FEDERCHIMICA
CONFINDUSTRIA

TES/PRO

NORMATIVA

CORONAVIRUS

2 aprile 2020

Q&A di ECHA sui prodotti disinfettanti

In breve

L'ECHA ha preparato un documento contenente alcune Domande e Risposte al fine di aiutare coloro che vogliono mettere sul mercato prodotti disinfettanti per le mani e per le superfici in questo periodo in relazione alla pandemia di CoVID-19.

TES/PRO 120/20

Precedenti comunicazioni

A seguito del diffondersi a livello globale di un nuovo ceppo di Coronavirus (SARS-CoV-2), Federchimica si è attivata, dal 22 Febbraio scorso, per fornire alle Imprese indicazioni operative ed aggiornamenti tempestivi e costanti sull'evoluzione normativa delle misure messe in atto per limitare la diffusione del virus.

Tutte le comunicazioni inviate alle Imprese associate sono consultabili anche nell'area dedicata "In Evidenza – CORONAVIRUS – Circolari" del Portale dei Servizi. Nello stesso box sono disponibili diversi "Link utili", anche quelli per l'accesso ai siti delle Prefetture per le istruzioni relative alle necessarie comunicazioni di prosecuzione dell'attività in ottemperanza a quanto previsto dal DPCM 22 marzo 2020.

Documento dell'ECHA

L'ECHA[(1)] ha pubblicato sulla pagina del sito dedicata al CoVID-19 un breve documento di domande e risposte (allegato) – ad integrazione delle precedenti indicazioni già a voi segnalate - rivolto alle aziende che cercano di rendere disponibili sul mercato dell'UE i disinfettanti ai fini della gestione della pandemia di COVID-19.

In particolare fornisce indicazioni per i biocidi delle seguenti tipologie di prodotto (PT):

- igiene umana (PT 1); e
- disinfezione delle superfici (PT 2).

Il documento si basa sul tipo di sostanza attiva (SA) che si intende utilizzare nel prodotto biocida:

1) SA esistente in corso di valutazione per l'approvazione – Esempio: etanolo in PT 1, 2 (Vedi domanda 1 nel documento di ECHA)
2) SA approvata – Esempi:propan-1-olo in PT 1, 2 o propan-2-olo in PT 1, 2 o perossido di idrogeno in PT 1, 2 (vedi domanda 2 nel documento di ECHA)

SA nuova in fase di valutazione per l'approvazione – Esempi: cloro attivo generato dal cloruro di sodio per elettrolisi in PT1 o cloro attivo rilasciato dall'acido ipocloroso in PT1 (vedi domanda 3 nel

documento di ECHA).
A seconda della casistica in cui si ricade bisogna poi seguire le domande specifiche, riassumiamo di seguito i due casi principali rimandando al documento dell'ECHA per approfondimenti:

Prodotto con SA esistente in corso di valutazione per l'approvazione (esempio: etanolo)
Al momento tali sostanze attive sono in fase di valutazione. Di conseguenza, per i prodotti che le contengono si applicano ancora le norme nazionali e perciò in Italia il DPR 392 del 1998[(2)] che disciplina i Presidi Medico Chirurgici.

Prodotto con SA approvata (esempio: propan-1-olo, 2 o propan-2-olo, perossido di idrogeno)
In questo caso la sostanza è già approvata ai sensi del Regolamento biocidi[(3)] pertanto il prodotto è a tutti gli effetti un biocida che deve essere autorizzato prima di essere messo a disposizione sul mercato e utilizzato, conformemente agli Articoli 17 e 19 del BPR. Inoltre deve anche essere dimostrata l'equivalenza tecnica.

Tuttavia, in situazioni eccezionali (ad es. In caso di pericolo per la salute pubblica), uno Stato membro può autorizzare sul proprio mercato prodotti non conformi al BPR, ai sensi dell'articolo 55, paragrafo 1. La decisione di applicare l'articolo 55, paragrafo 1, rientra interamente nelle competenze degli Stati membri e i prodotti che godono della deroga possono essere concessi solo all'interno di un determinato territorio nazionale. Ogni Paese è pertanto responsabile riguardo alla decisione di come gestire i prodotti sul proprio territorio in questa situazione di emergenza.
Per quanto riguarda l'Italia è necessario fare riferimento alla circolare TES/PRO 106/20**.**

Per questioni riguardanti l'equivalenza tecnica, la relazione delle sostanze con il REACH, i fornitori extra-UE, etc. si consiglia di leggere il documento di ECHA.

