The MAK Collection for Occupational Health and Safety

White mineral oil, pharmaceutical

MAK Value Documentation, addendum – Translation of the German version from 2018

A. Hartwig[1,*], MAK Commission[2,*]

[1] Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Institute of Applied Biosciences, Department of Food Chemistry and Toxicology, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany

[2] Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany

* email: A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)

Keywords: white mineral oil, pharmaceutical; lung; aerosol; overload effect; MAK value; developmental toxicity; respiratory volume; lubricant

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

1994

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A. Hartwig[1, *], MAK Commission[2, *]

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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) and the Pregnancy Risk Group of pharmaceutical white mineral oil [8042-47-5].

Critical effect is lung toxicity which is observed as microgranulomas in two long-term studies with rats and dogs at a respirable aerosol concentration of 100 mg/m^3 with a NOAEC of 5 mg/m^3. A MAK value of 5 mg/m^3 had been set as the respirable fraction (R). This value is now reaffirmed even considering the increased respiratory volume at the workplace (see List of MAK and BAT Values, Sections I b and I c).

Pharmaceutical white mineral oil had been classified in Pregnancy Risk Group C because the NOAEC for developmental toxicity is 1000 mg/m^3 in rats. There is no new data on developmental toxicity. This classification is retained even considering the increased respiratory volume at the workplace.

Keywords

white mineral oil; paraffin wax; prenatal toxicity; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

Author Information

[1] Chair of the Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Department of Food Chemistry and Toxicology, Institute of Applied Biosciences, Karlsruhe Institute of Technology (KIT), Adenauerring 20a, Building 50.41, 76131 Karlsruhe, Germany

[2] Permanent Senate Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area, Deutsche Forschungsgemeinschaft, Kennedyallee 40, 53175 Bonn, Germany

[*] Email: A. Hartwig (andrea.hartwig@kit.edu), MAK Commission (arbeitsstoffkommission@dfg.de)

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[8042-47-5]

Supplement 2018

MAK value (2014)	**5 mg/m³ R (respirable fraction)**
Peak limitation (2014)	**Category II, excursion factor 4**
Absorption through the skin	**–**
Sensitization	**–**
Carcinogenicity	**–**
Prenatal toxicity (2014)	**Pregnancy Risk Group C**
Germ cell mutagenicity	**–**
BAT value	**–**

Documentation for pharmaceutical white mineral oil was published in 2015 (documentation "White mineral oil, pharmaceutical" 2015).

In 2016, the Commission began using a revised approach for assessing substances with a MAK value based on systemic effects and derived from inhalation studies in animals or studies with volunteers at rest; this new approach takes into account that the respiratory volume at the workplace is higher than under experimental conditions. However, this applies only to gases or vapours with a blood:air partition coefficient > 5 and aerosols (see List of MAK and BAT Values, Sections I b and I c). This supplement evaluates whether the MAK value and the pregnancy risk group for pharmaceutical white mineral oil need to be re-assessed as a result of the higher respiratory volume at the workplace.

As pharmaceutical white mineral oil and highly refined mineral oils cause the same pulmonary effects after repeated exposure by inhalation as a result of their common basic structure (saturated hydrocarbons), molecular size (> C15), low solubility in water and lack of functional groups, studies with repeated inhalation exposure to highly refined mineral oils were used to derive a MAK value for pharmaceutical white mineral oil (documentation "White mineral oil, pharmaceutical" 2015).

Manifesto (MAK value/classification)

There are no new data available that are relevant for the derivation of the MAK value. The target organs in animal studies were the lungs; the dog and the rat were the most sensitive species.

MAK value. After repeated exposure by inhalation to highly refined respirable mineral oil aerosols, the target organs in dogs, rats, mice, rabbits and hamsters were the lungs. A NOAEC (no observed adverse effect concentration) of 50 mg/m^3 was reported after 13-week exposure of rats, a NOAEC of 5 mg/m^3 after 12 and 24-month exposure of rats and dogs. These NOAECs were based on the formation of microgranulomas in the lungs, which were detected at 100 mg/m^3. In view of the NOAEC of 50 mg/m^3 after 13-week exposure of rats, the difference between the NOAEC of 5 mg/m^3 from the long-term studies in rats and dogs and the LOAEC (lowest observed adverse effect concentration) of 100 mg/m^3 is sufficiently large. The critical effect was observed to be pulmonary overloading, but as no great variation from individual to individual and no differences in metabolism are to be expected, and because elimination occurs via the macrophages into the lymph, a MAK value of 5 mg/m^3 R has been established for pharmaceutical white mineral oil (documentation "White mineral oil, pharmaceutical" 2015). Even if the increased respiratory volume is taken into consideration, there is a sufficient margin between the NOAEC of 5 mg/m^3 and the LOAEC of 100 mg/m^3; the MAK value can therefore be retained.

The same value is obtained if an alternative approach is used to derive the MAK value that is based on the NOAEC of the 13-week study and takes into consideration the possible decrease in the NOAEC after long-term exposure (1:2), the increased respiratory volume (1:2) and the extrapolation of the data from animal studies (1:2) and the preferred value approach.

Prenatal toxicity. There are no new data available.
Taking the increased respiratory volume (1:2) into consideration, the NOAEC of 1000 mg/m^3 for the developmental toxicity of pharmaceutical white mineral oil in rats (documentation "White mineral oil, pharmaceutical" 2015) is 100 times higher than the MAK value, which means that the classification of the substance in Pregnancy Risk Group C can be retained.

completed October 5, 2016