



Formaldehyde – how long has it got left?

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On the 1st January 2016, the EU officially adopted the reclassification of formaldehyde, under the CLP (Classification, Labelling and Packaging) Regulations EC 1272/2008, as a Class 1B Carcinogen and Class 2 Mutagen. In simple terms, a Class 1B identification means that formaldehyde is presumed to have carcinogenic potential in humans – i.e. it is thought to cause cancer.

This paper explores some of the background and discusses the potential banning of this commonly used laboratory chemical as a biocide.

Formaldehyde & the BPR

The Biocidal Products Regulation is designed to ensure that biocides placed on the European market are safe for humans to use and do not pose an unacceptable risk to the environment. The reclassification of formaldehyde as a Class 1B carcinogen has profound consequences in relation to its use as a biocidal product under the BPR.

Article 5 (1)(a) of the BPR states that any active substances which have been classified under EC Regulation 1272/2008 as either Class 1A or Class 1B carcinogens shall not be approved. However, under Article 5 (2) formaldehyde may gain approval as a biocide for certain limited applications, with specific conditions associated with its use.

In December 2015, formaldehyde was given an approval opinion for use as a biocidal active in products intended for disinfection of animal housing, animal feet, veterinary-associated vehicles and eggs within a hatchery. These applications are known as Product Type (PT) 3 applications. The approval opinion states that formaldehyde application must be carried out by professionals who have adequate training. It has also been identified as a substance of concern.

What's a substance of concern?

Products that have characteristics that pose a particular concern to the public health or the environment are classified as substances of concern. When a product is identified as a substance for concern, it acquires another label under the BPR as a 'candidate for substitution'. Candidates for substitution are basically substances that the EU has determined shouldn't really be on the market and which should be phased out and replaced by more suitable alternatives over time. Candidates for substitution can only be authorised for a period of 5 years, in comparison to the standard authorisation of 10 years for other biocidal products. Further, when an active substance is identified as a candidate for substitution, products containing that active will have to undergo a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives.

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What is formaldehyde?

Formaldehyde is a colourless, flammable gas at room temperature and has a strong odour. Formaldehyde gas at a concentration of between 5-10g/ cubic metre for four hours is often used for space decontamination.

Gaseous formaldehyde can be generated by heating flake paraformaldehyde (at around 5g per cubic metre) in a 'frying' pan, thereby converting it to formaldehyde gas. It is also possible to add around 35ml of formalin (40% formaldehyde) to 10g potassium permanganate per cubic metre of space. The humidity must be controlled and the system works optimally at 80% relative humidity. These methods are effective in killing microorganisms but toxicity issues are present.

Formaldehyde is relatively inexpensive and easy to use; however, it is a possible carcinogen and leaves residues after treatment. This residue (either paraformaldehyde or methenamine) must be cleaned from all work surfaces. Residual formaldehyde due to off-gassing from the paraformaldehyde is a concern because of its toxic and irritating properties and potential for adverse effect on the research being conducted in the biological safety cabinet (BSC). Cleaning the residue is usually done by wiping down all surfaces within the BSC, which is difficult to accomplish in the plenums, blower modules, below the work surface, etc., with an ammonia-based solution.

Exposure to formaldehyde may cause adverse health effects. Formaldehyde can cause irritation of the skin, eyes, nose, and throat. High levels of exposure may cause some types of cancers.



What about laboratories?

Formaldehyde underwent review for use in both PT2 (public area) and PT3 (veterinary); however, as of June 2016, only the opinion related to its use in PT3 has been released – it is currently unknown as to whether formaldehyde will be authorised for use in PT2. Laboratory and biological safety cabinet decontamination (non-animal facility) come under the PT2 use area. If the Biocidal Products Committee decides not to authorise formaldehyde for PT2 applications, formaldehyde fumigation within laboratories will become illegal.

Is it REALLY going to get banned?

In PT2 applications, the answer is 'probably'. During the EU's public consultation on alternatives to formaldehyde, hydrogen peroxide vapour (HPV) was put forward as an alternative technology in PT2 use scenarios. The response to the public consultation was predominantly in support of the use of formaldehyde in PT3 applications, where the presence of gross organic (i.e. cow sheds, chicken houses, etc contain very high levels of organic) makes the use of oxidation-based biocides non-

viable. This support and lack of an alternative, is likely to be the reason why formaldehyde was approved for PT3 use.

The UK Health and Safety Executive (HSE) also believe that the future of formaldehyde as a biocide is looking uncertain. In the July 2015 edition of its 'Biological Agents eBulletin' the HSE identified the impact of the Class 1B reclassification in relation to the authorisation of formaldehyde under the BPR. The following statement was presented in the eBulletin in bold text:

"HSE therefore recommends that users start to look into the development of alternative gaseous disinfectants for rooms and equipment, whilst there is time to do so."

Hydrogen peroxide is authorised as a biocidal active under the BPR for a wide range of PTs (including PT2 & PT3). Bioquell's HPV technology is fully compliant with the BPR and is being used as a replacement for formaldehyde by a large and growing number of customers. Should you wish to discuss the information contained in this document, or the advantages of HPV decontamination over formaldehyde, please contact us via our website.

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