Vi informiamo inoltre che sulla pagina del sito dedicata al CoVID-19 sono disponibili altri utili documenti tra cui uno relativo ad una procedura di richiesta di equivalenza te tecnica per il propan-1-olo e il propan-2-olo.

Allegato

ECHA - Questions and answers

Note

(1) Agenzia Europea per le Sostanze Chimiche
(2) Decreto del Presidente della Repubblica 6 ottobre 1998, n. 392 Regolamento recante norme per la semplificazione dei procedimenti di autorizzazione alla produzione ed all'immissione in commercio di presidi medicochirurgici, a norma dell'articolo 20, comma 8, della legge 15 marzo 1997, n. 59.
(3) GUUE L 167 del 27.6.2012 - Regolamento 528/2012

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Questions and answers

This advice is aimed at companies seeking to make available on the EU market disinfectants for the purpose of managing the COVID-19 pandemic. It particularly aims to target biocidal products that are meant to be used in the following product types (PTs):

- human hygiene (PT 1); and
- surface disinfection (PT 2)

For a more thorough description of these PTs see:
https://echa.europa.eu/regulations/biocidal-products-regulation/product-types

Applicable rules will depend on the type of active substance (AS) included in your product:

- 'Existing' AS being evaluated for approval – see Q&A 1
  - E.g. ethanol in PT 1, 2
- 'New' AS being evaluated for approval – see Q&A 3
  - E.g. active chlorine generated from sodium chloride by electrolysis in PT1
  - E.g. active chlorine released from hypochlorous acid in PT1
- Approved AS – see Q&A 2
  - E.g. propan-1-ol in PT 1, 2
  - E.g. propan-2-ol in PT 1, 2
  - E.g. hydrogen peroxide in PT 1, 2

To start, you need to:

- Identify the AS/PT combinations relevant for your product; subsequently
- Contact the relevant National Helpdesk(s) to learn how to proceed further. Each country (EU/EEA/Switzerland/UK) is responsible for deciding how products can be on their market in this emergency situation.
- See our COVID-19 webpage: https://echa.europa.eu/covid-19

Question 1:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss/UK market **ethanol** based products (e.g hand sanitisers). What do I need to do to quickly place on the market my products?

Answer 1:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**.

It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

Products containing ethanol used for disinfection purposes are covered by the scope of the Biocidal Products Regulation (EU) No 528/2012 (BPR). At the moment, ethanol is being evaluated for approval under the BPR in the following disinfectant product types PT 1, 2 and 4. Accordingly, it is the national rules of each country that apply both for regular authorisation of the products and also to any derogation from those rules due to the current situation (Covid-19 pandemic).

Since the substance ethanol is still under evaluation, it is not possible to get a Union wide authorisation for products containing it.

Suppliers of ethanol based biocidal products (e.g. hand sanitisers) need to:

- Contact the **national helpdesk of the country where the product will be marketed**: https://echa.europa.eu/support/helpdesks/
  The national helpdesks will indicate what you need to do to place the biocidal product on their market.

Question 2:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss/UK market **isopropanol (propan-2-ol)** based hand sanitisers. What do I need to do to quickly place on the market my products?

Answer 2:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**.

It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

The substance is already approved under the BPR for use in PT 1 and 2, therefore suppliers of propanol based products need to consider that:

Normally, biocidal products must be authorised **prior** to being made available on the market and used, in accordance with Article 17 and 19 of the BPR. Technical Equivalence

must be proved **prior** to submitting an application for biocidal product authorisation (Article 54 BPR).

However, in **exceptional situations** (e.g. in case of danger to public health), a Member State may permit products on its market that do not comply with the BPR, under **Article 55(1)** of the BPR.

