Doc IIIA / Section 7.5.2.1 BPD Data IIIA/ Annex point XIII.3.2	Reproduction study with other soil non-target macro-organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified** [✓] **Other existing data** [✓] **Limited exposure** [✓]	
Detailed justification:	It is accepted that the toxicity of hydrochloric acid is based on the presence of the hydrogen ion (H+) and its effect on pH. Based on the aquatic data (Doc IIA, Section 4.2) very low pH is expected to lead to detrimental effects on most soil organisms. The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of the soil environment (Doc IIB, Section 3.3). Therefore no significant alteration of soil pH is expected from the proposed use. 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 chronic reproduction data on the toxicity of hydrochloric acid to soil macro-organisms.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable: see Doc IIIA / Section 7.5.1.3. Aditionally there is a methoological difficulties to conduct the chronic reproduction test (with spiked soil/sediment) due to instability of active substance (pH) in the long-term test system. It is not scientifically necessary to perform the chronic reproduction study with soil non-target macro-organisms.*	
Conclusion	*Agree with the applicants justificationis* *Submission of specific test/study data is not required.*	
Remarks	_	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.2.2 BPD Data Set IIIA/ Annex Point XIII.3.2	Long-term test with terrestrial plants	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified** [✓] **Other existing data** [✓] **Limited exposure** [✓]	
Detailed justification:	It is accepted that the toxicity of hydrochloric acid is based on the presence of the hydrogen ion (H+) and its effect on pH. It is also known that very acid conditions can be detrimental to many species plants. The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of either the outdoor atmosphere or the soil (Doc IIB, Section 3.3). Therefore no significant perturbation of pH in either the soil or atmospheric moisture is expected. Given that no perturbation of soil or atmospheric moisture pH is expected from the proposed indoor use, no risk to plants is anticipated. It is therefore considered that there is no justification for the generation of long-term toxicity data on plants.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable: The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of the soil environment (Doc IIB, Section 3.3). Also significant emmission and perturbation of pH in either the soil or atmospheric moisture environment is not expected. Accordingly we agree to applicant that it is not necessary to conduct the long-term test with terrestrial plants.*	
Conclusion	*Agree with the applicants justificationis* *Submission of specific test/study data is not required.*	
Remarks	_	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.3.1.1 **BPD Data IIIA/ Annex point XIII.1.1**	**Effects on birds – acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	Based on the mammalian toxicology data (Doc IIA, Section 3) it is expected that surface (skin/eye) applications of hydrochloric acid to birds would be corrosive and that damage to the respiratory tract could occur from high levels of inhalation. The formulation of product and use of hydrochloric acid in household toilets (PT2) is not expected to lead to significant exposure of water, soil or air (Doc IIB, Section 3.3). 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. Additionally the generation of such data with a substance known to be corrosive would contravene animal welfare considerations.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable*	
Conclusion	*Agree with the applicants justification.* *Submission of specific test/study data is not required.*	
Remarks	*There is applicant's argumentation of very importance: in concrete case predicted concentrations of HCl in air as a result of the use of Harpic Limescale Remover are 1.83 x 10^{-10} mg/m^3 (normal use) and 2.7 x 10^{-9} mg/m^3 (worst case) that is considered to be insignificant to compare to that from other natural and man-made sources (Doc. IIIA/ Section A7.3.1).*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.3.1.2 **BPD Data IIIA/ Annex point XIII.1.2**	**Effects on birds – short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	The most likely route of exposure from hydrochloric acid is inhalation, and a repeated dose as well as a subchronic study by this route of exposure for mammals are summarised in Doc IIA, Section 3. Similar effects to those seen in mammals would be expected with birds. The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant environmental exposure (Doc IIB, Section 3.3). 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. Additionally it would be considered an inappropriate use of birds given the known corrosive properties of hydrogen chloride.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable: The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant environmental exposure (Doc IIB, Section 3.3). Additionally it would be considered an inappropriate use of birds given the known corrosive properties of hydrogen chloride. Additionally it would be considered an inappropriate use of birds given the known corrosive properties of hydrogen chloride. Additionally it would be considered an inappropriate use of birds given the known corrosive properties of hydrogen chloride.*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data not required*	
Remarks	*The argumentation as in Doc IIIA / Section 7.5.3.1.1*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.3.1.3 **BPD Data IIIA/ Annex point XIII.1.3**	**Effects on birds – effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of water, soil or air (Doc IIB, Section 3.3). 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. Additionally it would be considered an inappropriate use of birds given the known corrosive properties of hydrogen chloride.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*17.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable*	
Conclusion	*Agree with applicant's justification* *Submission of specific test/study data not required*	
Remarks	*The argumentation is the same as in Doc IIIA / Section 7.5.3.1.1 and 7.5.3.1.2.*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.4.1 BPD Data IIIA/ Annex point XIII.3.1	Acute toxicity to honeybees and other beneficial arthropods, for example predators	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	It is accepted that the toxicity of hydrochloric acid is based on the presence of the hydrogen ion (H+) and its effect on pH (Doc IIA, Section 4.2). Based on the known corrosive effects of hydrochloric acid, high exposures resulting in very low pH in the various environmental compartments would be expected to have detrimental effects on bees and other beneficial arthropods. The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of outdoor environmental compartments (Doc IIB, Section 3.3). Due to the insignificant exposure *via* either air and/or soil the need to conduct studies on the toxicity to honeybees and other beneficial arthropods is considered to be scientifically unjustified. It is therefore considered that this additional data requirement in not relevant for the proposed uses of hydrochloric acid in the EU.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*17.07.2009*	
Evaluation of applicant's justification	*Agree with applicant's*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data is not required*	
Remarks	–	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.5 **BPD Data IIA/ Annex point VII.7.5**	**Bioconcentration, terrestrial**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	Exposure of the terrestrial environment from the formulation of the product and use in toilets is considered to be negligible (Doc IIB, Section 3.3). Any small amounts of hydrochloric acid from atmospheric and sewage sludge routes will lead to insignificant perturbations of chloride and pH in soil moisture. In any case as hydrochloric acid dissociates completely in water there is no potential for bio-concentration in terrestrial organisms. Based on the lack of exposure and inability of hydrochloric acid to accumulate, it is considered scientifically unjustified to require data on terrestrial bioconcentration.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*17.07.2009*	
Evaluation of applicant's justification	*Agree with applicant's justification*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data is not required*	
Remarks	–	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.5.1 BPD Data IIA/ Annex point VII.7.5	Bioconcentration, terrestrial further studies	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [ ] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	Exposure of the terrestrial environment from the formulation of the product and use in toilets is considered to be negligible (Doc IIB, Section 3.3). Any small amounts of hydrochloric acid from atmospheric and sewage sludge routes will lead to insignificant perturbations of chloride and pH levels in soil moisture. In any case as hydrochloric acid dissociates completely in water there is no potential for bio-concentration in terrestrial organisms. Based on the lack of exposure and inability of hydrochloric acid to accumulate, it is considered scientifically unjustified to require further data on terrestrial bioconcentration.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable: Based on the lack of exposure and inability of hydrochloric acid to accumulate, it is considered scientifically unjustified to require further data on terrestrial bioconcentration.*	
Conclusion	*Agree with applicant's justification* *Submission of specific test/study data is not required*	
Remarks	*The argumentation is the same as in Doc IIIA / Section 7.4.2.*	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.6 BPD Data IIIA/ Annex point XIII.3	Effects on other terrestrial non-target organisms	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified** [✓] **Other existing data** [✓] **Limited exposure** [✓]	
Detailed justification:	Exposure of the terrestrial environment from the formulation of the product and use in toilets is considered to be negligible (Doc IIB, Section 3.3). Any small amounts of hydrochloric acid from atmospheric and sewage sludge routes will lead to insignificant perturbations of chloride and pH levels in soil moisture. Based on the lack of exposure, it is considered scientifically unjustified to require data on other terrestrial non-target organisms.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Agree with applicant's justification*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data not required*	
Remarks	–	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.7.1.1 **BPD Data IIIA/ Annex point XIII.3.4**	**Effects on mammals – acute oral toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	Available mammalian toxicology data (Doc IIA, Section 3) show that surface (skin/eye) applications of hydrochloric acid is corrosive and that damage to the respiratory tract can occur from high levels of inhalation. The formulation of product and use of hydrochloric acid in household toilets (PT2) is not expected to lead to significant exposure of water, soil or air (Doc IIB, Section 3.3). Given that no significant environmental exposure is expected from the proposed indoor use, no acute risk to mammals is anticipated. It is therefore considered that there is no scientific justification for the generation of additional acute toxicity data on mammals. Additionally the generation of such data with a substance known to be corrosive would contravene animal welfare considerations.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*17.07.2009*	
Evaluation of applicant's justification	*Agree with applicant's justification*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data not required*	
Remarks	–	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.7.1.2 **BPD Data IIIA/ Annex point XIII.3.4**	**Effects on mammals – short-term toxicity**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	The most likely route of exposure from hydrochloric acid is inhalation, and a repeated dose as well as a subchronic study by this route of exposure for mammals are summarised in Doc IIA, Section 3. The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant environmental exposure (Doc IIB, Section 3.3). Given the insignificant exposure of all environmental compartments and therefore insignificant short-term risk to mammals it is considered that there is no scientific justification for any additional short-term toxicity studies with mammals. Additionally it would be considered an inappropriate use of animals given the known corrosive properties of hydrogen chloride.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*16.07.2009*	
Evaluation of applicant's justification	*Agree with applicant's justification*	
Conclusion	*Applicant's justification is acceptable* *Submission of specific test/study data not required*	
Remarks	*The argumentation is the same as in IIIA / Section 7.5.7.1.1.*	
	COMMENTS FROM OTHER MEMBER STATE	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section 7.5.7.1.3 **BPD Data IIIA/ Annex point XIII.3.4**	**Effects on mammals - effects on reproduction**	
	JUSTIFICATION FOR NON-SUBMISSION OF DATA	Official use only
	Technically not feasible [] **Scientifically unjustified [✓]** **Other existing data [✓]** **Limited exposure [✓]**	
Detailed justification:	The formulation of the product and its use in household toilets (PT2) is not expected to lead to significant exposure of water, soil or air (Doc IIB, Section 3.3). Given the insignificant exposure of all environmental compartments and therefore insignificant long-term risk to mammals it is considered that there is no scientific justification for long-term mammalian toxicity studies. Additionally it would be considered an inappropriate use of animals given the know corrosive properties of hydrogen chloride.	
	Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted	
	EVALUATION BY RAPPORTEUR MEMBER STATE	
Date	*06.07.2009*	
Evaluation of applicant's justification	*Applicant's justification is acceptable*	
Conclusion	*Agree with applicant's justification*	
Remarks	–	
	COMMENTS FROM OTHER MEMBER STATE *(specify)*	
Date	*Give date of comments submitted*	
Evaluation of applicant's justification	*Discuss if deviating from view of rapporteur member state*	
Conclusion	*Discuss if deviating from view of rapporteur member state*	
Remarks		

