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10
YEARS
ANNIVERSARY

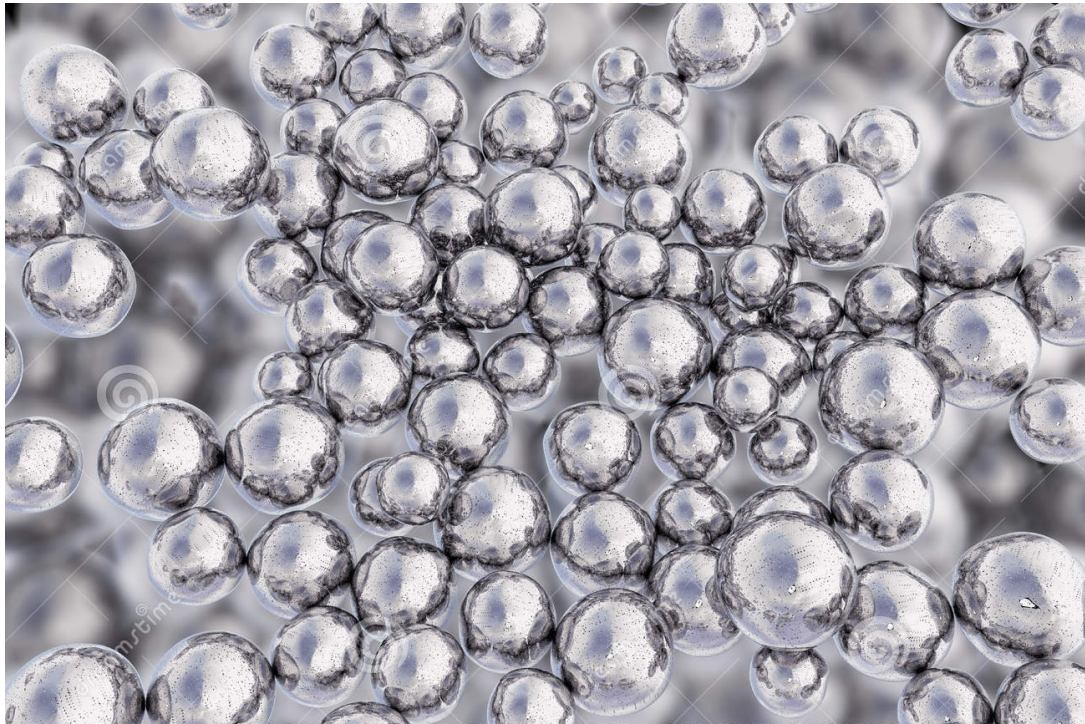


REACHUP
Regulatory services

NEWSLETTER

Newsletter RNI srl 18.12.2020

SILVER NANOPARTICLES AND MEDICAL DEVICES



The medical use of nanomaterials is growing rapidly, and one of the main innovations is the use of silver nanoparticles as antimicrobial agents in the treatment of burns and chronic wounds. The specific ability of silver (Ag) to inhibit microbial growth could in fact be systematically exploited in the clinical setting to protect the wound from infections, complications that can slow down, or even hinder, the spontaneous regeneration of damaged tissues.

In the article "Spatiotemporal distribution and speciation of silver nanoparticles in the healing wound" it was shown that MD based on metallic silver nanoparticles appears to have optimal antibacterial efficacy and a reduced risk for the patient.

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RESTRICTION TO INKS IN TATTOOS AND PERMANENT MAKEUP



Regulation (EU) 2020/2081 was published in the Official Journal of the European Union which made changes to Annex XVII of the REACH regulation concerning restrictions. Specifically, the restriction adopted takes into consideration the mixtures used for tattoos and permanent make-up that contain substances falling into the following hazard classes:

- carcinogenicity, mutagenicity, toxicity for reproduction of category 1A, 1B or 2;
- skin sensitization of category 1.1A or 1B;
- skin corrosion of category 1, 1A, 1B, 1C;
- skin irritation category 2;
- serious eye damage category 1;
- eye irritation category 2;
- and the substances listed in Annex II (list of prohibited substances) and Annex IV (list of dyes) of the Cosmetics Regulation (Regulation No. 1223/2009 and subsequent amendments).

The restriction takes effect on January 4, 2021.

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ADDITIVE APPROACH FOR CHEMICAL MIXTURES

On November 27, 2020, news provider Chemical Watch reported on a review by researchers from Brunel University London and the European Commission's Joint Research Centre (JRC), confirming that an additive approach is a "robust" way to describe chemical mixtures. The problem lies in the fact that most of the published studies focus on binary mixtures and therefore even the evaluations turn out to be repetitive and overly descriptive.

In October 2020, the European Commission published its chemical strategy that recognizes a need "to apply practical and workable approaches to dealing with unintentional mixtures." This would include the utility of a mixture assessment factor (MAF) for REACH as proposed by the Dutch and Swedish governments earlier this year.

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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.

SEA UPDATES:

The SEA CLP like Regulation has been updated, adding 110 new substances to the Harmonized List of classification and labeling "and new hazard classifications. Furthermore, only polymers must be notified and not their ingredients.

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AssICC has signed an agreement with the associated company RNI (ReachUp Regulatory Network Italy) srl, which offers advice on product regulations for the European and extra-European markets.

Thanks to the stipulated agreement, for all the companies associated with AssICC will be reserved a 10% discount on the RNI srl services.

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From this month, REACHUP offers import and export worldwide consultant services on TRADE ITALIAN AGENCY. You can access on the ICE online vetrina previous registration.

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