SCIENTIFIC ADVISORY GROUP ON CHEMICAL SAFETY OF NON-FOOD AND NON-MEDICINAL CONSUMER PRODUCTS (SAG-CS)

Final Opinion on Dihydroxyacetone in Cosmetic Products.

1. Introduction

1.1 Dihydroxyacetone (DHA; 1,3-dihydroxypropan-2-one; CAS No. 96-26-4; see figure 1) is not currently named in the Cosmetic Products Regulation UK No 1223/2009 (as amended)[1]. DHA has, however, been added to Annex III of the EU Cosmetics Regulation and use levels are restricted in the European Union to 10% in self-tan products and 6.25% in non-oxidative hair dyes.

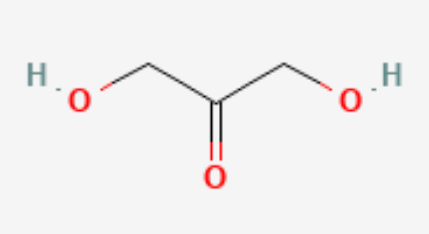

Figure 1: The structure of DHA; CAS No. 96-26-4 (PubChem 2023)

1.2 DHA does not have any harmonised classifications in relation to human health under the GB Classification, Labelling and Packaging (CLP) regulation No 1272/2008 (as amended)[2]. Currently, no EU harmonised or GB mandatory classification and labelling entries exist for DHA (databases accessed March 2023).

1.3 With the aim of supporting the safe use of DHA in cosmetic products (as outlined in Table 1), the UK Cosmetics Industry proactively provided a dossier of information and original studies to OPSS. This follows a review that was undertaken in the EU.

Product Category	Application area	Product format	Maximum DHA Concentration (%)

[1] The UK Regulation currently consists of the Regulation UK No 1223/2009 as amended by SI 696/2019 Product Safety and Metrology (EU Exit) Regulations. The full consolidated UK text will be available soon.

[2] The GB CLP Regulation No 1272/2008 as amended by the Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019. The full consolidated UK text will be available soon.

Leave-on self-tan	Face and body	Lotion and non-aerosol spray	14%
Leave-on self-tan	Face and body	Spray booth weekly application	14%
Rinse-off self-tan	Body	Rinse-off lotion	22.5%
Non-oxidative hair colourant	Hair	Leave-on non-oxidative hair colourant	6.25%

Table1: Industry-proposed UK use levels for DHA in cosmetic products.

2. Background

Intended function and uses of DHA.

2.1 DHA is currently used in cosmetic products intended to produce a tanned appearance without exposure to UV light. DHA binds to the protein, keratin, in the skin surface to produce melanoidins in a reaction similar to the Maillard reaction which occurs when food browns during cooking. This brown pigment remains in the stratum corneum and is sloughed off naturally with the upper layers of the skin surface (Nguyen & Kochevar, 2003).

2.2 The phosphorylated form of DHA, dihydroxyacetone phosphate, is produced endogenously during glycolysis and fructolysis along with its isomer glyceraldehyde-3-phosphate (GAP) (Burch et al, 1970).

3. Previous Scientific Opinions

3.1 The safety of DHA has been evaluated twice by the Scientific Committee on Consumer Safety (SCCS), in 2010 and in 2020 (SCCS, 2010; SCCS, 2020).

3.2 In 2010, the SCCS reviewed safety data on DHA alongside a Danish review of the potential exposures to DHA through use in spray tanning booths (Höglund et al. 2006). In this review, estimated exposures from manual turbine sprays, third generation (closed) spray booths and fourth generation (open) spray booths were 0.06mg, 0.61mg and 0.04 mg DHA respectively per application.

3.3 The SCCS derived a NOAEL of 1000 mg/kg bw/day from a 13-week oral study in rats (unpublished report cited in SCCS, 2010) and a dermal absorption of 48.03% (37.2% + 1SD) derived from an *in vitro* study using human skin membranes and 10% DHA (Maas, 2007).

3.4 Genotoxicity data showed that DHA produced positive results in TA100 and TA102 strains of *Salmonella typhimurium* in several OECD TD 471 compliant reverse mutation tests. A summary of a negative *in vivo* micronucleus test undertaken at the Shiseido Research Centre in 1986 and translated in 2006 was available to the SCCS (SCCS, 2020)

which enabled them to conclude that DHA was not mutagenic *in vivo*. However, these data were not available for review by the SAG-CS.

