Helsinki, 7 April 2020

Recommended requirements for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid

Due to the current COVID-19 situation, there is the need to ensure adequate supply of active substances for use in biocidal products for disinfection purposes. The most effective way to address the needs to have more biocidal products on the market is that MSCAs use Article 55(1) of the BPR to permit the placing on the market and use of biocidal products under derogation from Article 19 and in particular derogation from the technical equivalence requirement in Article 19(1)(c).

The present document provides the key compositional requirements for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid to be used in such products, for the purposes of ensuring their optimal efficacy and to help minimise risk.

Active chlorine released from sodium hypochlorite

Parameter	Limit	Note
Active chlorine released from sodium hypochlorite	Aqueous solution with an available (active) chlorine concentration ≤ 18% w/w	
Sodium chlorate	≤ 5.4% w/w of available chlorine	Relevant impurity
Sodium chloride*	As indicated in EN 901:2013	
Sodium bromate*	As indicated in EN 901:2013	
Antimony*	As indicated in EN 901:2013	
Arsenic*	As indicated in EN 901:2013	
Cadmium*	As indicated in EN 901:2013	
Chromium*	As indicated in EN 901:2013	
Lead*	As indicated in EN 901:2013	
Mercury*	As indicated in EN 901:2013	
Nickel*	As indicated in EN 901:2013	
Selenium*	As indicated in EN 901:2013	

*It is recommended that all parameters listed in the sections related to impurities, by-products and chemical parameters in European Standard EN 901:2013, Chemicals used for treatment of water intended for human consumption – Sodium hypochlorite, are fulfilled. The norm also lists test methods for determining the content of available chlorine and impurities.

Links to relevant documents:

BPC opinion PT 01: https://www.echa.europa.eu/documents/10162/7b557dfd-328b-130d-09ba-bff7491adf14
BPC opinion PT 02: https://www.echa.europa.eu/documents/10162/37e58a1e-70b6-e074-8d50-ed71c880c8e1

Assessment report PT 01: https://echa.europa.eu/documents/10162/0f87765c-1bb2-9bb0-6b41-c8b54841dfd5
Assessment report PT 02: https://www.echa.europa.eu/documents/10162/a5a4a737-ae9d-ca03-c24e-cf573490fa2a

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Hydrogen peroxide

Parameter	**Limit**
Hydrogen peroxide	The active substance as manufactured is an aqueous solution of 350-<700 g/kg (35-<70 %, w/w) solution of hydrogen peroxide. The theoretical (calculated) dry weight specification: minimum purity of hydrogen peroxide is 995 g/kg (99.5% w/w).
Individual impurities	No individual impurity > 0.1% w/w
Total amount of organic impurities	< 0.1% w/w (aqueous solution)
Sum of organic and inorganic impurities	< 0.2% w/w (aqueous solution)
Arsenic	<1 mg/kg
Cadmium	<1 mg/kg
Lead	<1 mg/kg
Mercury	<1 mg/kg

Links to relevant documents:

BPC opinion PT 01: https://www.echa.europa.eu/documents/10162/5669c776-9f10-a6d9-8c2a-d7662c00e6de
BPC opinion PT 02: https://www.echa.europa.eu/documents/10162/1f4e92e4-839c-847c-db34-4a90c1592a75

Assessment report PT 01 and 02: https://www.echa.europa.eu/documents/10162/f4b6ac51-c4e8-b45c-f7ba-b38f48f3cf67

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Peracetic acid

The active substance is peracetic acid in an aqueous solution containing acetic acid, hydrogen peroxide and water. The specification is based on the minimum purity of the starting materials hydrogen peroxide (as in Regulation (EU) 2015/1730) and acetic acid (as in Regulation (EU) No 231/2012).

Parameter	Limit	Note
Active substance – Peracetic acid		
Peracetic acid	The hazard and risk assessment in the CAR are only covering products containing peracetic acid concentrations up to 15%.	
Sulphuric acid	≤ 10 g/kg	Additive
1-hydroxyethane-1,1-diphosphonic acid (HEDP)	≤ 14 g/kg	Additive
Dipicolinic acid	≤ 1.6 g/kg	Additive
Starting material – Acetic acid		
Acetic acid	Acetic acid used as starting material should fulfil the requirements of Regulation (EU) No 231/2012 (COMMISSION REGULATION (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council).	
Starting material – Hydrogen peroxide		
Hydrogen peroxide	Hydrogen peroxide used as starting material should fulfil the requirements of Regulation (EU) 2015/1730 (Commission Implementing Regulation (EU) 2015/1730 of 28 September 2015 approving hydrogen peroxide as an existing active substance for use in biocidal products for product-types 1, 2, 3, 4, 5 and 6). See table for Hydrogen peroxide above.	

Links to relevant documents:

BPC opinion PT 01: https://www.echa.europa.eu/documents/10162/f204fd1d-67b5-3308-6a07-4c83362d11cf
BPC opinion PT 02: https://www.echa.europa.eu/documents/10162/a15fd9e5-38ba-3414-a2a0-39a0828b0f9e

Assessment report PT 01 and 02: https://www.echa.europa.eu/documents/10162/c9726797-83ed-9d53-7dea-d18229e534c1