The MAK Collection for Occupational Health and Safety

Lauric acid

MAK Value Documentation, addendum – Translation of the German version from 2017

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Keywords: lauric acid; eye; irritation; MAK value; analogy; maximum workplace concentration; peak limitation

Citation Note: Hartwig A, MAK Commission. Lauric acid. MAK Value Documentation, addendum – Translation of the German version from 2017. MAK Collect Occup Health Saf [Original edition. Weinheim: Wiley-VCH; 2018 Jul;3(3):1123-1131]. Corrected republication without content-related editing. Düsseldorf: German Medical Science; 2026. https://doi.org/10.34865/mb14307kske6218_w

Republished (online): 06 Mar 2026

Originally published by Wiley-VCH Verlag GmbH & Co. KGaA; https://doi.org/10.1002/3527600418.mb14307kske6218

Addendum completed: 24 Feb 2016

Published (online): 26 Jul 2018

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

Lauric acid / dodecanoic acid

MAK Value Documentation

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DOI: 10.1002/3527600418.mb14307kske6218

Abstract

The German Commission for the Investigation of Health Hazards of Chemical Compounds in the Work Area has re-evaluated lauric acid [143-07-7], considering all toxicity endpoints.
In an oral 18-week study no substance-related effects were observed in rats up to 9000 mg/kg body weight and day. As lauric acid is an organic acid, the respiratory tract might be a target organ; however, inhalation studies are not available. A maximum concentration at the workplace (MAK value) was derived by read across to other solid acids. Lauric acid is irritating to the rabbit eye but less so than succinic and adipic acid. Also the acidity of saturated solutions of lauric acid is less than that of succinic and adipic acid. For the latter acids, a MAK value of 2 mg/m3 for the inhalable fraction was set like that for phosphoric acid. Phosphoric acid is a stronger acid that is corrosive to the eyes of rabbits. Therefore, in analogy to phosphoric acid as a worst-case, a MAK value of 2 mg/m3 for the inhalable fraction is set for lauric acid.
As the MAK value has been derived in analogy to phosphoric acid, lauric acid is also classified in Peak Limitation Category I with an excursion factor of 2.
Lauric acid does not have genotoxic potential. There are no carcinogenicity studies available with lauric acid. Results of a dermal initiation-promotion study with lauric acid alone were negative; promoting activity was seen only after application of an initiator. Lauric acid is no longer classified as carcinogenic to humans, based on the Commission's evaluation of this type of study.
No significant contribution to systemic toxicity was demonstrated in calculations of dermal absorption. Limited data in animals do not indicate a sensitizing potential for lauric acid.
Developmental toxicity studies are lacking; therefore, lauric acid is assigned to Pregnancy Risk Group D.
Completed: February 24, 2016

Keywords

lauric acid; dodecanoic acid; toxicokinetics; metabolism; (sub)acute toxicity; (sub)chronic toxicity; irritation; allergenic effects; genotoxicity; carcinogenicity; peak limitation; prenatal toxicity; germ cell mutagenicity; absorption through the skin; sensitization; occupational exposure; maximum workplace concentration; MAK value; toxicity; hazardous substance

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Lauric acid[1)]

[143-07-7]

Supplement 2017

MAK value (2016)	**2 mg/m³ I (inhalable fraction)**
Peak limitation (2016)	**Category I, excursion factor 2**
Absorption through the skin	**–**
Sensitization	**–**
Carcinogenicity	**–**
Prenatal toxicity (2016)	**Pregnancy Risk Group D**
Germ cell mutagenicity	**–**
BAT value	**–**
Structural formula	CH_3-$(CH_2)_{10}$-COOH
Molecular formula	$C_{12}H_{24}O_2$
Molar mass	200 g/mol
Melting point	43 °C (SRC 2015)
Vapour pressure at 25 °C	0.000021 hPa (SRC 2015) vapour saturation 0.17 mg/m³
log K_{OW}[2)]	4.2 (EDQM 2013) 4.6 (SRC 2015)
Solubility	4.81 mg/l water (SRC 2015)
pKa value at 20 °C	5.3 (SRC 2015)
1 ml/m³ (ppm) ≙ 8.299 mg/m³	**1 mg/m³ ≙ 0.121 ml/m³ (ppm)**

In the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only) lauric acid is classified in category 3A for carcinogens.