3.5 There was no evidence to suggest that DHA was acutely toxic, carcinogenic, reprotoxic, irritating, or acts as a skin sensitiser. The SCCS concluded that use of DHA at 10% in self-tanning products would not pose a risk to the consumer. They also concluded that use in different types of spray tanning booth up to 14% would not pose a risk to consumer health (SCCS, 2010).

3.6 In 2020, the SCCS reviewed safety data relating to the use of DHA as a hair colouring ingredient in non-oxidative leave-on products up to a maximum concentration of 6.25%. The SCCS derived a NOAEL of 1000 mg/kg bw/day from the same 13-week oral toxicity study in rats (Broich et al, 2007). Given a lack of bioavailability data following oral intake, the SCCS used standard procedure as defined in the SCCS notes of guidance (SCCS, 2023) and assumed 50% bioavailability. The SCCS, therefore, derived an adjusted NOAEL of 500mg/kg bw/day. The SCCS derived a dermal absorption of 9.87% from an *in vitro* study using human skin membranes and a leave on hair care formulation containing 6.25% DHA (Davies, 2018). The SCCS did not calculate aggregate exposure estimates in 2020, because they considered that their previous assessment from 2010 had used overly conservative exposure estimates based on absorption of 48.03%. Exposure through inhalation was not considered (SCCS 2010).

3.7 In the US, DHA has been approved by the FDA for dermal applications only “in amounts consistent with good manufacturing practice”. Safety data has not been submitted by industry to support any use that may expose the lips, eyes, or mucous membranes to DHA (this includes inhalation). Therefore, DHA containing products have not been approved by the FDA for use in tanning booths where these exposures may occur. This does not make their use in tanning booths illegal under US law, but tanning booth operators and consumers should be aware of the potential risks and are advised to take appropriate precautions (FDA, 2022).

4. Discussion by the Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products (SAG-CS)

4.1 At their April 2023 meeting, the SAG-CS discussed a paper and associated industry-prepared dossier, which focused on the available safety data on dihydroxyacetone when used in self-tanning and hair colouring cosmetic products, which do not require exposure to UV light.

4.2 Aside from being found in self-tanning and hair-colouring cosmetic products, DHA is also found naturally in Manuka honey at varying

concentrations and as a reaction product in the aerosols from some e-cigarettes (Vreeke et al, 2018).

4.3 Members noted that there are instances in which children may use self-tan products containing DHA. Given the lack of available safety data and use levels specifically in children, they have not been specifically considered in this risk assessment.

4.4 Similarly, adolescents may use self-tan products containing DHA. Again, there is a lack of available safety data and use levels specifically for adolescents. However, an adequate margin of safety was calculated using a worst-case aggregate exposure scenario for a bodyweight of 55kg and above. This bodyweight is roughly equivalent to an adolescent aged 14-18 years where the mean bodyweight is estimated at 61.3kg (EFSA, 2012).

4.5 The pivotal toxicology study for performing a safety assessment of systemic toxicity was the 13-week repeat dose study reported by Broich, Flade and Weber (2007). The SAG-CS reviewed the original study and agreed with the authors conclusion that no effects were observed and the top dose of 1000 mg/kg/day is a No Observed Adverse Effect Level (NOAEL) from this study. Given the lack of ADME data via the oral route for DHA, a default ADME correction factor of 50% (as per SCCS 12th Notes of Guidance (2023)) should be applied to the NOAEL. The PODsys as corrected for bioavailability is therefore 500 mg/kg/day and this should be taken forward into the safety evaluation for systemic toxicity.

4.6 Members discussed the applicant's proposal for read across to DHA from safety and absorption data on glycerol, to avoid the need to apply a default bioavailability correction. Given that glycerol is 100% absorbed and is non-reactive, whereas DHA is reactive, and protein bound, this was not considered a good read-across substance.

4.7 The retention factor for the rinse off shower tanning product was also discussed. A value of 0.5 was deemed appropriate as there is evidence which shows DHA is bound in the skin (Nguyen & Kochevar, 2003), and therefore, even with rinsing off the product, some DHA will remain. Using a 0.5 retention factor is likely to result in a relatively conservative risk assessment.

4.8 Members agreed to use a dermal absorption value of 9.87% (derived from Davies, 2018) in their safety assessment.

4.9 Mutagenicity and genotoxicity data for DHA were discussed. Members queried the two positive Ames test results for DHA, which appeared in two strains (TA100 and TA102 +/- S9). All other *in vitro* tests for mutagenicity/genotoxicity and the *in vivo* study were negative. The SCCS "…unanimously came to the conclusion that, based on the presented raw data and a weight of evidence approach, there is no

reason to consider DHA as an *in vivo* mutagenic/genotoxic substance". However, the SAG-CS have not seen the original study data.

