On 24th of July, 2019 ECHA published a CLH proposal of the German MSCA to classify Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate, EC number 227-561-6, for its potential skin sensitisation properties.

We are herewith commenting as Evonik Resource Efficiency GmbH on behalf of Evonik Röhm GmbH as the Lead Registrant of this substance.

With reference to the CLH dossier regarding Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate (EC number 227-561-6), we fully agree with the harmonised classification as Skin Sens 1, H317, proposed by the German MSCA.

However, in the CLH dossier, the dossier submitter assessed the Local Lymph Node Assay (LLNA) provided as key study in the registration dossier as invalid due to the observation that the test material was expired at the time of testing. Subsequently, we checked the information given in the IUCLID data base and found that there is a typing error we have not recognized earlier.

Now, we corrected this error in the IUCLID data base and provide you the detailed information indicating the integrity of the test substance as confidential attachment in order to prove our statement. Therefore, we are confident that the LLNA used as key study is valid. We agree with the dossier submitter that the test is clearly positive, but the results do not allow a differentiation between Skin Sens 1A or B.

We disagree with the statement of the dossier submitter that it seems likely that Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate is used in consumer products. We read the cited publication of Foti et al., 2016. They discussed that traces of Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate (approx. 0.5 ppm) found in the products addressed in the publication might be due to a contamination by contact with vessels, tubes or valves during its industrial production. Consequently, there is no evidence for the existence of consumer products based on raw materials containing Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate.

Regarding the use of Exo-1,7,7-trimethylbicyclo[2.2.1]hept-2-yl acrylate in insulin pumps or glucose measuring devices, we would like to comment that these products are in the scope of the medical device regulation.