1) The substance may be present simultaneously in vapour and aerosol form.

2) Octanol/water partition coefficient.

This supplement has been drawn up as the Commission has evaluated the relevance of the mouse skin initiation–promotion model with regard to the carcinogenicity of the substance in humans (Schwarz et al. 2015).

There are no new studies with lauric acid relevant to the evaluation.

Toxic Effects and Mode of Action

After ingestion, lauric acid is readily absorbed and distributed throughout the body, where it is metabolized to CO_2 by β-oxidation in the fatty acid metabolism. After repeated application, lauric acid is moderately irritating to the eyes of rabbits. No studies are available with longer-term oral administration or inhalation of lauric acid from which a NOAEL (no observed adverse effect level) or a NOAEC (no observed adverse effect concentration) could be obtained. After the administration of an initiator, a 20% solution of lauric acid had a tumour-promoting effect on mouse skin; a genotoxic mode of action can be excluded (documentation "Laurinsäure" 2000, available in German only).

Toxicokinetics and Metabolism

Animal studies have demonstrated the dermal absorbability of the compound, both in its form as a non-dissociated acid and in the form of the laurate anion. As a result of the weak acidity of lauric acid, both species must be assumed to be present in unbuffered aqueous solutions of the acid or its salt.

After 24-hour occlusive application of 0.5% lauric acid in squalane to the skin of hairless mice, 18% of the dose was absorbed. The application of 100 µl to a 2 cm^2 area of skin would thus result in a flux of 45 µg/cm^2 in 24 hours or 1.88 µg/cm^2 and hour (see documentation "Laurinsäure" 2000, available in German only; Iwata et al. 1987). Assuming a flux of similar magnitude under aqueous conditions, an absorbed amount of about 3.8 mg would be obtained after the exposure of a 2000 cm^2 area of skin for a one hour.

For a saturated aqueous solution of lauric acid (concentration 4.81 mg/l), fluxes of 79.2, 0.97 and 0.29 mg/cm^2 and hour are calculated using the models of Fiserova-Bergerova et al. (1990), Guy and Potts (1993) and Wilschut et al. (1995), respectively. Assuming the exposure of a 2000 cm^2 area of skin for one hour, this would correspond to absorbed amounts of 158, 1.94 and 0.58 mg, respectively.

After epicutaneous application of sodium laurate (concentration 6 mM, corresponding to 1.334 g/l, pH 9.5) for 15 minutes, the permeation of the substance through the skin of rats was determined to be 0.675 µg/cm^2 (see documentation "Laurinsäure" 2000, available in German only). Extrapolated to the standard conditions of a saturated aqueous solution (estimated solubility of sodium laurate in water 3240 mg/l (SRC 2016)) and assuming the exposure of a 2000 cm^2 area of skin for one hour, amounts of 13.2 mg sodium laurate would be absorbed.

Effects in Humans

In the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only) only data for the allergenic effects of the substance were available; no contact sensitization potential was revealed. New findings are not available.

Animal Experiments and in vitro Studies

Acute toxicity

Inhalation

Studies with lauric acid are still not available.

No deaths occurred in an inhalation risk test with octanoic acid (CAS number 124-07-2), in which 6 male and 6 female rats were exposed to a vapour-saturated atmosphere (0.1621 mg/l) for 4 hours (ECHA 2016).

Oral administration

In male and female Wistar rats, the LD_{50} was above 5000 mg lauric acid/kg body weight (purity 98% to 100%) in a study with gavage administration carried out according to OECD Test Guideline 401 (ECHA 2016). However, values of above 10 000 mg/kg body weight are given in the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only) and of 12 000 mg/kg body weight in a safety data sheet (EDQM 2013).

Dermal application

Studies with lauric acid are still not available.

An LD_{50} of more than 2000 mg/kg body weight was obtained in a study in which 2000 mg stearic acid (C18)/kg body weight was applied occlusively to the dorsal skin of New Zealand White rabbits for 24 hours (ECHA 2016).

Subacute, subchronic and chronic toxicity

Inhalation

Studies with lauric acid are still not available.

