SCCS/1588/17
Revised version of 16 May 2018

Scientific Committee on Consumer Safety

SCCS

Checklists for Applicants submitting dossiers on Cosmetic Ingredients to be evaluated by the SCCS

The SCCS adopted these Checklists

on 07 March 2017 and the 1st revised version on 16 May 2018

About the Scientific Committees

Two independent non-food Scientific Committees provide the Commission with the scientific advice it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The Committees also draw the Commission's attention to the new or emerging problems that may pose an actual or potential threat.
They are: the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and are made up of independent experts.

In addition, the Commission relies upon the work of the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease prevention and Control (ECDC) and the European Chemicals Agency (ECHA).

SCCS

The Committee shall provide Opinions on questions concerning all types of health and safety risks (notably chemical, biological, mechanical and other physical risks) of non-food consumer products (for example: cosmetic products and their ingredients, toys, textiles, clothing, personal care and household products such as detergents, etc.) and services (for example: tattooing, artificial sun tanning, etc.).

Scientific Committee members

Contact
European Commission
Health and Food Safety
Directorate C: Public Health, Country Knowledge, Crisis Management
Unit C2 – Country Knowledge and Scientific Committees
L-2920 Luxembourg
SANTE-C2-SCCS@ec.europa.eu

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http://ec.europa.eu/health/scientific_committees/consumer_safety/index_en.htm

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Dr U. Bernauer
Prof. Q. Chaudhry (Chairman)
Prof. P.J. Coenraads (Vice-Chair)
Dr M. Dusinska
Prof. V. Rogiers (Vice-Chair)
Prof. T. Vanhaecke

SCCS external expert
Dr N. von Götz

All Declarations of Working Group members are available on the following webpage:
http://ec.europa.eu/health/scientific_committees/experts/declarations/sccs_en.htm

This revision includes an additional box for the Applicants to confirm that the information contained in their dossier complies with the provisions on animal testing as laid down in Article 18(1) of Regulation (EC) No 1223/2009.

Keywords: SCCS, Checklists, Applicants, cosmetic ingredients

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1. BACKGROUND

Certain categories of cosmetic ingredients are regulated under the EU Cosmetic Regulation 1223/2009 to ensure consumer safety. These include the ingredients listed in the Annexes of the EU Cosmetic Regulation (colorants, preservatives, UV filters,), the list of 26 potential allergens (see SCCS/1559/11), and any nanomaterial in cosmetic ingredient. Detailed guidance on the testing of cosmetic ingredients and their safety assessment has been provided in the SCCS Notes of Guidance (9th revision, SCCS/1564/15).

The Regulation also specifically covers the use of nanomaterials in cosmetic products. In this respect, the Regulation provides a definition of a nanomaterial under Article 2 (1) (k), and requires the European Commission to be notified six months prior to placing a cosmetic product containing nanomaterial(s) on the market. If there are concerns over the safety of a nanomaterial, the Commission will refer it to the Scientific Committee on Consumer Safety (SCCS) for a scientific Opinion. The Regulation requires the nanoscale ingredients used in cosmetic products to be labelled (name of the ingredient, followed by 'nano' in brackets). This provides a mechanism for premarket notification, risk assessment, authorisation, and labelling of cosmetic products that contain nanomaterials. The SCCS has already published a specific Guidance on the main elements to consider when submitting a safety dossier on nanomaterials in cosmetics (SCCS/1484/12) and a memorandum on the relevance, adequacy and quality of the data presented in such dossiers (SCCS/1524/13).

For timely assessment of the dossiers submitted in support of safety of cosmetics ingredients, it is of utmost importance that they are as complete as possible and contain data that are adequate, relevant, and of suitable quality for use in risk assessment. In this context, this document provides checklists for the parameters that are essential for the SCCS evaluation of cosmetic ingredients, including nanomaterials in cosmetics. The main purpose of these checklists is to enable both the Applicant and the SCCS to quickly assess if the dossiers are complete and to prevent submissions that are incomplete or contain inadequate/irrelevant data. This should streamline the safety evaluation process and save time and resources for both the Applicants and the SCCS.

2. CHECKLISTS FOR NON-NANOMATERIALS COSMETIC INGREDIENTS

2.1 Compliance with animal testing ban

Information required	***Answer***
Confirmation by the Applicant that the information included in the dossier complies with the animal testing ban as laid down in Article 18(1) of the EU Cosmetics Regulation. The dossier should therefore include the following statement: 'The Applicant hereby confirms that the information contained in this dossier complies with the provisions on animal testing as laid down in Article 18(1) of Regulation (EC) No 1223/2009.'	

