

Biocidal Products Committee (BPC)

Opinion on the Union authorisation of the single biocidal product:

ARIEL Chlorine Professional System 5

Chlorine bleach for white wash

ECHA/BPC/282/2021

Adopted

16 June 2021

Opinion of the Biocidal Products Committee

on the Union authorisation of the biocidal product ARIEL Chlorine Professional System 5 Chlorine bleach for white wash

In accordance with Article 44(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council 22 May 2012 concerning the making available on the market and use of biocidal products, the Biocidal Products Committee (BPC) has adopted this opinion on the Union authorisation of:

Name of the biocidal product:	ARIEL Chlorine Professional System 5 Chlorine bleach for white wash
Authorisation holder:	Procter & Gamble Services Company NV
Active substance common name:	Active chlorine released from sodium hypochlorite (CAS number sodium hypochlorite 7681-52-9)
Product type:	2

This document presents the opinion adopted by the BPC, having regard to the conclusions of the evaluating Competent Authority (eCA).

Process for the adoption of BPC opinions

Following the submission of an application on 11 December 2018, recorded in R4BP3 under case number BC-ER045796-14, the evaluating Competent Authority submitted a draft product assessment report (PAR) containing the conclusions of its evaluation and the draft Summary of Product Characteristics (SPC) to ECHA on 25 November 2020. In order to review the draft PAR, the conclusions of the eCA and the draft SPC, the Agency organised consultations via the BPC (BPC-39) and its Working Groups (WG-I-2021). Revisions agreed upon were presented and the draft PAR and the draft SPC were finalised accordingly.

Adoption of the BPC opinion

Rapporteur: Belgium

The BPC opinion on the Union authorisation of the biocidal product was reached on 16 June 2021.

The BPC opinion was adopted by consensus. The opinion is published on the ECHA website.

Detailed BPC opinion and background

1. Overall conclusion

The overall conclusion of the BPC is that the single biocidal product is eligible for Union authorisation in accordance with Article 42(1) of Regulation (EU) No 528/2012, as defined in Article 3(r).

The single biocidal product meets the conditions laid down in Article 19(1) of Regulation (EU) No 528/2012 and therefore may be authorised for the uses specified in this opinion.

The detailed grounds for the overall conclusion are described in the PAR.

The BPC agreed on the draft SPC of ARIEL Chlorine Professional System 5 Chlorine bleach for white wash referred to in Article 22(2) of Regulation (EU) No 528/2012.

2. BPC Opinion

2.1 BPC Conclusions of the evaluation

a) Summary of the evaluation and conclusions of the risk assessment

General

ARIEL Chlorine Professional System 5 (Ariel S5) is a hypochlorite bleach and disinfection system for linen disinfection in professional washing machines (e.g. washing machines in restaurants, hotels, care-homes, non-healthcare facilities). It can only be used with Procter & Gamble professional automatic dosing equipment. It is not authorized for manual dosing. ARIEL Chlorine Professional System 5 is to be used by professional users only.

ARIEL Chlorine Professional System 5 contains 9.05% w/w of active chlorine released from sodium hypochlorite as active substance. No substance of concern has been identified in the biocidal product.

Physico-chemical properties

The ARIEL Chlorine Professional System 5 is a SL formulation. The product is a clear yellow-green liquid with a density of 1.1524 g/mL (at 20 °C) and 1.1436 g/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. The product has a surface tension of 73.18 nN/m at 20 °C.

Storage conditions should include restrictions ("Do not store at temperatures above 30 °C", "Keep away from direct sunlight" and "Protect from frost").

The physical and chemical properties were adequately addressed, supporting a shelf-life of 12 months in HDPE packaging.

Physical hazards and respective characteristics

With regard to the physical and chemical hazards, the product ARIEL Chlorine Professional System 5 is classified as Corrosive to Metal – Category 1.

Moreover, the product is incompatible with acids and the classification "Contact with acids liberates toxic gas (chlorine)" should be included.

Methods for detection and identification

The provided titration method is adequately validated for the determination of the content of the active substances in the biocidal product ARIEL Chlorine Professional System 5. For the determination of the relevant impurity sodium chlorate, the provided IC method is also validated.

Efficacy

According to the results of the efficacy tests provided, the product ARIEL System 5 (always used after the product Ariel System S1 and after fleet drain), is active against bacteria and yeasts on clean items when used at 10 mL/L during 15 min contact time at +40 °C.

Human health

No toxicological test data are available for 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.

