Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products

PRODUCT ASSESSMENT REPORT OF A BIOCIDAL PRODUCT FOR UNION AUTHORISATION APPLICATIONS

(submitted by the Belgian ECA)

ARIEL Chlorine Professional System 5

Chlorine bleach for white wash

Product type 2

Active chlorine released from sodium hypochlorite as included in the Union list of approved active substances

Case Number in R4BP: BC-ER045796-14

Evaluating Competent Authority: Belgium

Date: 24/6/2021

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1 CONCLUSION

The outcome of the assessment for the biocidal product 'ARIEL Chlorine Professional System 5' is specified in the BPC opinion following discussions at the BPC-16 June 2021 meeting of the Biocidal Products Committee (BPC). The BPC opinion is available from the ECHA website.

2 ASSESSMENT REPORT

2.1 Summary of the product assessment

2.1.1 Administrative information

2.1.1.1 Identifier of the product / product family

Identifier	Country (if relevant)
ARIEL Chlorine Professional System 5 Chlorine Bleach for white wash	Union Authorisation

2.1.1.2 Authorisation holder

Name and address of the authorisation holder	**Name**	Procter & Gamble Services Company NV
	Address	Temselaan 100 box 43, 1853 Strombeek-Bever, Belgium
Pre-submission phase started on	21/06/2018	
Pre-submission phase concluded on	09/08/2018	
Authorisation number	/	
Date of the authorisation	/	
Expiry date of the authorisation	/	

2.1.1.3 Manufacturer(s) of the products of the family

Name of manufacturer	Sutter Industries S.p.A.
Address of manufacturer	Località Leigozze 1, Borghetto, 15060 Borbera, Italy
Location of manufacturing sites	Località Leigozze 1, Borghetto, 15060 Borbera, Italy

2.1.1.4 Manufacturer(s) of the active substance(s)

Active substance	Active chlorine released from sodium hypochlorite
Name of manufacturer	ALTAIR CHIMICA S.p.A.
Address of manufacturer	Via Moie Vecchie n.13 56048 Saline di Volterra (PI) Italy
Location of manufacturing sites	Via Moie Vecchie n.13 56048 Saline di Volterra (PI) Italy

2.1.2 Product composition and formulation

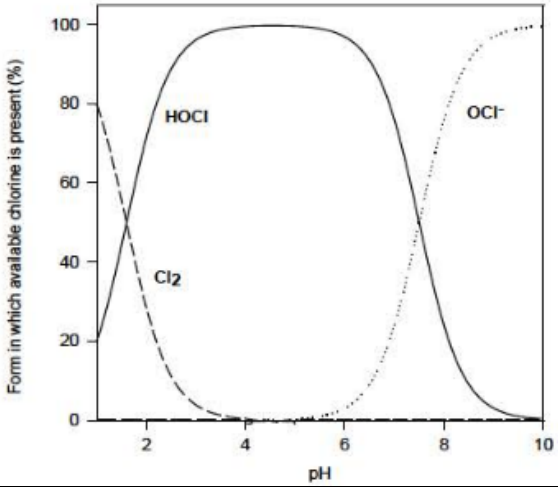
NB: the full composition of the product according to Annex III Title 1 should be provided in the confidential annex.

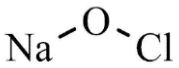
Does the product have the same identity and composition as the product evaluated in connection with the approval for listing of the active substance(s) on the Union list of approved active substances under Regulation No. 528/2012?

Yes ☐

No ☒

2.1.2.1 Identity of the active substance

Active substance	
ISO name	Active chlorine released from sodium hypochlorite
Remarks	As per the CAR: In water sodium hypochlorite (NaClO) hydrolyzes to hypochlorous acid (HClO) according to: $NaClO + H_2O \rightleftharpoons Na^+ + HClO + OH^-$ Furthermore, hypochlorous acid participates in the following equilibrium with chlorine (Cl_2): $HClO + H_3O^+ + Cl^- \rightleftharpoons Cl_2 + 2H_2O$ The ratio of Cl_2/HClO/ClO^- is pH and temperature dependent. The pH-dependence is displayed in the following figure, where the percentage of the different species at the equilibrium is showed as a function of pH. Hypochlorous acid is predominant in the pH range 4 to 5.5, whereas the hypochlorite anion predominates at pH >10. Chlorine can be present at pH < 4 only. 

Releaser	
IUPAC or EC name	Sodium hypochlorite
EC number	231-668-3
CAS number	7681-52-9
Index number in Annex VI of CLP	017-011-00-1
Minimum purity / content	Aqueous solution with an available (active) chlorine concentration ≤18% (w/w), in compliance with the EN 901:2013
Structural formula	

2.1.2.2 Candidate(s) for substitution

Sodium hypochlorite should not be considered a candidate for substitution since none of the conditions of Article 10 of the BPR are met.

2.1.2.3 Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
Sodium hypochlorite **Purity: 18.5%**	Sodium hypochlorite	Releaser	7681-52-9	231-668-3	51.4% of 18.5% solution; **9.5% sodium hypochlorite**
Active chlorine released from sodium hypochlorite	/	Active substance released	/	/	9.05% active chlorine

Sodium hypochlorite has a typical purity of 18.5%. For formulating the product ARIEL Chlorine Professional System 5, the solution of sodium hypochlorite is diluted to obtain a nominal concentration of 9.5% sodium hypochlorite (or 9.05% active chlorine) in the final product.

2.1.2.4 Information on technical equivalence

The active substance is supplied from ALTAIR CHIMICA, which is a member of the Euro Chlor Sodium hypochlorite Biocide Registration Group and complies with the reference specification of sodium hypochlorite as set forward in the assessment report of sodium hypochlorite (See IUCLID section 13).

2.1.2.5 Information on the substance(s) of concern

Not relevant, no other ingredients/co-formulants present in the product.

One relevant impurity might be present in the product; sodium chlorate, which can be formed during storage. For more details on analytical methods and results of chlorate analysis during storage stability testing, see sections 2.2.2 and 2.2.4.

The sodium chlorate has mainly systemic effects via food (ADI and ArfD), the exposure via oral exposure routes is not expected because this product is not intended to treat surfaces that may come into contact with food. Therefore, no risk assessment has been carried out for this substance.

2.1.2.6 Type of formulation

SL – Soluble concentrate

2.1.3 Hazard and precautionary statements

Classification and labelling of the product according to the Regulation (EC) 1272/2008

Classification and labelling of the biocidal product is based upon the classification for "sodium hypochlorite, solution 9.05 % Cl active" as adopted by the Risk Assessment Committee (RAC) in June 2016[1] and indicated in the Opinion of the Biocidal Products Committee (BPC) of December 2016[2] .

Based on the tests, the product ARIEL Chlorine Professional System 5 is classified for metal corrosion, skin corrosion and eye damage. As the product contains >5% NaOCl the EUH031 phrase is used.

[1] Committee for Risk Assessment (RAC) (2016) Opinion proposing harmonized classification and labelling at EU level of sodium hypochlorite, solution … % Cl active, adopted 3 June 2016

[2] Biocidal Products Committee (BPC) (2016) Opinion on the application for approval of the active substance: Active chlorine released from sodium hypochlorite, Product type 2, ECHA/BPC/128/2016, adopted 14 December 2016

Classification	
Hazard category	Metal Corrosion 1 Skin Corr. 1B Eye Damage 1 Aquatic Acute 1 Aquatic Chronic 2
Hazard statement	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H318: Causes serious eye damage. H400: Very toxic to aquatic life. H411: Toxic to aquatic life with long-lasting effects.
Suppl. hazard statement	EUH031: Contact with acids liberates toxic gas.
Labelling	
GHS pictogram	GHS05, GHS09 
Signal words	Danger (Dgr)
Hazard statements	H290: May be corrosive to metals. H314: Causes severe skin burns and eye damage. H410: Very toxic to aquatic life with long lasting effects.
Suppl. hazard statement	EUH031: Contact with acids liberates toxic gas.
Specific concentration limits, M factor	M-factor acute: 10; M-factor chronic: 1
Precautionary statements	P234 – Keep only in original packaging P260 - Do not breathe vapours P264 - Wash hands thoroughly after handling P273 - Avoid release to the environment P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+330 +331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. P304 + P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing. P303+P361+P353 - IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water (or shower). P305+P351+P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do – continue rinsing. P310 - Immediately call a POISON CENTER or doctor/physician P363 - Wash contaminated clothing before reuse. P390 - Absorb spillage to prevent material damage P391 - Collect spillage. P405 - Store locked up.

	P501 - Dispose of contents/container in accordance with local regulation.
Additional labelling requirements	EUH031: Contact with acids liberates toxic gas. (EUH031: C ≥ 5 % (active chlorine))
Note	1. Based on the tests, the biocidal product is classified for metal corrosion, skin corrosion and eye damage. 2. H318 is not indicated on the label because of redundancy as H314 is assigned (CLP Article 27); H410 is indicated on the label as this covers both H400 and H411. 3. The formation of sodium chlorate shouldn't increase the product toxicity if the user do not exceed the established shelf life of the biocidal product. Please take into consideration that there is a new CLH proposal for sodium chlorate (https://echa.europa.eu/documents/10162/13626/clh_rep_sodium_chlorate_en.pdf/c4184cf9-96a7-e363-055c-52b0f8f492c8)

2.1.4 Authorised use

The biocidal product ARIEL Chlorine Professional System 5 is used for disinfection of textile, handled only by (trained) professionals, using an automated dosing system.

2.1.4.1 Use description

Use # 1 – **Laundry disinfection (machine wash) in the post-wash rinsing phase**

Product Type	PT2
Where relevant, an exact description of the authorised use	Not relevant, see Application method(s)
Target organism (including development stage)	Bacteria Yeasts
Field of use	Indoor – In professional washing machines (such as washing-machines in restaurants, hotels, care-homes and non-healthcare facilities) via closed automatic dosing programs : Disinfection of linen after cleaning. It can only be used with Procter & Gamble professional automatic dosing equipment. It is not authorized for manual dosing.
Application method(s)	In machines for professional use via closed automatic dosing programs – in post-wash rinsing phase. **NOT AUTHORIZED** for manual dosing.
Application rate(s) and frequency	The product ***ARIEL Chlorine Professional System 5*** is added once via automatic dosing (only with P&G Professional dosing equipment), for disinfection of clean laundry : after the washing/cleaning step delivered by using ***Ariel S1 Actilift***

	detergent (commercial name of ***Ariel System S1***), the water is drained/extracted. After a refill step with fresh water, the BP is added for the 1st rinse bath. The product ***ARIEL Chlorine Professional System 5*** is bactericidal & yeasticidal on clean items when used at 10 mL/L during 15 min contact time at +40°C (Liquor ratio = 1:5; with 4 kg ballast load)
Category(ies) of users	Professional users
Pack sizes and packaging material	10-20L HDPE canister with moulded handle and safety lock & key cap. UN certified for Dangerous goods.

2.1.4.2 Use-specific instructions for use

Please refer to general instructions of use

2.1.4.3 Use-specific risk mitigation measures

Please refer to general section under 2.1.5

2.1.4.4 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Please refer to general section under 2.1.5

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

Only for use with Procter & Gamble professional automatic dosing equipment.
Use the product at 10 mL/L at min 40°C and 10 min contact time, after pre-wash phase.

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

Please refer to the section 2.1.5.5

2.1.5 General directions for use

2.1.5.1 Instructions for use

The product ***ARIEL Chlorine Professional System 5*** is intended to be used only after prewash with P&G Professional dosing equipment for disinfection of clean laundry:

- Step 1 cleaning with Ariel System S1 (can be referred to as prewash or main wash) at 40°C for 10 mins. Wash water is drained, extracted, and refilled with fresh water prior to step 2.

- Step 2 disinfection this can be referred to as main wash (if the first step is a prewash) or 1st rinse bath (if the first step is a main wash). The second step containing Ariel System S5 is always perform at 40°C for 15 mins. This is followed by 1-2 rinse and drain phases and finally an extraction by spin.

2.1.5.2 Risk mitigation measures

Always read the label or leaflet before use and follow all the instructions provided.

During handling product and during the maintenance of machines (repair broken dosing system):

- Wear protective chemical resistant gloves (EN374).
- Wear eyes protection (EN166).
- Wear protective coverall (to be specified by the authorisation holder within the product information).

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

IF SWALLOWED: Immediately rinse mouth. Give something to drink, if exposed person is able to swallow. Do NOT induce vomiting. Call 112/ambulance for medical assistance.

IF ON SKIN: Immediately wash with plenty of water. Take off all contaminated clothing and wash it before reuse. Wash with soap and water and continue rinsing for 15 minutes. Call a POISON CENTRE or a doctor.

IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing for at least 15 minutes. Immediately call a Call 112/ambulance for medical assistance.

IF INHALED: Move to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTRE or a doctor.

2.1.5.4 Instructions for safe disposal of the product and its packaging

For containment:
Scoop absorbed substance into closing containers. Do not use metal containers.

Methods for cleaning up:
Small quantities of liquid spill: take up in non-combustible absorbent material and

shovel into container for disposal. Large spills: contain released substance, pump into suitable containers. Do not use metal containers.

Disposal:

This material and its container must be disposed of in a safe way, in accordance with local/regional/national legislation.

Do not discharge unused product on the ground, into water courses, into pipes (sink, toilets…) nor down the drains

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

Storage conditions:
Store in original container.

Incompatible materials:
Metals. Acids.

Reacts with (some) acids: release of (highly) toxic gases/vapours (chlorine).

May be corrosive to metals.

Prohibitions on mixed storage:
Keep only in the original container in a cool, well-ventilated place away from (strong) acids.