Oral administration

A study from 1960, in which lauric acid (purity not specified) was administered with the diet (10% in the diet, according to EFSA (2012), about 9000 mg/kg body weight and day) to 5 male Osborne-Mendel rats for 18 weeks, is not cited in the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only). There were no substance-related findings with regard to clinical obser-

vations, mortality, body weight gains and body weights, organ weights and histopathology (no other details; Fitzhugh et al. 1960). This seems plausible as lauric acid presumably enters the metabolism and is rapidly metabolized.

Dermal application

Studies with lauric acid are still not available.

Local effects on skin and mucous membranes

Skin

In the studies described in the documentation from 2000, lauric acid was reported to be slightly irritating on the skin (documentation "Laurinsäure" 2000, available in German only).

In a study from 1989 carried out according to OECD Test Guideline 404, lauric acid was regarded as not irritating, as after the semi-occlusive application of 0.5 g lauric acid in water to the shaved dorsal skin of New Zealand White rabbits for 4 hours the maximum score for erythema was 0.4 (on a scale with a maximum of 4) and the effect was reversible after 7 days (ECHA 2016).

Another study from1988, similar to OECD Test Guideline 404, in which 0.5 g lauric acid without a solvent was applied occlusively to the shaved dorsal skin of Himalayan Rabbits for 4 hours, yielded an erythema score of 3.1 after 24, 48 and 72 hours and a maximum oedema score of 2 (on a scale up to 4) after 24 and 48 hours. All findings were reversible after 10 days. The substance was classified as "irritating" (ECHA 2016). As occlusive application no longer complies with the currently valid guidelines, this study is not included in the evaluation.

On the basis of the study with semi-occlusive application according to OECD Test Guideline 404, lauric acid is now classified by the Commission as not irritating to the skin.

Eyes

In the studies cited in the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only) lauric acid was moderately irritating in the eyes. In these studies, also described in ECHA (2016), a maximum score of 0.9 (on a scale up to 4) was obtained in two different investigations of the cornea. The effects were, however, not reversible during the 21-day recovery period. In one investigation, the effect on the conjunctiva, which was initially given a score of 2.9 (of a maximum of 3), was likewise not reversible.

As, in addition to irritation, lauric acid is thought to cause, for example, also surfactant-like effects, a study with sodium dodecyl sulfate was used to compare the severity of the effects in the rabbit eye. The maximum scores of 1.4 (of 4) for the cornea and 2 (of 3) for the conjunctiva following treatment with sodium dodecyl sulfate were likewise not reversible by the end of the 21-day recovery period (ECHA 2015).

This means that lauric acid and sodium dodecyl sulfate have similar effects with a similar degree of severity in the rabbit eye.

Allergenic Effects

Sensitizing effects on the skin

In a very incompletely documented maximization test with 20 Pirbright White guinea pigs, lauric acid was not found to have sensitizing effects after intradermal induction treatment, for which no concentration is given, and occlusive epicutaneous induction with a 2.5% preparation in ethanol. Information as to whether and how topical induction treatment was carried out is not provided (ECHA 2016).

Sensitizing effects on the airways

There are still no studies available for the sensitizing effects of lauric acid on the airways.

Reproductive and developmental toxicity

There are still no studies available for the reproductive and developmental toxicity of lauric acid.

Genotoxicity

Lauric acid was neither mutagenic nor clastogenic in the studies cited in the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only).

There are no other studies available.

Carcinogenicity

In the documentation from 2000 (documentation "Laurinsäure" 2000, available in German only), a study by Holsti (1959) is described in which mice were treated dermally with 20% or 40% lauric acid once a day for 31 weeks. In this study period there was no increase in the incidence of tumours. A single initiation treatment with 9,10-dimethyl-1,2-benzanthracene, followed by single daily treatments with 20% lauric acid on 6 days a week for 31 weeks, led to an incidence of skin papillomas of 33%. Lauric acid, therefore, has promoting effects.

Another study with dermal application in mice is not included in the evaluation because of the low number of animals used and the short duration of treatment.

Manifesto (MAK value/classification)

Lauric acid is moderately irritating in the eyes of rabbits.

