



INGENIERÍA DEL OZONO SL, ZONOSISTEM

is a full member of the European Ozone Trade Association (EuOTA) and is a co-owner/and/or has a rights of access to the EuOTA Ozone Active Substance Biocide Dossiers. As listed by ECHA under Article 93.







fabricante de generadores de ozono

EuOTA Membership Number: S001-23

EuOTA LoA Certificate Number: Not Applicable

Date of Certificate: 07/07/2017

Substance: Ozone

EC No. 233-069-2 CAS No.10028-15-6

The Biocidal Products Regulation (EU) 528/2012 (BPR) came into force on 1 September 2013 repealing the Biocidal Product Directive (Directive 98/8/EC). From 1 September 2013, Ozone is regulated as an "Active Substance" under the BPR.

Following Active Substance approval under the BPR, any Company that wishes to place a biocidal product on the market which contains ozone generated in-situ within the EU or EFTA must have its product authorised in accordance with the BPR. This process first requires a dossier on the active substance or a Letter of Access to an "Active Substance" dossier from a dossier owner in respect of Ozone and thereafter a specific application for each product to be Authorised for sale and use within the EU or EFTA. Companies without such a letters of access cannot support their products for future Authorisation.

Details of the BPR can be found on the European Chemicals Agency ECHA) website: https://echa.europa.eu/regulations/biocidal-products-regulation.

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INGENIERÍA DEL OZONO SL, ZONOSISTEM as a Full Member of EuOTA and a co- owner of The European Ozone Trade Association Limited Active Substance Dossiers for Product Types 2, 4, 5 and 11 entitled, "Ozone generated from oxygen (generated from ambient air, water or pure oxygen not supplied with the intention to generate ozone for a biocidal use)" that has been submitted to The Netherlands Competent Authority (Ctgb) (August 2016).

Once Ozone is approved only products that have an Active substance dossier or a Letter of Access to an Ozone Active Substance Dossier can continue to be placed on the European Market. This certificate confirms that INGENIERÍA DEL OZONO SL, ZONOSISTEM has access to the Active Substance dossiers for Ozone.

Signature: EuOTA

Signature: INGENIERÍA DEL OZONO SL, ZONOSISTEM