Storage area:
Store in a cool area. Store in a dry area.

Do not store at temperatures above 30°C.
Protect from frost.
Keep away from direct sunlight.

Shelf life:12 months

2.1.6 Other information

Sodium chlorate may be formed during storage. To avoid increasing formation of this degradation product, do not exceed the established shelf life of the biocidal product.

2.1.7 Packaging of the biocidal product

Type of packaging	Size/volume of the packaging	Material of the packaging	Type and material of closure(s)	Intended user (e.g. professional, non-professional)	Compatibility of the product with the proposed packaging materials (Yes/No)
Canister	10-20L	HDPE untransparent	Cap, HDPE	Professional	Yes

HDPE canister with moulded handle and safety lock & key cap. UN certified for Dangerous goods.

2.1.8 Documentation

2.1.8.1 Data submitted in relation to product application

New test data has been generated regarding the biocidal product. Tests with ARIEL Chlorine Professional System 5 have been performed regarding physicochemical properties and efficacy. All new studies are included in the reference list in Annex 3.1 and are available in IUCLID.

2.1.8.2 Access to documentation

The applicant holds a letter of access (LoA) to the complete active substance dossier as submitted by Eurochlor to the Rapporteur Member state in support of the approval of Active chlorine released from sodium hypochlorite. This LoA is included in IUCLID section 13.

2.1.8.3 Similar conditions of use

The outcome of the pre-submission consultation is submitted via R4BP. The biocidal product is deemed to be eligible for Union Authorisation.

2.2 Assessment of the biocidal product

2.2.1 Intended use(s) as applied for by the applicant

See section 2.1.4 Authorised uses for a detailed use description of the biocidal product.

2.2.2 Physical, chemical and technical properties

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Physical state at 20 °C and 101.3 kPa	Visual assessment	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	Liquid, free flowing and transparent, allowing light to pass through the liquid. No signs of separation into oil, cream, claying, sediment or suspended solids	[redacted], 2019 DNA4911
Colour at 20 °C and 101.3 kPa	Visual assessment	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	Uniform yellow-green colour	[redacted], 2019 DNA4911
Odour at 20 °C and 101.3 kPa	Olfactory inspection	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	Disinfectant odour	[redacted], 2019 DNA4911
Acidity / alkalinity	CIPAC MT191	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	3.9810% m/m as Sodium Hydroxide	[redacted], 2019 DNA4911
pH	CIPAC MT75.3	8.9% NaOCl Test product: ARIEL Chlorine	*Neat*: 11.48 (20°C)	[redacted], 2019 DNA4911

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
		Professional System 5 Lot: 9014857303	*1% Dilution:* 11.41 (20°C)	
	e-CA remark: As the pH meter has been calibrated with buffers of pH 4, 7 and 9, the measured pH (neat, diluted) of the product is out of the calibration range of the pH meter and the measured values should be taken as approximate.			
Density / bulk density	OECD 109 (Oscillating U-tube)	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	1.1524 g/mL (20.1°C) 1.1436 g/mL (40.0°C)	[redacted], 2019 DNA4911
Storage stability test – **accelerated storage**	Test waived – "Do not store at temperatures above 30°C" will be added to the label. According to the Guidance on the BPR Vol I Parts A+B+C (May 2018) under these conditions an accelerated storage study is not required.			
Storage stability test – **long term storage at ambient temperature**	FAO/WHO Manual, CropLife International Technical Monograph No. 17	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	Ariel S5 Stainbuster containing 8.9% w/w Sodium Hypochlorite at ambient temperature for one year	[redacted], 2019 DNA4911 (T0) [redacted], 2020 DNA4912 (final report)
	Validated methods; DNA4913 (key study)		<u>Active substance (m/m % av. chlorine)</u> T0: 8.9468% T3: 8.0790% T6: 6.7039% T9: 5.9819% T12: 5.3815% (39.85% degradation)	
	Validated methods; DNA4913		<u>Chlorate (w/w%)</u> T0: 0.321%	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
	(key study)		T3: 1.059% T6: 1.391% T9: 1.767% T12: 1.9341%	
	Visual inspection		<u>Stability of packaging:</u> Packaging: a blue PE-HD 10L drum. The container had a black screw to lid and an aperture size of 4.5cm and an external cap sealing ring and no internal seal. T0: The sample packaging arrived sealed and intact T3: no change T6: no change T9: no change T12: no change	
	CIPAC MT75.3		<u>pH</u> T0: *Neat*: 11.48 (20°C) *1% Dilution:* 11.41 (20°C) T3: Neat: 11.64 (20.0°C) 1% Dilution: 11.30 (20.0°C) T6: Neat:11.69 (20.0°C)	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			1% Dilution: 11.16 (20.0°C) T9: Neat:12.09 (20.0°C) 1% Dilution: 11.43 (20.0°C) T12: Neat:11.74 (20.0°C) 1% Dilution: 11.14 (20.0°C)	
	CIPAC MT191		<u>Acidity/Alkalinity</u> T0: 3.9810% m/m as Sodium Hydroxide T3: 3.8012% m/m as Sodium Hydroxide T6: 3.7689% m/m as Sodium Hydroxide T9: 3.2648% m/m as Sodium Hydroxide T12: 2.9433% m/m as Sodium Hydroxide	
	CIPAC MT 41.1		<u>Dilution Stability</u> 2% v/v (CIPAC Water A) T0: No separation seen post 24 hours at 30.0°C ±2°C T3: No separation seen post 24 hours at 30.0°C ±2°C T6: No separation seen post 24 hours at 30.0°C ±2°C	

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			T9: No separation seen post 24 hours at 30.0°C ±2°C T12: No separation seen post 24 hours at 30.0°C ±2°C	
	e-CA remark: The analytical methods for determination of the active substance and chlorate content are validated within the study and are the same as reported in section 2.2.4. (DNA4913). Results show degradation of 39.85% after 12 months. As more than 10% degradation of the active substance during storage was expected and observed, in line with the Guidance on the BPR Vol. II Part A (ECHA, May 2018), an efficacy and a degradation products assessment have been performed. Chlorate is a relevant impurity and degradation product (metabolite) of sodium hypochlorite. The degradation rate is a function of the active substance concentration, pH and temperature. Solutions are kept alkaline in order to decrease the degradation rate of hypochlorite (CAR NaOCl, Jan 2017). Chlorate concentrations are therefore monitored and increase during the stability testing. The increased level of chlorate in the aged product does not cause risk for the user. The measured concentration after 12 months stability testing is 1.934% chlorate. As more than 10% degradation of the active substance during storage was expected and observed, in line with the Guidance on the BPR Vol. II Part A (ECHA, May 2018), an efficacy assessment has been performed. Based upon available efficacy test data according to EN1276 on a 12-months aged sample (Hygcen report B21312), a shelf-life of 12 months is currently claimed (see section 2.2.5.3 for more details). e-CA considers the applicant's explanation to be acceptable. Shelf-life: 12 months			
Storage stability test – **low temperature stability test for liquids**	Test waived – "Protect from frost" will be added to the label.			
Effects on content of the active substance and technical	Test waived – "Keep away from direct sunlight" will be added to the label. Product should be packaged in untransparent containers.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
characteristics of the biocidal product - **light**				
Effects on content of the active substance and technical characteristics of the biocidal product – **temperature and humidity**	Temperature: Refer to storage stability testing. Humidity: Not relevant. The product is an aqueous solution.			
Effects on content of the active substance and technical characteristics of the biocidal product - **reactivity towards container material**	Refer to storage stability testing. The product is corrosive to metals; however, since the product is stored in HPDE containers, this is not relevant for commercial packages.			
Wettability	Test waived - Not relevant for liquid formulations.			
Suspensibility, spontaneity and dispersion stability	Test waived - Not relevant for soluble concentrates. Product does not form a suspension.			
Wet sieve analysis and dry sieve test	Test waived – Not relevant for liquids.			
Emulsifiability, re-emulsifiability and emulsion stability	Test waived – Not relevant since no emulsions are formed.			
Disintegration time	Test waived – Not relevant for liquids.			
Particle size distribution, content of dust/fines, attrition, friability	Test waived – Not relevant for liquids.			
Persistent foaming	CIPAC MT47.3	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	0.0mL after 1 minute and 0.0mL after 12 minutes at both low and high application rates.	[redacted], 2019 DNA4911
Flowability/Pourability/Dustability	Test waived – Not relevant for liquids.			
Burning rate — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Burning completeness — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			
Composition of smoke — smoke generators	Test waived – Not relevant. Product is not a smoke generator.			
Spraying pattern — aerosols	Test waived – Not relevant. No spray product.			
Physical compatibility	Not relevant. Product is not intended to be used in combination with other products.			
Chemical compatibility	Not relevant. The product ARIEL Chlorine Professional System 5 is used by professional users only for laundry disinfection, in professional washing machines. The formula should only be used in combination with P&G Professional dosing equipment and is not recommended for manual dosing or for use in combination with other products. The computer-controlled dosage equipment ensures that product is dosed after the main wash cycle, and not mixed with or used in combination with other products.			
Degree of dissolution and dilution stability	CIPAC MT 41.1	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	2% v/v (CIPAC Water A) No separation seen after 24h (30.0°C ±2°C)	[redacted], 2019 DNA4911
Surface tension	OECD 115	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	73.18 ± 0.0687 mN/m (20°C) 75.87 ± 0.0335 mN/m (25°C) (hightest in use concentration)	[redacted], 2019 DNA4911
Viscosity	OECD 114	8.9% NaOCl Test product: ARIEL Chlorine Professional System 5 Lot: 9014857303	The sample is a Newtonian liquid. Dynamic Viscosity 13.29 ±0.052 mPa.s (20.0°C) Kinematic Viscosity 0.1153 cm2/s (20.0°C) Dynamic Viscosity 10.27	[redacted], 2019 DNA4911

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
			±0.04l mPa.s (40.0°C) Kinematic Viscosity is 0.0898 cm2/s (40.0°C)	

Conclusion on the physical, chemical and technical properties of the product
The product is a clear yellow-green liquid with a density of 1.1524 g/mL (at 20°C) and 1.1436g/mL (40.0°C). The pH of the pure product is 11.48 and the pH of the 1% dilution is 11.41. No foam is formed after 1 and 12 min. No phase separation is observed after 24 h. It has a surface tension 73.18nN/m at 20°C. The product is a Newtonian liquid. With regard to product stability, no accelerated storage data and low temperature data are available, which is addressed by storage condition restrictions ("Do not store at temperatures above 30°C", "Keep away from direct sunlight" and "Protect from frost"). Long term storage studies at ambient temperature are available (DNA4911 and DNA4912) for ARIEL Chlorine Professional System 5. The active substance content decrease of 39.85% after 12 months. As more than 10% degradation of the active substance during storage was expected and observed, in line with the Guidance on the BPR Vol. II Part A (ECHA, May 2018), an efficacy assessment and an assessment of the degradation products have been performed. The degradation product is identified as Chlorate. Chlorate is a relevant impurity and degradation product (metabolite) of sodium hypochlorite. Chlorate concentrations are therefore monitored and increase during the stability testing (T0: 0.321% and T12: 1.9341%). Based upon available efficacy test data according to EN1276 on a 12-months aged sample (Hygcen report B21312), a shelf-life of 12 months is currently claimed (see section 2.2.5.3 for more details). The product ARIEL Chlorine Professional System 5 is a SL formulation. All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. Shelf-life: 12 months

2.2.3 Physical hazards and respective characteristics

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Explosives	Test waived – The study does not need to be conducted because none of the components of the biocidal product has explosive properties. For the active substance reference is made to the CAR of Active chlorine released from sodium hypochlorite (updated: 2020): Not explosive, based on the available thermodynamic data (DSC-measurements), theoretical considerations and experience in handling and use of the sodium hypochlorite solutions			
Flammable gases	Not relevant, product is a liquid.			
Flammable aerosols	Not relevant, product is not an aerosol.			
Oxidising gases	Not relevant, product is a liquid.			
Gases under pressure	Not relevant, product is a liquid and not under pressure.			
Flammable liquids	Test waived - The product does not contain flammable components. Therefore, the product is not considered to be flammable. For the active substance reference is made to the CAR of Active chlorine released from sodium hypochlorite (2017): Flash-point >110°C. Sodium hypochlorite solutions are not known to spontaneously ignite when exposed to air or to emit flammable gases.			
Flammable solids	Not relevant, product is a liquid.			
Self-reactive substances and mixtures	Test waived – The study does not need to be conducted because there are no chemical groups present in the molecule which are associated with explosive or self-reactive properties. Not self-reactive, product does not contain self-reactive substances.			
Pyrophoric liquids	Test waived – The product is not pyrophoric; it does not ignite spontaneously in contact with air at normal temperature. The product is known to be stable at room temperature for prolonged periods of time (Reference: [redacted], 2019; DNA4912).			
Pyrophoric solids	Not relevant, product is a liquid.			
Self-heating substances and mixtures	Test waived – The study does not need to be conducted because the phenomenon of self-heating applies only to solids. Moreover, substances or mixtures with a low melting point (<160°C) does not have to be considered for this hazard class.			
Substances and mixtures which in contact with water emit	Test waived – The product does not emit flammable gases in contact with water. The product is manufactured with water and the mixture is known to be soluble in water to form a stable mixture (Reference: [redacted], 2019; DNA4912).			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
flammable gases				
Oxidising liquids	Test waived – The study does not need to be conducted because none of the components of the biocidal product has oxidising properties. For the active substance reference is made to the CAR of Active chlorine released from sodium hypochlorite (updated: 2020): Not an oxidising liquid (EC A.21, equivalent to UN Test O.2: Test for oxidizing liquids)			
Oxidising solids	Not relevant, product is a liquid.			
Organic peroxides	Test waived – The study does not need to be conducted because the substance does not fall under the definition of organic peroxides according to GHS and the relevant UN Manual of tests and criteria. No organic peroxides present in the product.			
Corrosive to metals	ADR/CLP-regulation (UN RTDG, Manual of tests and criteria, sub-section 37.4.3, Classification method by United Nations Economic Commission for Europe)	Ariel professional System – S5 White Wash Stainbuster	Based on the performed 4 weeks corrosion tests at 55°C the following conclusions could be drawn: • The test results related to liquid ''Ariel professional System – S5 White Wash Stainbuster'' are not in correspondence with the criteria mentioned in CLP sub-section 37.4.3: <u>The local corrosion depth of carbon steel is higher than 480 µm for all three coupons.</u> • The local corrosion depth of aluminum is less than 480 µm in the immersed phase / vapor phase. • The observed mass loss of carbon steel and aluminum is less than 51.5% in the immersed phase / vapor phase.	[redacted], 2020 200617/PGSC/TV/CR/2/053
	<u>e-CA remark:</u> The report shows that the results don't meet the criteria mentioned in Guidance on the application of the CLP criteria (Version 5.0 – July 2017). Indeed, the local corrosion depth of carbon steel is higher than 480 µm for all three coupons. The Ariel System 5 is considered as Corrosive to metals: **H290: May be corrosive to metals**			

Property	Guideline and Method	Purity of the test substance (% (w/w)	Results	Reference
Auto-ignition temperatures of products (liquids and gases)	Test waived - The product does not ignite spontaneously. The product is not considered to be auto-ignitable (Reference: CAR Active chlorine released from sodium hypochlorite; January 2017).			
Relative self-ignition temperature for solids	Not relevant, product is a liquid.			
Dust explosion hazard	Not relevant, product is a liquid.			

