

ANNEX I

NOTIFICATION OF DEROGATION PURSUANT TO ARTICLE 55(1) OF REGULATION (EU) NO 528/2012

- Notifying Member State¹

Spain

- Competent Authority granting the temporary derogation

Organisation	Email address
Ministry of Health	sgsasl@mscbs.es

- In case of repeated action: number of previous action(s)

- Product name

Active substance mentioned below

- KORUMA SODYUM HYPOCHLORITE

- Product type

PT 2, PT4

- Active substance(s)

Active chlorine released from sodium hypochlorite (CAS number: 7681-52-9)

- Target organism(s)

SARS-CoV-2

- User category

Non-professional user (general public)
Professional user
Trained professional

- Starting date of the action based on Art. 55 (1) of the BPR

01/10/2020

¹ In this form "Member State" refers to EU Member States, Iceland, Liechtenstein, Norway and Switzerland.

- End date of the action based on Art. 55 (1) of the BPR

01/04/2021

- Description of danger the derogation is intended to address

danger to public health

Due to a potential worsening of the pandemic situation caused by the coronavirus disease (SARS CoV 2), it is absolutely essential to ensure that the demand of disinfectant products is covered in order to contain the spread of the virus and protect the population.

In addition, the disinfectant's market is quite globalized and any increase of the demand on third countries that compete for the active substances or raw materials may produce a shortage of biocidal active substances and biocide products, which will endanger the public health in ES. Considering the latter, it is necessary to authorize the additional supplier of the active substance indicated above.

danger to animal health

(describe briefly the danger, the area affected and the effects of the danger)

danger to environment

(describe briefly the danger, the area affected and the effects of the danger)

- Geographical area of use

Spain

- Absence of any other means to contain the danger

Shortage due to SARS-CoV-2 outbreaks

- Limited and controlled use

The competent authority is already in possession of information on the source of active substance that invokes this measure. In order to ensure that this exceptional situation does not constitute a loop in the ordinary procedures, the Ministry of Health is gathering information on the intentions of the holders of the exceptional authorization to include this supplier as a supplier listed in Article 95. This information will allow us to plan any future regulatory action to include this supplier as a supplier listed in Article 95

- Applications submitted for the product and/or granted authorisations*

The status of these products are under national laws in Spain.

* This section will be removed when publishing the notification in CIRCABC