Brussels, 10 April 2014

Statement from FABI members in response to the public consultation on potential candidates for substitution for MBM

The following represents a common statement of all EU formaldehyde-releaser producers participating in the Biocidal Products Regulation (BPR) Review Programme, as represented by the Formaldehyde Biocide Interest Group (FABI) which is a CEFIC registration group.

Summary

N,N'-methylenebismorpholine (MBM) belongs to a category of biocidal actives known as formaldehyde-releasers (or formaldehyde-donors). These substances control microbial growth in a water-containing product or equipment by the slow release of formaldehyde directly into the matrix. There are at least ten other formaldehyde-releasers being considered for authorisation under BPR for several different product types including PT6 and PT13.

A recommendation by ECHA's Biocidal Products Committee to consider MBM as a candidate for substitution and therefore authorise only for a limited time period would act as a precedent and necessarily impact all other formaldehyde-releasers; as a consequence all formaldehyde-releasers currently part of the Review Programme could eventually be subject to the same decision since they all act by the same mode of action.

The potential outcome of this regulatory activity could therefore result in the elimination from the market of an entire, important category of active substances.

This would significantly restrict the choice of biocidal products available to downstream users for some applications, especially for PT13 where the choice of bactericides available to downstream users would be reduced by as much as 60% (as illustrated by Table 1). This would have potentially serious consequences such as, for example, the ability to have a sufficient spectrum of activity to control the wide range of deleterious organisms encountered in the production and use of the preserved products. Such limitations on the type of available activities will present major practical problems for downstream users who need to control microbial activity in their products and/or end uses as described below.

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Impact on the diversity of biocidal active substances

Biocides are an essential part of the sustainability of aqueous-based products. The trend from solvent-containing systems towards water-containing systems for some applications, which is seen as a more environmentally-beneficial option, demands increased biocidal protection during production and subsequent storage and use. In the absence of effective preservation there would be considerably greater spoilage of water-based products, requiring higher disposal levels and the greater consumption of resources to produce replacement stocks. Consequently the use of biocides is not an optional element in aqueous formulations, it is essential.

The range of biocidal active substances available to downstream users for particular end-use applications has been unchanged for at least a decade. This is due in part to their effectiveness, their ease of incorporation into products and the apparent lack of harm to workers at typical use levels and/or when handled according to the manufacturer's recommendation (based on the absence of significant levels of reportable worker health problems in the supply chain being attributed to specific substances). Currently downstream users have the option to use different chemical types in combination to achieve effective biocidal control. Such combinations are essential as any preservative system needs to address a wide range of different microbial threats, which on the simplest level includes bactericides and fungicides.

An unintended outcome of the proposal to recommend MBM (and by analogy all formaldehyde-releasers) as a candidate for substitution could be to reduce the chemical diversity of available biocides especially for metalworking (PT13) where there are a limited number of biocidal actives and associated chemical types notified under the BPR.

Typically, where the range of microbial control chemistries is limited then there is a greater risk and frequency of bacterial contamination developing in the products that need protecting. All biocidal actives have a limited spectrum of efficacy against microorganisms and therefore removal of a whole class of active substances such as formaldehyde-releasers from the EU market will make it more difficult to provide protection from bacterial contamination and spoilage.

Reducing the spectrum of biocidal active substances that are available to downstream users is also expected to generate increased levels of waste as companies may have to discard contaminated fluid more frequently. This, together with the likelihood that fluid maintenance will require greater and more frequent attention, could significantly increase costs for the various industries that rely on biocides and could impact SMEs disproportionately. There is also a greater risk in particular to metalworkers due to the possibility of colonies of harmful human pathogens contaminating end use fluids and equipment resulting from the probable elimination of a proven effective control mechanism for such organisms.

It is also important to recognise that no new technology is expected to be developed in future to fill the void left by the potential disappearance of an entire category of biocidal active substances. This is due to the relatively high cost, regulatory complexity and uncertainty of commercial success of bringing new active substances to market under the BPR (and its predecessor legislation). In this context it is important to realise that even if 'new' biocidal active substances were brought to market with a complete set of supporting toxicity data these products would not have the benefit of the long-term, in-use experience that exists with formaldehyde-releasers. As a result, there is a possibility that such products may introduce different, unexpected 'risk issues' for specific end uses.

