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**REACHUP**

Regulatory services

NEWSLETTER

**Newsletter RNI srl 09.10.2020**

**BIODIESEL REACH REGISTRATION UPDATES  
COMPLETED**



**We are pleased to inform you that on behalf of the Lead Registrant SAIPOL SAS, the update of the three biodiesel substances REACH Registrations are successfully completed, according to EU regulations and guidance changes.**

Below is reported the table containing the name and CAS of the three substances:

substance	CAS	EC
Fatty acids, C14-18 and C16-18-unsatd., Me esters	67762-26-9	267-007-0
Fatty acids, C16-18 and C18-unsatd., Me esters	67762-38-3	267-015-4
Fatty acids, vegetable-oil, Me esters	68990-52-3	273-606-8

The most relevant changes applied to the last revision with respect to the previous dossier submitted in 2014 are:

- Replace & correct the previous data on Vapour Pressure, based on new study available
- Inclusion of new Dev tox chronic studies OECD 414 rats/rabbit, *in vitro* gene mutation study in mammalian cells OECD 476 performed on C6-24 residues – read across approach
- Actualization of the 2020 IUCLID dossier format
- Life cycle revision
- Exposure scenarios creation and related Risk characterizations according to Annex XI p.3.2a REACH Regulation

The next steps are:

- **We remind you the obligation for all co-registrants to updated their own dossiers (IU6/CSR) without undue delay started from 1/10/2020.**
- **In compliance with the signed LR Agreement, only sect. 3-10 of the Chemical Safety Report templates for joint submissions will be provided under specific request of each co-registrant.**

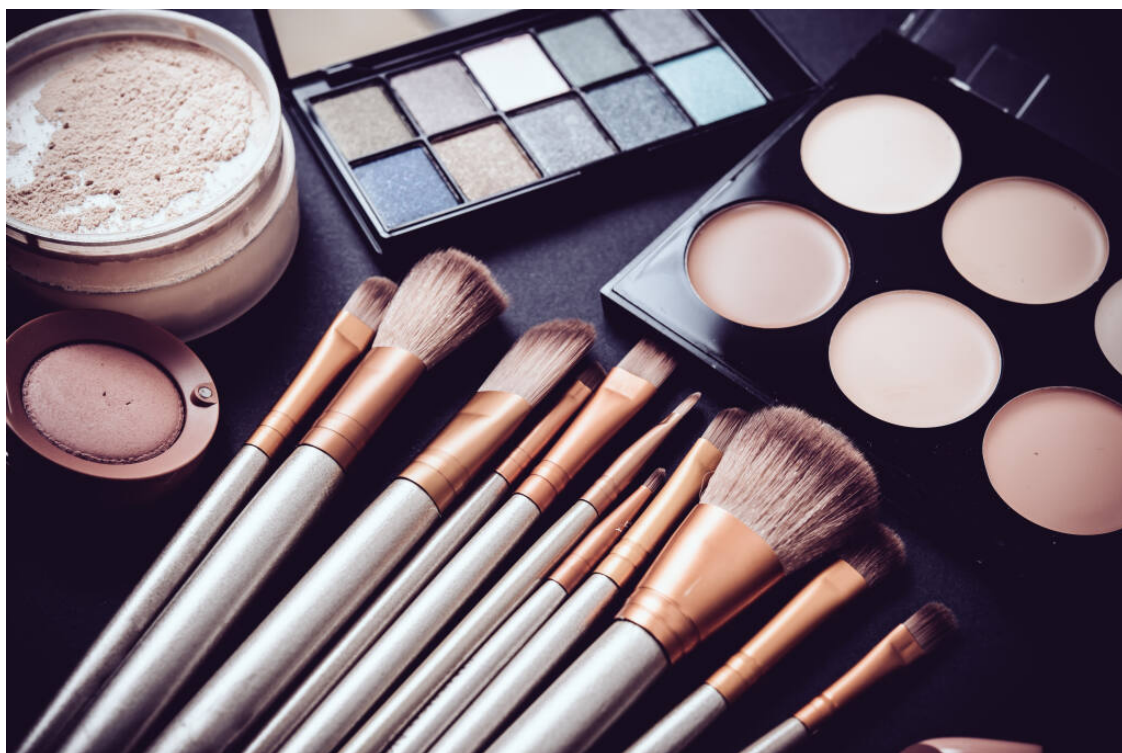
- **We also recommend to update the existing SDS information in accordance with data available, taking into account the new exposure scenarios data.**

If you have any technical question you can send it directly to RNI srl, or the EBB REACH Consortium Secretariat, at [reach@ebb-eu.org](mailto:reach@ebb-eu.org).

