

Tantalum (respirable fraction)

MAK Value Documentation, supplement – Translation of the German version from 2020

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Abstract

The German Commission for the Investigation of Health Hazards of Chemicals in the Work Area has re-evaluated tantalum [7440-25-7]. Tantalum dust is a biopersistent granular dust with high density. It is not known how the high density of 16.6 g/cm³ influences the translocation of particles in the lung. Therefore, the respirable fraction of tantalum is classified in Carcinogen Category 4 and a maximum concentration at the workplace (MAK value) of 0.3 mg/m³ × material density is established by analogy with other biopersistent granular dusts. Additionally, this fraction is classified in Peak Limitation Category II with an excursion factor of 8. As tantalum is not systemically distributed and accumulates only locally in the lungs, damage to the embryo or foetus is unlikely when the MAK value is not exceeded. Accordingly, the respirable fraction of tantalum is classified in Pregnancy Risk Group C. Tantalum is not a sensitizer and is not taken up via the skin in toxicologically relevant amounts.

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MAK value (2019)	0.3 mg/m³ × material density R^{a)}
Peak limitation (2019)	Category II, excursion factor 8
Absorption through the skin	–
Sensitization	–
Carcinogenicity (2019)	Category 4
Prenatal toxicity (2019)	Pregnancy Risk Group C
Germ cell mutagenicity	–
BAT value	–
Chemical name	tantalum
CAS number	7440-25-7
Density	16.6 g/cm ³ (Hartwig and MAK Commission 2017)
Solubility	insoluble in water (≤ 21.3 µg/l), insoluble in acids, except for hydrogen fluoride and fuming sulfuric acid, soluble in strong alkaline solutions (Hartwig and MAK Commission 2017)

^{a)} The effect of tantalum is based on the effect of biopersistent granular dusts. The value of 0.3 mg/m³ for the R fraction applies to a material density of 1 g/cm³

Note: ultrafine particles are excluded, see List of MAK and BAT Values, Section V h (DFG 2019)

In 2016, the respirable fraction (R fraction) of tantalum dust was assigned to Carcinogen Category 3 A (Hartwig and MAK Commission 2017, available in German only).

The inflammation-promoting and potentially carcinogenic effect of biopersistent granular dusts is based on the volume overload of alveolar macrophages. The volume of biopersistent granular dusts is calculated by dividing the particle mass by the particle density (volume = mass/density). Thus, in order to obtain the same volume for a biopersistent granular dust with a higher density as for a biopersistent granular dust of density 1, the general threshold limit value for dust applicable to density 1 (0.3 mg/m³) must be multiplied by the density of the respective substance, that is by 16.6 g/cm³ in the case of tantalum.

Studies with inhalation (1 g/m³) and insufflation of radioactively labelled tantalum dust with particle sizes of 1, 5 and 50 µm were performed in beagles (Bianco et al. 1974; Morrow et al. 1976). Depending on the particle size, prolonged retention in the lungs was observed for the small particles. Alveolar macrophage clearance was not investigated. The authors reported that no pathological changes were observed in the animals during the study period of up to 816 days (Morrow et al. 1976).

There is no evidence that particles with higher density have an effect on macrophages in addition to the volume effect.

Data for tantalum concentrations in the urine and blood of patients after the insertion of tantalum prostheses are not available.

The general threshold limit value for dust for the inhalable fraction (I fraction) was not derived on the basis of an overload effect on macrophages and is therefore not comparable with the value for the R fraction.

Manifesto (MAK value/classification)

The critical effect of the poorly soluble tantalum is the non-specific particle effect.

Carcinogenicity. Unlike for other biopersistent granular dusts, no studies are available for tantalum. The respirable fraction of tantalum dust is classified in Carcinogen Category 4 like that of other biopersistent granular dusts.

MAK value. Tantalum particles are poorly soluble dusts which can act according to the general particle effect of biopersistent granular dusts. On the basis of the current data, no statement can be made as to the extent to which the high density of tantalum particles has an influence on macrophage loading and particle translocation by the macrophages. In the case of tantalum dust, therefore, the general threshold limit value for dust of $0.3 \text{ mg/m}^3 \times \text{material density}$ for the respirable fraction applies.

Peak limitation. The critical effect is the effect of biopersistent granular particles on the lungs. For this reason, tantalum dust (respirable fraction), like other biopersistent granular dusts, is assigned to Peak Limitation Category II. Since the clearance half-life of biopersistent granular dusts is about 400 days, an excursion factor of 8 has been set.

Prenatal toxicity. There are no developmental toxicity studies available for tantalum. Since tantalum is a poorly soluble dust, prenatal toxicity is not to be expected if the MAK value of $0.3 \text{ mg/m}^3 \times \text{material density}$ for the respirable dust fraction is observed. Therefore, by analogy with other biopersistent granular dusts, the substance has been assigned to Pregnancy Risk Group C.

Germ cell mutagenicity. From the available data for genotoxicity, a mutagenic effect of tantalum dust on germ cells is not to be suspected. Therefore, by analogy with other biopersistent granular dusts, the substance has not been classified in one of the categories for germ cell mutagens.

Absorption through the skin. Dermal absorption of tantalum is unknown. Like other biopersistent granular dusts, the substance has not been designated with an “H” (for substances which can be absorbed through the skin in toxicologically relevant amounts).

Sensitization. There are no clinical findings of skin-sensitizing effects of tantalum in humans and no positive results from experimental studies in animals. Likewise, there is no evidence of a sensitizing effect of tantalum on the airways. Tantalum has therefore not been designated with “Sh” or “Sa” (for substances which cause sensitization of the skin or airways).

Notes

Competing interests

The established rules and measures of the commission to avoid conflicts of interest (https://www.dfg.de/en/dfg_profile/statutory_bodies/senate/health_hazards/conflicts_interest/index.html) ensure that the content and conclusions of the publication are strictly science-based.

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