

To whom soever it may concern

Biokar is aware of the current concerns among our customers and the wider market regarding the inclusion of octylphenol ethoxylates (OPE), such as Triton X-100, in the European Authorisation list (Annex XIV) of REACH.

The key ingredient of Triton X-100, 2-[4-(2,4,4-trimethylpentan-2-yl)phenoxy]ethanol, is on the REACH authorisation list. This means that the compound cannot be used or sold within the European Union after its sunset date of January 4, 2021 unless an authorisation has been granted by the European Commission or an exemption applies.

We have determined that the following exemption applies, having carefully reviewed the ECHA Q&A on the scope of Annex XIV:

https://echa.europa.eu/da/support/qas-support/browse/-/qa/70Qx/view/scope/reach/authorisation

There is indeed an exemption from authorisation for the use of Annex XIV substances in scientific research and development (SRD), meaning scientific experimentation, analysis or chemical research carried out <u>under controlled conditions</u> in a <u>volume less than one tonne</u> <u>per year</u> (REACH Articles 3 (23) and 56 (3)). This exemption also covers the life-cycle steps (such as formulation) preceding the end-use of the substance in SRD

Essentially, based on the above exemptions, Biokar believes that its downstream users can continue to use Eugon LT100 broth (BK137HA) and Eugon LT 100 agar (BK138HA). The ready to use presentations of our Eugon LT100 agar and broth are not subject to authorization as the concentration of TritonX is bellow 0,1% (w/w)

We are confident in our assessment and are happy to ensure business can continue without disruption.

On behalf of BIOKAR DIAGNOSTICS

05/02/2021

Athanassios Giannakopoulos Export Manager