Doc IIIA / Section A8 — Measures necessary to Protect Man, Animals and the Environment

BPD Data Set IIA / Annex Point VIII

8	**Reference**	IIIA8/01 Safety Data Sheet. Hydrochloric acid Technical Grade Issue 6. [redacted] IIIA8/02 Safety Data Sheet. Hydrochloric acid Concentrated Revision 07 (UK07). [redacted] Date: 10/02	**Official use only**
8.1	**Recommended methods and precautions concerning handling, use, storage, transport or fire (Annex IIA, point 8.1)**	**HANDLING AND USE** Hydrochloric acid should be stored and transported in closed containers. Avoid contact with skin, eyes, respiratory system and digestive system. Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. Keep away from common metals, oxidising agents, alkalis. Goggles or full face shield, acid resistant gloves and footwear are essential. Wear suitable respiratory protective equipment. Where a cartridge/canister respirator is suitable use: Type E (CEN 141). Check with protective equipment manufacturer's data. Personal protective equipment must be adjusted to the concentration at the work station and other possible risks, exposure duration and tasks performed by the worker. **Respiratory system** – gas mask with a multi-gas filter (e.g. P22/1-W). **Eyes** – protective glasses, safety goggles, ensure easy access to eyewash facilities – safety shower, water container for a driver. **Hands** – acid-proof safety gloves **Skin** – safety acid – proof and alkali resistant clothing (K.o.), rubber footwear. **STORAGE** Hydrochloric acid should be stored in ceramic containers, metal containers lined with acid-proof material or plastic containers. The acid must not be stored in metal packaging. Containers should be placed on acid-proof trays drained by sink basins, filled with limestone. Storage rooms should be properly ventilated. Degassing products from the container should be released to air via water scrubber. Hydrochloric acid should not be stored together with or close to oxidising materials, especially nitric acid and chlorates, flammable materials and heat sources. Keep smaller quantities in suitable plastic or glass containers. Keep container in a well ventilated place. **TRANSPORT** Transport must comply with the relevant provisions of the modal regulations:	

