



Guideline for users of MWF

Formaldehyde-Releasers and Safety-precautions according to the Hazardous substances ordinance

1 Introduction, terms

A proper risk assessment according to § 7 of the hazardous substances ordinance [1] requires a high degree of technical skills of the respective persons in charge. This assessment is particularly complex for formaldehyde, if

- classification and labeling do not only result from the active substance (= **Formaldehyde-releaser**), but also depend on impurities and not reacted raw material (= **Formaldehyde**) of preparations,
- the composition changes during use due to dilution (intended) and degradation (partly not intended, e.g. by pH-values too low),
- assessment is subject of some discrepancies.

For formaldehyde-releasers these three items are correlated.

2 Classification and labeling of formaldehyde (according to 67/548/EEC)

Formaldehyde has a number of different hazardous properties which are followed by R-phrases dependent on concentration-limits:

Conc. < 0,2%	none
0,2% ≤ Conc. < 1%	X _i ; R 43
1% ≤ Conc. < 5%	X _n ; R 40, 43
5% ≤ Conc. < 25%	X _n ; R 20/21//22 ; 36/37/38, 40, 43
25% ≤ Conc.	T ; R 23/24/25, 34, 40, 43

Classification and labeling of the traded preparation are defined by the **concentration of free formaldehyde**, some products with more than 5% are available.

Request binding information from your biocide-producer! Important notice: The BPD 98/8/EC bindingly demands the declaration of all hazardous substances in the biocidal product only since 31.07.2007.

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The most extensive protective measures are necessary, if products are used that contain more than 25% of free formaldehyde.

3 Threshold Limit values and Hazard evaluation

The former MAK for formaldehyde, cited in the TRGS 900 [2] in the amount of 0,62 mg/m³ has been withdrawn, because the justification on a basis of occupational medicine and toxicology was thought to be inadequate - that means presently, there exists no legally binding threshold limit value („AGW“).

The scientific committee (MAK-Kommission) proposes a TLV in amount of 0,37 mg/m³, with the status of a reference.

For risk assessment as well we have to follow the directives for hazardous substances and preparations, that means not only existence of formaldehyde leads to a classification with „Toxic – T and R 23/24/25“, but only if specific limits are exceeded.

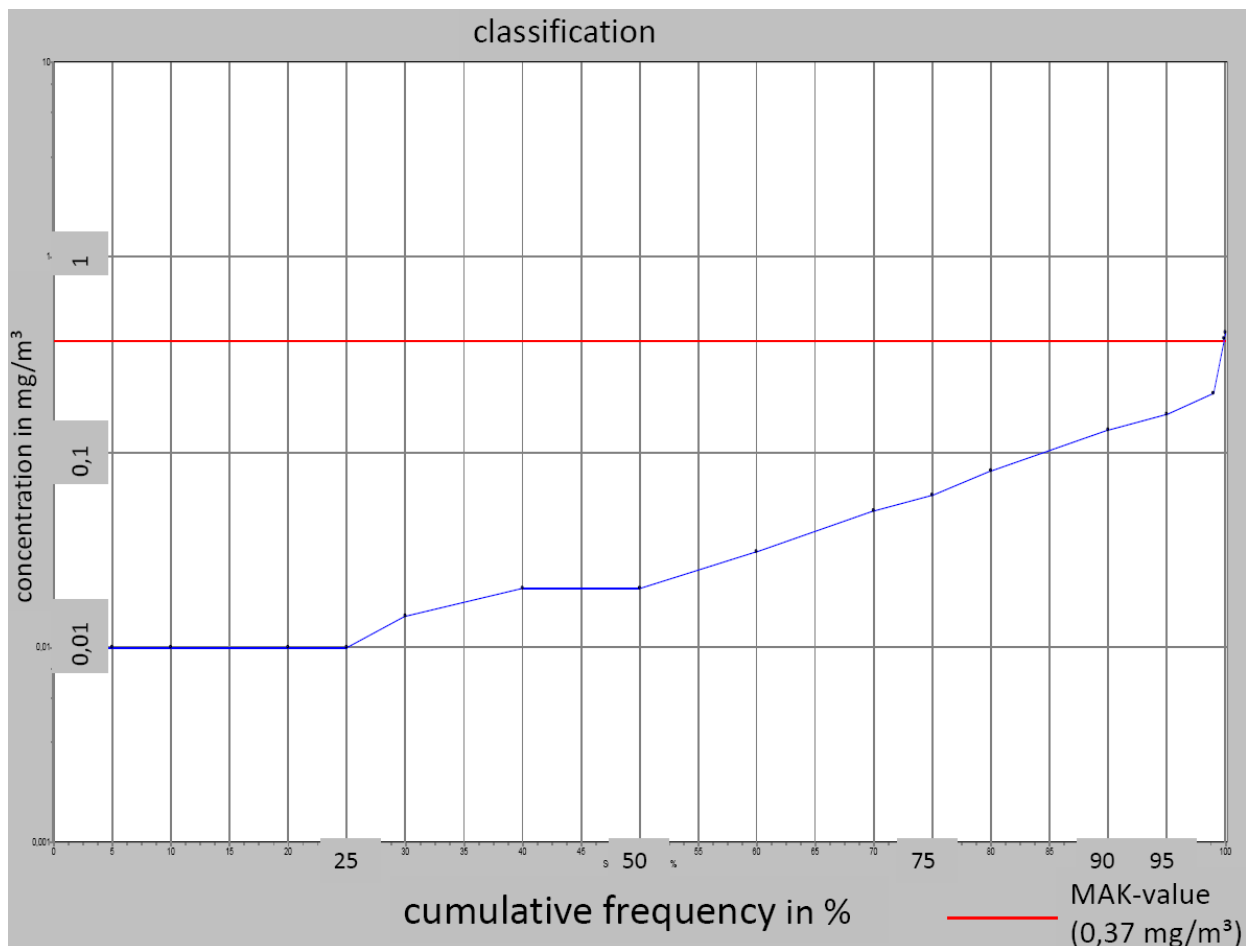
Presently, about 150 measurements of formaldehyde in the air (workplaces with parallel exposure to MWF) are evaluated for the period 2004 – 2009 (excerpt from MEGA)