2.2 Completeness of the dossier

Information required	***Answer***
Same number of annexes as provided in the summary	
Same content of annexes as provided in the summary	
Consistency in numbering	

2.3 General information on the cosmetic ingredient

Information required	***Answer***
Type of cosmetic ingredient (preservative, UV-filter, colourant, hair dye, other)	

Maximal concentration in finished cosmetic product leave-on rinse-off	
Exposure (oral, dermal, inhalation)	
Current use(s)	

The checklists provide a maximum of 4 possible options for the Applicant to fill in the columns. In some cases, only one or two options are available. The Applicant shall select only one option by double clicking on the most appropriate one to indicate the answer as follows:

YES The required information or documentation is included.

IN PART Only partial information or documentation is included. Justification for the missing elements must be provided in a separate document.

NO The required information or documentation is not included in the dossier. Reasons for not providing the information must be included in a separate document.

NOT RELEVANT The information or documentation is not relevant or requested for the application in question. Justification for their non-submission must be provided in a separate document.

Confidentiality of commercial name(s) to be considered?	

Table 2.1: Checklist for <u>minimal</u> physicochemical characterisation

Information required	***Provided?***
Primary name and/or INCI name	
CAS / EC number	
Structural formula	
Empirical formula	
Physical form	
Molecular weight	
Purity and isomer composition*	
Impurities/accompanying contaminants	
Solubility	
Partition coefficient (Log P_{ow})	
Homogeneity	
Stability	

* for substances which are mixtures of isomers

Table 2.2: Checklist for <u>more specific</u> physicochemical characterisation

Information required	***Provided?***
Organoleptic properties	
Flash point	
<u>For liquids:</u>	
▪ boiling point	
▪ relative density	
▪ pK_a	
▪ viscosity	
▪ vapour pressure	
<u>For solids:</u>	
▪ general appearance	
▪ melting temperature	
▪ pKa	
<u>For gases:</u>	
▪ density	
▪ auto-ignition temperature	
UV light absorption spectrum**	

** for UV light-absorbing substance

Table 2.3: Checklist for hazard identification (toxicological data)

Information required	***Reference***	***Provided?***
Likelihood and extent of internal exposure via skin, lung, or oral route considering the use type	Section 3-4.1 of SCCS/1564/15	
Dermal absorption	SCCS/1358/10	
Acute Toxicity	Section 3-4.2 of SCCS/1564/15	
Irritation and Corrosivity	Section 3-4.3 of SCCS/1564/15	
Skin Sensitisation	Section 3-4.4 of SCCS/1564/15	
Mutagenicity/ Genotoxicity	Section 3-4.7 of SCCS/1564/15	
Repeated dose toxicity	Section 3-4.5 of SCCS/1564/15	
Phototoxicity - for products intended for use in sunlight-exposed skin	Section 3-4.9 of SCCS/1564/15	
Reproductive Toxicity [(a)]	Section 3-4.6 of SCCS/1564/15	
Developmental Toxicity	Section 3-4.6 of SCCS/1564/15	

Carcinogenicity [b]	Section 3-4.8 of SCCS/1564/15	
Human data (where available)	Section 3-4.10 of SCCS/1564/15 and SCCNFP/0633/02	
Other relevant information		

[a] Where points 1 and 2 indicate significant systemic uptake
[b] Where points 1 and 2 indicate significant systemic uptake and/or bioaccumulation

Table 2.4: Checklist for information on exposure

Information required [a]	***Provided?***
Category of cosmetic products in which the ingredient is intended for use	
Concentration of the ingredient in the finished cosmetic product	
Quantity of the product used at each application	
Frequency of use	
Total area of skin contact	
Duration of exposure	
Foreseeable uses which may increase exposure	
Consumer target groups (e.g., children, people with sensitive, damaged or compromised skin) where specifically required	
Quantity likely to enter the body (fraction absorbed) for each target group	
Application on skin areas exposed to sunlight	
Estimated dermal exposure based on the intended use of the product	
Estimated oral exposure based on the intended use of the product	
Estimated inhalation exposure based on the intended use of the product	
Exposure calculation for each target group	
Other relevant information	

[a] In the absence of information, default values for some of the parameters may be used (SCCS Notes of Guidance SCCS/1564/15)

3. CHECKLISTS FOR NANOMATERIALS IN COSMETICS

3.1 Introduction

The SCCS Guidance (SCCS/1484/12) has recommended that, as a minimum, the data provided on characterisation of nanomaterials intended for use in a cosmetic product should include a clear description of

1. the pristine nanoparticles as produced (raw material),
2. the nanoparticles present in the cosmetic product (after formulation), and
3. the nanoparticles present during toxicological investigations covering realistic exposure scenarios for the exposure assessments

If characterisation of a nanomaterial at any of these stages is not feasible, for example, due to the lack of methods, or due to degradation of the nanomaterial, it should be justified and documented.