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BPD Data Set IIA / Annex Point VIII

ADR class:	8
RID class:	8
Sea Transport:	Class 8
IMDG Code:	8102
Packaging Group:	II
UN No.:	1789
Hazard No.:	80

Transport vehicle identification

Transport vehicles – orange, reflective warning plates

Train cars – warning sticker No. 8

Cisterns and cistern wagons – orange warning plates with identification numbers 80/1789, warning sticker No. 8

Transport packaging identification

Phrase "UN 1789" and a warning plate No. 8

Packaging type

Train cisterns lined with z acid proof material, car tanks and other specified in RID and ADR regulations.

Product name according to ADR

HYDROCHLORIC ACID

FIRE

Suitable extinguishing media - cool containers exposed to high temperatures with water and remove from the danger zone.

Personal protective equipment - acid-proof gear, rubber boots, tight eye and face protection, safety gloves, in case of high levels of hydrogen chloride released from the acid use equipment protecting respiratory airways.

Prohibited media – do not use water in the presence of hydrochloric acid.

8.2 In case of fire, nature of reaction products, combustion gases, etc. (Annex IIA, point 8.2)

In the event of fire, hydrogen formed following contact with metals may form explosive mixtures with air. Can react violently if in contact with oxidizing agents, liberating chlorine. Exothermic reaction with alkalis.

8.3.1 Emergency measures in case of an accident (Annex IIA, point 8.3)

SYMPTOMS

Respiratory system – vapours can cause runny nose, coughing, stifling sensation, whooping cough, pains in chest, headaches and nausea. In more severe cases, where concentrations exceed maximum allowable values glottis shrinkage, laryngeal oedema and pulmonary oedema may

occur up to 48 hours after exposure and could prove fatal. Concentrations of 50 – 100 ppm are barely tolerated for up to 1 hour.

Eyes - reversible conjunctiva infection and corneal swelling, cloudy vision, decreased visual acuity, weakened light perception, the vapours may cause eye irritation. May cause permanent impairment of vision.

Skin – allergic reactions, mild irritation, itchy irritation, reddening, temporary skin rash as hives or stain and pellet changes to the skin.

Long Term exposure – repeated exposure to low levels may produce erosion of the teeth and ulceration of the nasal septum and gums.

FIRST AID

SPEED IS ESSENTIAL. OBTAIN IMMEDIATE MEDICAL ATTENTION

Inhalation – remove from affected area, check and maintain airway patency (bend the head of the lying person slightly to the left and remove mucus from oral cavity and throat with an aspirator or fingers, remove artificial teeth, keep the jaw up, check for the tongue collapse). Apply artificial respiration if breathing has ceased or shows signs of failing. During resuscitation, care must be taken to avoid contamination by the substance from the patient.

Administer oxygen if necessary. Ensure fresh air, peace and protect from movements (due to the risk of larynx and lungs dropsy), keep warm e.g. with blankets over feet.

Eye contact – SPEED IS ESSENTIAL. Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes, call a doctor. If transported to a doctor, keep continuing to wash the eye on the way.

Skin contact – wash burnt area with plenty of lukewarm water, remove contaminated clothing. Continue to wash the affected area for at least 10 minutes. Burnt spot must be treated as an injury and protected from further infection, cover the burn with a sterile dressing and a thick layer of sterile gauze. Tape the dressing in place. In case of blisters, do not cut, do not apply oils of ointments. If burns are extensive, instead of applying dressings, if possible, cover the pateint with a sheet sterilized by ironing. Give painkillers and call medical help. Do not leave the patient unattended until the physician arrives.

Ingestion – do not induce vomiting (there is a risk of further perforation of digestive tract). Do not give stomach lavage and do not give water to neutralise the acid. Call for medical help. Give whites of 2 – 3 eggs beaten with small amount of water or milk. Do not give painkillers without taking the doctor's advice, ensure warmth and peace. Do not leave unattended until the doctor arrives.

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BPD Data Set IIA / Annex Point VIII

8.3.2	**Emergency measures to protect the environment (Annex IIA, point 8.3)**	**Environmental protection** Call the fire services. If possible, park the vehicle in a free space with the motor shut off. Remove ignition sources, do not use open fire or smoke cigarettes. Secure the road and warn other drivers. Remove unauthorized persons. Remain windward and if possible remove the leak. Protect the sewage system from liquid penetration. Build a bunding around the spilled liquid. If the liquid has already entered the sewage system or water pipes, contaminated soil or plants, inform the rescue services. Spillages or uncontrolled discharge into watercourses must be alerted to the Environmental Agency or other appropriate regulatory body. The liquid has high volatility and will freely dissociate to hydrogen and chloride ions.
8.4	**Possibility of destruction or decontamination following release in or on the following: (a) air (b) water, including drinking water (c) soil (Annex IIA, point 8.4)**	Comply with local legislation. For larger quantities contact manufacturer. For decontamination measures, each of the environmental compartments are considered as follows: a) Air: Significant contamination of air is unlikely to occur under conditions of normal use. Reference values in the air for hydrogen chloride are 200 $\mu g/m^3$ for 1 hr and 25 $\mu g/m^3$ for a calendar year. b) Water: Significant contamination of water is unlikely to occur under conditions of normal use. In contact with water the acid is diluted, it does not cause biological oxygen sag. Soil: Significant contamination of soil is unlikely to occur under conditions of normal use. The product does not bioaccumulate and is predicted to have high mobility in soil.
8.5	**Procedures for waste management of the active substance for industry or professional users**	Collect (pump) to a tightly closed container and contact the manufacturer about potential re-use of the material or contact approved waste disposal company for advice on how to dispose of waste. Disposal should be in accordance with local, state or national legislation.
8.5.1	**Possibility of re-use or recycling (Annex IIA, point 8.5.1)**	The product should only be used for the intended purpose. Re-use and recycling are not recommended.
8.5.2	**Possibility of neutralisation of effects (Annex IIA, point 8.5.2)**	A small acid spill can be powdered with acid sodium carbonate ($NaHCO_3$), and then washed off with plenty of water. Larger quantities may be neutralized with slaked lime or sodium hydroxide in a solution – add the neutralizer in small portions. The solutions formed must be neutralized to pH 7 – 8 before draining to sewage waste.
8.5.3	**Conditions for controlled discharge including leachate qualities on disposal (Annex IIA, point 8.5.3)**	Not applicable. Discharge is not permitted.
8.5.4	**Conditions for**	Any disposal must comply with Local and National Requirements which

