

## 12.6.20 NEWSLETTER FOR RNI CUSTOMERS - BIOCIDES DEROGATIONS IN EU AND WORLDWIDE

For your information and interest, we provide you with the update on the measures implemented to face the COVID19 outbreak.

Following the main updates of the week relating to disinfectant products and the authorization procedures in derogation in Europe and worldwide.

Do not hesitate to contact us, we remain available to provide more information on specific customer requests.

## **ECHA - Hand Disinfectants**

The high demand for disinfectants to combat COVID-19 and the granting by Member States of subsidized permits and derogations has attracted new producers and suppliers from positioning themselves on the market. These companies may not have adequate knowledge of the applicable legal framework and although many act in good faith and use all the available help offered by ECHA and national authorities, some seem to benefit from the situation in an irregular way.

As of March 2020, 20 EU Member States have reported an increase in hand sanitizers that do not comply with the regulations in force in their national markets.

The irregularities are different types as from the lack of authorization or of the exemption permits; to the lack of or incorrect danger labeling. Many countries also indicated that they had found products that were declared as disinfectants but that had a formulation that did not contain a sufficient amount of active substances to demonstrate this type of action, in particular the virudic claim.

When Member States believe that these products pose a serious risk to the health of users, both professional and consumer, communicate measures taken through the Rapid Alert System for Non-Food Products (RAPEX), providing a single, secure EU market and raising awareness the public to a greater awareness of these products.

National enforcement appointed authorities continue to carry out inspections, including on e-commerce, to prevent ineffective products from being marketed as disinfectants and from being used inappropriately against COVID-19. The penalties include fines and withdrawal of products from the market.

## **PPE face masks - Certifications**

In Italy, DL. of 17 March 2020 (art.15) gave the possibility of producing face masks in derogation from the standard validation process. This extraordinary validation task is managed by INAIL, which publishes on its website all the producers authorized in derogation. Here the link.

This derogation concerns the procedure and the relative timing and not the quality standards of the products that will be produced, imported and marketed, which must comply with current regulations. At the end of the emergency period, in order to continue being produced, imported and marketed, these devices must follow the ordinary authorization procedure and thus obtain the CE marking.

Furthermore, during the emergency period, several companies have started to produce and in particular to import PPE masks from outside the EU, also promoting their effectiveness and compliance, even though they are real "fakes".

The fake certifications consist either in falsification of documents headed to Notified Bodies that have never issued them, or in the production of "fake" certificates of non-existent Notified Bodies. In this regard, ESF (European Safety Federation) has published a series of data.

It is therefore advisable to verify that the "certificates" that are received for PPE are correctly titled and that they are issued by a notified body competent in the EU (or admitted by international agreements as EFTA and Turkey). Certificates validated and issued by bodies unrelated to these conventions are not accepted in the EU.

We are pleased to inform that RNI srl is listed in the ChemicalWatch Service Providers Guide for 2020 (pag. 212)

download: Global\_Service\_Providers\_Guide\_2020



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