The MAK Collection for Occupational Health and Safety

Peak limitation: Limitation of exposure peaks and short-term exposures

MAK Value Documentation

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The commission established rules and measures to avoid conflicts of interest.

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Limitation of exposure peaks and short-term exposures

Date of inclusion in the List of MAK Values: 1983 amended: 2002, 2011

Introduction

Section VI "Limitation of exposure peaks" of the List of MAK and BAT Values states that the MAK value is conceived as an average value and therefore the evaluation of short-term exposures[1)] to higher concentrations requires an additional ruling that takes into account the particular mode of action of the substance in question. The Commission has drawn up such a ruling.

Peak values and excursion factors

1. Peak values serve to evaluate and avoid hazards resulting from increased short-term exposures. They supplement the MAK value by limiting the permissible variation in concentration above the average value of the shift as well as its duration and frequency. The variation in concentration permissible depends on the very different modes of action of the individual substances. It is therefore not possible to set a universal parameter for the peak value.
2. In most cases exposure peaks are limited by setting an excursion factor, which, multiplied with the MAK value, gives the maximum permissible peak concentration as average of a sampling period of 15 minutes. For substances in Peak Limitation Category II with an excursion factor of 4 or 8, the average value can be exceeded also for longer periods as long as the product of the excursion factor and duration of the peak is observed. In justified cases peak limitation is regulated via a momentary value, which may not be exceeded at any time. Otherwise Table 1 applies.
3. There should be intervals of one hour between the periods of increased exposure.

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1) In the following, according to the usual international convention, this is understood to be the concentration at the workplace.

4. The categories and corresponding peak limitation parameters are:

Table 1 Excursion factors, the duration of peaks and number per shift, and the interval between peaks

Category	Excursion factor	Duration	Number per shift	Interval[***]
I Substances for which local irritant effects determine the MAK value, also respiratory allergens	1[*]	15 min, average value[**]	4	1 hour
II Substances with systemic effects	2[*]	15 min, average value	4	1 hour

[*] default value, or a substance-specific value (maximum 8)
[**] In certain cases, a momentary value (concentration which should not be exceeded at any time) can also be established
[***] only for excursion factors > 1

5. For the substances in Peak Limitation Category I, the concentration of the substance is the decisive factor for the effects. When establishing the excursion factor for substances in Peak Limitation Category I, the following criteria apply:
   - The database for the establishment of excursion factors is usually the current documentation of the MAK value. In the case of substances in Peak Limitation Category I for which a MAK value documentation has not yet been published, a provisional excursion factor of 1 is set.
   - For all substances in Peak Limitation Category I for which the LOAEL (lowest observed adverse effect level) for local irritation and the MAK value are close together, an excursion factor of 1 is set.
   - For substances for which there is a sufficiently large margin between the LOAEL for local irritation in humans and the MAK value, an excursion factor > 1 can be set.
   - Mild, short-term eye irritation, in particular if this was observed in studies with volunteers, is regarded as tolerable. At other sites (for example, the respiratory tract), no effects should occur, however, after exposure at the peak concentration.
   - If there are no data from humans, but suitable long-term studies with animals are available, an excursion factor can likewise be derived from these.
   - For substances classified in a carcinogen category that have a MAK value and for which the formation of tumours can be attributed to the effects of irritation, generally an excursion factor of 1 is set.
   - An excursion factor > 1 can be established only for those carcinogenic substances for which the cancer risk is not increased even after exposure at the peak concentration.

6. Also for substances with mainly systemic effects (Peak Limitation Category II) the substances must be regarded individually, taking the following criteria into consideration when establishing the excursion factors:
   - The excursion above the MAK value must not be so high that it leads to irritation (criteria as for substances in Peak Limitation Category I) or narcotic effects.
   - Also with excursions above the MAK value the kinetics of the detoxifying metabolic pathway should still be linear.
   - If the effects correlate with the concentration of the substance in blood, the excursion factor should be so small that the LOAEL cannot be reached at the excursion concentration. The same applies to substances which rapidly lead to effects. The concentration of a substance in blood depends, among other things, on its half-life. The excursion factor is therefore dependent on the elimination half-time of the substance or the critical metabolite in blood determined in humans or experimental animals. The maximum concentration of a substance in blood at the end of a working day with constant exposure at the level of the MAK value (Cmaxc), and with 4 additional 15-minute exposure peaks at hourly intervals in the last half of the shift can be calculated by means of kinetic modelling (first order). If the last exposure peak is reached in the last quarter of an hour of the working day, it represents the maximum concentration reached in the body (Cmaxp) (Figure 1). The MAK value, which is defined as the 8-hour average value (represented as the area under the concentration-time curve), is observed by both exposure scenarios.

