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# **Zinc distearate**

(CAS No: 557-05-1)

Health-based Reassessment of Administrative Occupational Exposure Limits

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Committee on Updating of Occupational Exposure Limits,  
a committee of the Health Council of the Netherlands

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No. 2000/15OSH/142 The Hague, November 9, 2004

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## 1 Introduction

The present document contains the assessment of the health hazard of zinc distearate by the Committee on Updating of Occupational Exposure Limits, a committee of the Health Council of the Netherlands. The first draft of this document was prepared by MA Maclaine Pont, M.Sc. (Wageningen University and Research Centre, Wageningen, the Netherlands).

In November 1997, literature was searched in the databases Medline, Toxline and Chemical Abstracts, starting from 1966, 1981, and 1937, respectively, and using the following key words: 557-05-1; zinc stearate; octadecanoic acid, zinc salt; and stearic acid, zinc salt.

In July 2000, the President of the Health Council released a draft of the document for public review. No comments were received.

An additional search in Toxline and Medline in September 2004 did not result in information changing the committee's conclusions.

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## 2 Identity

name	:	zinc distearate
synonyms	:	zinc stearate; dibasic zinc stearate; octadecanoic acid, zinc salt; stearic acid, zinc salt; zinc octadecanoate; coad; dermarone; hydense; metallac
molecular formula	:	$C_{36}H_{70}O_4Zn$
structural formula	:	$H_3C-(CH_2)_{16}-CO-O-Zn-O-CO-(CH_2)_{16}-CH_3$
CAS number	:	557-05-1

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## 3 Physical and chemical properties

molecular weight	:	632.34
melting point	:	130°C
boiling point	:	not available
flash point	:	277°C (open cup)
vapour pressure	:	not available
solubility in water	:	insoluble
$\log P_{\text{octanol/water}}$	:	14.44 (estimated)
conversion factors	:	not applicable

Data from NLM04, [http://www.syrres.com/esc/est\\_kowdemo.htm](http://www.syrres.com/esc/est_kowdemo.htm).

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Zinc distearate is a fine, white, hydrophobic powder with a faint, characteristic odour (Bus95). The powder can generate electrostatic charges upon whirling, pneumatic transport, etc. The compound decomposes upon heating and combustion, forming acid vapours, and zinc oxide (Che98).

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#### **4 Uses**

Stearic acid and its salts are widely used in cosmetics and pharmaceuticals in concentrations from 0.1% to 50%. For example, relatively pure zinc distearate (usually containing zinc oxide and zinc palmitate) has found wide use in cosmetic powders due to its adhesive properties. It is also used as a dusting agent for rubber (ACG91).

Other uses of zinc distearate are as a stabilising agent, a mould release agent, a delustring agent, as a filler, to impregnate paper, cloth, rope, cement, etc, as a foam inhibitor in the processing of such products as beet sugar and yeast (Lun94).

In the USA, zinc distearate (still) has a GRAS ('generally recognised as safe') status for use as a direct human food ingredient (see Code of Federal Regulations: 21CFR182.8994; revised as of April 1, 2003), although the Food and Drug Administration (FDA) proposed to remove the compound from this list (FDA82).

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#### **5 Biotransformation and kinetics**

The committee did not find data on the biotransformation and kinetics of zinc distearate.

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#### **6 Effects and mechanism of action**

##### Human data

Out of the 27 cases of irritant contact dermatitis diagnosed among footwear workers in a Finnish factory in the period 1976-1980, one had been caused by zinc distearate (Kil82). Testing of 2 eyeshadow formulations, each containing 10% zinc distearate, by means of the Schwartz-Peck Prophetic Patch Test and the Draize-Shelanski Repeated Insult Patch Test did not caused reactions in 202 and 99 subjects, respectively. No irritation or sensitisation potential was found at examinations 1, 2, 3, and 4 weeks after application of one of the formulations to

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52 female panellists, twice a day for 28 days (unpublished studies, cited in Bus82).

In a study in rubber workers, reddened nasal mucosa were observed in all 18 subjects. They had been exposed to zinc distearate at air concentrations ranging from 4.4 to 7.8 mg/m<sup>3</sup> for periods ranging from 3 months to 5 years. It is most likely that the subjects had also been exposed to other substances (Bou68).

Harding cited a case of 'pneumoconiosis with probable heart failure' in a rubber worker who was occupationally exposed to zinc distearate dust for 29 years. Histological examination of the lungs showed an increase in connective tissue and chronic inflammation (Har58).

Weber et al. described a case of pulmonary fibrosis (of the Hamman-Rich type) in a worker exposed to unknown levels of zinc distearate dust for 7 years. The amount of zinc retained in the lungs of this worker (6.2 mg/100 g of dry lung tissue) was at the upper end of the range of zinc concentrations found in the pathologically normal lungs of not exposed persons (n=30; range: 0.33-6.93 mg/100 mg dry tissue). Weber et al. concluded that zinc distearate was not the cause of the lung fibrosis in this case (Web76).

In 1922, 12 cases were reported in which infants developed respiratory distress and, in some instances, acute fatal pneumonitis on aspiration of zinc distearate powder. The pulmonary pathology resembled that seen after exposure to talc (ACG91).

#### Animal data

No irritation was observed following application of a paste of zinc distearate to the shaven skin of rabbits and rats (Tar76). Primary irritation scores of 0.0 (maximum possible score: 8.0) were obtained following 4-hour occluded applications of 0.5 g or 24-hour occluded applications of unreported amounts of pure zinc distearate to the intact and abraded skin of rabbits (n=6/group). A similar result was found following application of a 10% zinc distearate-containing eyeshadow (unpublished studies, cited in Bus82).