Conclusion on the physical hazards and respective characteristics of the product
The product ARIEL Chlorine Professional System 5 is considered to be corrosive to metals. Therefore, H290 (Metal corrosion 1) is assigned. The product does not require classification for other physical hazards.

2.2.4 Methods for detection and identification

Analytical methods for the analysis of the product as such including the active substance, impurities and residues										
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Precision**	**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD			
NaOCl (active substance, expressed as available chlorine)	Sodium thiosulfate titration	100% of nominal level of NaOCl in the product (6 measurements)	0.219 – 22.338% w/w NaOCl as available chlorine (0.31-32.1 mL thiosulfate) 7 levels, duplicate, linear; y= 0.0312x – 0.0005 R^2= 0.9999	No initial reactions occurred with the Formulation Blank or chlorate showing the absence of NaOCl (available chlorine). A reaction (shown by a colour change) occurred for the Sodium Hypochlorite confirming the presence of available chlorine.	99.37 %- 101.9 %	100.20%	SD= 0.956 RDS= 0.954 %	6 samples determination, Mean NaOCl as available chlorine : 8.96% (w/w) SD = 0.0384 %RSD = 0.4288 %RSDr = 1.93 Horwitz ratio = 0.22	LOQ/LOD considered as lowest concentration on the linearity (0.11% available chlorine, corresponding to 0.01g NaOCl standard solution and 0.32 mL thiosulfate) Mean LOQ Recovery at 0.11% (w/w) was 100.9% (n=6; SD = 1.071) %RSD= 1.061)	[redacted], 2019 DNA4913
e-CA remark: Available Chlorine determination by Sodium thiosulfate titration. The active ingredient in the Sodium Hypochlorite formulation is Available Chlorine. Available Chlorine is determined using methodology: BS EN 901:2013: Chemicals used for treatment of water intended for human consumption – Sodium Hypochlorite.										

Chlorate	Ion chromatography (IC)	100% of nominal level of Chlorate in the product (6 measurements)	0.05-75 mg/L standard 7 levels, duplicate, linear; y= 11.16x-0.0518 R^2= 0.9995	Chlorate eluted at approximately 15.5 minutes, and there were no other peaks present at the same elution time.	108.4 %-109.9 %	109.0 %	SD=0.492 RSD= 0.450 %	6 samples determination, 0.321% chlorate 3.585% relative to active substance SD = 0.00156 %RSD = 0.487 %RSDr = 3.18 Horwitz ratio = 0.15	LOQ considered as lowest point on the linearity (0.05 mg/L, 0.0025%) Mean LOQ Recovery at 0.0025% (w/w) was 78.05% (n=6; SD = 1.678, % RSD = 2.150)	[redacted], 2019 DNA4913

e-CA remark:

The sample was performed using approximatively 0.2g of sample DNA4911/1. The mass of the formulation was accurately recorded, transferred to a 100 mL volumetric flask and partially filled with Deionized Water and sonicated for 5 minutes. Once cooled to room temperature, the solution were made to volume with Deionized Water (6 solutions in total). These solutions were then used for assay by injection each solution once into the Ion Chromatograph.

Analytical methods for monitoring									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
NaOCl (active substance)	See above								
Chlorate	See above								

Analytical methods for soil									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residue definition: HClO/ClO$^-$									
Not required. For the intended use, soil is not the first receiving compartment. Environmental exposure is expected via the facility drain into the STP. Active chlorine (HClO/ClO$^-$) can reach the soil compartment only indirectly, via sewage sludge: rapid degradation occurs already with organic matter therein. In the event of contamination of soil, e.g. due to direct application of chlorinated water, hypochlorous acid/hypochlorite anion would react rapidly with organic matter in soil, anyway. (CAR Active chlorine released from sodium hypochlorite; January 2017)									

Analytical methods for air									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Residue definition: Cl_2/HClO/ClO$^-$									
Hypochlorite is a non-volatile species. Hypochlorous acid is volatile, but according to literature data, the Henry's Law constant is ≈ 0.1 Pa m3 mol-1, i.e. volatilization from the aqueous phase is expected to be slow. Furthermore, there are indications that the half-life in air is only a few hours, i.e. much shorter than the value derived by Atkinson calculation. So, occurrence in air is not probable for this species, either. Exposure to gaseous chlorine is not expected and can only happen through accidental events (chlorine can be formed and released when the active chlorine equilibrium is shifted to low pH by strong acids, e.g. by mixing hypochlorite-based solutions with acidic cleaning agents). In case of an accidental release of chlorine, two analytical methods[3] for the monitoring of chlorine in workplace air are available in the CAR, which allow the determination of chlorine in workplace air in the									

[3] OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; Smith & Cochran Spectrophotometric determination of Free Chlorine in Air using Sulphamic acid/Tri-iodide procedure - Anal Chem 1986 Vol 58 pp 1591-1592; OSHA Method «Chlorine in Work place Atmosphere» 05.01.83; NIOSH free chlorine in air 01.01.75; ISO 7392/2

range 0.3-7.0 mg Cl_2/m^3. In principle, the range can be expanded. Though not validated, the two available methods are published methods, so they can still be concluded to be acceptable for the purpose (determination of chlorine in workplace air).

(CAR Active chlorine released from sodium hypochlorite; January 2017)

Analytical methods for water									
Analyte (type of analyte e.g. active substance)	**Analytical method**	**Fortification range / Number of measurements**	**Linearity**	**Specificity**	**Recovery rate (%)**			**Limit of quantification (LOQ) or other limits**	**Reference**
					Range	Mean	RSD		
Analytical method for residues in drinking water **Residue definition: HClO/ClO^- and relevant metabolite chlorate $ClO3^-$** A fully-validated analytical method for active chlorine (HClO/ClO^-) residues in drinking water is available, using N,N-diethyl-p-phenylenediamine (DPD) and a double-beam photometer (λ = 510 nm), as specified in DIN EN ISO 7393-2:2000 Water quality - determination of free chlorine and total chlorine - part 2: colorimetric method using n,n-diethyl-1,4- phenylenediamine, for routine control purposes. The method enables the determination of active chlorine in water down to 30 µg/L, by formation of a red compound in the pH range 6.2 to 6.5. The method is a colorimetric method and, therefore, not 'highly specific' in the meaning of the Guidance on the BPR: Volume 1 Parts A+B+C (Version 2.0, May 2018). However, the test system given by DIN EN ISO 7393-2:2000 is historically well-known and readily applicable to field testing (commercial kits are available for in-field determination, e.g. by potable waternetwork technicians), so it can be considered specific enough for the purpose. A fully validated analytical method is also available for the relevant metabolite chlorate ($ClO3^-$), using HPLC coupled with tandem mass spectrometry. The method was validated at 0.1 µg/L and 1.0 µg/L according to SANCO/825/00 rev. 8.1. Residues of chlorate in drinking water were analysed by direct injection into the HPLC-MS/MS system. Detection was carried out by an ionspray tandem mass spectrometer in SRM mode. Analytical method for residues in surface water **Residue definition: HClO/ClO^- Not required.** Environmental exposure is expected via the facility drain into the STP or via the treated effluent directly into the surface water, but rapid degradation occurs with organic matter therein. Rapid degradation occurs also with the organic matter in surface water ($DT50_{surface\ water}$ = 56 min at environmental temperature).									

Analytical methods for animal and human body fluids and tissues

Water quality – Determination of free and total chlorine Part 2 Colorimetric method using DPD for routine control purposes 15.10.85

Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Residue definition: $HClO/ClO^-$ Not required. Hypochlorous acid/ hypochlorite anion are oxidizing agents and degrade rapidly with organic matter. Besides, due to corrosive properties, systemic toxicity would be secondary to local effects. Nevertheless, in case of an accidental release of chlorine, the analytical methods available for the monitoring of chlorine in workplace air are meaningful for monitoring human exposure. (CAR Active chlorine released from sodium hypochlorite; January 2017)									

Analytical methods for monitoring of active substances and residues in food and feeding stuff									
Analyte (type of analyte e.g. active substance)	Analytical method	Fortification range / Number of measurements	Linearity	Specificity	Recovery rate (%)			Limit of quantification (LOQ) or other limits	Reference
					Range	Mean	RSD		
Reference is made to the CAR of Active chlorine released from sodium hypochlorite; January 2017: Residue definition: $HClO/ClO^-$ and relevant metabolite chlorate ClO_3^- Not required for PT2.									

Conclusion on the methods for detection and identification of the product
The provided titration method is adequately validated for determination of the content of the active substances in the biocidal product ARIEL Chlorine Professional System 5. The provided IC method is adequately validated for determination of the content of the relevant impurity chlorate in the biocidal product ARIEL Chlorine Professional System 5. Analytical methods for detection are available in the active substance dossier (January 2017).

2.2.5 Efficacy against target organisms

2.2.5.1 Function (organisms to be controlled) and field of use (products/objects to be protected) for the product *ARIEL Chlorine Professional System 5*

Main group 01: DISINFECTANTS

Product type : **PT2** (Disinfectants and algaecides not intended for direct applications to humans or animals)

The product **ARIEL Chlorine Professional System 5** contains 9.5% sodium hypochlorite (N°CAS 7681-52-9) (equivalent to 9.05% active chlorine) as active substance approved for the product type 2 from 01/01/2019 (for PT1 to PT5).

The product **ARIEL Chlorine Professional System 5** is a liquid soluble concentrate, intended to be used by professional users in professional washing machines via closed automatic dosing programs. The product **ARIEL Chlorine Professional System 5** is intended to be used only for disinfection of clean laundry i.e. after the washing/cleaning step delivered by using ***Ariel S1 Actilift detergent*** (commercial name of ***Ariel System S1***), the water is drained/extracted. After a refill step with fresh water, the BP is added for the 1st rinse bath.

The product is used in nonhealthcare areas, such as restaurants and hotels. In addition, the product is also used in care homes (residential facilities for elderly people), but not in hospitals.

According to the Applicant, the product **ARIEL Chlorine Professional System 5** should be used only in combination with P&G Professional dosing equipment. This statement should be added on the product label.

The computer-controlled dosage equipment uses carefully designed blends of several products that are pumped into the machine at specific dosages and specific timings to create wash conditions that provide optimum cleaning/disinfection whilst caring for fabrics.

Please see Confidential Annex for additional information about the use of the product.

For PT2 applications, the "organisms to be protected" is human beings from pathogenic organisms which may result in spreading of contagious disease due to contact with contaminated surfaces (textile) or contaminated water.

2.2.5.2 Mode of action and effects on target organisms, including unacceptable suffering

Mode of action

The chlorination and the oxidation reaction of hypochlorous acid are unspecific. Hypochlorous acid reacts by chlorination of nitrogen within amino acids. This results in:

- A destructive permeability change in bacterial walls and leakage of cell contents
- Inactivation of enzymes essential to cell metabolism
- Destruction of virus capsids

At low concentrations in water hypochlorite is able to inhibit bacterial growth. In this case the proteins of the membrane are partly destroyed, and the bacteria are not able to multiply.

Sodium hypochlorite (NaClO) hydrolyses to hypochlorous acid (HClO) according to:

$NaClO + H_2O <-> Na+ + HClO + OH—$.

Hypochlorous acid participates in the following equilibrium with chlorine (Cl_2):

$HClO + H_3O+ + Cl— <-> Cl_2 + 2\ H_2O$.

The ratio of Cl_2/HClO/ClO— is pH and temperature dependent. Hypochlorous acid (HClO) is far more reactive than hypochlorite anion (ClO—). HClO and ClO— are in equilibrium at pH 7.5.

Time delay

The time delay or contact time needed for sufficient efficacy depends on the hypochlorite concentration, the organic matter content, pH and temperature of the disinfectant mixture and on the tolerance of the species to be controlled.

