Polyalphaolefins

MAK Value Documentation

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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 polyalphaolefins [e.g. 68649-11-6].

Polyalphaolefins are synthetic mineral oils. For refined mineral oils, the 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/m³ with a NOAEC of 5 mg/m³. With these studies, a MAK value of 5 mg/m³ had been set as the respirable fraction (R) for polyalphaolefins. 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).

Polyalphaolefins had been classified in Pregnancy Risk Group C because of studies with oral and dermal application in rats. Additionally, now an inhalation study with white mineral oil and a NOAEC for developmental toxicity of 1000 mg/m³ in rats is used to confirm the assignment of polyalphaolefins to Pregnancy Risk Group C even considering the increased respiratory volume at the workplace.

Keywords

polyalphaolefins; hydrogenated 1-decene; peak limitation; prenatal toxicity; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

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[68649-11-6]

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MAK value (2010)	**5 mg/m³ R (respirable fraction)**
Peak limitation (2010)	**Category II, excursion factor 4**
Absorption through the skin	**–**
Sensitization	**–**
Carcinogenicity	**–**
Prenatal toxicity (2010)	**Pregnancy Risk Group C**
Germ cell mutagenicity	**–**
BAT value	**–**

Polyalphaolefins have been assigned different CAS numbers depending upon their physicochemical properties and number of carbon atoms (C16 to C60). One example is CAS No. 68649-11-6, which has been assigned to hydrogenated 1-decene, dimer.

Documentation for polyalphaolefins was published in 2011 (documentation "Polyalphaolefine" 2011, available in German only).

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 polyalphaolefins need to be re-assessed as a result of the higher respiratory volume at the workplace.

Polyalphaolefins are synthetic mineral oils. As it may be assumed that highly refined mineral oils and polyalphaolefins cause the same local pulmonary effects after repeated exposure by inhalation because 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 mineral oils were used to derive a MAK value (documentation "Polyalphaolefine" 2011, available in German only). The same approach was used to assess pharmaceutical white mineral oil because it is also a mineral oil fraction (documentation "White mineral oil, pharmaceutical" 2015).

Manifesto (MAK value/classification)

There are no new data available that are relevant for the derivation of a MAK value. The lungs are the target organs.

MAK value and peak limitation. 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/m³ was reported after 13-week exposure of rats, a NOAEC of 5 mg/m³ after 12 and 24-month exposure of rats and dogs. These NOAECs were based on microgranulomas in the lungs that were detected at 100 mg/m³. The difference between the NOAEC of 5 mg/m³ from the long-term studies in rats and dogs and the NOAEC of 50 mg/m³ after 13-week exposure of rats is considerable; it is therefore likely that the NOAEC of 5 mg/m³ was in fact somewhat higher than 5 mg/m³. Pulmonary overloading was the effect observed at the next-higher concentration of 100 mg/m³, but neither great variation from individual to individual nor significant systemic absorption are to be expected. Based on these data, a MAK value of 5 mg/m³ R has been established for polyalphaolefins (documentation "Polyalphaolefine" 2011, available in German only). Even taking the increased respiratory volume into consideration, there is a sufficient margin between the NOAEC of 5 mg/m³ and the LOAEC of 100 mg/m³, which means that the MAK value can be retained. This also applies to the classification of polyalphaolefins in Peak Limitation Category II with an excursion factor of 4.

The same value is obtained if an alternative approach is used to derive the MAK value that is based on the NOAEC of 50 mg/m³ from 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), the extrapolation of the data from animal studies (1:2) and the preferred value approach.

Prenatal toxicity. Up until this point, the classification in Pregnancy Risk Group C was based on the following data: 1.) a combined study of the toxic effects after repeated oral administration and reproductive toxicity after exposure of rats to decene homopolymers, which yielded a NOAEL (no observed adverse effect level) of 1000 mg/kg body weight and day for effects on the offspring (it is not meaningful to convert the value into a concentration at the workplace because oral absorption was below 1%) and 2.) a study of the toxic effects on prenatal development with dermal application of decene homopolymers in rats, which yielded a NOAEL for developmental toxicity at the highest dose applied of 2000 mg/kg body weight. Both studies confirm the slight systemic toxicity observed for all polyalphaolefins (documentation "Polyalphaolefine" 2011, available in German only).

In addition, studies with pharmaceutical white mineral oil were used for the assessment: taking the increased respiratory volume (1:2) into consideration, the NOAEC of 1000 mg/m³ for developmental toxicity in rats after inhalation exposure to pharmaceutical white mineral oil (documentation "White mineral oil, pharmaceutical" 2015) is 100 times higher than the MAK value of 5 mg/m³. For this reason, the classification of polyalphaolefins in Pregnancy Risk Group C has been retained.

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