FABI – Formaldehyde Biocide Interest Group

Brussels, 10 April 2015

Statement from FABI members in response to the public consultation on potential candidates for substitution for formaldehyde in PT 2

The members of the Formaldehyde Biocide Interest Group (FABI) would like to submit the below expert statement regarding the essential use of formaldehyde as a biocide for private area and public health area disinfectants (PT2).

FABI is a CEFIC registration group representing all European producers of formaldehyde and formaldehyde releasers participating in the Biocidal Products Regulation (BPR) Review Programme. FABI members strongly recommend taking into account the considerations laid out in this expert statement in view of the preparation of the opinion of the Biocidal Products Committee for formaldehyde and product-type 2.

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Fraunhofer
ITEM

Formaldehyde as a biocide for private area and public health area disinfectants and other biocidal products (PT2) and its impact on human health

Public summary of the essential uses of formaldehyde in PT2

Fraunhofer Institute for Toxicology and Experimental Medicine (ITEM), Hanover, Germany

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1. Introduction

Infectious diseases are caused by bacteria, viruses and fungi; some of the pathogens have an epidemic potential such as tuberculosis, HIV or influenza. The control of pathogens and disease outbreaks is hence an important measure to prevent human suffering and poses challenge for the society.

Surfaces may contribute to transmission of epidemiologically important microbes as viruses, fungi and bacteria can contaminate and survive in the inanimate environment and may hence pose a risk for nosocomial infections. Known nosocomial infections comprise methicillin resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile*, enteric viruses (i.e. *norovirus, rotavirus*), Tuberculosis or *Pseudomonas aeruginosa*.

Good hygiene practice and biosecurity is the most effective starting in the beginning of the chain of infections and transmission. Disinfection regimes are a crucial part to prevent transmission and outbreaks of disease and are, hence, indicated by international recommendation and national legislation.

2. Formaldehyde and its use as a disinfectant in public health area

Formaldehyde has been used as decontamination treatment in the public health area over many decades. Since formaldehyde has a broad antimicrobial spectrum with extensive experimental data, it is an important measure of users for efficient disinfection (Bodenschatz 2006, Ewart SL 2001, Kramer & Assadian 2008).

Disinfection regimes involving formaldehyde were found to be the most effective (DGHM 2002, Wallhäuser 1995, Reinbaben 2002). Formaldehyde is a high level disinfectant inactivating vegetative bacteria, mycobacteria, fungi, enveloped and non-enveloped viruses and bacterial spores (SCENIHR, 2009).

Important factors for the efficacy of disinfectants are time, temperature, pH value, surfaces and contamination with faeces and organic matter. Moreover, material compatibility and corrosive effects have to be considered. Formaldehyde is non-corrosive and exhibits good

material compatibility towards wooden surfaces, electronic and mechanical equipment. The efficacy of formaldehyde is also due to its superior penetration properties and the resistance to inactivation by blood and organic matter. Additionally the fumigated substance can reach all inaccessible areas and crevices in the facility. Due to its antimicrobial efficiency and compatibility, formaldehyde enables a high control of infectious diseases (Bodenschatz 2006, Kramer & Assadian 2008).

Disinfection of contaminated surfaces, instruments, rooms and equipment by formaldehyde is indicated by national legislation for several highly contagious diseases and epidemic plagues. For example a list of plagues with highly infectious and highly contagious properties that require most efficient decontamination by formaldehyde is provided by the RKI (Desinfektionsrichtlinie RKI 2007)

Commercial biocidal products contain approx. up to 35 - 37% formaldehyde. Formaldehyde is applied in closed rooms at concentration of 2-7.5 % solution, in general, or as fume at 5 g/m³ with a relative humanity of 70 % (Desinfektionsrichtlinie BMELV, Desinfektionmittelliste RKI).

3. Consideration of risk to humans and environment from the use of formaldehyde in room, instrument and textile disinfection

Room disinfection by formaldehyde and preparations containing formaldehyde is regulated by national legislation, e.g. the TRGS 522 in Germany. In general, the disinfection regime consists of disinfection validation, room cleansing (if applicable), application of the disinfectant, elimination of residual disinfectant and decontrolling of the room. The application of formaldehyde for room disinfections is restricted to professionals only. A safe application requires automated application devices e.g. evaporators that enable the application of formaldehyde as spray and fume in closed room. The handling of the automated disinfection regime requires full personal protection equipment (PPE) which prevents human contact with the active substance during decontrolling, for example. Personnel protective equipment including hazmat suit, a mask, gloves, protective eye shield/goggles/safety glasses, safety shoes, overalls and protection aprons is indicated.

When fumigation and neutralization are complete the rooms/houses can be ventilated without human exposure. The elimination of formaldehyde is controlled by the disinfection

operator and the room decontrolled according to national regulation (TRGS 522 in Germany).

For all involved personnel the dermal exposure to formaldehyde during normal activities is negligible.

Due to the safe handling and the use of personal protection equipment in closed and sealed rooms the exposure of humans to formaldehyde aerosol/vapour has to be considered low.

An indirect exposure to formaldehyde via drinking water and via food is negligible since no direct exposure of water and agricultural soil is given. Direct contact to food is not assumed. Furthermore, formaldehyde is expected to have no potential for adsorption on sludge, soil and sediments. Formaldehyde is tested to be readily biodegradable and not persistent. Due to its reactivity and the capability of photodegradation and biodegradation, the half-life of formaldehyde in water or under atmospheric conditions is relatively short (EHC 89, 1989). In the gas phase, formaldehyde is rapidly degraded in air, giving the main transformation products hydrogen and carbon monoxide.
An accumulation in the atmosphere is not to be expected. In conclusion, there is no indication for indirect exposure via environment.

4. Summary

Formaldehyde is indicated by European directives and national legislation for disinfection regimes to prevent several diseases including highly contagious and highly infectious diseases that require most efficient decontamination.

Since the active substance formaldehyde has favourable characteristics concerning its extraordinary and superior antimicrobial efficacy and compatibility compared to other mechanical and/or chemical treatment, it has unique features that account for the use as a disinfection agent in private area and public health area (PT2).

For the intended use formaldehyde is applied in a safe way without risk to humans and the environment.

5. References

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