2.2.5.3 Efficacy data

<table>
<tr><th colspan="5">Experimental data on the efficacy of the biocidal products against target organisms</th></tr>
<tr><td colspan="5"></td></tr>
<tr><th>Test product</th><th>Function &
Test organism(s)</th><th>Test method / Test system / concentrations applied / exposure time</th><th>Test results : effects</th><th>Reference & R.I.</th></tr>
<tr><td>Professional Ace C (fresh product)

8.9% Sodium Hypochlorite</td><td>Bactericidal activity

Enterococcus hirae
E.coli
Pseudomonas aeruginosa
Staphylococcus aureus</td><td>EN 1276 (2007)
Quantitative suspension test

• Temperature : +40 ± 1°C
• Contact time :
10 – 15 - 20 min
• Concentrations tested :
1 – 2 – 3 mL/L
• I.S. : 0.3g/L BSA (clean conditions)</td><td>Bactericidal activity
at 1 mL/L in 10 min at +40°C in clean conditions.

<table><tr><th></th><th colspan="3">Log Reduction</th></tr><tr><th></th><th>1 mL/L</th><th>2 mL/L</th><th>3 mL/L</th></tr><tr><td>pH</td><td>8.31</td><td>8.43</td><td>8.63</td></tr><tr><td>S. aureus</td><td colspan="3">> 5.09</td></tr><tr><td>E. hirae</td><td colspan="3">> 5.14</td></tr><tr><td>E. coli</td><td colspan="3">> 5.04</td></tr><tr><td>P. aeruginosa</td><td colspan="3">> 5.24</td></tr></table></td><td>Doc. “6.7 Efficacy data to support these claims_EN1276_40°C_10min_0,3gL bovine albumin_clean_P2S1”

R.I. 2
non-effective concentration not tested</td></tr>
<tr><td>Professional Ace C

8.9% Sodium Hypochlorite</td><td>Bactericidal activity

Enterococcus faecium-Vancomycin resistent

Staphylococcus aureus - Vancomycin resistant

Staphylococcus aureus - MRSA</td><td>EN 1276 (2007)
Quantitative suspension test

• Temperature : +40 ± 1°C
• Contact time :
10 – 15 - 20 min
• Concentrations tested :
1 – 2 – 3 mL/L
• I.S. : 0.3g/L BSA (clean conditions)</td><td>Active against Enterococcus faecium-Vancomycin resistant, Staphylococcus aureus - Vancomycin resistant and Staphylococcus aureus - MRSA
at 1 mL/L in 10 min at +40°C in clean conditions.

<table><tr><th></th><th colspan="3">Log Reduction</th></tr><tr><th></th><th>1 mL/L</th><th>2 mL/L</th><th>3 mL/L</th></tr><tr><td>pH</td><td>7.96</td><td>8.27</td><td>8.43</td></tr><tr><td>E. faecium VR</td><td colspan="3">> 5.03</td></tr><tr><td>S. aureus VR</td><td colspan="3">> 5.24</td></tr><tr><td>S. aureus MRSA</td><td colspan="3">> 5.54</td></tr></table></td><td>Doc. « 6.7 Efficacy data to support these claims_EN1276_40°C_10min_0,3gL bovine albumin_clean_P2S1_resistant bacteria»

R.I. 2
non-effective concentration not tested</td></tr>
</table>

<table>
<tr>
<td>ARIEL Chlorine Professional System 5
5.7% Sodium Hypochlorite
(12 months old aged sample)</td>
<td>Bactericidal activity

Enterococcus hirae
E.coli
Pseudomonas aeruginosa
Staphylococcus aureus
+ MRSA</td>
<td>EN 1276 (2010)
Quantitative suspension test

• Temperature : +40 ± 1°C
• Contact time : 10 min
• Concentrations tested : 0.5 - 1 – 2 mL/L
• I.S. : 0.3g/L BSA (clean conditions)</td>
<td>Bactericidal activity (including MRSA)
at 2 mL/L in 10 min at +40°C in clean conditions.

<table>
<tr><th></th><th colspan="3">Log Reduction</th></tr>
<tr><th></th><th>0.5 mL/L</th><th>1 mL/L</th><th>2 mL/L</th></tr>
<tr><td>pH</td><td>8.04</td><td>8.36</td><td>8.93</td></tr>
<tr><td>E. hirae</td><td>< 3.77</td><td>< 3.77</td><td>> 5.14</td></tr>
<tr><td>E. coli</td><td>< 3.89</td><td>> 5.26</td><td>> 5.26</td></tr>
<tr><td>S. aureus MRSA</td><td>< 3.99</td><td>< 3.99</td><td>> 5.36</td></tr>
<tr><td>S. aureus</td><td>< 3.91</td><td>< 3.91</td><td>> 5.26</td></tr>
<tr><td>P. aeruginosa</td><td>< 3.88</td><td>> 5.25</td><td>> 5.25</td></tr>
</table>
</td>
<td>Doc. « S5 hygcen B21312 Dec 2017»

R.I. 1</td>
</tr>
<tr>
<td>Ariel System 5 White Wash Stain buster

8.08% Sodium Hypochlorite</td>
<td>Yeasticidal activity
Candida albicans</td>
<td>EN 1650 (2013)
Quantitative suspension test

• Temperature : +40 ± 1°C
• Contact time : 10 min
• Concentrations tested : 1 – 2 – 5 mL/L
• I.S. : 0.3g/L BSA (clean conditions)</td>
<td>Yeasticidal activity
at 1 mL/L in 10 min at +40°C in clean conditions.

<table>
<tr><th></th><th colspan="3">Log Reduction</th></tr>
<tr><th></th><th>1 mL/L</th><th>2 mL/L</th><th>5 mL/L</th></tr>
<tr><td>C. albicans</td><td colspan="3">> 4.26</td></tr>
</table>
</td>
<td>Doc. « PB2019-1428_SN 27705_EN 1650_140619»

R.I. 2
non-effective concentration not tested</td>
</tr>
<tr>
<td>Ariel System 5 White Wash Stain buster

5.9% Sodium Hypochlorite
(12 months old aged sample)</td>
<td>Bactericidal activity + Yeasticidal activity

Enterococcus hirae
E.coli K12
Pseudomonas aeruginosa
Staphylococcus aureus</td>
<td>EN 16616 (2015)
Quantitative carrier test

A two-step procedure
1) Pre-Wash /main Wash
with Ariel System S1 (liquid detergent)
2 mL/L – 10 min - + 40°C</td>
<td>

<table>
<tr><th></th><th colspan="3">Log Reduction</th></tr>
<tr><th></th><th>1+2</th><th>1 only</th><th>water</th></tr>
<tr><td>S. aureus</td><td>8.05</td><td>< 2.93</td><td>< 2.93</td></tr>
<tr><td>E. hirae</td><td>7.88</td><td>< 2.81</td><td>< 2.81</td></tr>
<tr><td>E. coli</td><td>7.76</td><td>1.51</td><td>1.29</td></tr>
</table>
</td>
<td>Doc. " PB2019-2302 + 2019-2485_28253_SN 28254_Ariel_EN 16616_101219”

R.I. 2
Deviation in methodology i.e. mandatory I.S. not tested (as duly decided & advised during</td>
</tr>
</table>

<table>
<tr>
<td>Documents provided by the Applicant "S5 aged product confirmation July 2020" & "S5 name and batch confirmation July 2020"</td>
<td>Candida albicans</td>
<td>2) Post-wash rinsing phase (after fleet drain)
with Ariel System S5 White Wash Stain buster
10 mL/L – 15 min - + 40°C

Liquor ratio : 1:5
<u>Ballast load</u> : 4 kg blended fabric (35% cotton/65% Polyester)
<u>I.S.</u> : 3g BSA /kg load (dirty conditions)

- The carriers have been contaminated with blood and germ according to the norm. All three (germ carrier, wash load and soiling) have been introduced before water inlet starts. Therefore it was only the modification of the soiling …. instead of blood, it was used 3 g BSA per kg load (⇔ modified clean conditions)</td>
<td>
<table>
<tr><td>P. aeruginosa</td><td>8.51</td><td>< 1.22</td><td>< 1.22</td></tr>
<tr><td>C. albicans</td><td>7.33</td><td>< 2.06</td><td>< 2.06</td></tr>
</table>
According to the results of this test,
the product ARIEL Chlorine Professional System 5
(always used after the product Ariel System S1), is bactericidal & yeasticidal when used at 10 mL/L during 15 min at +40°C.
</td>
<td>the e-consultation & early WG discussion)</td>
</tr>
</table>

According to the document "*Declaration of identical composition System 5*" provided by the Applicant, they do confirm that the compositions of the following products mentioned in the various reports are identical:

- Professional Ace C
- ARIEL S 5 white wash Stainbuster
- Ariel Professional System 5

Reason for differences in naming is due to the fact that this product has been marketed under different names in the past.

Comment from the Applicant (6/11/2020) to justify the choice of such soiling solution :
The applicant would like to refer to the TAB Efficacy point 9.1 Table 1 and also BPR Guidance Vol II section 5.4.2.10.2:

- TAB Efficacy point 9.1 Table 1: In case the disinfection is done in the last rinse, testing can be done under clean conditions. The following is also stated: *"EN 16616 describes dirty conditions only. When clean conditions are in line with the intended use testing can be done with a modified EN test with justified modifications."*
- BPR Guidance Vol II section 5.4.2.10.2: *"The interfering substance most appropriate for the in-use conditions should be used. For instance, blood for products used in the medical area and protein for products used in industry, institutional and domestic areas are recommended. The soiling on a domestic product for use in pre-soak (dirty clothes) will be very much higher than the soiling present for a post-wash rinse additive (clean clothes). For products used during pre-soak and wash, tests should be done under dirty conditions. For products used during post-wash rinse, tests should be done under clean conditions."*

The product ARIEL Chlorine Professional System 5 is used in the post-wash rinsing phase. According to the above mentioned guidance, testing under clean conditions is sufficient to demonstrate the efficacy of the products and can be done with a modified EN test. Currently, the product is mainly used in non-healthcare settings. Therefore, and since no clean conditions are described in EN 16616, the test has been done with 3 g BSA as modified clean condition since this is the most appropriate interfering substance for industry, institutional and domestic areas.

In addition, as already indicated previously, in case the eCA does not accept the argumentation, the applicant is willing to drop the claim for healthcare use and only claim non-healthcare use. In that case, the use of 3g BSA as soiling can be justified based on what is stated in the BPR guidance ("*… protein for products used in industry, institutional and domestic areas are recommended"*).

Conclusion on the efficacy of the product
According to the results of the efficacy tests provided by the Applicant, the product ***ARIEL Chlorine Professional System 5*** (always used after the product Ariel System S1), is bactericidal & yeasticidal when used at 10 mL/L during 15 min at +40°C up to 12 months (stored in a blue HDPE canister at room temperature). The product **ARIEL Chlorine Professional System 5** is a liquid soluble concentrate, intended to be used by professional users in professional washing machines via closed automatic dosing programs. The product **ARIEL Chlorine Professional System 5** is intended to be used only for disinfection of CLEAN laundry i.e. after the washing/cleaning step delivered by using ***Ariel S1 Actilift detergent*** (commercial name of ***Ariel System S1***), the water is drained/extracted. After a refill step with fresh water, the BP is added for the 1st rinse bath. The product is used in nonhealthcare areas, such as restaurants and hotels. In addition, the product is also used in care homes (residential facilities for elderly people), but not in hospitals. According to the Applicant, the product **ARIEL Chlorine Professional System 5** should be used only in combination with P&G Professional dosing equipment. This statement should be added on the product label.

2.2.5.4 Occurrence of resistance and resistance management

Although different species vary in their sensitivity to active chlorine, development of acquired resistance is not expected since its multiple molecular sites of attack on the surface and within the microbial cells. Active chlorine is in fact regarded by experts [see IFH (International Scientific Forum on Home Hygiene) review October 2003 and Submission to SCENIHR, February 2008)] as one of the biocides where acquired resistance is least likely to develop. For the same reasons cross-resistance is not to be expected, nor has it been observed. Despite its use for almost a century in purifying drinking water, where very low (sub-ppm) concentrations are continuously maintained, the development of acquired resistance has not been observed.

Adaptation of organisms to hypochlorite can be determined by comparison of the Minimum Inhibitory Concentration (MIC) but this is not relevant in practice as the actual use concentrations are much higher and thus a sufficient margin of safety is provided.

2.2.5.5 Known limitations

The activity of hypochlorite ion can be reduced by the presence of organic load and in general by the presence of particles.

Do not bring the product in contact with acids; may release toxic gas.
Do not store the product in metal containers (metal corrosive).

2.2.5.6 Relevant information if the product is intended to be authorised for use with other biocidal product(s)

This biocidal product is not intended to be used in combination with other biocidal products.

2.2.6 Risk assessment for human health

No toxicological test data are available on the biocidal product ARIEL Chlorine Professional System 5. For all endpoints, effects on human health are derived from information on the individual components, using CLP mixture rules for product classification.

Active substance effects and critical concentrations are described in the sodium hypochlorite assessment report (CAR)[4]. According to the CAR, adverse effects of the active substance in humans are limited to local effects at the site of first contact and primary health hazards are associated with potential exposure to skin and eyes.

In the absence of clear systemic adverse effects, the risk assessment for the active substance is mainly focused on local effects and not on systemic exposure.

Sodium chlorate can be formed during storage (measured concentration after 12 months stability testing is 1.934% chlorate). The chlorate have mainly systemic effects via food (ADI and ArfD), the exposure via oral exposure routes is not expected because this product is not intended to treat surfaces that may come into contact with food (PT2).