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	controlled incineration (Annex IIA, point 8.5.4)	are derived from the EU Directives 94/67/EC of 16 December 1994 on the incineration of hazardous waste and 2000/76/EC of 4 December 2000 on the incineration of hazardous waste. These Directives establish operating conditions under which hazardous/controlled waste must be incinerated and include details such as a minimum temperature of 850°C, as measured near the inner wall or at another representative point of the combustion chamber as authorised by the competent authority, for two seconds; prescribe limits for air emissions; control discharges of waste water; control the disposal of incineration residues; and provide prescriptive methods and calculations for the determination of air emissions etc.
8.6	**Observations on undesirable or unintended side-effects, e.g. on beneficial and other non-target organisms (Annex IIA, point 8.6)**	As the proposed use is indoor only, the potential exposure to the terrestrial environment has been demonstrated to be very low (refer to Doc IIB, Section 3.3). Therefore the risk to terrestrial organisms such as non-target organisms is negligible. 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.
8.7	**Identification of any substances falling within the scope of List I or List II of the Annex to Directive 80/68/EEC on the protection of ground water against pollution caused by certain dangerous substances**	Hydrochloric acid does not come under any of the categories in list I or list II, and hence is considered to be included in list III (as a biocide). The proposed uses of hydrochloric acid are predominantly indoors and the potential soil contamination will be minimal, hence contamination of pore water is extremely unlikely (Doc IIB, Section 3.3).

Doc IIIA / Section A8 — Measures necessary to Protect Man, Animals and the Environment

BPD Data Set IIA / Annex Point VIII

	Evaluation by Competent Authorities
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*3.07.2009.*

Doc IIIA / Section A8	Measures necessary to Protect Man, Animals and the Environment
BPD Data Set IIA / Annex Point VIII	
Materials and methods	*Applicant`s version is acceptable.* *HANDLING AND USE* *Hydrochloric acid should be stored and transported in closed containers. Avoid contact with skin, eyes, respiratory system and digestive system. Provide adequate ventilation, including appropriate local extraction, to ensure that the defined occupational exposure limit is not exceeded. Keep away from common metals, oxidising agents, alkalis.* *Goggles or full face shield, acid resistant gloves and footwear are essential. Wear suitable respiratory protective equipment. Where a cartridge/canister respirator is suitable use: Type E (CEN 141). Check with protective equipment manufacturer's data.* *Personal protective equipment must be adjusted to the concentration at the work station and other possible risks, exposure duration and tasks performed by the worker.* ***Respiratory system** – gas mask with a multi-gas filter (e.g. P22/1-W).* ***Eyes** – protective glasses, safety goggles, ensure easy access to eyewash facilities – safety shower, water container for a driver.* ***Hands** – acid-proof safety gloves* ***Skin** – safety acid – proof and alkali resistant clothing (K.o.), rubber footwear.* *FIRST AID* *SPEED IS ESSENTIAL. OBTAIN IMMEDIATE MEDICAL ATTENTION* ***Inhalation** – remove from affected area, check and maintain airway patency (bend the head of the lying person slightly to the left and remove mucus from oral cavity and throat with an aspirator or fingers, remove artificial teeth, keep the jaw up, check for the tongue collapse). Apply artificial respiration if breathing has ceased or shows signs of failing. During resuscitation, care must be taken to avoid contamination by the substance from the patient.* *Administer oxygen if necessary. Ensure fresh air, peace and protect from movements (due to the risk of larynx and lungs dropsy), keep warm e.g. with blankets over feet.* ***Eye contact** – SPEED IS ESSENTIAL. Immediately irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 15 minutes, call a doctor. If transported to a doctor, keep continuing to wash the eye on the way.* ***Skin contact** – wash burnt area with plenty of lukewarm water, remove contaminated clothing. Continue to wash the affected area for at least 10 minutes. Burnt spot must be treated as an injury and protected from further infection, cover the burn with a sterile dressing and a thick layer of sterile gauze. Tape the dressing in place. In case of blisters, do not cut, do not apply oils of ointments. If burns are extensive, instead of applying dressings, if possible, cover the pateint with a sheet sterilized by ironing. Give painkillers and call medical help. Do not leave the patient unattended until the physician arrives.* ***Ingestion** – do not induce vomiting (there is a risk of further perforation of digestive tract). Do not give stomach lavage and do not give water to neutralise the acid. Call for medical help. Give whites of 2 – 3 eggs beaten with small amount of water or milk.* *Do not give painkillers without taking the doctor's advice, ensure warmth and peace. Do not leave unattended until the doctor arrives.*

Doc IIIA / Section A8

Measures necessary to Protect Man, Animals and the Environment

BPD Data Set IIA / Annex Point VIII

ENVIRONMENTAL PROTECTION

Emergency measures to protect the environment. *CALL THE FIRE SERVICES. Park the vehicle in a free space with the motor shut off.* Secure the road and warn other drivers. *Remove ignition sources, do not use open fire or smoke. Remain windward and if possible remove the leak.*

Protect the sewage system from liquid penetration. Build a bunding around the spilled liquid. If the liquid has already entered the sewage system or water pipes, contaminated soil or plants, inform the rescue services.

