negative bacteria, common fungal species and common viral types, collectively known as « germs »	Liquid	6% w/w	Direct nozzle under toilet rim. Squeeze bottle to apply.	1-2	30 min	80 – 160 ml	n.a.	n.a.	Method of use: Apply approximat 80ml of product to unc the toilet rim. Leave 30 minutes, then bru and flush. Reapply, lea for 15 minutes, th flush.

---

[15] adapted from: EU (1998a): European Commission: Guidelines and criteria for the preparation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EC (Article 5.3 and 8,2). Document 1663/VI/94 Rev 8, 22 April 1998

(a) *e.g.* biting and suckling insects, fungi, molds; (b) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(c) GCPF Codes - GIFAP Technical Monograph No 2, 1989 ISBN 3-8263-3152-4); (d) All abbreviations used must be explained
(e) g/kg or g/l;(f) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench;
(g) Kind, *e.g.* overall, broadcast, aerial spraying, row, bait, crack and crevice equipment used must be indicated;
(h) Indicate the minimum and maximum number of application possible under practical conditions of use;
(i) Remarks may include: Extent of use/economic importance/restrictions

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

Document IIIA Reference list

Section No / Reference No[16]	**Author(s)** [17]	**Year**	**Title**[18] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
IIIA3.1.1/01	Bell, A.	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP Unpublished	Y	Reckitt Benckiser
IIIA3.1.3/01	Bell, A.	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP Unpublished	Y	Reckitt Benckiser
IIIA3.3.1/01	Bell, A.	2007	Physical and Chemical Properties of	Y	Reckitt

---

[16] ***Section Number/Reference Number*** should refer to the section number in Doc III-A or III-B. If the study is non-key, and hence not summarised in Doc III but mentioned in Doc II, it should be included in the reference list alongside related references and its location in Doc II indicated in brackets. (If there is a need to include a cross-reference to PPP references then an additional column can be inserted).

[17] ***Author's Name*** should include the author's surname before initial (s) to enable the column to be sorted alphabetically. If the Human Rights Charter prevents author's surnames on unpublished references being included in non-confidential documents, then it will be necessary to consider including 'Unpublished [number/year & letter] ' in Doc II, and both ' Unpublished [number/year & letter]' and the 'Authors Name' in the reference list'. This may necessitate the need for an additional column to state whether a reference is unpublished which can then be sorted.

[18] ***Title, Source (where different from company), Company, Report No., GLP (where relevant), (Un)Published*** should contain information relevant to each item (ideally on separate lines within the table cell for clarity). If useful, the name of the electronic file containing the specific study/reference could be added in brackets.

Section No / Reference No[16]	**Author(s) [17]**	**Year**	**Title[18]** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP, Unpublished		Benckiser
IIIA3.3.2/01	Bell, A.	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP Unpublished	Y	Reckitt Benckiser
IIIA3.14/01	Bell, A.	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP, Unpublished	Y	Reckitt Benckiser
IIIA5.3.1/02	Grudzinski, P.	2006	Evaluation of bactericidal and fungicidal activity of ‘Cillit TBC Lime and Rust’ Laboratory Tests & Assays of Pharmaceuticals, Cosmetics and Food Products, Katowice, Poland. Report No.: D/04/06/06 Not GLP Unpublished	Y	Reckitt Benckiser
IIIA5.3.1/03	Smith, K.T.	2003	Evaluation of the bactericidal activity of ‘Microshield LSR, [master formula]’ Reckitt Benckiser Inc. Report No.: Not given Not GLP Unpublished	Y	Reckitt Benckiser
IIIA5.3.1/04	Manzo, C.	2004	Inactivation of Rotavirus in the presence of organic soil on inanimate environmental surfaces Reckitt Benckiser Inc. Report No.: Not given Not GLP Unpublished	Y	Reckitt Benckiser
IIIA5/02	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIA5/03	Cavalleri,	2008a	Evaluation of disinfectant	Y	Reckitt