It follows, therefore, that if formaldehyde-releasers are recommended for substitution or are subject to time-limited authorisation and are subsequently eliminated from commerce then it is highly probable that no new types of active substance will be developed and/or brought to market as an alternative way of controlling microbial activity for many end uses; this is particularly relevant for industrial applications as described above. This lack of innovation, together with the observation that formaldehyde-releasers are the predominant means of controlling microbial activity in the end-use fluid for applications such as PT13 (where they are currently used in more than 50% of biocidal products to control deterioration of water-containing products by bacteria) means that any recommendation to substitute MBM (and by analogy all formaldehyde-releasers) would create significant, new fluid management problems among those downstream users who currently use these products with full knowledge of their mechanism of action in controlling microbial activity (i.e. releasing formaldehyde into the product matrix).

Harmonized classification and labelling as justification for substitution

The regulatory basis for substitution under the BPR is that biocidal products containing active substances with the worst hazard profiles should be replaced where possible, unless there are no suitable alternatives that have already been authorised and that can demonstrably present a significantly lower overall risk for human health or the environment.

It must be emphasised that no harmonised classification currently exists for any formaldehyde-releaser (including MBM) covering the carcinogenic endpoint. The Annex XV dossier for harmonised classification and labelling presents different options including to classify MBM (and by analogy all formaldehyde-releasers) on the basis of the amount of 'free' (unbound) formaldehyde present in the active substance as placed on the market.

To be considered as a candidate for substitution it would have to be convincingly demonstrated for MBM, and indeed for the entire class of formaldehyde-releasers, that the

active substance as placed on the market and under conditions of reasonably expected use meet the criteria to be classified as Carcinogen Category 1A or 1B. It is therefore suggested that the harmonised classification discussion should be concluded before any decision is taken on substitution.

The rationale for the harmonised classification and labelling proposal for MBM by the Austrian Competent Authority (Carcinogen Category 1B) does not consider the physico-chemical properties of the parent compound but instead is based on the potential for local formaldehyde effects following hydrolysis of the formaldehyde-releasing molecule where it comes into contact with moisture either in the preserved product or human tissue. It is known for example that in the absence of water there is no release of formaldehyde from formaldehyde-releasing molecules and only slow release of formaldehyde in highly concentrated aqueous systems rather than an instantaneous release of all bound formaldehyde. In fact, this 'reservoir effect' is actually essential to contribute to the required long-term preservation of the product. It is acknowledged by the evaluating Member State that the high risk species is the small amount of formaldehyde that is released. In accordance with accepted classification guidance MBM (and all formaldehyde-releasers) as placed on the market should therefore be classified on the basis of the amount of 'free' (unbound) formaldehyde present, and that the parent molecule cannot be considered as carcinogenic in its own right.

The hypothesis used to justify the proposal to classify MBM (and by analogy all formaldehyde-releasers) as a potential carcinogen (i.e. its complete, instantaneous hydrolysis to release all bound formaldehyde) is therefore strongly disputed by FABI members, and further supportive comments will be provided when the harmonised classification and labelling proposal for MBM (and subsequently for all other formaldehyde-releasers) is published for public consultation.

Additionally, this hypothesis, which is the basis of the Austrian Competent Authority's proposal of MBM as a candidate for substitution must relate only to potential local effects of formaldehyde following hydrolysis of the formaldehyde-releasing substance. This is because the recent RAC opinion on formaldehyde recognised that there is no convincing evidence of formaldehyde exerting adverse systemic effects distant to the site of exposure.