2.2.6.1 Assessment of effects on Human Health

Skin corrosion and irritation

Conclusion used in Risk Assessment – Skin corrosion and irritation	
Value/conclusion	The product is classified as skin corrosive
Justification for the value/conclusion	According to the CLP regulation the biocidal product is classified as skin corr.1B (9.05 % active chlorine > 5% GCL).
Classification of the product according to CLP and DSD	Skin corrosion Cat. 1B (H314)

[4] Assessment report Active chlorine released from sodium hypochlorite, PT2, January 2017, eCA: Italy

Eye irritation

Conclusion used in Risk Assessment – Eye irritation	
Value/conclusion	The product is classified as serious eye damaging
Justification for the value/conclusion	According to the CLP regulation the biocidal product is classified as skin corr.1B (9.05 % active chlorine > 5% GCL). Based on the classification as skin corrosive, the product is by default also classified as eye damaging. The available information indicates that the product should be classified as serious eye damage.
Classification of the product according to CLP and DSD	Eye damage Cat. 1 (H318)

Respiratory tract irritation

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to respiratory tract irritation according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for respiratory tract irritation, the product is also not classified.

Skin sensitization

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to skin sensitization according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for skin sensitization, the product is also not classified.

Respiratory sensitization (ADS)

Data waiving	
Information requirement	Not relevant

Justification	Sodium hypochlorite is not classified with respect to respiratory sensitization according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for respiratory sensitization, the product is also not classified.

Acute toxicity

Acute toxicity by oral route

Conclusion used in Risk Assessment – Acute toxicity by oral route	
Value/conclusion	Not classified
Justification for the value/conclusion	The formation of sodium chlorate during storage of the product may increase product toxicity. There is an ongoing processing of the new CLH proposal for sodium chlorate (https://echa.europa.eu/documents/10162/13626/clh_rep_sodium_chlorate_en.pdf/c4184cf9-96a7-e363-055c-52b0f8f492c8) submitted by SE in April 2020 for upgrading its CLH from Acute Tox. 4 (oral) to Acute Tox. 3 (oral), and setting SCL at ATE = 100 mg/kg bw (oral) . According to the CLP regulation, taking into account that the max chlorate generated at the end of storage (12 months) is equal to 1.934% w/w and ATE 100 mg/kg bw (oral).We obtained an ATE mix = 5170, the product isn't classified as acute tox oral. Therefore the degradation of sodium hypochlorite to sodium chlorate doesn't lead to the changing of product classification.
Classification of the product according to CLP and DSD	Not classified

Data waiving	
Information requirement	Not relevant for sodium hypochlorite.
Justification	Sodium hypochlorite is not classified with respect to acute oral toxicity according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for acute oral toxicity, the product is also not classified.

Acute toxicity by inhalation

Data waiving	
Information requirement	Not relevant

Justification	Sodium hypochlorite is not classified with respect to acute inhalation toxicity according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for acute inhalation toxicity, the product is also not classified.

Acute toxicity by dermal route

Data waiving	
Information requirement	Not relevant
Justification	Sodium hypochlorite is not classified with respect to acute dermal toxicity according to Regulation (EC) No 1272/2008 (CLP). Classification is based upon CLP mixture rules. Since none of the components is classified for acute dermal toxicity, the product is also not classified.

Information on dermal absorption

Value(s) used in the Risk Assessment – Dermal absorption	
Substance	Active chlorine
Value(s)*	Not applicable
Justification for the selected value(s)	The following text, included in the assessment report in the LoEP: BPC TOX-WGIII-2016, agreed that human health effects are primarily due to the local mode of action of sodium hypochlorite (and related chlorine species) and potential systemic effects are secondary to its direct irritating reactivity. Moreover, regarding dermal exposure, the potential of hypochlorite solutions to penetrate the skin is low given its reactivity to proteinaceous material at the site of first contact. Consequently, dermal absorption of chlorine is not relevant

Available toxicological data relating to non-active substance(s) (i.e. *substance(s) of concern)*

/

Available toxicological data relating to a mixture

/

Other

Assessment of disinfection by-products (DBPs)

Please keep in mind that the available guidance (*Guidance on the BPR:Volume V Disinfection By-Products, Version 1.0 January 2017*) offers no methodology for assessing the risk of exposure for human health to DBPs from the use of the biocidal product for laundry disinfection.

As the product is only used for textile disinfection under clean conditions, in the post-wash rinsing phase, allows to reduce the risk of contact with organic material, therefore the formation of DBP should be reduced.

Knowing that the disinfection step with S5 (biocidal product) is followed by 1-2 rinse and drain phases and finally an extraction by spin.

The exposure to DBPs could be low according to the HERA, Guidance Document Methodology (2005).

Please find in the confidential annex the available data about DBP formed during laundry disinfection.

Food and feeding stuff studies

As the product is only used in closed systems for textile disinfection (PT2), no contact with food or feed areas is expected.

2.2.6.2 Exposure assessment

Identification of main paths of human exposure towards active substance(s) and substances of concern from its use in biocidal product

Only local exposure for the risk assessment is performed for all relevant routes of exposure (i.e. oral, dermal, inhalation) which is considered to also cover the risk resulting from potential systemic effects.

Dermal exposure: For the dermal route of exposure, a semi-quantitative (Tier-1) assessment, and if required (i.e. in case the dermal NOAEC is exceeded in Tier-1), a qualitative (Tier-2) assessment is performed.

Oral exposure: Not relevant, not oral exposure is expected.

Inhalation exposure: For the inhalation route of exposure, a quantitative assessment (Tier-1 and Tier-2) is performed. Exposure towards aerosol (NaOCl as avCl) and vapour (HClO as avCl) is conceivable.

Summary table: relevant paths of human exposure							
Exposure path	**Primary (direct) exposure**			**Secondary (indirect) exposure**			
	Industrial use	**Professional use**	**Non-professional use**	**Industrial use**	**Professional use**	**General public**	**Via food**
Inhalation	n.a.	n.a.	n.a.	n.a.	yes	no	n.a.
Dermal	n.a.	yes	n.a.	n.a.	yes	yes	n.a.
Oral	n.a.	no	n.a.	n.a.	no	no	no

List of scenarios

Summary table: scenarios			
Scenario number	**Scenario** (e.g. mixing/ loading)	**Primary or secondary exposure** **Description of scenario**	**Exposed group** (e.g. professionals, non-professionals, bystanders)
1.	**Mixing and loading – automated system**	Primary exposure. The product is loaded and diluted into the system by automated pumping from the packaging. The user (de)connects (this step consists of unscrewing the closure of the canister, introducing a tube that feeds to the machine, and again closing the canister's screw cap.) the containers to the pumping system or (de)connects the transfer lines.	Professional
-	**Application – textile disinfection (washing machine)**	Not relevant exposure. The washing process takes place in a closed system.	-
2.	**Post-application - Maintenance**	Secondary exposure. Maintenance of dosing system (e.g. repair broken dosing system or washing machine)	Professional
-	**Post-application - Empty containers**	As only minor amounts remain in the containers, exposure to sodium hypochlorite from empty containers is negligible, and thus considered not relevant.	Professional
-	**Indirect exposure - bystanders**	Secondary exposure. The exposure of bystanders present in the room during connecting or disconnecting of canister is very low (this task takes only few minutes by day). We can consider the exposure during this task is negligible.	General public
3.	**Indirect exposure – Wearing treated laundry**	Secondary exposure The people can also be exposed (dermal route) following use of the biocidal product, i.e. people can be exposed when wearing disinfected laundry. Regarding DBP risk assessment, see section "*Assessment of disinfection by-products (DBPs)*"	General public

Industrial exposure

The product "ARIEL Chlorine Professional System 5" is intended to be used by the professional users.

Professional exposure

Scenario [1]- Mixing and loading – automated system:

Semi-quantitative risk assessment – dermal route:

The local exposure to the concentrated biocidal product is upper than the $NOAEC_{dermal}$ (1% avCl), so a local qualitative risk assessment should be performed (tier 2).

Quantitative risk assessment – Inhalation route:

The exposure during connecting or disconnecting of canister is very low (this task takes only few minutes by day). We can consider the exposure during this task is negligible.

Calculations for Scenario [1]

Summary table: estimated of local exposure from professional uses				
Task	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Mixing & loading	1/no PPE	n.g.	9.05	n.r.

Further information and considerations on scenario [1]

/

Scenario [2] – Post application – Maintenance of machines:

Dermal and inhalation exposure can occur during maintenance of machines: repair of broken washing machine (contact to the in-use dilution, 104.3 mg/L of AC) and repair of broken dosing system (contact to the concentrate product). The relevant approach consists to consider the worst case exposure which is the maintenance of dosing system.

Semi-quantitative risk assessment – dermal route:

Repair broken washing machine: The local exposure to the in-use solution (0.104 % AC) is lower than the $NOAEC_{dermal}$ (1% avCl), so a local qualitative risk assessment shouldn't be performed.

Repair broken dosing system: The local exposure to the concentrated biocidal product (9.05% AC) is upper than the $NOAEC_{dermal}$ (1% avCl), so a local qualitative risk assessment should be performed.

Quantitative risk assessment - Inhalation route:

Description of Scenario [2]		
Secondary exposure: Inhalation exposure can occur during maintenance of the dosing system (contact to the concentrated product). The product "ARIEL Chlorine Professional System 55" is an alkaline solution with pH >10, at this pH, the equilibrium is shifted to OCl. Which does not evaporate, while no significant amount of volatile HOCl is present. Inhalation exposure to aerosols is calculated by using the Mixing and loading model 7 from the Technical Notes for Guidance (TNsG 2002, p.142, following HEEG opinion 1, 2008) according to the CAR of active substance (PT02).		
	Parameters	Value
Tier 1	Weight fraction compounds - Active Chlorine	9.5% sodium hypochlorite (9.05% active chlorine)
	Indicative value inhalation (aerosol) exposure	0.94 mg/m^3
	Body weight	60 kg (adult) HEAdhoc recommendation 14
	Inhale absorption value (%)	100 %

Calculations for Scenario [2]

See calculations in Annex 3.2 (table 2.)

Summary table: estimated of local exposure from professional uses				
Task	**Tier/PPE**	**Local inhalation exposure** [mg avCl/m^3]	**Local dermal exposure** [concentration, % avCl]	**Local oral exposure** [concentration, % avCl]
Maintenance of dosing system	1/no PPE	0.085	9.05	n.r.

Further information and considerations on scenario [2]

/

Combined scenarios

Not relevant

Non-professional exposure

The product "ARIEL Chlorine Professional System 5" is intended to be used by the professional users.

Exposure of the general public

Scenario [3] – Indirect exposure – General public wearing disinfected laundry

The people can be exposed by dermal route when wearing treated laundry.

Due to the high reactivity of chlorine species, residues on surfaces degrade very rapidly (decomposition to physiological sodium and chloride). However if we postulate that the active substance present in the laundry will not decompose (worst case).

According to the HERA, Guidance Document Methodology (2005):

- product deposit on clothes:5%
- product transfer from pullover to skin: 1%

Weight fraction compounds (active chlorine): 9.05%
Application rate: 10 ml/l or 1% of product

Calculations for Scenario [3]

EXP: 9.05% × 1% × 5% × 1% = 0.00004525 %

Taking into account rinsing, draining phases and finally an extraction by spin which are foreseen after laundry disinfection, the amount of active chlorine transfer from clothes to skin will be negligible.

Combined scenarios

Not relevant

Monitoring data

/

Dietary exposure

The BPC APCP WGII-2016 concluded that chlorate residues may still be relevant as chlorate is considered a stable metabolite. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage (relevant impurities, threshold ≥ 5.4% for more information see the CAR of active substance). Thus, chlorate may represent a worst-case for NaOCl.

The BPC TOX working group (WGII-2016) agreed that exposure via food should be assessed during active substance approval so this is available at product authorisation.

In the BPC TOX working group (WGIII-2016) it was finally discussed that only chlorate is relevant for the dietary risk assessment. The product "ARIEL Chlorine Professional System 5" is intended to be used as PT2 so no food contact is expected.