Section No / Reference No[16]	**Author(s)** [17]	**Year**	**Title**[18] **Source (where different from company) Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
	M.		effectiveness Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished		Benckiser
IIIA5/04	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIA5/05	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIA5/06	Cavalleri, M.	2008b	Virucidal quantitative suspension test (EN 14476) Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-2 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIA7.4.1.2	Cross, N.	2008	A study to determine the acute toxicity of Hydrochloric Acid to *Daphnia magna.* CEM Analytical Services Ltd., (CEMAS), Glendale Park, Fernbank Road, North Ascot, Berkshire, UK. Report No. CEMR-4127 GLP Unpublished	Y	Reckitt Benckiser
IIIA7.4.1.3	Brown, R.J.	2008	Hydrochloric Acid: Toxicity to the green alga *Chlorella vulgaris.* Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon, UK Report No. BL8644/B GLP Unpublished	Y	Reckitt Benckiser

Section No / Reference No[16]	**Author(s)** [17]	**Year**	**Title**[18] **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
IIIA7.4.1.4	Daniels, M.	2008	Hydrochloric acid: Effect on the respiration rate of activated sludge. Brixham Environmental Laboratory, AstraZeneca UK Limited, Brixham, Devon, UK Report No. BL8626/B GLP Unpublished	Y	Reckitt Benckiser

Document IIIB Reference list

Section No / Reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
IIIB2.2/09	Reckitt Benckiser	2007	Harpic Microshield Lime Scale Remover – [master formula] and Formulation Confirmation for HCl dossier Unpublished	Y	Reckitt Benckiser
IIIB3.1.1	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.1.2	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.1.3/01	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
IIIB3.2	Bell, A	2008	Additional Testing on Harpic LSR Fresh Microshield. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3795 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.3	Bell, A	2008	Additional Testing on Harpic LSR Fresh Microshield. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3795 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.5	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.6	Oliver-Kang, J	2008	Relative Density Study on Harpic LSR Fresh Microshield CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-4156 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.7	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.8	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.10	Beardmore, D.	2009	Accelerated and Long-Term Storage Stability Study on a 6% w/w HCl Formulation.	Y	Reckitt Benckiser

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3304 GLP Unpublished		
IIIB3.10	Bell, A	2008	Additional Testing on Harpic LSR Fresh Microshield. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3795 GLP Unpublished	Y	Reckitt Benckiser
IIIB3.11	Bell, A	2008	Additional Testing on Harpic LSR Fresh Microshield. CEM Analytical Services Ltd (CEMAS) Report no.: CEMR-3795 GLP Unpublished	Y	Reckitt Benckiser
IIIB4.1/01	Gaudio, C.	2007	Validation of Test Method GLP-V15-1541-HCl-08 with Harpic Liquid Toilet Bowl Cleaner, Formula 962-037. Reckitt Benckiser, Inc. Report no.: 2007-0033 GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/01	Grudzinski, P.	2006	Evaluation of bactericidal and fungicidal activity of 'Cillit TBC Lime and Rust' Laboratory Tests & Assays of Pharmaceuticals, Cosmetics and Food Products, Katowice, Poland. Report No.: D/04/06/06 25 June 2006 Not GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/02	Smith, K.T.	2003	Evaluation of the bactericidal activity of 'Microshield LSR, [master formula]' Reckitt Benckiser Inc. Report No.: Not given 19 November 2003 Not GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/03	Manzo, C.	2004	Inactivation of Rotavirus in the presence of organic soil on inanimate environmental surfaces	Y	Reckitt Benckiser

Section No / Reference No	Author(s)	Year	Title Source (where different from company) Company Report No. GLP (where relevant) (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Reckitt Benckiser Inc. Report No.: Not given 10 March 2004 Not GLP Unpublished		
IIIB5.10/04	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Bioloab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/05	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Bioloab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/06	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Bioloab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/07	Cavalleri, M.	2008a	Evaluation of disinfectant effectiveness Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-1 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIB5.10/08	Cavalleri, M.	2008b	Virucidal quantitative suspension test (EN 14476) Eurofins|Biolab, Biolab S.p.A., Via Bruno Buzzoni, 2, 20090 Vimodrone (Mi) – Italia. Report No.: 2008/474-2 Ami Rev.1 GLP Unpublished	Y	Reckitt Benckiser
IIIB6.2s	Dreher, D.	2005	Harpic LSR: Transcutaneous Electrical Resistance Assay Covance Laboratories Ltd., UK No.	Y	Reckitt Benckiser