Spillages or uncontrolled discharge into watercourses must be alerted to the Environmental Agency or other appropriate regulatory body. The liquid has high volatility and will freely dissociate to hydrogen and chloride ions.

Possibility of destruction or decontamination. Comply with local legislation. For larger quantities contact manufacturer. For decontamination measures, each of the environmental compartments are considered as follows: **Air:** Significant contamination of air is unlikely to occur under conditions of normal use (see above reference values in the air for hydrogen chloride). ***Water:*** *Significant contamination of water is unlikely to occur under conditions of normal use. In contact with water the acid is diluted and it does not cause biological oxygen sag.* ***Soil:*** *Significant contamination of soil is unlikely to occur under conditions of normal use. The product does not bioaccumulate and is predicted to have high mobility in soil.*

Procedures for waste management of the active substance for industry or professional users. *Collect (pump) to a tightly closed container and contact the manufacturer about potential re-use of the material or contact approved waste disposal company for advice on how to dispose of waste. Disposal should be in accordance with local, state or national legislation.*

Possibility of re-use or recycling. *The product should only be used for the intended purpose. Re-use and recycling are not recommended.*

Possibility of neutralisation of effects. *A small acid spill can be powdered with acid sodium carbonate ($NaHCO_3$), and then washed off with plenty of water. Larger quantities may be neutralized with slaked lime or sodium hydroxide in a solution – add the neutralizer in small portions. The solutions formed must be neutralized to pH 7 – 8 before draining to sewage waste.*

Conditions for controlled discharge including leachate qualities on disposal. *Not applicable. Discharge is not permitted.*

Conditions for controlled incineration. *Any disposal must comply with Local and National Requirements which are derived from the EU Directives 94/67/EC of 16 December 1994 on the incineration of hazardous waste and 2000/76/EC of 4 December 2000 on the incineration of hazardous waste.*

Observations on undesirable or unintended side-effects. *As the proposed use is indoor only, the potential exposure to the terrestrial environment has been demonstrated to be very low (refer to Doc IIB, Section 3.3). 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.*

Protection of ground water against pollution caused by certain dangerous substances. *Hydrochloric acid does not come under any of the categories in list I or list II, and hence is considered to be included in list III (as a biocide). The proposed uses of hydrochloric acid are predominantly indoors and the potential soil contamination will be minimal, hence contamination of pore water is extremely unlikely (Doc IIB, Section 3.3).*

Doc IIIA / Section A8 — Measures necessary to Protect Man, Animals and the Environment

BPD Data Set IIA / Annex Point VIII

Conclusion	*Adopt applicant´s version.*
Reliability	*n/a*
Acceptability	*Acceptable*
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant´s summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Doc IIIA/Section 9 Classification and Labelling

BPD Data Set IIA/Annex Point IX

Classification and labeling in accordance with the requirements of Article 20 of 98/8/EC, in accordance with the provisions of the Dangerous Substance Directive 67/548/EC.

CLASSIFICATION

Corrosive, irritant

SYMBOL(S)

C

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)

Specific concentration limits:

C ≥ 25 % C; R34-37

10 % ≤ C < 25 %; Xi; R36/37/38

Evaluation by Competent Authorities	
	Evaluation by Rapporteur Member State
Date	*29.07.2008.*
Evaluation of applicant`s version	The applicant`s version is acceptable.
Conclusion	Adopt the applicant`s version.
Remarks	
	Comments from ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Document IIIA Reference list – by Author

Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key (Y)/ Non-Key (N)	Data Protection Claimed (Yes/No)	Owner
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Anon	IIIA3.3.3/02	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.1.1/03	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.1.2/02	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
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Anon.	IIIA3.1.3/03	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
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Anon.	IIIA3.16/02	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.17/02	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.2/02	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.3.1/03	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.3.2/03	2006	Safety Data Sheet Hydrochloric Acid, Concentrated. Ineos Chlor, Revision 07 (UK07) Published	Y	N	Ineos Chlor
Anon.	IIIA3.5/02	2001	The Merck Index, 2001 p857 13th edition Merck & Co. Inc, NJ Published	Y	N	NA
Anon.	IIIA3.5/03	2006	Safety Data Sheet Hydrochloric Acid,	Y	N	Ineos

Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key (Y)/ Non-Key (N)	Data Protection Claimed (Yes/No)	Owner
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Bell, A.	IIIA3.14/01	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP, Unpublished	Y	Y	Reckitt Benckiser
Bell, A.	IIIA3.3.1/01	2007	Physical and Chemical Properties of Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP, Unpublished	Y	Y	Reckitt Benckiser
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			Unpublished			
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Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key (Y)/ Non-Key (N)	Data Protection Claimed (Yes/No)	Owner
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Madej, W.	IIIA3.1.2/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.1.3/02	2006	Material Safety Data Sheet Hydrochloric Acid	Y	N	Zachem