Estimating Livestock Exposure to Active Substances used in Biocidal Products

Not relevant

Estimating transfer of biocidal active substances into foods as a result of professional and/or industrial application(s)

Not relevant

Exposure associated with production, formulation and disposal of the biocidal product

/

Aggregated exposure

/

Summary of exposure assessment

Scenario number	Exposed group (e.g. professionals, general publics, bystanders)	Local oral exposure [concentration, % avCl]	Local dermal exposure [concentration, % avCl]	Local inhalation exposure [mg avCl/m3]		
				Aerosol (NaOCl as avCl)	Vapour (HClO as avCl)	Total (avCl)
1.	professionals	n.r.	9.05 % (no PPE)	negligible	negligible	negligible
2.	professionals	n.r.	9.05 % (no PPE)	0.085 (no RPE)	negligible	0.085 (no RPE)
3.	general public	n.r.	negligible	negligible	negligible	negligible

2.2.6.3 Risk characterisation for human health

Reference values to be used in Risk Characterisation[5]

Reference	Study	Safety factor	Value
$NOAEC_{dermal}$	Human (dermatitis patients) 48 h-patch test study	1	1% avCl
$NOAEC_{oral}$	rat 90-d subchronic repeated dose oral (drinking water) study rat 104-wks chronic repeated dose oral (drinking water) study	1	0.1% avCl
$NOAEC_{inhalation\ (chlorine)}$	Monkey 52-wks subchronic repeated dose inhalation study human volunteer single dose inhalation study (4-8 h)	3.2	1.5 mg avCl/m³

[5] https://echa.europa.eu/documents/10162/a5a4a737-ae9d-ca03-c24e-cf573490fa2a

	human volunteer repeated dose inhalation study (3 d, 6 h/d)		
$AEC_{inhalation\ (NaOCl)}$	No repeated dose inhalation toxicity study on NaOCl is available. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an $AEC_{inhalation}$ based on chlorine data (NOAEC= 1.5 mg avCl/m³)	-	0.5 mg avCl/m³
$AEC_{inhalation\ (HClO)}$	No repeated dose inhalation toxicity study on HClO is available since HClO does not exist as such but is only formed in aqueous solutions of chlorine. In the absence of data, the BPC TOX-WGIII-2016 agreed to derive an $AEC_{inhalation}$ based on chlorine data (NOAEC= 1.5 mg avCl/m³)	-	0.5 mg avCl/m³
ADI	A tolerable daily intake (TDI) of 3 µg chlorate/kg body weight (b.w.) was set by read-across from a TDI of 0.3 µg/kg b.w. derived for this effect for perchlorate, multiplied by a factor of 10 to account for the lower potency of chlorate.	-	3 µg chlorate/kg b.w./d
ArfD	An acute reference dose (ARfD) of 36 µg chlorate/kg b.w. was derived from a no-observed-effect-level for chlorate in a controlled clinical study.	-	36 µg chlorate/kg b.w./d

Maximum residue limits or equivalent

MRLs or other relevant reference values	Reference	Relevant commodities	Value
NaOCl	-	Not relevant	-
Chlorate	WHO	Drinking water	0.7 mg/L[6]
Chlorate	EU commission	Drinking water	0.25 to 0.7 mg/L[7]
Chlorate	EU commission	Food	0.05 mg/kg[8] (lowest value)

Specific reference value for groundwater

/

Risk for industrial users

The product "ARIEL Chlorine Professional System 5" is intended to be used by professional users.

Risk for professional users

Systemic effects

Not relevant only local effects is expected.

Local effects

Only local exposure is performed for relevant routes of exposure (i.e. dermal, inhalation).

Inhalation:

[6] 2017 WHO Guidelines for Drinking Water Quality: First Addendum to the Fourth Edition

[7] DIRECTIVE (EU) 2020/2184 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2020

[8] COMMISSION REGULATION (EU) 2020/749 of 4 June 2020 amending Annex III to Regulation (EC) No 396/2005 of the European Parliament and of the Council as regards maximum residue levels for chlorate in or on certain products

Scenario	Tier/PPE	AEC (mg/m³)	Estimated exposure concentration (mg/m³)		Ratio (%)	Acceptable (yes/no)
2	1/No RPE	0.5	Maintenance of dosing system	0.085	17	Yes

Dermal:

Scenario	Tier/PPE	NOAEC-dermal (%)	Estimated exposure concentration (%)		Ratio (%)	Acceptable (yes/no)
1	1/No PPE	1	9.05		905	No
2	1/No PPE	1	Maintenance of dosing system	9.05	905	No

Qualitative risk assessment:

Scenario [1]- Mixing and loading – automated system:

Hazard			Exposure							
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)**
High	Skin Corr 1 (H314, covering the classification H318)	-	2	Professional users	M&L: Connecting containers containing the biocidal product to automated dosing system (9.05 % avCl)	Skin and Eyes	M&L: few minutes per day	9.05 % avCl (splashes, hand to eyes transfer)	**Organisation** • Training for staff on good practice • Procedures and training for emergency decontamination and disposal • Good standard of personal hygiene	No uncertanties are expected, because the biocidal product will be used by (trained) professionals only.

									RMM Labelling: • Labelling according to CLP Formulation: • Product formulation which reduces e.g. splashes **PPE** Hand protection: Wear protective chemical resistant gloves during product handling phase (EN374). Eye protection: The use of eye protection (EN166) during handling of the product is mandatory. Body protection:	

									A protective coverall (to be specified by the authorisation holder within the product information).	

Scenario [2] – Post application – Maintenance of machine:

Hazard			**Exposure**							
Hazard Category	**Effects in terms of C&L**	**Additional relevant hazard information**	**PT**	**Who is exposed?**	**Tasks, uses, processes**	**Potential exposure route**	**Frequency and duration of potential exposure**	**Potential degree of exposure**	**Relevant RMM&PPE**	**Uncertainties attached to conclusion may increase (↑) or decrease (↓) risk or both (↑↓)**

High	Skin Corr 1 (H314, covering the classification H318)	-	2	Professional users	<u>Post-application:</u> Repair of broken dosing system; contact to concentrate (9.05 % avCl)	Skin and Eyes	<u>Post-application:</u> Maintenance as required	9.05 % avCl (splashes, hand to eyes transfer)	**Organisation** • Training for staff on good practice • Procedures and training for emergency decontamination and disposal • Good standard of personal hygiene **RMM** <u>Labelling:</u> • Labelling according to CLP <u>Formulation:</u> • Product form	No uncertanties are expected, because the biocidal product will be used by (trained) professionals only..

									ulation which reduces e.g. splashes **PPE** Hand protection: Wear protective chemical resistant gloves during product handling phase (EN374). Eye protection: The use of eye protection (EN166) during handling of the product is mandatory. Body protection: A protective coverall (to be specified by the authorisation holder within the product information).	

Conclusion
Taking into account of qualitative risk assessment, we conclude that the risk is acceptable for the professional users through the use of PPE.

During handling product and during the maintenance of machines (repair broken dosing system): - Wear protective chemical resistant gloves (EN374). - Wear eyes protection (EN166). - - Wear protective coverall (to be specified by the authorization holder within the product information).

Risk for non-professional users

The product "ARIEL Chlorine Professional System 5" is intended to be used by the professional users.

Risk for the general public

Systemic effects

Not relevant only local effects are expected.

Local effects

Scenario	Tier/PPE	NOAEC-$_{dermal}$ (%)	Estimated exposure concentration (%)	Ratio (%)	Acceptable (yes/no)
3	1/No PPE	1	negligible	<100	yes

Qualitative assessment:

The risk of indirect exposure of the general public by inhalation during handling and/or maintenance processes is considered negligible.

Regarding exposure via laundry after disinfection is also judged as negligible according to the scenario [3].

Conclusion
There is no unacceptable risk for the general public.

Risk for consumers via residues in food

Not relevant.

Risk characterisation from combined exposure to several active substances or substances of concern within a biocidal product

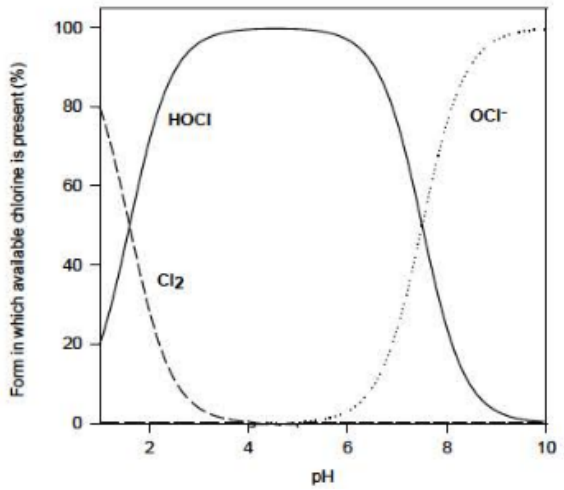
/

2.2.7 Risk assessment for animal health

No exposure risk has been identified for domestic animals.

2.2.8 Risk assessment for the environment

The active substance released from sodium hypochlorite, calcium chlorite or chlorine in water, is active chlorine. Hypochlorous acid (HClO) is in equilibrium with the hypochlorite ion (ClO^-) and chlorine (Cl_2). The equilibrium depends on the pH value: chlorine is available below pH 4, in the neutral pH range hypochlorous acid is predominant, and at pH values higher than 10, the only species present is the hypochlorite ion, see figure below.



The sum of these species [hypochlorite ion + hypochlorous acid + chlorine] is defined as active chlorine or available chlorine. For the chemical reactivity in aqueous solution with the same active chlorine concentrations and the same pH conditions, it is irrelevant whether active chlorine is generated from either chlorine gas, calcium hypochlorite or sodium hypochlorite. Therefore, all studies investigating hypochlorite aqueous solutions can be used for evaluation and assessment of active chlorine released from any of the three substances.

The product ARIEL Chlorine Professional System 5 is a soluble concentrate disinfectant containing 9.5% of sodium hypochlorite corresponding to 9.05% of active chlorine released from sodium hypochlorite (CAS No.7681-52-9). No substances of concern for the environment have been identified.

During the ENV WG-I-2020 several conclusions were taken regarding the harmonisation of the assessment of the products containing chlorine substances:

(1) On the assessment of the active substance:

"*It was agreed that for releases via STP and direct release to soil a qualitative assessment for the active substance is sufficient due to the high reactivity with organic matter. Uses resulting in a direct release to surface water however should be assessed quantitatively.*"

The use of the product ARIEL Chlorine Professional System 5, when used as described in the authorised use section of this product assessment report, won't lead to a direct release to the surface water compartment (See "Fate and distribution in exposed environmental compartments" below). Therefore, a qualitative assessment for the active substance has been performed. See section 2.2.8.3 for further details.

(2) On the assessment of the Disinfection by-products (DBPs):

As indicated in the Assessment Report of Sodium Hypochlorite, an assessment of disinfection by-products (DBPs) should be done at product authorisation stage. The ENV-WG-I-2020 took the following conclusion : "*It was agreed that for the time being the information provided by the applicants in their dossiers on DBPs of all ongoing authorisation applications should be only summarized and no conclusion should be drawn referring to the current lack of guidance. In fact, all the participants agreed that the current 'guidance' covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.*"

See section 2.2.8.3 for further details.

(3) On the assessment of Chlorate as relevant impurity formed during the storage:

"*Chlorate is a by-product of the manufacturing process and can be formed during storage. It is also a disinfection by-product (DBP). Chlorate is considered as a relevant metabolite in drinking water. The discussion concerned only chlorate as an impurity (i.e., formed only during the storage) of products containing sodium/calcium hypochlorite. Generation of chlorate as a DBP was not considered under this discussion. The WG agreed that chlorate can be assessed qualitatively for all the environmental compartments […] [including] for groundwater."*

See section 2.2.8.3 for further details.

2.2.8.1 Effects assessment on the environment

Sodium Hypochlorite: Short- and long-term toxicity data from literature are available for fish, invertebrates, algae and micro-organisms, resulting from flow-through or static tests. Most tests with a static test design result in a factor of 100-500 higher endpoints (NOEC, LC_{50}) than studies performed according to a flow-through design. Due to very fast hypochlorite decay, a static test system is continuously exposed to the same hypochlorite concentration. When data from literature were considered not valid or incomplete for the risk assessment, new toxicity laboratory studies were performed and included in the CAR. TRC (total residual chlorine) is a measurement of both free and combined chlorine (such as chloramines). It is difficult to separate the contribution to toxicity of the FAC (free available chlorine) such as HClO/ClO- from that of the combined chlorine species. For studies where the percentage of FAC (free available chlorine) in TRC (total residual chlorine) was measured, the toxicity endpoints were expressed as FAC/L as well.

Chlorate: As explained at the beginning of the environmental assessment section, this assessment should be perfomed qualitatively for all compartments.

No agreed endpoints for Sodium Chlorate are available at European level for biocides. Nevertheless, some data can be collected in the REACH dossier of the substance.

Toxicity to microorganisms is expected to be low (NOEC ≥ 1000 mg/L).

Short-term as well as long-term aquatic toxicity tests show that Sodium Chlorate is not very toxic to aquatic organisms and is less toxic than Active Chlorine (No EC50 or NOEC value under 10 mg/L was obtained for Sodium Chlorate).

No tests on sediment organisms were performed due to fast dissipation under anaerobic conditions, low toxicity to invertebrates, logKow of -2.9 (estimated value) and the high water solubility (approx. 700 g/l sodium chlorate).

For the soil compartment the lowest endpoint obtained is a NOEC = 333 mg/kg soil dw.

Information relating to the ecotoxicity of the biocidal product which is sufficient to enable a decision to be made concerning the classification of the product is required

No studies have been conducted on the product ARIEL Chlorine Professional System 5. Effects are based on data on the active substance. The applied endpoints are taken from the CAR of sodium hypochlorite (2017) and summarised below.

PNEC	Lowest endpoint	AF	PNEC	Test/species
Free available chlorine (FAC)				
STP	NOEC: 41.1 mg/L[a]	10	4.11 mg FAC/L	Respiration inhibition test
fresh water	NOEC: 2.1 µg/L	50	0.042 FAC µg/L	Algae
sediment	-	-	0.045 µg FAC/kg wwt	Equilibrium partitioning from aquatic data using a theoretical K_{oc} of 13.22 L/kg. Calculated according to the Guidance part B, vol. IV.
Soil	-	-	0.015 µg FAC/kg wwt	
groundwater	Reference value for groundwater = 0.1 µg/L			
atmosphere	At environmental pH (6.5-8.5) half of the active chlorine is available as the involatile hypochlorite ion; half as hypochlorous acid with a Henry's law constant as 0.11 Pa m³/mol. Hence, the concentration in air will be very low and the air is not an environmental compartment of concern.			
Birds	No data available for birds and mammals as primary and secondary poisoning is not considered relevant (see paragraph 2.2.8.2)			
mammals				

FAC: Free available chorine, wwt: wet weight; bw: body weight; [a] endpoint is converted to standard soil

Sodium hypochlorite is classified as Aquatic Acute Cat. 1 with an M-factor of 10 and Aquatic Chronic Cat.1 with M-factor of 1 (harmonized CLP classification). Testing on the biocidal product does not need to be conducted as the product contains no other ingredients and classification is based upon the active substance. The product is classified as Aquatic acute 1 and Aquatic chronic 2.

