

Reprint of Ozone News by the International Ozone Association, Ozone News Vol.43 #3, June 2015

Biocidal Product Registration for Ozone – Update from the ORG

The ORG is now finalizing the active substance dossier and is ready for its submission to the European Chemicals Agency (ECHA) for union authorization by end of May 2015. Following the active substance dossier will be sent by ECHA, after a format check and acceptance, to the selected competent authority (CA) for the completeness check. In case the dossier is deemed to be complete the evaluation period begins.

Letters of Access (LoAs) will be offered by an international association located in Belgium - Euro₃zon. Euro₃zon is a non-commercial organization that will also manage the granting of the selling letter of access for the active substance dossier of the Ozone Registration Group. This allows anyone in the market to grant access to the active substance dossier for ozone to their evaluating authorities- This is required for undertaking the biocidal product authorization for in-situ produced Ozone.

LoAs will be offered including all 4 product types (PTs 2, 4, 5 and 11) covered by the dossier. It will be independent of the tonnage of ozone generated by the ozone devices sold or operated by the customer. The price level strongly depends on the number of countries the LoA is available for and here only of indicative nature:

1 country	75,000 Euro
3 countries	150,000 Euro
5 countries	225,000 Euro
All countries	350,000 Euro

The countries can be freely selected by the customer from all EU-members and associated countries.

Due to the situation about the unclear scenario of the authorization holders for registration of ozone as biocidal product, it is nearly impossible to provide a true estimation about the number of letter of access that could be sold. Resulting prices as shown above have been set by the Ozone Registration Group (ORG) based on assumptions of this niche LoA market.

It is expected that the cost for the inclusion of ozone into the EU List of Approved Active Substances must not exceed 2.25 MEUR. In an attempt to offer a fair pricing structure it was decided that if the value of ordered letters of access (LoA) before the inclusion of ozone into the EU List of Approved Active Substances is exceeding this amount above, all surplus will be paid back and thus distributed between all LoA-owners.

For the applicants it will be a good investment to buy a LoA as they can benefit from the knowledge in the dossier of the group for a minimum period of 10 years.

Please note: The information above is not to be seen as an offer of the ORG or Euro₃zon. Valid terms and conditions for LoAs will be made available by Euro₃zon.

You can contact Euro₃zon by email: info@euro3zon.org and or by the website: www.euro3zon.org