As mentioned above it is recognised that the same harmonised classification and labelling opinion would apply to all formaldehyde-releasers that are part of the Review Programme if the proposal of the Austrian Competent Authority for MBM was ultimately accepted. However it must also be recognised that there is a very limited range of alternative biocidal active substances that are included in the Review Programme as bactericides for some applications, and especially for PT13 for example (see Table 1). All of the alternatives are also classified as hazardous for a range of endpoints. The potential elimination of formaldehyde releasers as a class of biocidal actives would then significantly increase the

use of an even smaller pool of suitable biocidal actives, each of which has a hazard profile that might equally cause concern for EU workers, including the potential to cause occupational dermatitis at (or close to) the effective dose. It is therefore expected to be challenging for the authorities to be able to demonstrate conclusively, as they must, that alternative products are of significantly lower overall risk for human health thereby fulfilling the BPR criteria for the eventual restriction of formaldehyde-releasers in the EU market. Furthermore this analysis must be taken in the context of those alternatives which are already authorised (or likely to be authorised) at the time of the substitution review process.

Control options for MBM (an alternative approach for hazard/risk communication)

The basis for concern with MBM (and by analogy all formaldehyde-releasers) should not focus on the 'parent' formaldehyde releaser but instead with the small amount of free formaldehyde generated in the preserved product. Therefore control measures should be directed at the 'free' (unbound) formaldehyde content of the biocidal active substance as placed on the market rather than the active substance per se.

The current proposal for a harmonised classification and labelling for MBM (and by analogy all other formaldehyde-releasers) has resulted in a BPR substitution evaluation, a process which could accelerate their disappearance from the EU market. FABI members propose consideration of other ways of more effective hazard communication to ensure protection of EU workers. The intent to protect workers by assigning the precautionary classification of Carcinogen Category 1B to MBM (and by analogy all other formaldehyde-releasers) due to the perceived hazard associated with the potential local release of formaldehyde by hydrolysis following exposure to MBM by inhalation of aerosol particles (given its low volatility) is understandable but will result in significant administrative burden for those downstream users who are required to continue to use formaldehyde-releasers to maintain fluid integrity. Again, it can be anticipated that this will disproportionately impact SMEs who are less likely to have the appropriate in-house expertise to perform the administrative tasks required by other EU legislation to continue to use substances classified in this way.

Instead, improved worker safety and hazard awareness could be achieved more proportionately by, for example, the development of a voluntary code of conduct to be agreed by all EU formaldehyde-releaser producers to include a warning on the product label that low levels of formaldehyde will be released upon contact with water. Many EU producers of formaldehyde-releasing biocides already include such statements on their Safety Data Sheet alerting users to the possibility of formaldehyde release under certain conditions of use, and extension of this approach to labels, which are often the primary means of hazard communication for most workers handling and using chemicals, is already being considered by the industry as a voluntary measure. This alternative approach would ensure that EU

workers are properly informed of the risks associated with handling and working with a biocidal product without adopting an unjustified precautionary approach to the actual hazard of the product as placed on the market.

Comparative Assessment

In terms of the comparative assessment of safety to workers that is part of the substitution process it is worthwhile highlighting that exposure of EU workers to formaldehyde itself is already extremely well controlled in contrast to human exposure to other active substances that are part of the Review Programme but do not rely on release of formaldehyde for their biocidal activity. This is because a significant number of EU Member States have an Occupational Exposure Limit in place for formaldehyde and an EU-wide Indicative Occupational Exposure Level Value for formaldehyde is under discussion by the Scientific Committee on Occupational Exposure Limits. This ongoing development is expected to further limit short-term and long-term exposure to formaldehyde in the workplace. Other national/EU-wide schemes that concern specific applications already include additional controls that minimise or eliminate products containing formaldehyde-releasing biocides.

Additionally, and perhaps more significantly, a recent study by the DGUV Fachbereich Holz und Metall and involving other stakeholders including the association of German Lubricant Manufacturers (Verbraucherkreis Industrie Schmierstoffe; VKIS) has demonstrated that measured airborne levels of formaldehyde were found to be below the national occupational exposure limit (safe working limit) in all but one metalworking machining locations examined. This study strongly indicates that there is no justification for additional regulatory measures for MBM (and by analogy all other formaldehyde-releasers) such as substitution under BPR on the basis of protecting EU worker from adverse effects associated with his/her potential exposure to formaldehyde, at least for this application.

Furthermore, the study findings agree with the theoretical calculation that at their effective dose formaldehyde-releasers would rarely generate a level of released formaldehyde in an aqueous solution that was greater than the regulatory threshold for classifying mixtures as potentially carcinogenic (i.e. 1000 ppm), even under the unrealistic scenario where all available formaldehyde was released instantaneously.