No substances of concern for the environment were identified according to the BPR Guidance Vol IV, Environmental Parts B+C (2017).

Further Ecotoxicological studies

No further ecotoxicological studies have been conducted on active chlorine or the active chlorine releasing product supported in this document.

Data waiving	
Information requirement	Not relevant
Justification	There are valid data available on each of the components and synergistic effects between any of the components are not expected.

Effects on any other specific, non-target organisms (flora and fauna) believed to be at risk (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on other target organisms is needed on the basis of intended uses, data available on the active substance or risk assessment.

Supervised trials to assess risks to non-target organisms under field conditions

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	The product is not in the form of bait or granules.

Studies on acceptance by ingestion of the biocidal product by any non-target organisms thought to be at risk

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	The product is not in the form of bait or granules.

Secondary ecological effect e.g. when a large proportion of a specific habitat type is treated (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant

Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Foreseeable routes of entry into the environment on the basis of the use envisaged

Reference is made to the section 'Fate and distribution in exposed environmental compartments'.

Further studies on fate and behaviour in the environment (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Leaching behaviour (ADS)

The performance of a study on leaching (e.g. from treated surfaces) is neither applicable nor relevant for the intended use within PT2.

Testing for distribution and dissipation in soil (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in water and sediment (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

Testing for distribution and dissipation in air (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	No additional test on secondary ecological effect is needed on the basis of intended uses, data available on the active substance or risk assessment.

If the biocidal product is to be sprayed near to surface waters then an overspray study may be required to assess risks to aquatic organisms or plants under field conditions (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	The product ARIEL Chlorine Professional System 5 is not intended to be sprayed near to surface waters.

If the biocidal product is to be sprayed outside or if potential for large scale formation of dust is given then data on overspray behaviour may be required to assess risks to bees and non-target arthropods under field conditions (ADS)

No new data is available for the product ARIEL Chlorine Professional System 5.

Data waiving	
Information requirement	Not relevant
Justification	The product ARIEL Chlorine Professional System 5 is not intended to be sprayed.

2.2.8.2 Exposure assessment

General information

The PT 2 biocidal product ARIEL Chlorine Professional System 5 is used for Laundry disinfection (washing machine) in the post-wash rinsing phase, by (trained) professional users. No substances of concern for the environment have been identified.

During the ENV WG-I-2020 several conclusions were taken regarding the harmonisation of the assessment of the products containing chlorine substances:

➔ On the assessment of Chlorate as relevant impurity formed during the storage:

"Chlorate is a by-product of the manufacturing process and can be formed during storage. It is also a disinfection by-product (DBP). Chlorate is considered as a relevant metabolite in drinking water. The discussion concerned only chlorate as an impurity (i.e., formed only during the storage) of products containing sodium/calcium hypochlorite. Generation of chlorate as a DBP was not considered under this discussion. The WG agreed that chlorate can be assessed qualitatively for all the environmental compartments […] [including] for groundwater."

Emission estimation

Sodium hypochlorite: As indicated above, as the product is evaluated qualitatively, no calculation of the emission to the environment is necessary. See section 2.2.8.3 below for further details on the qualitative assessment.

Chlorate: The amount of Sodium Chlorate (CAS : 7775-09-9) formed during storage has been identified in the storage with the storage tests (see section 2.2.2 for further details) :

Storage stability test – **long term storage at ambient temperature**	FAO/WHO Manual, CropLife International Technical Monograph No. 17 CIPAC MT 75.3 CIPAC MT 191 (Validated methods; DNA4913) (key study)	9.5% NaOCl (theoretical) Test product: Ariel S5	<u>Active substance (m/m % av. chlorine)</u> T0: 8.9468% T3: 8.0790% T6: 6.7039% T9: 5.9819% (33% degradation) <u>Chlorate (w/w%)</u> T0: 0.321% T3: 1.059% T6: 1.391% T9: 1.767%	[redacted], 2019 DNA4911 (T0) [redacted], 2019 DNA4912 (T3-T9, interim report)

This shows that the amount of chlorates formed during the storage only reaching the environmental compartments should be relatively low.

Fate and distribution in exposed environmental compartments

The product ARIEL Chlorine Professional System 5 is used as PT2 textile disinfectant, in closed systems, with release automatically and directly to the STP via the sewer system after use. There is no direct release to surface water or to the soil compartment.

Identification of relevant receiving compartments based on the exposure pathway								
	Fresh-water	Freshwater sediment	Sea-water	Seawater sediment	STP	Air	Soil	Ground-water
Laundry disinfection	Yes (+)	Yes (+)	No	No	Yes (++)	Yes (++)	Yes (+)	Yes (+)

++ compartment directly exposed; + compartment indirectly exposed

Sodium Hypochlorite

Parameters regarding the fate and distribution in the environment			
Input	*Value*	*Unit*	*Remarks*
Molecular weight	52.5	g/mol	Hypochlorite ion
Melting point	0	°C	Estimated, the substance should be treated as a liquid at environmental temperature.
Boiling point	Not available	°C	
Vapour pressure (at 25°C)	276	Pa	Hypochlorite ion
Water solubility (at 25°C)	1.0E+05	mg/L	
Log Octanol/water partition coefficient	-0.87	-	
Organic carbon/water partition coefficient (Koc)	13.22	L/kg	
Henry's Law Constant (at 20 oC)	0.11	Pa/m3/mol	Hypochlorous acid, measured
Biodegradability	Not applicable to inorganic substances	[-]	Due to rapid decomposition in organic matter, the default value for readily degradable substances can be used for the degradation

			constant in the STP (1 h-1)
Rate constant for STP *[if measured data available]*	44.6	h-1 (at 15oC)	CAR NaOCl (2017); converted to 15°C
DT_{50} for biodegradation in sewer system	56	s (at 12oC)	CAR NaOCl (2017)
DT_{50} for biodegradation in surface water/sediment	56	min (at 12oC)	CAR NaOCl (2017)
DT50 – hydrolysis	No hydrolysable groups	h (at 12oC)	Very rapid degradation in water in the presence of organic matter
DT50 – photo degradation	Stable	h (at 12oC)	
DT_{50} for degradation in soil	56	s (at 12oC)	CAR NaOCl (2017)
DT_{50} for degradation in air	114.6	days	CAR NaOCl (2017) Calculated (Atkinson calculation, 24-hour day)

***** Hypochlorite ion. Source:

AR. Active chlorine released from sodium hypochlorite. Product-type 2(Food and feed area) . January 2017. IT

Calculated fate and distribution in the STP *(SIMPLE TREAT 4.0)*		
Compartment	Percentage [%]	
	Degradation rate = $1h^{-1}$	Degradation rate =$44.6h^{-1}$
Air	0.04107	0.02199
Water	8.003	0.3099
Primary settler	0.1194	0.1194
Surplus sludge	0.004165	0.0001798
Degraded in STP	91.83	99.55

Chlorate: A valid ready biodegradability test is not available since Sodium Chlorate is inorganic and acts as an electron acceptor like molecular oxygen[9]. Nevertheless, reduction of chlorate has been detected in terrestrial ecosystems, fresh water, marine environment, compost, and aquifers. These findings do demonstrate the wide distribution of chlorate-reducing micro-organisms and that chlorate is rapidly biodegradable.

[9] Malmqvist, A., Welander, T., & Gunnarsson, L. (1991). *Anaerobic growth of microorganisms with chlorate as an electron acceptor*. Applied and environmental microbiology

Logan, Bruce & Zhang, HS & Mulvaney, Peter & Milner, Michael & Head, Ian & Unz, Richard. (2001). *Kinetics of Perchlorate and Chlorate-Respiring Bacteria*. Applied and environmental microbiology.

Sodium Chlorate is not expected to degrade due to hydrolysis, and no data is available regarding photodegradation.

Sodium chlorate is highly soluble in water, is not expected to adsorb onto soil and does not evaporate. From these findings the environmental compartment in which sodium chlorate is expected to be present is water.

The high tendency of sodium chlorate to ionise and the very low log Kow (<-2.9) suggest that no significant bioaccumulation would occur.

Calculated PEC values

As indicated above, as the product is evaluated qualitatively, no calculation of the predicted environmental concentrations is necessary. See section 2.2.8.3 below for further details on the qualitative assessment.

Primary and secondary poisoning

Active chlorine does not bio-accumulate and does not concentrate in the food chain. The low BCF indicates that the risk for birds and mammals is low regarding secondary poisoning. Hence the product meets the standards for the risk to birds and mammals. Primary poisoning is not expected for the intended use.

2.2.8.3 Risk characterisation

As indicated above, the risk characterisation presented below is only qualitative :

Atmosphere

Sodium Hypochlorite: Hypochlorite might enter the atmosphere due to volatilisation from the STP. Exposure assessment in the AR showed emission to air via this pathway is negligible. Given the adsorption of hypochlorite to aerosol particles, the volatilisation from water into air and the adsorption of hypochlorite onto soil are very low, thus hypochlorite will remain in the aqueous phase and degrade very rapidly. Exposure to air is thus not considered. There are no indications that active chlorine contributes to depletion of the ozone layer as it is not listed as 'controlled substance' in Annex I of Regulation (EC) No 1005/2009 of the European Parliament.

Chlorate: Sodium Chlorate is highly soluble in water (> 696 000 to < 736 000 mg/L at 20 °C ; pH 4.49 to 8.70) and its vapour pressure is low (< 3.5E-07 Pa at 20°C). Therefore the emission to air is expected to be negligible and atmosphere is not a compartment of concern.

Conclusion
No unacceptable risk for the atmosphere compartment is expected.

Sewage treatment plant (STP)

Sodium Hypochlorite: The measured DT50 of the active substance in the sewer is equal to 56 seconds i.e. a degradation rate of 44.6 h^{-1}. This rapid degradation is allowed by the

high reactivity of the active substance with organic matter and the high amount of organic matter in the sewer. The residence time of the product in the sewer before entering the sewage treatment plant is considered to be 1 hour (Sodium Hypochlorite CAR doc IIB). Taking these data into account, we can estimate that the concentration of active substance in the effluent to which microorganisms are exposed in the STP will be very low. The same approach has been used for a quantitative evaluation in the assessment report of Sodium Hypochlorite showing that the concentrations of active substance are divided by approximately $1x10^{20}$.

The concentration of hypochlorite in the environment is modelled by Vandepitte and Schowanek* and is estimated to drop down to "zero" within the first minutes after release in the sewer.

**The kinetic model of Vandepitte and Schowanek (1997), Doc.No. 989-003, Doc. IIIA, Section A7.1.2, Active chlorine released from sodium hypochlorite. Product-type 2 (Food and feed area). January 2017. IT*

Chlorate: Given the low toxicity of Sodium Chlorate to microorganisms, the rapid biodegradation and the low emissions to the environment, no unacceptable risks are expected for the microorganisms of the STP.

Conclusion
No unacceptable risk for the aquatic micro-organisms of the STP is expected.

Aquatic compartment

Sodium Hypochlorite: According to the reasoning followed for the STP, since the concentration entering the STP should already be very low, the concentration of active substance reaching the surface water compartment is expected to be even lower.

The SimpleTreat v4.0 estimations show that 8.003% of the active substance will be released from the STP to surface water when taking into account a degradation rate of $1h^{-1}$ which is known to be overly conservative. With a degradation rate of $44,6h^{-1}$ only 0.3099% of the active substance is expected to be released to surface water.

The degradation of the active substance is be expected to be very rapid in the STP taking into account the high amount of organic substance and the long residence times. Indeed, into a standard STP the retention times are estimated to be : 2 h in the primary settler, 6.9 h in the activated sludge tank, 6 h in solid-liquids separator and 9.2 d for the sewage sludge in the aeration tank. (Sodium Hypochlorite CAR doc IIB).

The risk assessment for surface water in the Assessment Report of Sodium Hypochlorite takes only into account the degradation in the sewer, shows very low concentration of active substance in surface water and does not highlight any risk for this compartment.

This reasoning is also valid for freshwater sediment organisms.

Chlorate: Given the low toxicity of Sodium Chlorate to fresh water organisms, the rapid biodegradation, the low emissions to the environment (even negligible for sediment organisms due to the physchem properties of Sodium Chlorate) no unacceptable risks are expected for freshwater organisms.

There is no direct discharge to surface water during the use of this product, we considered therefore that the assessment of abstraction of drinking water from surface water (WG-I-

2020) is unnecessary for this product. In the context of this product, an extremely low quantity of chlorates (as relevant impurity) would end up in surface waters after passing through a STP. In the eventuality of abstraction of drinking water from surface water, the chlorate drinking water limit of 700 µg/L should be monitored.

Conclusion
No unacceptable risk for the organisms of the aquatic compartment is expected.

Terrestrial compartment

Sodium Hypochlorite: Given the fact that the concentration of active substance in the STP sludge is assumed to be near-zero, the exposure of terrestrial compartment via sludge application is expected to be negligible. Additionally, the DT50 of the active substance in soil is equal to 56 seconds. Therefore, the terrestrial compartment should not be of concerned.

Chlorate: Given the low toxicity of Sodium Chlorate to terrestrial organisms, the low emissions to the environment and the fact that Sodium Chlorate is mainly expected to be distributed to water (not in the STP sludge), no unacceptable risks are expected for terrestrial organisms due to sludge application on soil.

Conclusion
No unacceptable risk for the organisms of the terrestrial compartment is expected.

