



Scientific Committee on Consumer Safety

SCCS

## **OPINION ON Dihydroxyacetone**



The SCCS adopted this opinion at its 9<sup>th</sup> plenary meeting on 14 December 2010

## 1. BACKGROUND

The substance dihydroxyacetone (DHA, CAS nr. 96-26-4) is used as an ingredient in self-tanning cosmetic products on the EU market since the 1960's. A rapid and indicative survey by the Dutch Food and Consumer Product Safety Authority (VWA) revealed that there is a widespread use of DHA in self-tanning cosmetic products on the Dutch market.

Besides the use in cosmetic products a recent development is the use of DHA solutions in spray cabins with the purpose of obtaining tanned skin without exposure to sunlight or UV radiation. The VWA has raised concerns about the safety of DHA in spray applications, because of the possibility of consumer exposure by inhalation. This exposure is quite different from DHA as an ingredient in self tanning creams, which occurs via the skin only. In a risk assessment on DHA the Dutch National Institute for Public Health and the Environment (RIVM) concluded that neither the risk of inhalatory, nor dermal exposure to DHA could be assessed, due to the lack of data.

In 2006, the Danish Toxicology Centre, on behalf of the Danish Ministry of the Environment, performed an assessment of DHA in self-tanning creams applied in spray booths, including exposure assessment from different kind of spray cabins. This report also states a lack of toxicological data with regard to the use of the substance in self-tanning products. In 2008, Colipa in 2008 submitted a dossier on the safety profile of DHA in cosmetic products.

## 2. TERMS OF REFERENCE

1. *Does SCCS consider the use of Dihydroxyacetone (DHA) in cosmetic products safe for the consumers when used in a maximum concentration up to 10.0%, taking into account the data provided?*
2. *DHA may also be used in "spray cabins" in aqueous solutions in concentrations between 8 and 14%. Does the SCCS consider this use and exposure safe for the consumers?*
3. *Does the SCCS have any further scientific concerns regarding the use of DHA in a spray solution as a tanning agent without UV?*

DHA has been used worldwide in cosmetic products, i.e. skin care products for face and body, instant tan formulations and 'flash bronzers' in combination with colorants.

The applicant (Colipa, representing 8 cosmetic companies) wishes to support the use of DHA in face creams and body lotions at a concentration of up to 10%. The recommended use levels depend on the skin type and tanning status of the user:

- Ca. 3 - 5 % in formulations for persons with light skin (skin type I - II),
- Ca. 5 - 10 % in formulations for persons with dark skin (skin type III - IV / V),
- Ca. 1 - 2 % in formulations for skin care products (creams and lotions).

The use of DHA solutions in spray cabins, however, is not supported by Colipa, as none of its member companies manufacture products used in spray cabins.

Ref.: 1

A report of the Danish Toxicology Centre (DTC) summarizes the major spraying systems used to treat customers with DHA self-tanning creams (containing 8-14% of DHA):

- 1) The **manual turbine spray** or spraying 'pistol', spraying a high air volume under low pressure onto the skin. The formulation is sprayed from about 15 cm distance from the customer's body.
- 2) The **third-generation spray booth**, consisting of a closed compartment in which, after a short countdown, 3 rows of nozzles spray lotion on the entire body. Turning around is not necessary, as the whole body is treated in one spray action. Once the spraying stops, the customer immediately leaves the spraying compartment, in which a thick aerosol mist has meanwhile been formed.
- 3) The **fourth-generation spray booth**, i.e. an open booth, in which the formulation is charged to 40,000 V and sprayed through 2 vertical rows of nozzles. The customer stands on two earthed metal plates so that the lotion hits her/his body very accurately through electrostatic energy. After 2-3 seconds, the customer turns around and the other side of the body is treated.

In addition, the DTC document reports on some important exposure parameters related to each of the spraying systems, and on the DHA levels measured in the air around the mouth/nose during treatment in a number of operational booths. They are summarized in the following table:

Parameter	Manual turbine spray	Third-generation (closed) spray booth	Fourth-generation (open) spray booth
Amount of formulation used	± 25 ml	± 60 ml	± 15 ml
Application time	2-3 minutes	6 seconds	4-6 seconds
Estimated inhalation exposure	Aerosol cloud is minimal, thus minimal inhalation exposure.	A thick aerosol mist is present in the spraying compartment, thus inhalation is likely.	Aerosol drops are 10 x smaller than in third generation booths; nevertheless, inhalation is expected to be low due to 'electrostatic precision'.
Protective measures to be taken	No specific measures	Customer is advised to keep eyes and mouth shut during treatment.	Customer is advised to use nose filters and eye protection.
Measured DHA concentration (droplets < 12µm)	0.8 mg/m <sup>3</sup> air	Up to 238 mg/m <sup>3</sup> air	Up to 17 mg/m <sup>3</sup> air
Calculated exposure level per treatment <sup>1</sup>	(0.05h x 1.5m <sup>3</sup> /hour x 0.8 mg/m <sup>3</sup> ) = <b>0.06 mg DHA</b>	(0.0017h x 1.5m <sup>3</sup> /hour x 238 mg/m <sup>3</sup> ) = <b>0.61 mg DHA</b>	(0.0017h x 1.5m <sup>3</sup> /hour x 17 mg/m <sup>3</sup> ) = <b>0.04 mg DHA</b>

Ref.: 12

<sup>1</sup> General inhalation rate of 1.5 m<sup>3</sup>/hour is assumed for adult man (low activity) [Technical Guidance Document on Risk Assessment, Part I, European Commission, ECB, 2003].

#### *Photo-mutagenicity*

Two photo-bacterial reverse mutation assays are presented and confirm the mutagenic potential of non-radiated DHA in *Salmonella typhimurium* strains TA100 and TA102. However, exposure of DHA to light did not result in an enhanced mutagenic response.

## 4. CONCLUSIONS

1. *Does SCCS consider the use of Dihydroxyacetone (DHA) in cosmetic products safe for the consumers when used in a maximum concentration up to 10.0%, taking into account the data provided?*

Based upon the available data, the SCCS is of the opinion that the use of Dihydroxyacetone as a self-tanning ingredient in cosmetic formulations up to 10% will not pose a risk to the health of the consumer.

2. *DHA may also be used in "spray cabins" in aqueous solutions in concentrations between 8 and 14%. Does the SCCS consider this use and exposure safe for the consumers?*

When using DHA in spray cabins in aqueous solutions, exposure via inhalation cannot be excluded. The exposure may be single (frequency of use less than once per month) or 'repeated' (e.g. in extreme cases once per week).

For the single exposure, reference is made to the presented acute inhalation study in rats, where the animals were exposed to DHA aerosols during 4 hours to the limit dose level of 5000 mg DHA/m<sup>3</sup>. No effects were observed on the clinical level or on macroscopic findings related to the respiratory tract or other organs.

As far as repeated exposure to DHA-containing self-tanning formulations is concerned, the potential systemic exposure through inhalation appears to be negligible compared to the calculated worst-case dermal exposure levels. The calculated overall systemic exposure level generates a sufficiently high Margin of Safety.

Therefore, based upon the available information, the SCCS considers that the use of Dihydroxyacetone as a self-tanning ingredient in spray cabins up to 14% will not pose a risk to the health of the consumer.

3. *Does the SCCS have any further scientific concerns regarding the use of DHA in a spray solution as a tanning agent without UV?*

In light of the answer to question 2, the SCCS has no further concerns.

## 5. MINORITY OPINION