Instillation of 100% zinc distearate into the eyes of 6 rabbits resulted in Draize scores of 2 and 0 on days 1 and 2, respectively. Scores were 0 in all animals at days 1, 2, and 3 following instillation of a 10% zinc distearate-containing eyeshadow (unpublished studies, cited in Bus82).

When albino rats were exposed to a concentration of zinc distearate of 200,000 mg/m<sup>3</sup> for 1 hour, 1/10 animals died during the 2-week observation period (unpublished study, cited in Bus82).

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When zinc distearate was applied to the skin of rats for 4 days, the body weight gain was less in the treatment group than in the control group (17 vs. 37 g,  $p=0.02$ ). Quantitative data are lacking (Tar76).

Oral  $LD_{50}$  of  $>5000$  and  $>10,000$  mg/kg bw in rats (unpublished studies, cited in Bus82; NIO03) and of  $>10,000$  mg/kg bw in mice (NIO03) have been reported.

A single intratracheal instillation of 50 mg zinc distearate into rats killed 50% of the animals. In the surviving rats, alveolar emphysema, bronchitis, and formation of xanthic cells was observed in the lungs after 2 months (Tar76). After a single injection of 50 mg zinc distearate into the lungs of rats, 20 out of 50 animals died within 24 hours, most of them within one hour. Those that were examined showed severe oedema and congestion of the lungs. Animals killed 7 days after injection showed some histiocytes scattered through the lungs. Not any fibrosis was detected in the lung of rats killed up to 259 days after the injection (Har58).

Ueda and co-workers did not find either any lung fibrosis in rats 9 months after intratracheal instillation of 1, 5, or 10 mg zinc distearate. A dose-related increase was found in atelectasis, emphysema, pneumonia, and abscess formation. No statistical calculation was performed (Ued84).

*In vitro* mutagenicity tests in *S. typhimurium* strains TA98, TA100, TA1535, TA1537, and TA1538 and in *S. cerevisiae* strain D4 with and without metabolic activation systems, prepared from mouse, rat, and monkey liver and lung tissues, were negative (Bru77).

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## **7 Existing guidelines**

The current administrative occupational exposure limit (MAC) for zinc distearate in the Netherlands is  $10 \text{ mg/m}^3$ , 8-hour TWA.

Existing occupational exposure limits for zinc distearate in some European countries and in the USA are summarised in the annex.

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## **8 Assessment of health hazard**

The committee did not find data on the biotransformation and kinetics of zinc distearate.

One case of irritant contact dermatitis following occupational exposure to zinc distearate has been reported. However, testing 10% zinc distearate-containing (cosmetic) formulations in groups of 52 to 202 subjects did not cause skin irritation or sensitisation. The committee did not find relevant data from

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which the local respiratory tract or systemic effects (including carcinogenicity or reproduction toxicity) could be assessed.

Zinc distearate was not irritating to the skin and eyes of experimental animals. Following 1-hour exposure to 200,000 mg/m<sup>3</sup>, 1/10 rats died. Oral LD<sub>50</sub> values were >5000 and >10,000 mg/kg bw for rats and >10,000 mg/kg bw for mice.

Single intratracheal instillation of 50 mg zinc distearate into rats was lethal to 40-50% of the animals and caused emphysema, bronchitis, pneumonia, oedema, and congestion, but not fibrosis. Similar lung effects were seen after single instillation of doses of 1-10 mg.

Zinc distearate was negative in mutation tests in bacterial systems.

The committee considers the toxicological database on zinc distearate too poor to justify recommendation of a health-based occupational exposure limit.

The committee concludes that there is insufficient information to comment on the present MAC-value.

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## Annex

### Occupational exposure limits for zinc distearate in various countries

country - organisation	occupational exposure limit		time-weighted average	type of exposure limit	note <sup>a</sup>	reference <sup>b</sup>
	ppm	mg/m <sup>3</sup>				
the Netherlands - Ministry of Social Affairs and Employment	-	10 <sup>c</sup>	8 h	administrative		SZW04
Germany - AGS	-	-				TRG04
- DFG MAK-Kommission	-	-				DFG04
Great Britain - HSE	-	10 <sup>c</sup>	8 h	OES		HSE02
	-	20 <sup>c</sup>	15 min			
	-	4 <sup>d</sup>	8 h	OES		
Sweden	-	-				Swe00
Denmark	-	-				Arb02
USA - ACGIH	-	10 <sup>e</sup>	8 h	TLV	A4 <sup>g</sup>	ACG04b
- OSHA	-	15 <sup>f</sup>	8 h	PEL		ACG04a
	-	5 <sup>d</sup>	8 h			
- NIOSH	-	10 <sup>f</sup>	10 h	REL		ACG04a
	-	5 <sup>d</sup>	10 h			
European Union - SCOEL	-	-				EC04

<sup>a</sup> S = skin notation, which means that skin absorption may contribute considerably to body burden; sens = substance can cause sensitisation.

<sup>b</sup> Reference to the most recent official publication of occupational exposure limits.

<sup>c</sup> (Total) inhalable dust.

<sup>d</sup> Respirable dust.

<sup>e</sup> For stearates that do not include toxic metals.

<sup>f</sup> Total dust.

<sup>g</sup> Classified in carcinogenicity category A4, i.e., not classifiable as a human carcinogen: agents which cause concern that they could be carcinogenic for humans but which cannot be assessed conclusively because of a lack of data. *In vitro* or animal studies do not provide indications of carcinogenicity which are sufficient to classify the agent into one of the other categories.

