

The MAK Collection for Occupational Health and Safety

Hydrogen peroxide

MAK Value Documentation, addendum – Translation of the German version from 2019

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Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has re-evaluated the maximum concentration at the workplace (MAK value) of hydrogen peroxide [7722-84-1] as new inhalation studies are available.

Hydrogen peroxide is an irritant to the respiratory tract and the eyes.

In a 90-day inhalation study in the rat a NOAEC of 7 ml/m³ was determined, which confirms the previous 28-day inhalation study and proves that the effects at the respiratory tract do not increase with exposure duration.

A new study of acute effects in volunteers suggests that hydrogen peroxide is slightly irritating at 2.2 ml/m³, but not at 0.5 ml/m³. These findings support all previously described results of inhalation studies in workers or volunteers.

Based on the NOAEC established for humans, the MAK value of 0.5 ml/m³ is retained.

Peak Limitation Category I and the excursion factor of 1 are retained as there are no new data.

Keywords

hydrogen peroxide; hydrogen dioxide; hydroperoxide; dihydrogen dioxide; (sub)acute toxicity; (sub)chronic toxicity; peak limitation; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

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Hydrogen peroxide

[7722-84-1]

Supplement 2019

MAK value (2005)	0.5 ml/m³ (ppm) \triangleq 0.71 mg/m³
Peak limitation (2000)	Category I, excursion factor 1
Absorption through the skin	–
Sensitization	–
Carcinogenicity (2005)	Category 4
Prenatal toxicity (2005)	Pregnancy Risk Group C
Germ cell mutagenicity	–
BAT value	–
1 ml/m³ (ppm) \triangleq 1.412 mg/m³	1 mg/m³ \triangleq 0.708 ml/m³ (ppm)

Documentation for hydrogen peroxide was published in 2006 (documentation “Hydrogen peroxide” 2010). New studies of the effects of exposure by inhalation have made re-evaluation of the MAK value necessary.

Effects in Humans

Single exposures

In a study investigating the acute effects, 5 male and 6 female volunteers were exposed to hydrogen peroxide concentrations of 0, 0.5 or 2.2 ml/m³ in an exposure chamber for 2 hours at rest. In addition to the subjective rating of symptoms on the basis of the Visual Analogue Scale (VAS), lung function, nasal swelling and airway resistance, breathing and blinking frequency, and markers of inflammation and coagulation in the blood (interleukin 6, C-reactive protein, serum amyloid A, fibrinogen, factor VIII, von Willebrand factor, Clara cell protein in plasma) were investigated. The only effect with statistical significance was a slight increase in nasal airway resistance that was observed directly after exposure to 2.2 ml/m³. The effect was regarded as evidence of slight irritation and swelling of the upper respiratory tract. This interpretation was supported by a slight, but not statistically significant, increase in

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the VAS score for nasal irritation given by women exposed to 2.2 ml/m³ (Ernstgård et al. 2012). For the evaluation of these data, it needs to be taken into account that the median nasal symptom score for irritation in women after exposure to 0.5 ml/m³ was about as high as that for the 90th percentile of men exposed to 2.2 ml/m³. Additionally, women had much higher symptom scores for “smell” than men after exposure to 2.2 ml/m³. The NOAEC (no observed adverse effect concentration) of this study was therefore 0.5 ml/m³; slight irritation was observed at 2.2 ml/m³.

Repeated exposure

Workers exposed to hydrogen peroxide at concentrations in the range of 1.2 to 2.4 ml/m³ with peak exposures of 8 ml/m³ reported irritation of the eyes and throat, nasal congestion, coughing and asthma symptoms. It is not clear from the study data whether these effects were caused by the peak exposures. No effects were described after 8-hour exposure at the workplace to concentrations of up to 0.5 ml/m³ (Riihimäki et al. 2002). Lung function tests also did not yield unusual findings at exposure levels up to 0.56 ml/m³ and 0.67 ml/m³ (EU 2003; Mastrangelo et al. 2005).

The data below have become available since the 2006 documentation was published (documentation “Hydrogen peroxide” 2010):

Two cross-sectional studies from 2005 and 2006 investigated 69 workers who were exposed to hydrogen peroxide during sterilization processes prior to bottling and 65 control persons without exposure. In the study from 2005, the hydrogen peroxide concentration in the sterilization chambers was 0.82 mg/m³ (0.58 ml/m³, geometric mean) with a geometric standard deviation and upper limit of the 95% confidence interval of 1.37 and 1.53 mg/m³ (0.97 and 1.09 ml/m³), respectively. The respective values in 2006 were 0.47 mg/m³ (0.33 ml/m³, geometric mean) with a geometric standard deviation and upper limit of the 95% confidence interval of 2.24 and 2.28 mg/m³ (1.59 and 1.62 ml/m³), respectively. The sampling time for these personal samples was 30 minutes. In 2005, a significant correlation was found between exposure and irritation of the eyes and respiratory tract (watering, burning or reddened eyes, nasal secretion or obstruction, nasal itching and sneezing, coughing). In 2006, 38 of the 40 workers wore respirators when entering the sterilization chambers. The levels of irritation in the eyes and nose determined at the bottling facility downstream of the sterilization chambers were not significantly increased in comparison with the scores for the unexposed controls. In 2005, hydrogen peroxide concentrations of 0.13 mg/m³ (0.09 ml/m³, geometric mean) with a geometric standard deviation and upper limit of the 95% confidence interval of 2.11 and 0.58 mg/m³ (1.50 and 0.41 ml/m³), respectively, were determined in this area by stationary air samplers; in 2006, concentrations of 0.07 mg/m³ were determined (0.05 ml/m³, geometric mean; 1.88 and 0.25 mg/m³ (1.33 and 0.18 ml/m³, respectively), geometric standard deviation and upper limit of the 95% confidence interval) (Mastrangelo et al. 2009). The study cannot be used to confirm or change the current MAK value because of the insufficient number of determinations, peak exposures, “reporting bias” of the workers (which the authors of the study also mentioned) and numerous other methodological limitations.

