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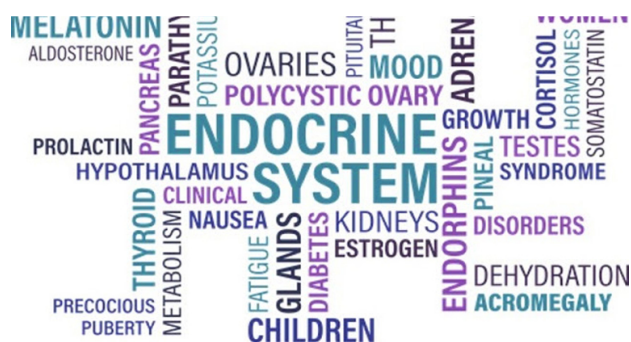
REACHUP

Regulatory services

NEWSLETTER

Newsletter RNI srl 10.7.2020

**NEWS FOR THE SDS WITH THE PUBLICATION OF THE
NEW REGULATION 2020/878**



On 18 June 2020, the new regulation was published which introduces changes in preparing the safety data sheets (SDS), modifying Annex II of the REACH Regulation.

The new regulation 2020/878 will apply from 1 January 2021, but non-compliant SDSs can be provided until 31 December 2022.

The most anticipated change was the introduction of a field for entering the UFI code for dangerous mixtures. The new code, provided for in Annex 8 of the CLP, must be inserted in section 1 of the SDS.

The change that impacts in more than one section of the SDS is the introduction of information due to **endocrine disruptors**.

In section 3.2 for hazardous and non-hazardous mixtures, substances with a content equal to or greater than 0.1% must be indicated if they meet the PBT/vPvB classification criteria, if they are in compliance with the provisions of art. 59 and also with regard to properties of interference with the endocrine system - in accordance with the criteria established by regulation (EU) 2017/2100 or in regulation (EU) 2018/605. Information on adverse health and/or environmental effects must be provided in the relevant sections 11 and 12, caused by the property of interference with the endocrine system, where available, for substances identified as having these properties in section 3.2.

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ECHA: NEW RESTRICTIONS ON PHTHALATES STARTING FROM 7 JULY 2020



Phthalates are chemicals often used as PVC additives. To make the plastic more flexible, plasticizers are needed and in most cases they are phthalates.

However, some phthalates are harmful to health. The following phthalates are classified as endocrine disruptors and are toxic to reproduction, which means that they can harm fertility or the unborn child.

- **Bis (2-ethylhexyl) phthalate (DEHP)**
- **Benzyl butyl phthalate (BBP)**
- **Dibutylphthalate (DBP)**
- **Diisobutyl phthalate (DIBP)**

They are commonly present in many children's items, such as inflatable water toys, coated fabrics, footwear, office materials, and many others. Exposure can also come from food, skin contact or even the air you breathe. DEHP, DIBP, BBP and DBP interfere with the development of male sexual characteristics, causing infertility.

The use of these substances has been restricted in the EU / EEA since 7 July 2020.

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US EPA APPROVES FIRST DISINFECTANTS TESTED DIRECTLY ON SARS-COV-2.

The U.S. EPA has approved the first two surface disinfection products that have proven effective against SARS-CoV-2.

The formulations contain ethanol and quaternary ammonium salts (quats) as biocidal active substances.

The agency added products to its N list: disinfectants for use against Sars-CoV-2 that have proven effective against a similar virus, such as SARS, or one that is considered more difficult to kill than SARS-CoV-2.

The two new approved products, Lysol Disinfectant Spray and Lysol Disinfectant Max Cover Mist, are produced by Reckitt Benckiser. The spray product was evaluated in a peer-reviewed study, published in the American Journal of Infection Control (AJIC) in May. The article indicates an efficacy greater than 99.9% against SARS-CoV-2.



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ITALIAN MINISTRY OF HEALTH SUSPENDS DEROGATION PROCEDURES FOR DISINFECTANTS FROM 15 JULY 2020



Through an official note issued on July 1, 2020, the Italian Ministry of Health communicates that the applications for authorization in derogation of disinfectant products (PT1-PT2-PT4) submitted after July 15, 2020 will no longer be taken care of due to the lack of the absence / lack of alternative means referred to in Article 55, par. 1 of Regulation (EU) no. 528/2012.

In accordance with the Istituto Superiore di Sanità, the procedures for issuing authorizations for new production plants for PMC disinfectants and those for issuing authorizations for placing disinfectant PMCs on the market will resume their normal procedure of authorization.

Since April 2020, the Italian authorities have received over 400 authorization requests in derogation pursuant to article 55, par. 1 of Regulation No. 528/2012, relating to disinfectant products (PT1-PT2-PT4) based on already approved or new active substances. Over 100 have already been accepted, and an additional 250 authorizations are expected to be released in the coming months.

In recent months there has also been a significant increase in authorized disinfectants such as PMCs based on active ingredients still under revision, thanks to the procedures developed with the collaboration of the Istituto Superiore di Sanità, again due to the covid-19 emergency. By virtue of the actions undertaken and described above, the shortage of disinfectant products on the Italian market found in March is no longer found, for this reason the emergency authorization measures will be suspended.



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