4.10 Upon contact with the skin, DHA binds with keratin to produce melanoidins (Nguyen & Kochevar, 2003). There are a small number of publications looking at the genotoxicity and mutagenicity of melanoidins with primarily negative results. A positive result was identified in a Sister Chromatid Exchange assay using human lymphocytes and Caco-2 cells (Taylor et al, 2004; Glösl et al, 2004). Members discussed the lack of testing and limited data available for melanoidins, which are found in many biological materials. There was uncertainty as to how melanoidins could break down. Despite these concerns, using a weight of evidence approach based on DHA data alone, i.e., not considering the potential effects of melanoidins, the SAG-CS concluded that there was no reason to consider DHA as an *in vivo* mutagenic or genotoxic compound.

4.11 Based on the information available, there was no evidence of DHA being a skin sensitiser or a contact allergen. There was also no evidence to suggest that DHA in the skin is affected by exposure to UV light.

4.12 The analytical chemistry of DHA is well known and at least one publication (Biondi et al., 2007) describes the validation of a method for DHA in self-tanning creams by HPLC as its pentafluorobenzyloxime derivative.

5. Conclusions

Members noted that DHA forms melanoidins in the skin after application and that no safety data for melanoidins in skin were available.

Based on the evidence available to the SAG-CS, members agreed that dihydroxyacetone is acceptable for use by adults, at the stated concentrations, when used in the following cosmetic products to produce a tanned appearance or brown colour in the absence of UV light:

- *Leave on self-tan (lotion and non-aerosol spray)- 14%*
- *Leave on self-tan (spray booth weekly application)- 14%*
- *Rinse-off self-tan (rinse-off lotion)- 22.5%*
- *Non-oxidative hair colourant (leave-on)- 6.25%*

Members also agreed that dihydroxyacetone is acceptable for use by adults at the concentrations stated above when considering an aggregate usage scenario. This is the rinse-off self-tan (body) + non-oxidative hair colourant (hair) + leave on self-tan lotion (face) + rinse-off self-tan (pump spray-inhalation). Margin of Safety calculations are provided in the appendix at the end of this opinion.

The SAG-CS noted the SCCS conclusions that the weight of evidence suggests that DHA is not genotoxic or mutagenic in vivo. The SAG-CS have not been able to draw conclusions on genotoxicity in vivo as the data were not available to them.

Given the lack of exposure studies and usage data specifically in children, the SAG-CS were unable to conclude on the safe use of DHA by children.

The Committee were of the opinion that adolescents aged 14-18 years may wish to use self-tan products. Following calculation of the MoS based on bodyweight and a high exposure scenario, members did note that an acceptable margin of safety was achieved using the estimated mean bodyweight for this age group. A full risk assessment in children and adolescents should be carried out when adequate data and an appropriate methodology become available.

Consideration of the environmental safety of chemicals does not fall within the remit of the SAG-CS.

Scientific Advisory Group on Chemical Safety of Non-Food and Non-Medicinal Consumer Products

December 2023

Appendix- Safety Assessment Calculations

The full industry safety dossier, key unpublished studies and other references from the peer review literature have been supplied to the SAG-CS.

Using the proposed use levels from Table 1, the following Margin of Safety (MoS) calculations have been performed.

Table 2. Calculation of dermal systemic exposure (SED_{Dermal}) and MoS for exposure to DHA from a leave on self-tan lotion/cream used on the face and body only. Calculations were carried out in accordance with the SCCS Notes of Guidance (2023) Section 3-3.5.4.

Product type/application	**Self-tan lotion/cream face and body combined**
Daily exposure to product (g/d)	9.36[1]
Concentration DHA (%)	14
Calculated daily exposure to DHA (mg/d)	1.34
$E_{product}$/bw (mg/kg bw/d)	147.34[2]
Dermal Absorption (%)	9.87[3]
Body weight (kg)	70
SED_{dermal} (mg/kg bw/d)	**2.04**
PoD (mg/kg bw/d)[4]	1000
Oral absorption (%)	50[5]
$PoD_{systemic}$ (mg/kg bw/day)	500
MoS	**246**
Safe MoS	100
Conclusion	**Acceptable safety margins**

SED – Systemic exposure dose
PoD – Point of departure
MoS – Margin of safety

1 – Combined estimates for face and body cream usage taken from the SCCS Notes of Guidance (SCCS, 2023)
2 - Combined estimates for face and body cream $E_{product}$ taken from the SCCS Notes of Guidance (SCCS, 2023) derived using actual bodyweights of participants.
3 – Is the value used by the SCCS, 2023 based on the absorption derived from Davies, 2018 plus 1 standard deviation.
4 - Based on the 13-week repeat dose toxicity test by Broich et al, 2007.
5 – Default value assumed in the absence of substance-specific data and used to adjust the POD for differences between dermal and oral absorption kinetics.