Author(s)	Section No / Reference No	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Key (Y)/ Non-Key (N)	Data Protection Claimed (Yes/No)	Owner
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Madej, W.	IIIA3.11/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
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Madej, W.	IIIA3.16/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.17/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.2/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.3.1/02	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.3.2/02	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.3.3/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.5/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA3.7/01	2006	Material Safety Data Sheet Hydrochloric Acid Zachem Synthesis Plant, Issue 6 Published	Y	N	Zachem S.A.
Madej, W.	IIIA8/01	2006	Material Safety Data Sheet: Hydrochloric acid Technical Grade. Issue 6. Date of first issue: 9 October 2001. Zaklady Chemiczne Zachem S.A., Wojska Polskiego, Poland. Last update 27 June 2006 Published.	Y	N	Zachem
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Kaplan, H.L., Anzuelo, A., Switzer, W.G. and Hinderer, R.K.	IIIA6.4.3/02-5	1988	Effects of hydrogen chloride on respiratory response and pulmonary function of the baboon. J. Toxicol. & Environ. Hlth. **23**: 473-493 Published (Summarised in IIIA6.1.3/05)
Kaplan, H.L., Anzuelo, A., Switzer, W.G. and Hinderer, R.K.	IIIA6.8.1/02-5	1988	Effects of hydrogen chloride on respiratory response and pulmonary function of the baboon. J. Toxicol. & Environ. Hlth. **23**: 473-493 Published
Marx, D. *et al.*	IIIA7.1-4	1999	The nature of the hydrated excess proton in water. Nature. 397 601 – 604. Published
Muñoz Muñoz, E., Bretcha Boix, P., Collera Ormazabal, P., Rodriguez Santiago, J., Gonzalez Pons, G., Veloso Veloso, E. and Marco Molina, C.	IIIA6.12.7-1	1998	Swallowing of hydrochloric acid:study of 25 cases. Rev. Esp. Enferm. Dig. **90**(10): 705-707 Published (Summarised in IIIA6.12.2/02)
Muñoz Muñoz, E., Bretcha Boix, P., Collera Ormazabal, P., Rodriguez Santiago, J., Gonzalez Pons, G., Veloso Veloso, E. and Marco Molina C.	IIIA6.12.8-1	1998	Swallowing of hydrochloric acid:study of 25 cases. Rev. Esp. Enferm. Dig. **90**(10): 705-707 Published (Summarised in IIIA6.12.2/02)
Pavlova, T.E.	IIIA6.8.1/02-6	1976	Disturbance of development of the progeny of rats exposed to hydrogen chloride. Bull. Exp. Biol. **82**: 615-617. Published
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Presser, K.A., Ratkowsky, D.A. and Ross, T.	IIIA7.4.1.4-4	1997	Modelling the growth rate of *Escherichia coli* as a function of pH and lactic acid concentration. Applied and environmental microbiology, June 1997, p2355-2360. Published

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Rotimi, V.O., Egwari, L. and Akande, B.	IIIA7.4.1.4-2	1990	Acidity and intestinal bacteria: an in-vitro assessment of the bactericidal activity of hydrochloric acid on intestinal pathogens. Afr, J. Med. Med Sci (1990) **19**:275-280. Published
Sellakumar, A.R., Snyder, C.A., Solomon, J.J. and Albert, R.E.	IIIA6.5-3	1985	Carcinogenicity of Formaldehyde and Hydrogen Chloride in Rats. Toxicology and Applied Pharmacology **81**: 401-406 Published (Summarised in IIIA6.7)
Sellakumar, A.R., Snyder, C.A., Solomon, J.J. and Albert, R.E.	IIIA6.8.1/02-7	1985	Carcinogenicity of Formaldehyde and Hydrogen Chloride in Rats. Toxicology and Applied Pharmacology **81**: 401-406 Published
Sellakumar, A.R., Snyder, C.A., Solomon, J.J. and Albert, R.E.	IIIA6.8.2-3	1985	Carcinogenicity of Formaldehyde and Hydrogen Chloride in Rats. Toxicology and Applied Pharmacology **81**: 401-406 Published (Summarised in IIIA6.7)
Smith, J.L.	IIIA7.4.1.4-1	2003	The role of gastric acid in preventing foodborne disease and how bacteria overcome acid conditions. Journal of Food Protection, Vol. **66**, No. 7: 1292-1303. Published
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WHO	IIIA7.1-2	1982	WHO (1982) World Health Organization Environmental Health Criteria 21 (Chlorine and Hydrogen Chloride) Published
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Zavitsas, A.A.	IIIA7.1-3	2001	Properties of water solutions of electrolytres and nonelectrolytes. J. Phys. Chem.. B. 105 7805 – 7815 Published

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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 Concentrated HCl. CEM Analytical Services Ltd (CEMAS), Report No. CEMR-3305 GLP, Unpublished	Y	Reckitt 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, Formula 962-012' 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, M.	2008a	Evaluation of disinfectant effectiveness	Y	Reckitt

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
			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
IIIA6.4.3/01	Dudek, B. R.	1984	90-day inhalation toxicity study of hydrogen chloride gas in $B_6C_3F_1$ mice, Sprague-Dawley rats and Fisher-344 rats. Toxigenics Inc, Decatur, Illinois. Report No. 420-1087 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
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	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
			Unpublished		

NA = Not Applicable

Doc IIIA Section A5
BPD Data Set IIA/ Annex Point V

Effectiveness against Target Organisms and Intended Uses

Subsection (Annex Point)			Official use only
5.1	**Function (IIA5.1)**	Bactericide, Fungicide, Virucide	
5.2	**Organism(s) to be controlled and products, organisms or objects to be protected (IIA5.2)**		
5.2.1	**Organism(s) to be controlled (IIA5.2)**	Broad spectrum of control of bacteria, fungi, viruses	
5.2.2	**Products, organisms or objects to be protected (IIA5.2)**	Surfaces which might harbour or otherwise permit the development and spread of bacteria, fungi or viruses	
5.3	**Effects on target organisms, and likely concentration at which the active substance will be used (IIA5.3)**		
5.3.1	**Effects on target organisms (IIA5.3)**	Reduction in infectivity of bacteria, fungi and viruses, by reduction in numbers of individuals capable of causing infection. Refer to Table A.5-1 for summary of effectiveness data.	
5.3.2	**Likely concentrations at which the A.S. will be used (IIA5.3)**	Products containing 6-18% hydrochloric acid to be used undiluted as surface disinfectants.	
5.4	**Mode of action (including time delay) (IIA5.4)**		
5.4.1	**Mode of action**	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).	
5.4.2	**Time delay**	Effects on cells can be immediate.	
5.5	**Field of use envisaged (IIA5.5)**		
	MG01: Disinfectants, general biocidal products	PT 02 Private area and public health area disinfectants and other biocidal products	
	MG02: Preservatives		
	MG03: Pest control		