Carcinogenicity. After the administration of an initiator, a 20% lauric acid solution had promoting effects on the skin of mice. Without the administration of an

initiator, however, no promoting activity was found, even with the 40% solution. There are no other valid studies available for the carcinogenicity of the substance. No studies are available that demonstrate the substance has a specific effect on the skin in the low dose range. The initiation–promotion tests on the skin of mice have been evaluated by the Commission with regard to their relevance for assessing the possible carcinogenicity of the substance in humans on the basis of the mechanistic information available (Schwarz et al. 2015). The study described did not yield evidence of a carcinogenic effect of lauric acid on the skin of humans, and lauric acid has been removed from Carcinogen Category 3A.

Germ cell mutagenicity. As the results of the studies available for the genotoxicity of the substance are negative, lauric acid is not classified in one of the categories for germ cell mutagens.

MAK value. In a 18-week study, in which 5 male Osborne-Mendel rats were given lauric acid doses of about 9000 mg/kg body weight and day with the diet, no substance-related findings were obtained (no other details; Fitzhugh et al. 1960). This seems plausible, as lauric acid presumably enters the metabolism and is rapidly metabolized. As lauric acid is moderately irritating in the eye of rabbits, and no inhalation studies with repeated exposure are available, a MAK value cannot be derived from the study with oral administration.

In the rabbit eye, lauric acid and sodium dodecyl sulfate have similar effects with a similar degree of severity. Therefore, in addition to the irritant effect resulting from the acid group to which it belongs, lauric acid could also have a surfactant-like effect as a result of the long hydrophobic hydrocarbon chain. The data for eye irritation indicate that the irritation caused by lauric acid is less pronounced than that caused by succinic acid and adipic acid. This is supported by the pH values of 2.2, 2.7 and 4.9 for saturated solutions of succinic, adipinic and lauric acid, respectively. In addition, the solubility of lauric acid in water of 4.8 mg/l is only low, whereas that of succinic acid and adipic acid is in the gram range, at 83 g/l and 2.3 g/l, respectively. As the available data are insufficient, the MAK value for phosphoric acid of 2 mg/m^3 has been adopted for lauric acid. The margin of safety is thus sufficiently large to take into account possible slight surfactant effects. The MAK value of 2 mg phosphoric acid/m^3 corresponds to a molecular concentration of 0.02 mmol/m^3, and 0.02 mmol lauric acid/m^3 corresponds to 4 mg/m^3.

Peak limitation. The MAK value for lauric acid is based on the irritant effect. The substance is therefore classified in Peak Limitation Category I. As the MAK value was established in analogy to phosphoric acid, an excursion factor of 2 has likewise been established for lauric acid in analogy to phosphoric acid.

Prenatal toxicity. There are no studies available for the prenatal toxicity of lauric acid. Lauric acid is therefore classified in Pregnancy Risk Group D.

Absorption through the skin. In animal studies with dermal application of lauric acid or its sodium salt, the maximum amount absorbed under standard conditions was found to be 13.2 mg. For a saturated aqueous solution of lauric acid, model calculations yielded a maximum dermal absorption of 185 mg under standard conditions (area of skin 2000 cm^2, exposure for one hour).

With a dermal LD_{50} of > 2000 mg/kg body weight, the compound is of low acute dermal toxicity. In an 18-week feeding study with rats, no substance-related findings were obtained after doses of 9000 mg/kg body weight and day. The following toxicokinetic data are taken into consideration for the extrapolation of this dose (as the systemic NOAEL) to humans: the corresponding species-specific correction value for the rat (1:4), the assumed oral absorption of 100%, the daily exposure of the animals in comparison with the 5 days per week exposure at the workplace (7:5), the body weight (70 kg) of the person, a possible increase in the effects with time (1:2), the assumed 100% absorption by inhalation and the extrapolation of the animal study to humans (1:2). The systemically tolerable amount calculated from this is 55 g lauric acid. It can be seen, both from the estimates based on in vivo data and the model calculations carried out, that the systemically tolerable dose is far above the doses attainable by dermal exposure. Lauric acid is therefore not designated with an "H" (for substances which can be absorbed through the skin in toxicologically relevant amounts).

Sensitization. There are no clinical findings available of a contact-sensitizing effect of lauric acid. An inadequately documented maximization test with negative results likewise provided no evidence of contact sensitization. There are no data available for respiratory sensitization. Lauric acid is therefore not designated with either "Sh" or "Sa" (for substances which cause sensitization of the skin or airways).

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completed 24.02.2016