Table 3: Calculation of SED_{Dermal} and MoS for exposure to DHA from different types of tanning booth.

Product type/application	**Manual turbine spray**	**Third generation tanning booth**	**Fourth generation tanning booth**
Amount of product used per application (mg)[1]	25000	60000	15000
Daily exposure to product (g/d)[2]	3571	8571	2143
Concentration DHA (%)	14%	14%	14%
Calculated daily exposure to DHA (mg/d)	500	1200	300
$E_{product}$/bw (mg/kg bw/d)	51.02	122.45	30.61
Dermal Absorption (%)[3]	9.87%	9.87%	9.87%
Body weight (kg)	70	70	70
SED_{dermal} (mg/kg bw/d)	0.705	1.692	0.423
PoD (mg/kg bw/d)[4]	1000	1000	1000
Oral absorption (%)[5]	50	50	50
$PoD_{systemic}$ (mg/kg bw/day)	500	500	500
MoS	**709**	**296**	**1182**
Safe MoS	100	100	100
Conclusion	**Acceptable safety margins**	**Acceptable safety margins**	**Acceptable safety margins**

SED – Systemic exposure dose
PoD – Point of departure
MoS – Margin of safety

1 –Based on the data from the Höglund et al, 2006
2 –Weekly application, row 1 divided by 7.
3 - Derived from Davies, 2018
4 - Based on the 13-week repeat dose toxicity test by Broich et al2007.
5 – Default value assumed in the absence of substance-specific data and used to adjust the POD for differences between dermal and oral absorption kinetics.

Table 4. Calculation of SED_{Dermal} and MoS for exposure to DHA from rinse-off self-tan products (body only).

Product type/application	**Rinse-off self-tan products (body only)**
Daily exposure to product (mg/d)[1]	18670
Concentration DHA (%)	22.5%
Calculated daily exposure to DHA (mg/d)	4200.75
$E_{product}$/bw (mg/kg bw/d)[2]	133.36
Dermal Absorption (%)[3]	9.87%
Body weight (kg)	70
SED_{dermal} (mg/kg bw/d)	2.96
PoD (mg/kg bw/d)[4]	1000
Oral absorption (%)[5]	50
$PoD_{systemic}$ (mg/kg bw/day)	500
MoS	**169**
Acceptable MoS	100
Conclusion	**Acceptable safety margins**

SED – Systemic exposure dose
PoD – Point of departure
MoS – Margin of safety

1 – Exposure estimate for shower gel taken from the SCCS Notes of Guidance (SCCS, 2023)
2 - Exposure estimate for shower gel taken from the SCCS Notes of Guidance (SCCS, 2023) divided by standard bw of 60kg and using a retention factor of 0.5. Applicant used a retention factor of 0.1, ten-fold more conservative than SCCS NoG for shower gel retention.
3 - Derived from Davies, 2018
4 - Based on the 13-week repeat dose toxicity test by Broich et al, 2007.
5 – Default value assumed in the absence of substance-specific data and used to adjust the POD for differences between dermal and oral absorption kinetics.

Table 5. Calculation of SED_{Dermal} and MoS for exposure to DHA from non-oxidative hair colourant.

Product type/application	**Non-oxidative hair colourant**
Amount of product used per application (mg)[1]	35000
Daily exposure to product (g/d)[2]	5000
Concentration DHA (%)	6.25%
Calculated daily exposure to DHA (mg/d)	312.5
$E_{product}$/bw (mg/kg bw/d)	71.43
Dermal Absorption (%)[3]	9.87%
Body weight (kg)	70
SED_{dermal} (mg/kg bw/d)	0.441
PoD (mg/kg bw/d)[4]	1000
Oral absorption (%)[5]	50
$PoD_{systemic}$ (mg/kg bw/day)	500
MoS	**1135**
MoS	100
Conclusion	**Acceptable safety margins**

SED – Systemic exposure dose
PoD – Point of departure
MoS – Margin of safety

1 – Exposure estimate for semi-permanent hair dyes taken from the SCCS Notes of Guidance (SCCS, 2023)
2- Weekly exposure to the product to row 1 divided by 7
3 - Derived from Davies, 2018
4 - Based on the 13-week repeat dose toxicity test by Broich et al, 2007.
5 – Default value assumed in the absence of substance-specific data and used to adjust the POD for differences between dermal and oral absorption kinetics.