Groundwater

The hypochlorite concentration in the pore water of agricultural soil (after application of sewage sludge) is taken as an indication of potential groundwater levels. This is a worst-case assumption, because degradation in soil, transformation and dilution in deeper soil layers are not taken into account. Under real life conditions, it is very unlikely that any hypochlorite will reach the groundwater because hypochlorite rapidly degrades in sewage sludge and soil.

Conclusion
No unacceptable risk for the groundwater compartment is expected.

Primary and secondary poisoning

Primary poisoning

Sodium Hypochlorite & Chlorate: Primary poisoning is not expected to occur during normal use of the product. Primary poisoning is therefore considered to be not relevant.

Secondary poisoning

Sodium Hypochlorite: Active chlorine does not bioaccumulate or bioconcentrate due to its high water solubility and high reactivity. Secondary poisoning is not of concern.

Chlorate: Sodium Chlorate is not expected to bioaccumulate. Secondary poisoning is not of concern.

Conclusion
No unacceptable risk of primary or secondary poisoning trough the ingestion of contaminated terrestrial or aquatic animals is expected.

Mixture toxicity

Not relevant for this product since it contains only one active substance and no other substances of concern.

Assessment of disinfection-by-products (DBPs)

As explained at the beginning of the environmental assessment section, the assessment of DBPs cannot be performed for the time being due to the lack of guidance and agreed parameters.

Aggregated exposure (combined for relevant emission sources)

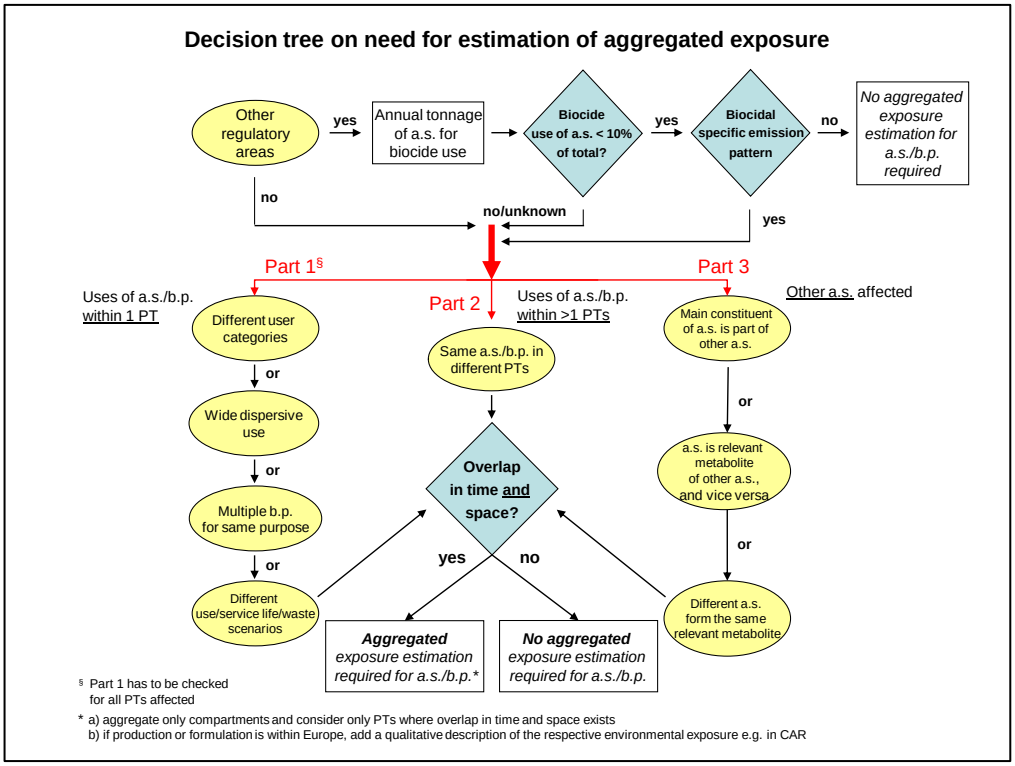


Figure 1: Decision tree on the need for estimation of aggregated exposure

Sodium Hypochlorite is used in other regulatory areas, the REACH dossier of the substance indicates that it is manufactured and/or imported in the European Economic Area in 1 000 000 - 10 000 000 tonnes per year.

All compartments exposed via the STP route are relevant for the aggregated exposure assessmentThe environmental exposure calculations are based on free available chlorine (FAC) independent from whether the exposure is based on sodium hypochlorite, calcium hypochlorite or chlorine. .Therefore, the total tonnage of the active substance and the two precusors should be considered to decide whether an aggregate exposure assessment is needed The tonnage of these three substances for the biocidal is unknown, therefore it is not possible to determine if "biocide use of the active substance is < 10% of total".

Nevertheless, the qualitative assessment performed for the active substance shows a very rapid degradation of the substance, which prevents the accumulation of releases over time and space. Therefore, no further aggregated exposure assessment is necessary.

Conclusion
No unacceptable risks for the environment are expected from the aggregated exposure.

Overall conclusion on the risk assessment for the environment of the product
No unacceptable risks for the Active Substance, or the Chlorates formed during the storage (relevant impurity) are expected neither for the aquatic compartment, nor for the terrestrial compartment. No unacceptable risk of secondary poisoning trough the aquatic or the terrestrial food chain is to be expected. No unacceptable risk to the groundwater is expected. **When used as described in the authorised uses section of this product assessment report, no unacceptable risk for the environment is expected for ARIEL Chlorine Professional System 5.**

2.2.9 Assessment of endocrine disrupting properties

A stepwise approach based on CA-March18.Doc.7.b-final was followed to assess the ED properties of the substances in Ariel Chlorine Professional System 5:

1. Assessment of the ED properties of the active substances Active Chlorine released from Sodium hypochlorite:

- According to section 2.1.1 of the final CA document, the assessment of ED properties of the active substances that have already been evaluated and approved will be coordinated at EU level. Hence, the rMS should not evaluate the ED properties of these substances nor request additional data on the ED properties in the context of product authorization procedures. As Active Chlorine released from Sodium hypochlorite is not part of the list[2] of approved active substances identified as having potential ED properties, it is for the moment not triggered for an early review.

  According to the CAR and BPC opinion on sodium hypochlorite: "Active chlorine released from sodium hypochlorite is not considered to have endocrine disrupting properties. Active chlorine released from sodium hypochlorite does not fulfil criterion (d) of Article 5(1)."

  However please note that Sodium chlorate, which can be formed during storage and is therefore considered as a relevant impurity, shows indications of ED properties. Indeed, the BPC opinion on Active chlorine generated from sodium chloride by electrolysis[10], published in 2020, refers to the EFSA Scientific Opinion on "*Risks for public health related to the presence of chlorate in food*"[11], which suggests that chlorate may disrupt the thyroid hormone homeostasis. However no assessment of the endocrine-disrupting properties of chlorate was performed and no clear conclusion can be drawn based on the available data. The same conclusion is available in the REACH registration dossier of Potassium chlorate, which is partially based on the same data[12].

[2] Please refer to CA-September18.Doc.7.5.a-final .

[10] Biocidal Products Committee (BPC) Opinion on the application for approval of the active substance: Active chlorine generated from sodium chloride by electrolysis - Product type: 3, ECHA/BPC/252/2020

[11] EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), 2015. Scientific Opinion on risks for public health related to the presence of chlorate in food. EFSA Journal 2015;13(6):4135, 103 pp.

[12] https://echa.europa.eu/registration-dossier/-/registered-dossier/10580/7/1

No CoRAP procedure has been launched for Sodium chlorate, unlike Perchlorate which has a similar mode of action and for which a conclusion is available. According to the evaluation report of Sodium perchlorate (CAS N° 7601-89-0), the substance shows clear thyroid disrupting effects on non-target organisms, as well as ED effects on metamorphosis, development, reproduction, sex ratio and stress tolerance, leading to potential long-term and population relevant impacts. Perchlorates will thus be part of an upcoming SVHC identification process.

Therefore, BE eCA would consider that no clear conclusion on ED properties of Sodium chlorate can be drawn up to the renewal of the approval of the active substance Sodium hypochlorite or up to the outcome of SVHC identification process.

2. Assessment of the ED properties of non-active substances (co-formulants):

- Since ARIEL Chlorine Professional System 5 only contain the active substance Active chlorine released from Sodium hypochlorite as well as water, without others co-formulants, no further assessment of the ED properties has been performed for the formulated product.

Overall conclusion on the biocidal product regarding ED properties:

Based on the existing knowledge, there is no indication of concern for humans and for non-target organisms regarding the ED properties of the substances used in the biocidal product "ARIEL Chlorine Professional System 5.

If, in the future, Sodium chlorate is identified as an endocrine disrupting substance, the conditions for granting the biocidal product authorization will be revised according to CA-March18.Doc.7.b-final, section 2.3 (47).

2.2.10 Measures to protect man, animals and the environment

Reference is made to section 2.1.5.

2.2.11 Assessment of a combination of biocidal products

The product is not intended to be used in combination with other biocidal products.

2.2.12 Comparative assessment

As stated in the BPR, Regulation 528/2012, article 23, a comparative assessment shall be performed as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing an active substance that is a candidate for substitution in accordance with Article 10(1). As active chlorine, nor any of the precursors, can be considered a candidate for substitution, a comparative assessment is not required.

3 ANNEXES

3.1 List of studies for the biocidal product

Type	Title	Author	Year	Test lab	Report no	Owner	Date
Long-term stability study (T0), incl. analysis phys-chem endpoints	Analysis of a formulation Ariel S5 Stainbuster containing 8.9% w/w sodium hypochlorite, in compliance with Good Laboratory Practice	[redacted]	2019	DNAL Ltd	DNA4911	Procter & Gamble	3 July 2019
Long-term stability study	Analysis of a formulation Ariel S5 Stainbuster containing 8.9% w/w sodium hypochlorite stored at ambient temperature for one year, in compliance with Good Laboratory Practice	[redacted]	2020	DNAL Ltd	DNA4912	Procter & Gamble	3 June 2020
Analytical methods	Validation of the methods of determination of sodium hypochlorite and a specified impurity in Ariel S5 Stainbuster, a formulation containing sodium hypochlorite, in compliance	[redacted]	2019	DNAL Ltd	DNA4913	Procter & Gamble	3 July 2019

Type	Title	Author	Year	Test lab	Report no	Owner	Date
	with Good Laboratory Practice						
Metal corrosive test	ADR/CLP corrosion tests	[redacted]	2020	META-Logic	200617/PGSC/TV/CR/2/053	Procter & Gamble	03 Aug 2020
Efficacy study report	Professional Ace C - EN1276 Draft for Revision (October 2007) - Quantitative suspension test for the evaluation of bactericidal activity (phase 2, step 1)	[redacted]	2009	HygCen GmbH	SN 9422 EN 1276	Procter & Gamble	2 Oct 2009
Efficacy study report	Professional Ace C - EN1276 Draft for Revision (October 2007) - Quantitative suspension test for the evaluation of bactericidal activity	[redacted]	2009	HygCen GmbH	SN 9422 EN 1276 MRSA	Procter & Gamble	14 Oct 2009
Efficacy study report	Ariel S5 White Wash Stainbuster (8.9%) EN 1650 Quantitative suspension test - yeasticidal activity (phase 2, step 1)	[redacted]	2019	HygCen GmbH	PB2019-1428 SN 27705	Procter & Gamble	14 June 2019

Type	Title	Author	Year	Test lab	Report no	Owner	Date
Efficacy study report (aged sample)	Test report B21312	[redacted]	2017	HygCen GmbH	B21312	Procter & Gamble	19 Dec 2017
Efficacy study report	Ariel System S1 and Ariel S5 White Wash Stainbuster (8.9%) EN 16616 Chemical-thermal textile disinfection – bactericidal and yeasticidal activity	[redacted]	2019	HygCen GmbH	2019-2302, 2019-2485	Procter & Gamble	10 Dec 2019

3.2 Output tables from exposure assessment tools

Human health and toxicity

TABLE 1: Scenario [2]

PT2: Laundry disinfection (washing machine) - professional use **Post application: Machine maintenance (broken dosing system repair; concentrate)**		
Model for inhalation of aerosol: Mixing and loading Model 7, manual loading/pouring of liquids (according to the HEEG opinion1,2008)		
	Units	**Tier 1: no PPE**
Product: Ariel System 5 Active substance [avCl] – concentrate	% W/W	9.05
Inhalation exposure: Exposure to aerosol [NaOCl as avCl] Indicative value Potential air concentration Penetration through RPE Actual air concentration [avCl]	 mg/m³ mg/m³ % mg/m³	 0.94 0.085 100 0.085
Total inhalation exposure [avCl]	**mg/m³**	**0.085**
AEC_{inhal}	**mg/m³**	**0.5**
% AEC_{inhal}	**%**	**17**
* See also qualitative local assessment		

3.3 New information on the active substance

No new information on the active substance is available. Reference is made to the active substance dossier of sodium hypochlorite. The studies included in the active substance dossier are applicable to the biocidal product as well considering the nature of the product (BPR regulation 528/2012). See IUCLID section 13 for a LoA to the active substance dossier (including annex with updated list of studies, August 2019).

3.4 Residue behaviour

Due to the high reactivity of chlorine species, residues degrade very rapidly (decomposition to physiological sodium and chloride). Hence residue formation is assumed to be negligible. Sodium chlorate is a by-product of the manufacturing process and can be formed during storage. Thus, chlorate may represent a worst-case for NaOCl residues (via food and feed). This product is not intended to treat surfaces that may come into contact with food.

3.5 Summaries of the efficacy studies

All efficacy studies are described in section 2.2.5.5 and available in IUCLID and therefore not required to list here. A list of all studies is available in section 2.2.5.5 and Annex 3.1.