Decyl oleate

see Section IIb of the List of MAK and BAT Values 1995
decyl 9-octadecenoate 9-octadecenoic acid decyl ester oleic acid decyl ester
9-octadecenoic acid (Z) decyl ester
3687-46-5
H ₃ C–(CH ₂) ₇ –CH=CH–(CH ₂) ₇ –COO–(CH ₂) ₉ –CH ₃
$C_{28}H_{54}O_2$
422.74
18.2°C
0.86–0.87 g/cm ³
soluble in alcohol, not soluble in water at 20°C
esterification of oleic acid with <i>n</i> -decyl alcohol
contaminated with up to 2.5 % oleic acid
 in the cosmetic industry in concentra- tions of 0.1 % to 50 % as an additive in the production of textiles and leather as a component of metal-working fluids (lubricity improver)
1 mg/m ³ = 0.05 ml/m ³ (ppm)

Note

Values for the boiling point or vapour pressure of decyl oleate could not be found in the literature. Consideration of the properties of analogous shorter chain aliphatic oleic acid esters suggests that the boiling point of decyl oleate is above 200°C. If one assumes that the boiling point is 240°C, the vapour pressure can be estimated by means of the

Clausius-Clapeyron equation which describes the temperature-dependence of the vapour pressure; this yields a vapour pressure of about 0.1 hPa at room temperature. Thus decyl oleate is slow-evaporating. This has also been confirmed by measurements of volatilization losses (5 % according to DIN 51581) and determination of the volatility by the "TGA method" (0 % at 200°C, 3 % at 250°C and 20 % at 300°C) (Henkel 1994).

1 Toxic Effects and Modes of Action

After oral administration to rats, decyl oleate is not toxic. Repeated administration of high doses for a period of 28 days produces no conspicuous symptoms in rats. Single doses of undiluted decyl oleate applied to rabbit skin and eyes produce only very slight irritative effects. Dermal application to rabbits, daily for 60 days, causes moderate irritation. Decyl oleate does not cause sensitization. The *Salmonella* mutagenicity test has yielded no evidence of mutagenic effects.

The mechanism of action, toxicokinetics and metabolism of decyl oleate have not been described.

2 Effects in Man

There are no reports available of the acute or chronic toxicity of decyl oleate in man, nor have studies of the reproductive toxicity, genotoxicity or carcinogenicity of the substance been carried out.

2.1 Effects on skin and mucous membranes

Undiluted decyl oleate was applied on a patch to the skin of the inside forearm of five volunteers for 2 hours. At the end of this time one of the five persons reported a mild burning sensation. Ten minutes after washing the substance off, the sensation had disappeared. Neither erythema nor any other skin reaction was observed (Henkel 1970a).

In another study, undiluted decyl oleate was applied to two marked sites on the inside forearm and massaged into the skin with a glass rod, every 30 seconds for 30 minutes (Burckhardt test). Skin reactions were not observed (Henkel 1970b).

2.2 Allergenic effects

Four ointment base formulations with 5 % decyl oleate were investigated on 402 test persons in the Schwartz-Peck prophetic patch test and on 204 test persons in the Draize-

Shelanski repeated insult patch test. Skin reactions could not be detected (CTFA 1975b, cited from the Cosmetic Ingredient Review 1982).

A 0.2 ml aliquot of a skin care preparation containing 1 % to 5 % decyl oleate was applied in a patch test to 103 volunteers, three times weekly for a period of three weeks (no other details). Provocation with the undiluted preparation took place 14 days after the last treatment (no other details). Inspection after 48 and 96 hours yielded no evidence of sensitization (CFTA 1976c, cited from the Cosmetic Ingredient Review 1982).

3 Effects on Animals

Neither reproductive toxicity nor carcinogenicity studies have been carried out with decyl oleate.

3.1 Acute toxicity

There are no reports of the effects of inhalation or dermal absorption of decyl oleate.

Single oral doses of decyl oleate are not toxic (Table 1). The symptoms described in the study of Henkel (1967) are a result of the large amounts of substance administered and have no toxicological relevance.

Dose (mg/kg body weight)	Symptoms (14-day recovery period)	References
5000	1 Q died, no treatment-related effects, autopsy revealed no treatment-related findings	CTFA 1975b; cited from the Cosmetic Ingredient Review 1982
17000	rapid, jerky respiration, piloerection, mild diarrhoea, no deaths	Henkel 1967
34000	no deaths	CTFA 1976a; cited from the Cosmetic Ingredient Review 1982

Table 1. Acute toxicity of orally administered undiluted decyl oleate in the rat

3.2 Subacute, subchronic and chronic toxicity

There are no reports of the effects of inhaled decyl oleate.

