

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

- Notifying Member State¹

Italy

- Competent Authority granting the temporary derogation

Organisation	Email address
Ministero della salute Direzione generale dei dispositivi medici e del servizio farmaceutico	dgfdm@postacert.sanita.it biocidi@sanita.it

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

- Product name

CLOROSAN

- Product type(s)

PT2/PT4

- Active substance(s)

Active chlorine generated from sodium hypochlorite

- Target organism(s)

Viruses, bacteria, fungi

- User category

Professional

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

10/06/2020

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

07/12/2020

- Description of danger the derogation is intended to address

danger to public health

The wide spread of the SARS-CoV-2 Coronavirus has led to a shortage of disinfectants in Italy.. .

It should be noted that the number of people in Italy diagnosed with SARS-CoV-2 infection is rapidly increasing. As a consequence of this development we expect a further grow of the demand for disinfectants for which shortage has been already notified.

In order to secure the supply of disinfecting products a temporary exemption for the making available on the market and use of CLOROSAN for surface disinfection (PT2/PT4) has been granted.

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

Italy

- Absence of any other means to contain the danger

Because of the high demand most of the products for hand disinfectants have been sold out. Italy is facing a shortage of disinfectant product that have been identified as essential to prevent SARS-Cov-2 spread.

- Limited and controlled use