

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 Transition	Olivier.gras@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](#)
[Ministerial order, June 29th](#)

- 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

31/12/2020

Previously 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 June 29th, extending the derogation from September 1st to December 31st.

Derogation for pharmacists will be included in the Ministerial order from March 13th starting October 1st.

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 December 31st.

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.

Tension on active substance (alcohol) remains high, and the current rebound of cases and worrying epidemic trends across EU means we must remain flexible regarding our production capacity.

- **Limited and controlled use**

Exemption has been granted 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.

Considering the exemption has been going on for a while, producers must progressively fulfil the legal requirements of the national transitory period starting October 1st. In particular, a more thorough labelling and registration of the products is mandatory from this date on.

Regarding sources of active substances, all producers have been informed that they must now turn to article 95 suppliers, or prove that those suppliers can't fulfil their need. Non article 95 suppliers and their clients have been informed that they must engage in procedures to comply with article 95 of the BPR as soon as possible, and at the latest on December 31st.