The biocidal product is skin and eyes corrosive based on the classification of the active substance:

- Skin Corr.1B
- Eye Dam.1

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.

The local risk assessment shows that according to the use claimed by the applicant, the risks are acceptable for primary and secondary exposure through the use of PPE and the application of the following risk mitigation measures 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).

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

According to the CLP regulation, taking into account that the maximum chlorate generated at the end of the storage period (12 months) is equal to 1.934% w/w and the ATE 100 mg/kg bw (oral) an ATE mix of 5170 is obtained. The product is not classified as acute tox oral.

Therefore, the degradation of sodium hypochlorite to sodium chlorate doesn't lead to the changing of product classification.

Disinfection by-products (DBP) risk assessment

The available guidance (*Guidance on the BPR: Volume V Disinfection By-Products, Version 1.0 January 2017*) offers no methodology for assessing the risk for human health due to exposure 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, it allows to reduce the risk of contact with organic material. Therefore the formation of DBP should be reduced. The disinfection step with S5 (biocidal product) is followed by 1-2 rinses and drain phases and finally an extraction by spin. The exposure to DBPs could be low according to the HERA, Guidance Document Methodology (2005). Overall, it is concluded that in the absence of a harmonised methodology and proper guidance for assessing DBPs for the laundry disinfection use, it is not possible to perform a proper DBP assessment for the product at this stage.

Environment

The product has the following environmental hazard classification: Aquatic Acute 1 and Aquatic Chronic 2.

No unacceptable risks for the active substance or the relevant impurity sodium chlorate formed during the storage are expected neither for the aquatic compartment, nor for the terrestrial compartment. No unacceptable risk of secondary poisoning through 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 authorized uses section of this product assessment report, no unacceptable risk for the environment is expected for ARIEL Chlorine Professional System.

Disinfection by-products (DBP) risk assessment

For all uses of biocidal products leading to the formation of DBPs, no guidance is currently available thus, no conclusion can be drawn. Due to insufficient data at present the full DBP evaluation cannot be carried out. The current 'guidance' (Volume V, Guidance on Disinfection By-Products) covering PT2, 11 and 12 is a strategy and not a concrete assessment method. This guidance does not allow any harmonized DBP assessment.

b) Presentation of the biocidal product including classification and labelling

The description of the biocidal product is available in the SPC.

The hazard and precautionary statements of the biocidal product according to the Regulation (EC) 1272/2008 is available in the SPC.

c) Description of uses proposed to be authorised

The uses claimed in the application and their assessment are described in the PAR. The description of the uses proposed to be authorised are available in the SPC.

d) Comparative assessment

The active substance **Active chlorine released from sodium hypochlorite** contained in the biocidal product does not meet the conditions laid down in Article 10(1) of Regulation (EU) No 528/2012 and is not considered a candidate for substitution. Therefore, a comparative assessment of the biocidal product is not required.

e) Overall conclusion of the evaluation of the uses proposed to be authorised

The physico-chemical properties, the safety for human and animal health and for the environment and the efficacy of the intended use of the biocidal product have been evaluated.

The chemical identity, quantity and technical equivalence requirements for the active substance(s) in the biocidal product are met.

The physico-chemical properties of the biocidal product are deemed acceptable for the appropriate use, storage and transportation of the biocidal product.

For the proposed authorised use(s), according to Article 19(1)(b) of the BPR, it has been concluded that:

1. the biocidal product is sufficiently effective;
2. the biocidal product has no unacceptable effects on the target organisms, in particular unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates;
3. the biocidal product has no immediate or delayed unacceptable effects itself, or as a result of its residues, on the health of humans, including that of vulnerable groups, or animals, directly or through drinking water, food, feed, air, or through other indirect effects;
4. the biocidal product has no unacceptable effects itself, or as a result of its residues, on the environment, having particular regard to the following considerations:
 - the fate and distribution of the biocidal product in the environment,
 - contamination of surface waters (including estuarial and seawater), groundwater and drinking water, air and soil, taking into account locations distant from its use following long-range environmental transportation,
 - the impact of the biocidal product on non-target organisms,
 - the impact of the biocidal product on biodiversity and the ecosystem.

The outcome of the evaluation, as reflected in the PAR, is that the use(s) described in the SPC, may be authorised.

2.2 BPC opinion on the Union authorisation of the biocidal product

As the conditions of Article 19(1) are met it is proposed that the single biocidal product shall be authorised, for the use described under section 2.1 of this opinion, subject to compliance with the proposed SPC.