PYLOTE regulatory compliance & strategy

European regulations on Biocidal products

ATOUT REACH is a service provider mandated by PYLOTE on regulatory compliance with the regulation of products EU biocides (BPR) n° 528/2012[1].

This communication from July 2nd ,2020 is based on the situation described by PYLOTE, and aims to support communication on their regulatory compliance and strategy to PYLOTE customers.

Biocidal products Regulation

BPR (PYLOTE and Customers)	The Antimicrobial technology developed by PYLOTE is subject to the obligations of the BPR as soon as allegations of the "disinfectant" or "antimicrobial" type are made. It relies on the use of a catalyst in order to generate hydroxyl free radicals. As a manufacturer, supplier and trader of these chemical, certain regulatory requirements apply.
Biocidal active substance and product (PYLOTE)	In accordance with article 3, PYLOTE technology can be considered as an In situ generation system[2] involving a biocidal product whose in situ generated active substance (hydroxyl radicals) is formally named "*free radicals generated in situ from ambient air or water*". Initial application for active substance approval under BPR is in progress. Biocidal product authorisation under BPR will be necessary afterwards.
Biocidal treated articles (PYLOTE and customers)	Mixtures and articles, as the **COVERSAFE** which are adhesive films activated by Pylote technology, can be considered as biocidal treated articles. These can be currently put in the market and details on PYLOTE compliance under BPR can be communicated upon request.

[1] https://echa.europa.eu/fr/regulations/biocidal-products-regulation/legislation

[2] Definition available in the CE note reference CA-Jul19-Doc 4.1_Clean

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