Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO

AUTHORIZATION PROCEDURES FOR THE MARKETING AND PRODUCTION OF DISINFECTANT PRODUCTS IN ITALY (PT1 /PT2)

PLACING ON THE MARKET

All products that claim a disinfectant, bactericidal, virucidal action or any action able to fight microorganisms must be previously authorized by the Ministry of Health.

Products containing an active ingredient not yet approved and under revision, in accordance with Regulation 528/2012 / (EU), can be placed on the Italian market pursuant to Presidential Decree 392/98, as ”Presidi Medico-Chirurgici” (PMC).

Instead, products containing an active ingredient that is already approved, pursuant to Regulation 528/2012 (EU), are regulated exclusively by this Regulation.

The list of active substances under review / approved is available on the page:

https://echa.europa.eu/it/information-on-chemicals/biocidal-active-substances

Italy in collaboration with ECHA, the European Chemical Agency, as part of the measures for the prevention and management of the epidemiological emergency from COVID-2019, is proceeding as well as the other European Countries to issue temporary authorizations of MAX 180 days, pursuant to art.55 Regulation 528/2012 (EU), in the cases illustrated in paragraph 1.2..

PROCEDURES

1.PRODUCT AUTHORIZATION

1.Products containing active substances under evaluation pursuant to Regulation (EU) 528/2012

Disinfectant products based on active substances under review can be placed on the Italian market pursuant to Presidential Decree 392/98, as ”Presidi Medico-Chirurgici”. For the dossier submission, please refer to the guideline of 19 March 2020 carry out by the Istituto Superiore di Sanità.

https://www.iss.it/documents/20126/0/LINEA_GUIDA_PMC_MINISTERO.pdf/9ff17dc3-ad2b-2049-e556-d8960205e2d0?t=1584962373070

http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3569&area=biocidi&menu=pmc

2.Products containing active substances approved pursuant to Regulation (EU) 528/2012

In the case of disinfectant products based on approved active substances, it is possible to obtain marketing authorization pursuant to Art. 55 (1) of the Biocides Regulation. This procedure can also be used for products authorized in other Member States and / or for products containing active substances with different technical specifications, different places and / or production processes. Applications must be accompanied by documents relating to active substance supplier, product efficacy study (EN 14476)*, technical data sheet, full composition and product label proposal that will show the following indication:"Exemption authorization pursuant to art. 55.1 BPR " and sent via pec to the address: dgfdm@postacert.sanita.it or to the helpdesk at: biocidi@sanita.it, with indication of the object: "Covid Emergency-19 - Request for authorization in derogation pursuant to art. 55 BPR".

* *It is not necessary to submit efficacy study in case of:*
  - *products with composition similar to the formulations recommended by ECDC and/or WHO;*
  - *products already authorized in other Member States and for which virucidal efficacy has been assessed (provide a copy of product authorization granted by a Member State that assessed the product efficacy)*
  - *products for which efficacy can be deduced by the composition (provide justification).*

https://echa.europa.eu/documents/10162/28801697/recommended_requirements_propanol_isopropanol_en.pdf/ff333754-ea2f-f81c-ca96-874e59802806

https://echa.europa.eu/documents/10162/28801697/accelerated_te_propanol_isopropanol_en.pdf/fe8d0741-3271-2938-1da8-f0e06b2aba8d

https://echa.europa.eu/documents/10162/28801697/q_a_covid_disinfectants_en.pdf/f380496a-d61a-1ff1-ee78-12d302c5d520

https://ec.europa.eu/docsroom/documents/40523

2.DISINFECTANT PRODUCTION

1.The production of "Presidi Medico-Chirurgici takes place in production plants authorized pursuant to Presidential Decree 392/98.

THE AUTHORIZATION OF NEW PLANTS OR NEW PRODUCTION LINES FOR THE PRODUCTION OF "PRESIDI MEDICO-CHIRURGICI IS GRANTED BY URGENCY PROCEDURE WHITOUT PREJUDICE TO THE PROVISIONS IN FORCE.

http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=3572&area=biocidi&menu=pmc

2.The production of biocidal products authorized pursuant to Regulation (EU) n.528 / 2012 takes place in compliance with the requirements of the Regulation itself and in particular with the article 65.

Rome,_____