Classification rules

It is proposed to classify the potential substitution candidate MBM in the same way as its hydrolysis product, namely formaldehyde. We would suggest that this is not in accordance with the intent of the rules regarding classification and labelling according to CLP where the classification normally relates to the substance itself as placed on the market. The classification rules do not typically require the person placing the product on the market to

consider potential released substances or degradation products which may occur during different use scenarios.

Under CLP MBM (and by analogy all formaldehyde-releasers undergoing the Review programme) is defined as a substance meaning a [discrete] chemical element and its compounds in the natural state or obtained by any manufacturing process…" Normally, information that is taken into consideration to classify the substance "… shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used." Additionally, where "…. a substance contains another substance, itself classified as hazardous, […], this shall be taken into account for the purposes of classification, if the concentration of the identified impurity, additive or individual constituent is equal to, or greater than, the applicable cut-off value in accordance with paragraph 3." It therefore follows that the content of free formaldehyde within MBM as placed on the market is relevant for classification and not the amount of formaldehyde potentially released during use. MBM (and by analogy all formaldehyde-releasers) should therefore be classified solely on the basis of its hazardous properties in the form that it is placed on the market, including any unbound (free) formaldehyde present as an impurity, without considering potential hydrolysis products released only under certain uses and specific physico-chemical conditions.

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Table 1: List of active substances included in the Review Programme for Product Type 13 (Metalworking fluid preservatives)

Substance	EC number	CAS number	Type	Category
Chlorocresol	200-431-6	59-50-7	Fungicide	Phenolic
Sodium p-chloro-m-cresolate	239-825-8	15733-22-9	Fungicide	Phenolic
Biphenyl-2-ol	201-993-5	90-43-7	Fungicide	Phenolic
2-Phenoxyethanol	204-589-7	122-99-6	Bactericide/ Fungicide	Phenolic
Sodium 2-biphenylate	205-055-6	132-27-4	Fungicide	Phenolic
Potassium 2-biphenylate	237-243-9	13707-65-8	Fungicide	Phenolic
Diamine	219-145-8	2372-82-9	Bactericide	Amine
BIT	220-120-9	2634-33-5	Bactericide	Isothiazolinone
MIT	220-239-6	2682-20-4	Bactericide	Isothiazolinone
OIT	247-761-7	26530-20-1	Bactericide	Isothiazolinone
BBIT	420-590-7	4299-07-4	Bactericide	Isothiazolinone
Mixture of CMIT/MIT	Mixture	55965-84-9	Bactericide	Isothiazolinone
Reaction products of ethylene glycol with paraformaldehyde (EGForm)	222-720-6	3586-55-8	Bactericide	Formaldehyde-releaser
HHT	225-208-0	4719-04-4	Bactericide	Formaldehyde-releaser
MBM	227-062-3	5625-90-1	Bactericide	Formaldehyde-releaser
DMDMH	229-222-8	6440-58-0	Bactericide	Formaldehyde-releaser
Oxazolidin/MBO	266-235-8	66204-44-2	Bactericide	Formaldehyde-releaser
CTAC	223-805-0	4080-31-3	Bactericide	Formaldehyde-releaser
Cis CTAC	426-020-3	51229-78-8	Bactericide	Formaldehyde-releaser
TMAD	226-408-0	5395-50-6	Bactericide	Formaldehyde-releaser
EDHO	231-810-4	7747-35-5	Bactericide	Formaldehyde-releaser
(benzyloxy)methanol	238-588-8	14548-60-8	Bactericide	Formaldehyde-releaser
HPT	246-764-0	25254-50-6	Bactericide	Formaldehyde-releaser
Sodium pyrithione	223-296-5	3811-73-2	Fungicide	Pyrithione
IPBC	259-627-5	55406-53-6	Fungicide	Carbamate
DBNPA (note 1)	233-539-7	10222-01-2	Bactericide	Electrophilic

Note 1 = the substance is unstable in metalworking fluids; its use is confined to situations where user desires short or no delay/quick kill of microbes.