Animal Experiments and in vitro Studies

Subacute, subchronic and chronic toxicity

Inhalation

Valid animal studies of the toxicity induced by inhalation exposure to hydrogen peroxide are listed in Table 1.

Table 1 Studies of the toxicity induced by repeated inhalation exposure to hydrogen peroxide

Species, strain, number per group	Exposure	Findings	References
rat , Wistar, groups of 5 ♂, 5 ♀	28 days , 6 hours/day, 5 days/week, 0, 2, 10 or 25 ml/m ³ , OECD Test Guideline 412, nose-only exposure	2 ml/m³ : NOAEC; 2 ml/m³ and above : ♂, ♀: perivascular neutrophilic infiltrate in the lungs without concentration dependency; 10 ml/m³ and above : ♂, ♀: reddened noses and stains around the nose, minimal to slight necrosis and inflammation in the anterior nasal cavity (all animals) and in the respiratory epithelium (one animal); 25 ml/m³ : ♂, ♀: salivation, ruffled fur and abnormal breathing sounds; rhinitis, infiltration of mononuclear cells, epithelial erosions in the larynx, ♂: body weight gains ↓ (8.2%)	CEFIC 2002
rat , Wistar, groups of 10 ♂, 10 ♀	90 days , 6 hours/day, 5 days/week, 0, 1, 2.5 or 7 ml/m ³ , OECD Test Guideline 413, nose-only exposure	7 ml/m³ : NOAEC; no substance-induced effects	CEFIC 2014

In a 90-day inhalation study from 2014 that was carried out according to OECD Test Guideline 413, 10 male and 10 female Wistar rats per concentration group were exposed nose-only to hydrogen peroxide vapour concentrations of 0, 1, 2.5 or 7 ml/m³ for 6 hours a day, on 5 days a week. No clinical findings or symptoms were observed. Examination of the eyes, body weight gains, feed consumption, and haematological and histopathological examinations including the respiratory tract and the nasal conchae, did not yield substance-induced findings. An increase in alkaline phosphatase in the blood of the males of the high concentration group was statistically significant, but within the range of the historical controls and therefore not regarded as adverse. In addition, the absolute and relative liver and thymus weights

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were significantly reduced (no other details) in this group compared with those in the control animals. There was no histopathological correlation and the values were within the range of the historical control data; these findings were likewise not regarded as adverse. The NOAEC for hydrogen peroxide vapour was 7 ml/m³ (CEFIC 2014).

The 28-day inhalation study in Wistar rats that was discussed in detail in the 2006 documentation (documentation “Hydrogen peroxide” 2010) determined a NOAEC of 2 ml/m³ and a LOAEC (lowest observed adverse effect concentration) of 10 ml/m³. The new 90-day study with a NOAEC of 7 ml/m³ demonstrated that the effects did not increase over time. The NOAEC of 7 ml/m³ was in the range between the NOAEC and the LOAEC of the 28-day study.

Manifesto (MAK value/classification)

The primary effect of hydrogen peroxide is local irritation of the respiratory tract and the eyes.

MAK value. As in the earlier documentation (documentation “Hydrogen peroxide” 2010), sensory irritation of the eyes and nose was used to derive a MAK value because it is not known at which tissue concentration the detoxification of hydrogen peroxide in the respiratory tract becomes overloaded.

The NOAEC of the 28-day inhalation study in rats was 2 ml/m³. Histological changes in the anterior region of the nasal cavity and the respiratory epithelium were observed at concentrations of 10 ml/m³ and above (CEFIC 2002). A new 90-day inhalation study in rats did not reveal substance-induced effects up to the highest concentration tested of 7 ml/m³ (CEFIC 2014) and demonstrated that the effects on the respiratory tract do not increase over time.

Irritation of the eyes and throat, nasal congestion, coughing and asthma symptoms were reported by workers who were exposed to hydrogen peroxide concentrations of 1.2 to 2.4 ml/m³ with peak exposures of 8 ml/m³. It cannot be concluded from the study data whether these effects were caused primarily by exposure peaks. No effects were described after exposure at the workplace to average 8-hour values of up to 0.5 ml/m³ (Riihimäki et al. 2002). Lung function tests yielded no unusual findings up to 0.56 ml/m³ and 0.67 ml/m³ (EU 2003; Mastrangelo et al. 2005). A new study investigated acute effects in test persons (Ernstgård et al. 2012). The NOAEC after 2-hour exposure was 0.5 ml/m³; slight irritation was observed at 2.2 ml/m³.

On the basis of the NOAEC for humans, the MAK value remains unchanged at 0.5 ml/m³.

Peak limitation. There are no new data available; the substance thus remains classified in Peak Limitation Category I with an excursion factor of 1.

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