WHITE PAPER

Formaldehyde – How long does it have left? (A further update!)

In 2016, Ecolab produced a whitepaper highlighting the reclassification of formaldehyde as a human carcinogen and identifying the possible consequences for its use as a biocidal product. In 2021, Ecolab produced an update based on the review of formaldehyde under the European Biocidal Products Regulation (BPR) and its authorised use as an active substance for a limited 3-year period. Once again, Ecolab is updating users on the current situation involving formaldehyde as a disinfectant chemistry and communicating the rapidly approaching restriction of formaldehyde as a biocide in the UK.

Ecolab, whilst operated as Bioquell, has been warning of the impending removal of formaldehyde as a disinfecting chemistry ever since the UK Health and Safety Executive (HSE) released its July 2015 Biological Agents eBulletin warning formaldehyde users to start looking into alternative gaseous disinfectants for rooms and equipment. Those UK based users who have not heeded the HSE's warning have a rapidly closing window to move away from formaldehyde before its ban comes into force on the **1st February 2025.**

Not all formaldehyde use scenario's will be banned in February 2025, the restriction applies to the use of applications coming under "Product Type 2" of the Great Britain Biocidal Product Regulation (GB BPR). Briefly, there are 22 different use areas or product types (PTs) under the BPR covering everything from metal working fluids to hand disinfectants. PT2 is the largest disinfectant use category called "Public Area Disinfectants" and covers everything from disinfection of hospitals to cleanrooms and office blocks. Examples of PT2 applications for formaldehyde include the disinfection of biological safety cabinets (BSCs), laboratories, pass-through chambers, manufacturing facilities, etc. The use of formaldehyde to disinfect these types of enclosures will be illegal in Great Britain from **1st February 2025**. The HSE eBulletin announcing this position can be accessed here.

The restriction on the use of formaldehyde in PT2 in GB has occurred because no supplier of formaldehyde was willing to support the use of the chemistry as a biocidal product. In Europe, formaldehyde has been supported for authorisation under the European BPR. Its current authorisation expires on the 31st January 2025 and will require renewal by the European Chemicals Agency (ECHA). As formaldehyde was limited to a 3-year authorisation in 2022 due to its toxicity profile, it is almost certain that it will be subject to another time-restricted authorisation if re-authorised.

The limitation on the use of formaldehyde in PT2 and its outright ban for use in PT2 in GB poses particular challenges for research companies and institutions in the biomedical / animal health area where formaldehyde is the default gaseous disinfectant chemistry. The Food and Agriculture Organization of the United Nations and the European Commission for the Control of Foot and Mouth Disease highlight in their guidance on Minimum Biorisk Management Standards (MBMS) that an application of formaldehyde at a concentration of 10 g/m^3 and relative humidity of 70% for a minimum of 10 minutes is an acceptable method for equipment and surface decontamination. The MBMS guidance also identifies that methods that have been validated and shown to be effective against Foot & Mouth Disease Virus (FMDV) may also be used as an alternative. Bioquell has worked with companies and institutions to evaluate the performance of Bioquell Hydrogen Peroxide Vapour (HPV) as an alternative to formaldehyde and has published a number of studies within the scientific literature. These studies include:

- Vannier et al. Hydrogen peroxide vapour is an effective replacement for formaldehyde in a BSL4 Foot and mouth disease vaccine manufacturing facility. *Lett. Appl. Microbiol*. 2019; 69: 237-245.

ECOLAB®

- Stuart et al. Comparing the efficacy of formaldehyde with hydrogen peroxide fumigation on infectious bronchitis virus. *Applied Biosafety*. 2020; 25: 83–9.
- Petit et al. Evaluating the efficacy of hydrogen peroxide vapour against foot-and-mouth disease virus within a BSL4 biosafety facility. *Lett Appl Microbiol.* 2017; 65: 281-284.

Ecolab's Bioquell HPV-AQ 35% hydrogen peroxide disinfectant has received a Union Authorisation under the European BPR for use in PTs 2, 3 and 4, in both large (>4 m^3) and small (0.25 – 4 m^3) enclosures, against bacteria, mycobacteria, spores, fungi, yeasts, viruses and bacteriophage.

At point of writing (June 2024), according to the ECHA list of authorised biocidal products, only one formaldehyde product has been authorised for use as a room fogging disinfectant and only for use in PT3 (animal housing) in the territories of Belgium and Italy. The product must be applied with a cold ultrasonic fogging device producing an average particle size of 5.15 microns. It is authorised for use in large enclosures (>4 m^3) against bacteria, fungi, yeasts and viruses. It is not authorised for use against mycobacteria or bacterial spores. The specified application rate is 5 g/m^3 with a 2-hour contact time, followed by a 2-4 day ventilation period. Whilst formaldehyde as an active substance was only authorised for 3 years, the product has been authorised for 5 years. The product authorisation can be accessed on the ECHA website here.

In summary, the use of formaldehyde as a PT2 disinfectant in GB will no longer be authorised by the HSE from February 2025. Whilst it is expected that formaldehyde will continue to be available as a PT2 disinfectant in Europe, the controls on its application are likely to be far greater than those employed by today's users of formaldehyde fumigation, as evidenced in the single formaldehyde product approval to date.

USE BIOQUELL PRODUCTS SAFELY. ALWAYS READ THE LABEL AND PRODUCT INFORMATION BEFORE USE.

ECOLAB LTD
52 Royce Cl
Andover
SP10 3TS, UK
www.bioquell.com

EUROPE HEADQUARTERS
Ecolab Europe GmbH
Hofwiesenstrasse 349
CH-8050 Zürich, Switzerland
www.ecolab.com/lifesciences

12163