Section No / Reference No	**Author(s)**	**Year**	**Title** **Source (where different from company)** **Company** **Report No.** **GLP (where relevant)** **(Un)Published**	**Data Protection Claimed (Yes/No)**	**Owner**
			1864/031 GLP Unpublished		
IIIB6.6/01-1	Rizzi, J.	2007a	Headspace Analysis of Formula 962-037. Reckitt Benckiser Report No:.2007-0044 Report date: 5 June 2007 GLP Unpublished	Y	Reckitt Benckiser
IIIB6.6/01-2	Rizzi, J.	2007b	Chemical Characterization of Formula 962-037. Reckitt Benckiser Report No:.2007-0045 Report date: 5 June 2007 GLP Unpublished	Y	Reckitt Benckiser
IIIB6.6/01-3	Burt, D.	2007	Bottle Weight, Master Schedule Ref # 2007-0044 Dates of experimental work:9-11 May 2007 Report date: 17 July 2007 Unpublished.	Y	Reckitt Benckiser

Appendix IV: List of standard terms and abbreviations

Stand. Term / Abbreviation	**Explanation**
A	ampere
Ach	acetylcholine
AchE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD_{50}	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
Ann.	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ArfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point

Stand. Term / Abbreviation	**Explanation**
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy
BSP	bromosulfophthalein
Bt	*Bacillus thuringiensis*
Bti	*Bacillus thuringiensis israelensis*
Btk	*Bacillus thuringiensis kurstaki*
Btt	*Bacillus thuringiensis tenebrionis*
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10^{-2})
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
cf	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)

Stand. Term / Abbreviation	**Explanation**
DES	diethylstilboestrol
DIS	draft international standard *(ISO)*
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper *(OECD)*
$DT_{50(lab)}$	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
$DT_{90(field)}$	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ε	decadic molar extinction coefficient
EC_{50}	median effective concentration
ECD	electron capture detector
ED_{50}	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F_0	parental generation

Stand. Term / Abbreviation	**Explanation**
F_1	filial generation, first
F_2	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay
FID	flame ionisation detector
F_{mol}	fractional equivalent of the metabolite´s molecular weight compared to the active substance
FOB	functional observation battery
f_{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system

Stand. Term / Abbreviation	**Explanation**
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry’s Law constant (calculated as a unitless value)
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography – mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H_S	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I_{50}	inhibitory dose, 50%
IC_{50}	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator

Stand. Term / Abbreviation	**Explanation**
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	*in vitro* fertilisation
k *(in combination)*	kilo
k	rate constant for biodegradation
K	Kelvin
Ka	acid dissociation constant
Kb	base dissociation constant
K_{ads}	adsorption constant
K_{des}	apparent desorption coefficient
kg	kilogram
K_H	Henry´s Law constant (in atmosphere per cubic metre per mole)
K_{oc}	organic carbon adsorption coefficient
K_{om}	organic matter adsorption coefficient
K_{ow}	octanol-water partition coefficient
Kp	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry

Stand. Term / Abbreviation	**Explanation**
LC_{50}	lethal concentration, median
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD_{50}	letal dose, median; dosis letales media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram

Stand. Term / Abbreviation	**Explanation**
MHC	moisture holding capacity
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n°	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

Stand. Term / Abbreviation	**Explanation**
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC_A	predicted environmental concentration in air
PEC_S	predicted environmental concentration in soil
PEC_{SW}	predicted environmental concentration in surface water
PEC_{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler’s exposure data
PIC	prior informed consent
pic	phage inhibitory capacity
PIXE	proton induced X-ray emission

Stand. Term / Abbreviation	**Explanation**
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10^{-9})
PPE	personal protective equipment
ppm	parts per million (10^{-6})
PPP	plant protection product
ppq	parts per quadrillion (10^{-24})
ppt	parts per trillion (10^{-12})
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r^2	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL_{50}	median residual lifetime
RNA	ribonucleic acid
RP	reversed phase

Stand. Term / Abbreviation	**Explanation**
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)

Stand. Term / Abbreviation	**Explanation**
$t_{½}$	half-life (define method of estimation)
T_3	tri-iodothyroxine
T_4	thyroxine
T_{25}	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TC	technical material
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectrometry
TER	toxicity exposure ratio
TER_I	toxicity exposure ratio for initial exposure
TER_{ST}	toxicity exposure ratio following repeated exposure
TER_{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TK	technical concentrate
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone

Stand. Term / Abbreviation	**Explanation**
	(thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to