

The MAK Collection for Occupational Health and Safety

Petroleum sulfonates, calcium salts (technical-grade mixture in mineral oil)

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

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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 petroleum sulfonates, calcium salts [61789-86-4].

Petroleum sulfonates, calcium salts are manufactured as solution in mineral oil. Critical effect is lung toxicity which is observed as macrophage accumulation and hyperplasia of the bronchioli in a 4-week inhalation study with petroleum sulfonates, calcium salts in rats at a respirable aerosol concentration of 156 mg/m³ with a NOAEC of 49.5 mg/m³. These effects are similar to those with highly refined mineral oils observed in rats and dogs. A MAK value of 5 mg/m³ had been set for petroleum sulfonates, calcium salts as the respirable fraction (R), which corresponds to the MAK value of white mineral oil. 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).

There is still no data on developmental toxicity with petroleum sulfonates, calcium salts. The classification in Pregnancy Risk Group D is therefore retained.

Keywords

petroleum sulfonates; peak limitation; prenatal toxicity; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

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[61789-86-4]

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 D
Germ cell mutagenicity	–
BAT value	–

Documentation for petroleum sulfonates, calcium salts (chain length of the alkyl group C10–C47), was published in 2015 (documentation “Petroleumsulfonate, Calcium-Salze (technisches Gemisch in Mineralöl)” 2015, 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 to aerosols (see List of MAK and BAT Values, Sections I b and I c). This supplement evaluates whether the MAK value for petroleum sulfonates, calcium salts, needs to be re-assessed as a result of the higher respiratory volume at the workplace. The classification of these substances in Pregnancy Risk Group D is also re-evaluated.

The calcium salts of petroleum sulfonates are found only in solution in mineral oils and are used as additives in oils. The MAK value was derived from a 4-week inhalation study with exposure to mineral oil containing a 35% fraction of the calcium salts of petroleum sulfonates (documentation “Petroleumsulfonate, Calcium-Salze (technisches Gemisch in Mineralöl)” 2015, available in German only).

The REACH dataset (status 2016) did not contain any new data that could be used to derive a MAK value or any studies on developmental toxicity (ECHA 2016).

Manifesto (MAK value/classification)

The lungs are the target organs in rats.

MAK value and peak limitation. In a 4-week inhalation study carried out according to OECD Guideline 412 male and female Sprague Dawley rats were whole-body exposed to the calcium salts of petroleum sulfonates (CAS No. 61789-86-4, Lubrizol (2013), 35% in mineral oil, aerosol). Concentrations of 156 mg/m³ and above caused red nasal discharge, an increase in alveolar macrophages and bronchial hyperplasia. The NOAEC (no observed adverse effect concentration) was 49.5 mg/m³ (documentation "Petroleumsulfonate, Calcium-Salze (technisches Gemisch in Mineralöl)" 2015, available in German only). The lungs were the target organs in animal studies with repeated inhalation exposure to highly refined respirable mineral oil aerosols. An increase in the number of macrophages is the first effect observed, which leads to the formation of microgranulomas in the lungs after long-term exposure. The NOAEC for pulmonary effects after 4-week exposure was 50 mg/m³ and the LOAEC (lowest observed adverse effect concentration) was 210 mg/m³ (documentation "stark raffinierte Mineralöle", 2018, english version available soon). These values are relatively similar to those of the study in which exposure to mineral oil containing a 35% fraction of the calcium salts of petroleum sulfonates likewise caused an increase in the number of macrophages in the lungs. Whether the pulmonary effects can be attributed only to the mineral oil cannot be determined on the basis of this study. The calcium salts of petroleum sulfonates do not seem to cause any effect beyond those caused by the mineral oil fraction, as suggested by the very slight skin irritation and the lack of irritation to the eye. This effect was more likely caused by the mineral oil. For this reason, a MAK value of 5 mg/m³ R has been established for the technical-grade mixture of petroleum sulfonates, calcium salts (35% in mineral oil), based on the NOAEC of 49.5 mg/m³ derived from the above study. This MAK value of 5 mg/m³ R is equivalent to the NOAEC for the long-term effects of mineral oil aerosols determined from studies in rats and dogs (documentation "Petroleum-sulfonate, Calcium-Salze (technisches Gemisch in Mineralöl)" 2015, available in German only) and the MAK values for pharmaceutical white mineral oil, highly refined mineral oils and polyalphaolefins that were all derived from these studies. A MAK value of 2 mg/m³ R would be established for a technical-grade mixture of petroleum sulfonates, calcium salts (35% in mineral oil), based on the NOAEC of 49.5 mg/m³ and taking into consideration the decrease in the NOAEC after long-term exposure (1:6), the extrapolation of the data from animal studies (1:2) and the increased respiratory volume (1:2). As the NOAEC for mineral oil was found to be 50 mg/m³ after exposure for both 4 and 13 weeks, it is likely that the NOAEC will decrease to a lesser extent after 4 weeks than assumed above (1:6). As also the increased respiratory volume was taken into consideration for the derivation of the MAK value of 5 mg/m³ R for mineral oil (documentation "stark raffinierte Mineralöle", 2018, english version available soon), the MAK value for petroleum sulfonates,

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calcium salts (technical-grade mixture in mineral oil), has been retained. The substances also remain classified in Peak Limitation Category II with an excursion factor of 4.

If the MAK value of 5 mg/m³ R for mineral oils is not exceeded, then the MAK value for petroleum sulfonates, calcium salts, will not be exceeded either, because the 35% concentration used in the study is higher than the maximum concentration of 10% found in the finished oil (HERTG 2005).

Prenatal toxicity. There are still no studies available of the developmental toxicity of the calcium salts of petroleum sulfonates. For this reason, they remain classified in Pregnancy Risk Group D.

References

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