In a 28-day study decyl oleate was administered to groups of 10 male and 10 female Wistar rats by gavage of doses of 100, 500 or 1000 mg/kg body weight on 5 days weekly. With each dose group 5 male and 5 female animals were included as controls and were given the olive oil vehicle according to the same dose scheme. After 21 doses, all the animals were observed for another 28 days without further treatment. All doses

were tolerated without substance-related deaths or symptoms of toxicity. Food and water consumption and body weight development of the animals given decyl oleate were not different from the control values. Absolute and relative organ weights revealed no substance-related or dose-related effects. Reductions in haemoglobin levels and slight reduction of the phosphorus level in the serum at 100, 500 and 1000 mg/kg body weight were not considered to be substance-related. Pathological-anatomical examination of all the animals and histological examination of the animals in the 1000 mg/kg group did not reveal any substance-related effects on internal organs. From these results the NOAEL for decyl oleate in the rat was given as 1000 mg/kg body weight and day (Henkel 1987).

3.3 Effects on skin and mucous membranes

3.3.1 Skin

In an occlusive patch test, groups of 6 rabbits were treated with doses of 0.5 ml decyl oleate (undiluted, 10 % in corn oil or 20 % in mineral oil) on the shaved or scarified skin for 24 hours. The irritative effects were recorded after 24 and 72 hours. Decyl oleate proved to be only very slightly irritating (CFTA 1975a, 1976a, cited from the Cosmetic Ingredient Review 1982).

In another study with the same methods, neither undiluted decyl oleate nor a 15% aqueous emulsion of the substance was irritating (Guillot *et al.* 1977).

In a 60-day study, decyl oleate was applied daily to the skin of each of three rabbits both undiluted and as a 15 % aqueous emulsion. After the end of the study two skin samples from each animal were subjected to histological examination. Irritant effects were found at both concentrations. In all three animals undiluted decyl oleate caused thickening of the skin. In one animal blister formation with congestion was also recorded. On the other hand, on the sites of application of the 15 % emulsion only a few nodules and blisters were observed. Histological examination did not reveal significant pathological findings. The blister formation was ascribed by the authors to the formation of an occlusive film of the incompletely removed substance on the skin of the animals (Guillot *et al.* 1977). Another explanation for the observed irritative effects could be a defatting of the skin which would be expected with this experimental protocol.

3.3.2 Eyes

In the rabbit eye, 0.1 ml undiluted decyl oleate, 15 % decyl oleate in corn oil and 20 % decyl oleate in mineral oil were found to be not irritating when tested by the Draize method (CFTA 1975a, 1976b, cited from the Cosmetic Ingredient Review 1982).

In a modified Draize test, undiluted decyl oleate had a maximum irritation index of 3 after 24 hours and is thus only very slightly irritating for the rabbit eye (Guillot *et al.* 1977).

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3.4 Allergenic effects

In the study of Guillot *et al.* (1977) described in Section 3.3.1, the 60 days of treatment were followed by 7 treatment-free days and then by provocation with a not specified concentration of decyl oleate. There was no evidence of allergic reactions (no other details).

In the sensitization test of Landsteiner and Jacobs, a test which is no longer commonly used, 10 male albino guinea pigs were treated three times weekly, intracutaneously in the shaved dorsal skin with a 15 % solution of decyl oleate in corn oil. The animals were given 0.05 ml of the test solution in the first injection and 0.1 ml in the subsequent 9 injections. Provocation was carried out two weeks after the last induction treatment by injection of 0.05 ml of the solution. For the controls 0.1 % corn oil in physiological saline was applied in the same way. No signs of sensitization were observed (CFTA 1976b, cited from the Cosmetic Ingredient Review 1982).

In a maximization test, 19 female Pirbright white guinea pigs were treated for induction by injection of 0.1 ml of a 5 % solution of decyl oleate in FCA or paraffin oil into the shaved skin of the shoulder. As control the animals were also given injections of FCA alone. After one week the animals were treated for 24 hours with 10 % sodium lauryl sulfate to provoke a mild inflammatory reaction and then the test substance was applied again, this time topically. Two weeks after the induction treatment, provocation was carried out by open topical application of a 1 % emulsion of decyl oleate in paraffin or by occlusive application of 1 % of the substance in ethanol. The test patch with the preparation in alcohol was removed after 24 hours and the reaction recorded after another 24 hours. Reactions were not seen in either the test animals or the controls 24 or 48 hours after the application. The authors concluded that decyl oleate does not induce allergic reactions in guinea pigs (Henkel 1979b).

3.5 Genotoxicity

In the *Salmonella* mutagenicity test in the *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538, decyl oleate in concentrations between 4 and 2500 μ g/plate was not mutagenic either with or without metabolic activation (Henkel 1979a).

6 Manifesto (MAK value, classification)

In animal studies, decyl oleate is of low acute and subchronic toxicity and the acute local irritative effects are very mild. Repeated dermal application of the undiluted substance leads to moderate irritation which is probably mainly a result of severe defatting of the skin. There is no evidence that decyl oleate has sensitizing potential. In a *Salmonella* mutagenicity test the substance was not mutagenic. Studies of carcinogenicity, reproduc-

tive toxicity and teratogenicity are not available. A MAK value cannot be derived from the results of the 28-day study with oral administration. In particular, studies are still required of the effects of inhalation of aerosols of decyl oleate which can readily occur during use of the substance as a metal-working fluid component. Therefore, decyl oleate is included in Section IIb of the "List of MAK and BAT Values".

7 References

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