

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

- Notifying Member State¹

France

- Competent Authority granting the temporary derogation

| Organisation | Email address |
|--|--|
| Ministry for an ecological and solidary Transition | biocides@developpement-durable.gouv.fr |

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

Updated derogation on the placing on the market for several hydroalcoholic products (PT1)
[Ministerial order, March 6th regarding pharmacists updated](#)
[Ministerial order, March 13th regarding industrials updated](#)

- Product name

3 products containing ethanol (WHO formulation as well as 2 additional formulations discussed with manufacturers)
1 product containing isopropanol (WHO formulation)

- Product type

PT 1

- Active substance(s)

Ethanol, Propan-2-ol

- Target organism(s)

SARS-CoV-2

- User category

General public
Professional user

- Starting date of the action based on Art. 55 (1) of the BPR
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06/03/2020 (pharmacists)

13/03/2020 (industrials)

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

01/09/2020

Previously 31/05/2020

- Description of danger the derogation is intended to address

danger to public health

The wide spread of the SARS-CoV-2 Corona virus has led to a shortage of disinfectants, especially hand disinfectants. The number of infections in France continues to grow rapidly, and demand for hand disinfectants keeps increasing following shortage all over the country especially in healthcare facilities.

The French ministry of health requested that the production of hand disinfectants be facilitated through the granting of derogations under the BPR.

The first derogation was granted on March 6th for the production of the two WHO formulations by pharmacists only.

As this didn't not solve the shortage, additional derogations were given on March 13th to allow industrial facilities with the appropriate knowledge and abilities to contribute to the production and to place on the market several formulations of hand disinfectant not currently authorized.

4 derogatory formulations are authorized in France and described in detail in the annex of [Ministerial order from March 13th](#).

The ministerial order was updated several times to take into account shortage of active substance and coformulants. It was last updated on April 17th, extending the derogation from May 31st to September 1st for industrial companies.

Derogation for pharmacists ends on May 31st, but is likely to be extended as well.

During the derogation period, alcohol may be purchased from producers other than art. 95 of the BPR considering the shortage of ethanol all over the country. However, the derogation specifies the sources allowed in order to guarantee the safety and efficacy of the end product. These sources can also be used for the production of PT2 and PT4 alcohol-based products, until September 1st.

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

France

- Absence of any other means to contain the danger

Because of the high demand most of the products for hand disinfection have been sold out and stocks of available products, in particular ethanol based products, are decreasing rapidly. Many hospitals and healthcare facilities are out of stock.

- Limited and controlled use

Exemption has been granted to certain producers only and for a limited time. Manufacturers must follow the formulations described in a ministerial order and meet requirements on the source of components. Regulation on production, including risk mitigation measures for storage of inflammable products, applies.

The following producers can manufacture the products described in the ministerial order:

- Pharmacists: formulation 1 (WHO, ethanol) and formulation 2 (WHO, propan-2-ol)
- Industrial facilities: WHO formulations 1 and 2, formulation 3 (ethanol), formulation 4 (ethanol)