Table 6. Calculation of $SED_{inhalation}$ and MoS for exposure to DHA from non-aerosol (pump) sprays. Calculations were carried out using the SCCS Notes of Guidance Section 3-3.5.4.1.

Product type/application	Pump spray	In-shower self-tan, pump spray	Third generation spray tanning booth	Fourth generation spray tanning booth
Amount per application (mg/application)	9000[1]	9000[1]	60000[2]	15000[2]
Content DHA (%)	14%	22.5%	14%	14%
Proportion propellant	0	0	0	0
Airborne fraction	0.2[3]	0.2[3]	1[2]	1[2]
Potential amount inhaled (mg/application)	252	405	8400	2100
Box 1 volume (L)[4]	1000	1000		
Duration in box 1 (min)	2[4]	2[4]		
Inhalation rate (L/min)	13[4]	13[4]		
Potential amount inhaled in box 1 (mg/application)	6.55	10.53		
Box 2 volume (L)[4]	10000	10000	10000	10000
Duration in box 2 (min)[4]	10	10	0.1	0.1
Inhalation rate (L/min)[4]	13	13	13	13
Potential amount inhaled in box 2 (mg/application)	3.28	5.265	1.092	0.273
Retention fraction in lungs (25% exhaled)[4]	0.75	0.75	0.75	0.75
Respirable fraction	1[5]	1[5]	0.40[6]	1.00[6]
Frequency of application (/day)	1	1	0.14	0.14
Body weight (kg)	70	70	70	70
$SED_{inhalation}$ (mg/kg bw/d)	0.1053	0.1692	0.0006552	0.0004095
PoD (mg/kg bw/d)[7]	1000	1000	1000	1000
Oral absorption (%)[8]	50%	50%	50%	50%
$PoD_{systemic}$ (mg/kg bw/day)	500	500	500	500
MoS	**4748**	**2955**	**763126**	**1221001**
MoS	100	100	100	100
Conclusion	**Acceptable**	**Acceptable**	**Acceptable**	**Acceptable**

SED – Systemic exposure dose
PoD – Point of departure
MoS – Margin of safety

1 – Estimate of body lotion and pump/aerosol application taken from the SCCS Notes of Guidance (SCCS, 2023).
2 - Based on the data from the Högland, 2006
3 – Based on Bremmer et al, 2006 as cited in SCCS Notes of Guidance (SCCS, 2023).
4 – Box 1 is near field of exposure, around the head. Box 2 is the far-field of exposure, e.g the bathroom. Based on default estimates from the SCCS Notes of Guidance, Appendix 11 (SCCS, 2023).
5 – Worst case assumption due to lack of data.
6 – Estimated from a graph from the Högland, 2006
7 - Based on the 13-week repeat dose toxicity test by Broich et al, 2007.
8 – Default value assumed in the absence of substance-specific data and used to adjust the POD for differences between lung and oral absorption kinetics.

Table 7. Calculation of aggregate SED and MoS for exposure to DHA from all anticipated combinations of products to produce an estimate of the margins of safety for the worst-case exposure scenarios.

Component	SED
Rinse off self-tan shower gel	2.962
Non oxidative hair colourant	0.441
Self-tan lotion - face	0.334
In-shower self-tan pump spray (inhalation)	0.169
PoD (mg/kg bw/day)	1000
Oral absorption	50%
PoD systemic (mg/kg bw/day)	500
Total SED (mg/kg bw/day)	3.9
MoS	128
MoS	100
Conclusion	**Acceptable**

Table 8. Calculation of aggregate SED and MoS for a 55kg individual following exposure to DHA from all anticipated combinations of products to produce an estimate of the margins of safety for the worst-case exposure scenario.

Component	SED
Rinse off self-tan shower gel	3.769
Non oxidative hair colourant	0.561
Self-tan lotion - face	0.387
In-shower self-tan pump spray (inhalation)	0.215
PoD (mg/kg bw/day)	1000
Oral absorption	50%
PoD systemic (mg/kg bw/day)	500
Total SED (mg/kg bw/day)	4.9
MoS	101
MoS	100
Conclusion	**Acceptable**

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