This is valid for:

- Biocidal products containing **approved** AS (such as propan-1-ol or propan-2-ol); or
- Biocidal products containing **new** AS (not supported in the Review Programme)

Note that the decision to apply Article 55(1) falls entirely **under the remit of the Member States and can be granted only within a given national territory**. For such matters, it is necessary to contact and liaise with the relevant national helpdesks:
https://echa.europa.eu/support/helpdesks/
For UK: https://www.hse.gov.uk/biocides/contact.htm

Question 3:

I represent a (non-)EU company that wishes to place on the EU/EEA/Swiss market products based on 'chlorine generated from sodium chloride by electrolysis' for use in PT1. This corresponds to a **'new' active**. How can I quickly access the market?

Answer 3:

If you are a non-EU based company – start reading from here:

Firstly, note that companies established outside of the EU are not bound by the obligations of the BPR, even if they export their products into the European Union. The responsibility for fulfilling the requirements of the BPR, such as the approval of active substances or the authorisation of biocidal products lies in principle with the **importers** established in the **European Union**.

It is the EU based importer which needs to comply with the BPR obligations illustrated below.

If you are an EU based company – start reading from here:

Biocidal products containing 'new' active substances can normally only be placed on the market, following approval of the substances and authorisation of the products.

However, in **exceptional situations** (e.g. in case of danger to public health), a Member State may permit products on its market that do not comply with the BPR, under **Article 55(1)** of the BPR.

This is valid for:

- Biocidal products containing **approved** AS (such as propan-1-ol or propan-2-ol); or
- Biocidal products containing **new** AS (not supported in the Review Programme)

Note that the decision to apply Article 55(1) falls entirely **under the remit of the Member States and can be granted only within a given national territory**. For such matters, it is necessary to contact and liaise with the relevant national helpdesks: https://echa.europa.eu/support/helpdesks/
For UK: https://www.hse.gov.uk/biocides/contact.htm

Question 4:

Do companies supplying disinfectants to be used for managing the Covid-19 pandemic need to comply with the Article 95 obligation?

Answer 4:

In principle, Article 95 of the BPR applies to all biocidal products put on the EU market. To comply with the Article 95 obligation, the supplier of:

- the active substance used in a biocidal product, or
- the product itself

has to be included in the Article 95 list.

To be included in the Article 95 list, companies that are not the original applicant for the active substance approval have submit an application to ECHA.

In practice, the national enforcement authorities are the ones checking whether the products comply with this requirement and some Member States have communicated that, **in the current Covid-19 circumstances, disinfectant products do not have to comply with this legal requirement**.

Question 5:

How can I quickly place on the market the hand rub formulations recommended by WHO?

Answer 5:

Formulation 1 contains ethanol and hydrogen peroxide – see Q&A 1 and Q&A 2 for clarification.

Formulation 2 contains propan-2-ol and hydrogen peroxide – see Q&A 2 for clarification.

Question 6:

How can I quickly place on the market alcohol based hand sanitisers?

Answer 6:

The applicable rules depend on which alcohol substance you intend to use. You first need to identify which alcohol is included in your product and then proceed as indicated in Q&A 1 or 2 or 3, whichever is applicable to your case.

Question 7:

Do I need to register the substances contained in the biocidal product under REACH?

Answer 7:

Approved active substances as well as existing active substances still being evaluated for approval are exempted from REACH registration for biocidal uses, however, 'new' active substances not yet approved and other substances used for producing the biocidal product are subject to REACH registration (if the manufactured or imported quantity is higher than a 1 tonne/year per company).

For further information, you can refer to Q&A 0906, as well as section 2.2.4.1- 'Substance for use in biocidal products' of the Guidance on registration

Question 8:

To manage the Covid-19 outbreak, is it possible to obtain a temporary permit, similar to a provisional union authorisation that allows the placing on the market of disinfectants EU wide?

Answer 8:

No. The applicability of Art 55(1) derogation as well national rules are decided at national level. To allow the temporary placing on the market of disinfectants EU wide, you need to contact each of the individual EU countries to find out what steps to take.