	MG04: Other biocidal products	
	Further specification	
5.6	**User (IIA5.6)**	
	Industrial	-
	Professional	-
	General public	General public (non-professional)
5.7	**Information on the occurrence or possible occurrence of the development of resistance and appropriate management strategies (IIA5.7)**	
5.7.1	**Development of resistance**	No resistance to HCl has been reported for any of the likely target species. Development of resistance is considered unlikely due to the non-specific mode of action.
5.7.2	**Management strategies**	As the risk of resistance developing to hydrochloric acid is low, no specific management strategies have been adopted. If resistance were to occur within populations of some target species, alternation with alternative products/modes of action would need to be considered.
5.8	**Likely tonnage to be placed on the market per year (IIA5.8)**	Please refer to IIIA Confidential data, 5-Efficacy Section A5.8 (Confidential)

Section A5 Effectiveness against Target Organisms and Intended Uses

BPD Data Set IIA/

Annex Point V

Evaluation by Competent Authorities	
	Use separate "evaluation boxes" to provide transparency as to the comments and views submitted
	EVALUATION BY RAPPORTEUR MEMBER STATE
Date	*20.06.2009.*
Materials and methods	*Applicant's version is applicable – applicant gives summary of effectiveness data – Table A.5-1 especially five references of Cavalleri, M (2008).*
Conclusion	*Applicant's version is adopted. No resistance to HCl has been reported for any of the likely target species. Development of resistance is considered unlikely due to the non-specific mode of action by means of hydronium ion (H_3O^+) which is highly reactive with organic molecules.*
Reliability	*1*
Acceptability	*Acceptable*
Remarks	-
	COMMENTS FROM ...
Date	*Give date of comments submitted*
Results and discussion	*Discuss additional relevant discrepancies referring to the (sub)heading numbers and to applicant's summary and conclusion.* *Discuss if deviating from view of rapporteur member state*
Conclusion	*Discuss if deviating from view of rapporteur member state*
Reliability	*Discuss if deviating from view of rapporteur member state*
Acceptability	*Discuss if deviating from view of rapporteur member state*
Remarks	

Table A.5-1 Experimental data on the effectiveness of the active substance against target organisms at different fields of use envisaged

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
MG01	PT02	Hydrochloric acid (0.5% solution)	*Pseudomonas aeruginosa** *Ps.alcaligenes** *Ps.diminuta* * *Ps.fluorescens** *Ps.picketti** *Flavobacterium aureum** *Acinetobacter lowffi** *Bacillus subtilis (ATCC 9372)* *Eschericia coli (ATCC 25922)* *Ps. aeruginosa (ATCC 15442)* *Ps.alcaligenes (INCQS)* *Ps.diminuta (ATCC 11568)* *Ps.fluorescens (ATCC 3178)* *Ps.picketti (ATCC 5031)* **wild strains*	Basic suspension test (Phase 1) [ISO 14698-3]	25 °C	Time taken to reduce initial bacterial population by 90%: *Ps.aeruginosa;* 6.88 min *Ps.alcaligenes;* 5.56 min *Ps.diminuta;* 6.49 min *Ps.fluorescens;* 9.12 min *Ps.picketti;* 10.81min *F. aureum;* 5.67 min *A. lowffi;* 7.26 min *B. subtilis (ATCC 9372);* 10.88 min *E. coli (ATCC 25922);* 3.70 min *Ps.aeruginosa (ATCC 15442);* 6.35 min *Ps.alcaligenes (INCQS);* 4.03 min *Ps.diminuta (ATCC 11568);* 2.81 min *Ps.fluorescens (ATCC 3178);* 4.22 min *Ps.picketti (ATCC 5031);* 4.78 min Calculated time for 4 $\log_{10}$ units reduction in population: *Ps.aeruginosa;* 27.52 min *Ps.alcaligenes;* 22.24 min *Ps.diminuta;* 25.96 min *Ps.fluorescens;* 36.48 min *Ps.picketti;* 43.24 min *F. aureum;* 22.68 min *A. lowffi;* 29.04 min *B. subtilis (ATCC 9372);* 43.52 min *E. coli (ATCC 25922);* 14.80 min *Ps.aeruginosa (ATCC 15442);* 25.40 min *Ps.alcaligenes (INCQS);* 16.12 min *Ps.diminuta (ATCC 11568);* 11.24 min *Ps.fluorescens (ATCC 3178);* 16.88 min *Ps.picketti (ATCC 5031);* 19.12 min	Mazzola, P.G. et al (2006)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
MG01	PT02	Cillit TBC Lime and Rust (17.6% HCl)	Bacteria; *Ps.aeruginosa* *Staphylococcus aureus* *E.coli* Fungi; *Candida albicans* *Aspergillus niger*	Basic suspension test (Phase 1)	20 °C Clean conditions Distilled water	Reduction in infectivity achieved; Bacteria (30 mins exposure); 0.1% dilution; >5 log_{10} units (acceptability criteria for this test type) Fungi (30 mins exposure); *C.albicans* 0.1% dilution >4 log_{10} units *A.niger* 20% dilution >4 log_{10} units (acceptability criteria for this test type)	Grudzinski, P. (2006)
			Bacteria; *Ps.aeruginosa* *S.aureus* *E.coli* *Enterococcus hirae* Fungi; *C.albicans* *A.niger*	Quantitative suspension test (Phase 2, Step 1)	20 °C Organic soiling Hard water	Reduction in infectivity achieved; Bacteria (5 mins exposure); 0.5% dilution; >5 log_{10} units (acceptability criteria for this test type) Fungi (15 mins exposure); *C.albicans* 0.5% dilution >4 log_{10} units *A.niger* 40% dilution >4 log_{10} units (acceptability criteria for this test type)	
			Bacteria; *Ps.aeruginosa* *S.aureus* *E.coli* *E.hirae* Fungi; *C.albicans* *A.niger*	Non-porous surface test (Phase 2, Step 2)	22 °C Organic soiling Hard water	Reduction in infectivity achieved; Bacteria (5 mins exposure); 1.0% dilution; >4 log_{10} units (acceptability criteria for this test type) Fungi (15 mins exposure); *C.albicans* 0.2% dilution >3 log_{10} units *A.niger* 10% dilution >3 log_{10} units (acceptability criteria for this test type)	
MG01	PT02	Microshield LSR (master formula) (6% HCl)	Bacteria; *Ps.aeruginosa* *S.aureus* *E.coli* *E.hirae*	Non-porous surface test (Phase 2, Step 2)	23 °C Organic soiling Hard water	Reduction in infectivity achieved following 30 minutes exposure; 1:25 dilution; >4 log_{10} units (acceptability criteria for this test type)	Smith, K.T. (2003)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
MG01	PT02	Microshield LSR (master formula) (6% HCl)	Rotavirus	Non-porous surface test (Phase 2, Step 2)	Hard water	Reduction in infectivity achieved following 30 minutes exposure; 1:25 dilution; ≥4 $\log_{10}$ units (acceptability criteria for this test type)	Manzo, C. (2004)
MG01	PT02	HCl Batch: XFA015 HH (35.58% HCl)	Bacteria: *Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) *Escherichia coli* (ATCC 10536) *Enterococcus hirae* (ATCC 10541)	EN 13697:2001 'Evaluation of bactericidal activity: Surface test'. Surface: stainless steel	Test conducted: 5 minutes exposure at 20°C (±1°C) Incubation: 48 hours at 37°C (±1°C)	Reduction in infectivity (>4 $\log_{10}$) 5 minutes exposure (dirty conditions): *Staphylococcus aureus* (ATCC 6538) 30% HCl, 6.0% HCl *Pseudomonas aeruginosa* (ATCC 15442) 30% HCl, 6.0% HCl *Escherichia coli* (ATCC 10536) 30% HCl, 6.0% HCl *Enterococcus hirae* (ATCC 10541) 30% HCl, 6.0% HCl	Cavalleri, M. (2008a)
MG01	PT02	HCl Batch: XFA015 HH (35.58% HCl)	Fungi: *Candida albicans* (ATCC10231) *Aspergillus niger* (ATCC 16404)	EN 13697:2001 'Evaluation of fungicidal activity: Surface test'. Surface: stainless steel	Test conducted: 15 minutes exposure at 20°C (±1°C) Incubation: 42-48 hours at 30°C (±1°C)	Reduction in infectivity (>3 $\log_{10}$) 15 minutes exposure (dirty conditions): *Candida albicans* (ATCC10231): 30% HCl, 6.0% HCl, 0.6% HCl *Aspergillus niger* (ATCC 16404): 30% HCl, 6.0% HCl	Cavalleri, M. (2008a)
MG01	PT02	HCl Batch: XFA015 HH (35.58% HCl)	Bacteria: *Staphylococcus aureus* (ATCC 6538) *Pseudomonas aeruginosa* (ATCC 15442) *Escherichia coli* (ATCC 10536) *Enterococcus hirae* (ATCC 10541)	EN 1276:1997 'Evaluation of bactericidal activity in suspension, filtration method'.	Test conducted: 5 minutes exposure at 20°C (±1°C) Incubation: 48 hours at 37°C (±1°C)	Reduction in infectivity (>5 $\log_{10}$) 5 minutes exposure (dirty conditions): *Staphylococcus aureus* (ATCC 6538) 30% HCl, 6.0% HCl, 0.6% HCl *Pseudomonas aeruginosa* (ATCC 15442) 30% HCl, 6.0% HCl, 0.6% HCl *Escherichia coli* (ATCC 10536) 30% HCl, 6.0% HCl, 0.6% HCl *Enterococcus hirae* (ATCC 10541) 30% HCl, 6.0% HCl, 0.6% HCl	Cavalleri, M. (2008a)