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## **CALIFORNIA FIRST STATE TO BAN 24 TOXIC CHEMICALS IN PERSONAL CARE PRODUCTS AND COSMETICS**



Governor Gavin Newsom today signed legislation banning 24 toxic chemicals in cosmetics, making California the first in the nation to stop the use of these hazardous ingredients that will come into force in 2025. These ingredients are already prohibited from cosmetics and other personal care products sold in the European Union and some other countries, but are still used in personal care products sold throughout the U.S. The banned chemicals can cause cancer, birth defects, damage to the reproductive system, organ system toxicity and endocrine disruption.

The US cosmetics industry is not enough regulated; therefore, the Food and Drug Administration could not ensure the safety of skin care products. The list of banned chemicals includes the toxic fluorinated chemicals known as PFAS, mercury and formaldehyde, as well as endocrine-disrupting phthalates and long-chain parabens, preservatives used in skincare products. Moreover, this legislation will also protect professional salon workers who are disproportionately exposed to toxic chemicals in the workplace. Hairdressers and beauticians have a 47-fold higher risk of fragrance skin allergies than people in other occupations.

By contrast, the EU has performed rigorous research to identify the chemicals that are not safe for use in cosmetics and other personal care products. By following Europe's science on chemical bans, Californians will be safer while also creating a more global standard for cosmetic safety.

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## BREXIT NEWS ON BIOCIDES



From 1st January 2021, the day after the end of the Brexit transition period, the new national regulation for biocidal products will come into force in the UK. The new UK regime will reflect the current EU BPR framework, but will make itself completely independent. Some features will be removed and replaced by full British features. The BPR principles and the evaluation rules on substances and products adopted up to now remain unchanged.

The new reference authority for the submission of active substance or product dossiers will be Health and Safety Executive (HSE), which also replaces the role of ECHA.

New IT tools will be made available to HSE and industry to replace the existing EU portals.

How data can be submitted to the HSE to meet the legislative requirements for the BPR regulations will be communicated as soon as it becomes available.

In any case, companies will have to re-submit to HSE the information previously submitted to ECHA or other competent authorities. The aim is to build a new UK database to be made available exclusively to HSE to support the authorizations of products and active substances, replacing the ECHA databases.

No fee will be required for these resubmission operations.

**Under the UK national regime, the authorization holders will have to be established in the UK. To allow companies to make the necessary decisions, there will be a transitional period of one year for existing authorization holders (legal entity to be established in the UK by 1 January 2022).**

Companies holders of a product authorization already issued and valid in Great Britain will continue to be so and their authorization will remain valid after 1 January 2021 until its normal expiry date. However, the authorization holder will need to be established in the UK within one year (by 1 January 2022) to continue to remain on the local market.

Applications for authorization of a biocidal product still under evaluation will continue to be evaluated by HSE until the end of the transition period. At the end of this, the HSE will continue, where possible, to

process applications to grant a national authorization. However, the information supporting the original application will need to be sent back to HSE to allow the UK authority to complete the assessment, as it will no longer have access to the ECHA portals.

If an application is being evaluated in another EU country or Switzerland as part of a Union authorization or mutual recognition process at the end of the transition period, it will need to be resubmitted to the HSE to apply for a national authorization in the UK.

For both cases, the date of the original application will be recognized for the purpose of complying with the deadlines set by the BPR.

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## **KKIDIK (TURKISH REACH): PREREGISTRATION DEADLINE SET ON 31/12/2020.**



In 2017, Turkey published and consolidated the text of the KKIDIK regulation regarding chemicals that can be placed on local national market. The scheme adopted follows the European REACH regulation in many prescriptions, so much so that it is often referred to as Turkey-REACH. One of the significant differences is that there is only one registration deadline for all tonnage bands, set for 31/12/2023.

**At this stage, the possibility is open to pre-register by 31/12/2020.**

As for REACH EU, applicants must be Turkish legal entities. Non-Turkish companies that want to keep the market will have to appoint a local OR (only Representative). RNI srl can offer this service.

For more information, contact [info@reachup.it](mailto:info@reachup.it)



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