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

- Notifying Member State[1]

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

RIFRAX SAN

- Product type

PT2, PT4

- Active substance(s)

Biphenyl-2-ol

- Target organism(s)

Bacteria, yeasts, fungi, viruses

- User category

Professional

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

22/04/2020

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

19/10/2020

- 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 RIFRAX SAN for disinfection of surfaces, materials, equipment 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