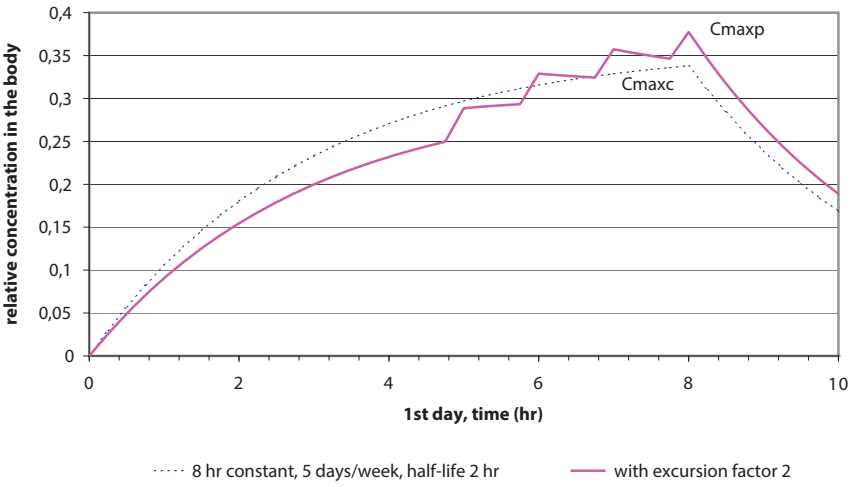

Figure 1 Calculated relative concentrations in the body with constant exposure and with 4 15-minute peak exposures with an excursion factor of 2

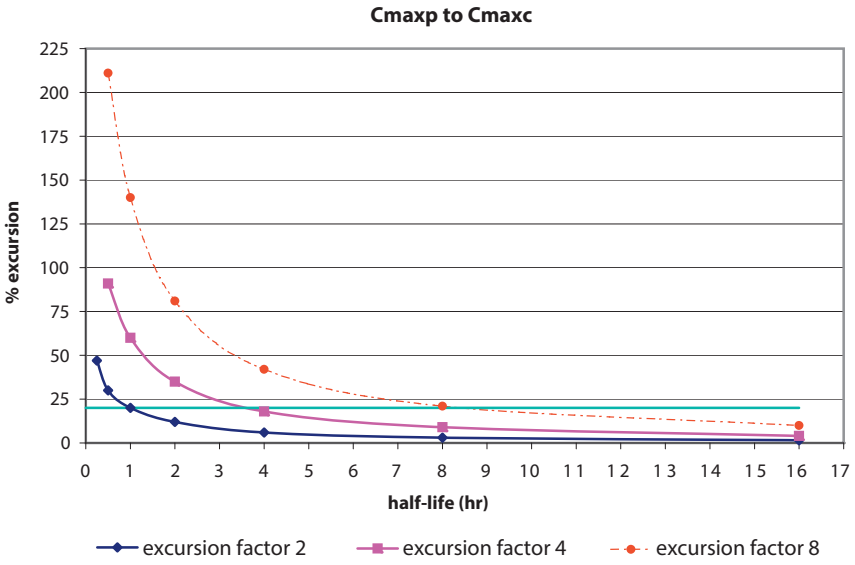

Figure 2 The relationship of Cmaxp to Cmaxc depending on the half-life and excursion factor

The relationship of Cmaxp to Cmaxc as the percentage by which the MAK value is exceeded in relation to the half-life of the substance, with excursion factors of 2, 4 and 8, is shown in Figure 2.

With a permissible excursion above the MAK value of 20% to 25%, an adverse effect is excluded, as the LOAEL is usually twice as high as the NOAEL (no observed adverse effect level), from which the MAK value is derived. The following excursion factors (see the line parallel to the x axis in Figure 2) are thus obtained depending on the half-life of the substance:

Half-life (hours)	**excursion factor**
≥ 8	8
≥ 4	4
≥ 1	2
< 1	1

With a half-life of below one hour, the excursion factor is 1

- If the AUC (area under the curve) is decisive for the systemic toxic effects, the average concentration is a suitable parameter for the internal exposure, as long as the detoxifying metabolic pathways are not saturated. A higher excursion

factor can therefore be selected if there are no other reasons (see point 1.) against this.

- The maximum excursion factor is 8. If the MAK value is exceeded 8-fold on 4 occasions for 15 minutes, no further exposure may take place in that shift, as otherwise the product of shift length and MAK value will be exceeded.
- If there are no relevant kinetic data, or documentation for the MAK value of the substance is not yet available, a provisional excursion factor of 2 is set, unless structure–effect considerations suggest another excursion factor can be selected.
- If the substance is carcinogenic, an excursion factor of 2 is set, unless the findings suggest another excursion factor.
- The database is usually the current documentation of the MAK value.

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