Function	Field of use envisaged	Test substance	Test organism(s)	Test method	Test conditions	Test results: effects, mode of action, resistance	Reference*)
MG01	PT02	HCl Batch: XFA015 HH (35.58% HCl)	Fungi: *Candida albicans* (ATCC10231) *Aspergillus niger* (ATCC 16404)	EN 1650:1997 'Evaluation of fungicidal activity in suspension, filtration method'.	Test conducted: 15 minutes exposure at 20°C (±1°C) Incubation: 42-48 hours at 30°C (±1°C)	Reduction in infectivity (>4 $\log_{10}$) 15 minutes exposure (dirty conditions): *Candida albicans* (ATCC10231): 30% HCl, 6.0% HCl *Aspergillus niger* (ATCC 16404): 30% HCl, 6.0% HCl	Cavalleri, M. (2008a)
MG01	PT02	HCl Batch: XFA015 HH (35.58% HCl)	Viruses: *Adenovirus* Type 5 (ATCC VR-5) *Poliovirus* Type 1 (Lsc2ab) Sabin strain	EN 14476 'Quantitative suspension test for the evaluation of virucidal activity'. (Apr 2005/A1: Oct 2006)	Test conducted: 60 minutes exposure at 20°C (±1°C) Incubation: 7 days at 37°C (±1°C)	Reduction in viral activity (>4 $\log_{10}$) 60 minutes exposure (dirty conditions): *Adenovirus* Type 5 (ATCC VR-5): 30% HCl + 0.3% BSA 6.0% HCL + 0.3% BSA 30% HCl + 0.3% BSA + erythrocytes 6.0% HCL + 0.3% BSA + erythrocytes *Poliovirus* Type 1 (Lsc2ab) Sabin strain: 30% HCl + 0.3% BSA 6.0% HCL + 0.3% BSA 30% HCl + 0.3% BSA + erythrocytes 6.0% HCL + 0.3% BSA + erythrocytes	Cavalleri, M. (2008b)

*) References:

Author	Year	Section	Title, Origin, Report No, Date
Anon.	1982	IIIA 5.4.1	Environmental Health Criteria No.21: Chlorine and Hydrogen Chloride World Health Organisation

*) References for efficacy studies:

Author	Year	Title, Origin, Report No, Date
Mazzola, P.G, et al	2006	Chemical resistance of the gram-negative bacteria to different sanitizers in a water purification system BMC Infectious Diseases 6:131 16 August 2006

Author	Year	Title, Origin, Report No, Date
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
Smith, K.T.	2003	Evaluation of the bactericidal activity of 'Microshield LSR, Formula 962-012' Reckitt Benckiser Inc. Report No.: Not given 19 November 2003 (Amended: 23 May 2007)
Manzo, C.	2004	Inactivation of Rotavirus in the presence of organic soil on inanimate environmental surfaces Reckitt Benckiser Inc. Report No.: Not given 10 March 2004
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. 30 October 2008
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 27 November 2008