Number of measurements	148
Number of companies	64
Number of analyses	148
Number of operation modes	17
Highest detection limit	0,01 mg/m ³

Measurements	Concentration	cumulative frequency %
37,000	0,010 mg/m ³	25
74,000	0,020 mg/m ³	50
111,000	0,060 mg/m ³	75
133,200	0,130 mg/m ³	90
140,600	0,156 mg/m ³	95
148,000	0,41 mg/m ³	100

Smallest value	< 0,01 mg/m ³
Arithmetic mean	0,0469 mg/m ³
Geometric mean	0,0264 mg/m ³
Median	0,02 mg/m ³

Largest value	= 0,41 mg/m ³
Standard deviation	0,0558 mg/m ³
Geometric standard deviation	2,989
Variation coefficient	1,189



Evaluation:

In all conscience we can state: there is no problem, with only a few exceptions.

The 95%-percentile is far below the discussed threshold limit value of the MAK-commission.

Even a much lower limit at 0,1 ppm = 0,124 mg/m³ can be maintained by about 90 % of all tested companies.

Main result of this investigation: in common all protective measures are sufficient, e.g. as published in BGR-GUV-R 143 [3].

4 Current discussion: Is Formaldehyde carcinogenic to humans?

In 2004 the International Agency for the research on Cancer (IARC) published in the monograph No. 88 [4]: Formaldehyde is a cancerogene for human.

Since that time, producers and users of formaldehyde and -releasers have to answer the question: Is a safe use of such products still ensured - and which type of precaution measures are necessary?

In April 2007, Marsh et al [6] published some results and assessed the exposure-data of the IARC to be insufficient.

In brief the following facts have to be considered:

- IARC reasoned from a cluster of persons exposed to formaldehyde and a high incidence of tumours of the upper respiratory system, that these tumours must be caused by formaldehyde. The data were accounted to be sufficient to state „C1 - cancerogene for human“,
- Marsh detected, that most of the affected persons from the cluster had different exposures, not only to formaldehyde, but also to a number of known cancerogenes, such as aerosols from sulfuric acid, welding fumes, anorganic dust.

Marsh stated, that it is not possible to find a monocausal link between the found tumours with the effect of formaldehyde.

Presently, the German MAK-commission has approved the current classification in July 2009 : category 4 [7].

This category has no equivalent in the international system and it is defined that *„... when maintaining the „MAK“ there is only a secondary role ... as a cancerogene and ... under these conditions there is no relevant effect on the risk for cancer to humans“*

Further statements, e.g. from the „Bundesinstitut für Risikobewertung (BfR)“, shall be published [5].

5 Summary

Formaldehyde is a substance with some severe properties, but risks can not be transferred 1 : 1 if formaldehyde-releasers are used.

When assessing risks/hazards the reference of the MAK-Kommission shall be used, as long as the TRGS 900 assigns a new AGW.

When using products without classification as “Toxic - T” and measures have verified, that the exposure is below the threshold limit values, there is no need for complex protective measures according to § 10 of the hazardous substances ordinance.

Following newest publications, there is no evidence for a relevant risk for cancer, therefore even § 11 shall not be implemented.

Under typical operating conditions - that means using formaldehyde-releasers for conservation of water-mixed MWF - all biocidal products with less than 25 % of free formaldehyde can be used safely.

Bibliography:

- [1] Verordnung zum Schutz vor Gefahrstoffen (Hazardous substances ordinance) from 23. Dezember 2004, last issue from 18.12.2008
- [2] TRGS 900 : AGW („TLV“), GMBI Nr. 28 S. 605 (v. 2.7.2009)
- [3] BGR-GUV-R 143: Tätigkeiten mit Kühlschmierstoffen, Issue: Mai 2009
- [4] Monography Nr. 88 of the IARC <http://monographs.iarc.fr/>
- [5] Press-releases of the BFR <http://www.bfr.bund.de/cd/7858>
http://www.bfr.bund.de/cm/238/assessment_of_the_carcinogenicity_of_formaldehyde.pdf
- [6] Marsh et. al. : Work in the metal industry and nasopharyngeal cancer mortality among formaldehyde-exposed workers, Regulatory Toxicology and Pharmacology, 48, S. 308-319 (2007)
- [7] Liste aller Änderungen und Neuaufnahmen in der MAK- und BAT-Werte-Liste 2009 (list of changes and new entries of the MAK-and-BAT-list 2009“ http://www.dfg.de/aktuelles_presse/reden_stellungnahmen/download/mak2009.pdf