Other important issues as highlighted in the SCCS Memorandum (SCCS/1524/13) are the following:

- The data provided in a safety dossier should contain detailed characterisation in relation to the unequivocal/unambiguous identity and composition of the nanomaterial(s) that are intended for use in the final product.
- The toxicity data provided in a safety dossier should include a detailed description of the materials and methods used and appropriate statistical indicators of the quality and reliability of the test results.
- Safety of a nanomaterial cannot be assumed on the argument that the bulk form of the materials is safe (and vice versa), without specific evidence to support it.
- If data from other materials are included (e.g. a bulk material as a comparator), it should be clearly defined and segregated from the data on nanomaterials, and not presented mixed-up with data on nanomaterial(s) under evaluation.
- Each submission should be supported by comprehensive data from the Applicants' studies as well as any relevant information available from the open literature. To facilitate the evaluation, the contents should be divided into general aspects and specific aspects. The submission should be in the form of a searchable text or pdf file with page numbering and appropriate indexing of the contents and supporting studies and publications in clear sections and separated appendices/annexes. Scanned files that are not searchable and embedded files within documents will not be accepted.
- Unless there is a close similarity between different nanomaterials, it is advisable to include a complete set of supporting data on each nanomaterial rather than presenting several different nanomaterials in a single, patchy and data-poor submission. If the same data included in the dossier is considered relevant for evaluation of more than one

nanomaterial, the basis for 'similarity' between the nanomaterials must also be provided to allow data read-across.

- Inclusion of irrelevant data – for example from unrelated materials, or materials with incomplete or unknown characterisation – must be avoided.

A schematic outline of nanomaterial risk assessment is given in the Figure attached to this document.

The following checklists provide a maximum of 4 possible options for an Applicant to fill in the columns as explained below. In some cases, only one or two options are available. The Applicant shall select only one option by double clicking on the most appropriate one to indicate the answer as follows:

YES	The required information or documentation is included.
IN PART	Only partial information or documentation is included. Justification for the missing elements must be provided in a separate document.
NO	The required information or documentation is not included in the dossier. Reasons for not providing the information must be included in a separate document.
NOT RELEVANT	The information or documentation is not relevant or requested for the application in question. Justification for their non-submission must be provided in a separate document.

3.2 Compliance with animal testing ban

Information required	***Answer***
Confirmation by the Applicant that the information included in the dossier complies with the animal testing ban as laid down in Article 18(1) of the EU Cosmetics Regulation. The dossier should therefore include the following statement: 'The Applicant hereby confirms that the information contained in this dossier complies with the provisions on animal testing as laid down in Article 18(1) of Regulation (EC) No 1223/2009.'	

3.3 Completeness of the dossier

Confidentiality of commercial name(s) to be considered?	

Table 3.1: Checklist for material characterisation

Information required [(a)]	***Provided for raw material as manufactured?***	***Provided for material in a final formulation?***	***Provided for material used for toxicological investigations and exposure assessment?***
Chemical identity			
Chemical composition			
Particle size [(b)]			
Morphology			
Surface Characteristics			
Solubility			
Surface area			
Catalytic Activity			
Concentration [(c)]			
Dustiness [(c)]			
Density and pour density [(d)]			
Redox potential			
pH [(e)]			
Viscosity [(f)]			
Stability			
UV absorption			
Other			

[(a)] For details on these parameters see Table 1 of SCCS/1484/12; [(b)] For any spray product, size distribution of the droplets after spraying as well as of the dried residual particles should be provided; [(c)] For dry powder products only; [(d)] For granular materials only; [(e)] For aqueous solutions; [(f)] For liquid dispersions

3.2: Checklist for Hazard Identification (Toxicological data)

Information required	***Reference***	***Provided?***
Likelihood and extent of internal exposure via skin, lung or oral route considering the use type	Section 3-4.1 of SCCS/1564/15	
Dermal absorption – for dermally applied products	SCCS/1358/10	
Biokinetic behaviour, aggregation/ agglomeration considered during tests?	Section 3-4.1 of SCCS/1564/15	
Acute Toxicity	Section 3-4.2 of SCCS/1564/15	
Irritation and Corrosivity	Section 3-4.3 of SCCS/1564/15	
Skin Sensitisation	Section 3-4.4 of SCCS/1564/15	
Mutagenicity/ Genotoxicity[(a)]	Section 3-4.7 of SCCS/1564/15	
Repeated dose toxicity	Section 3-4.5 of SCCS/1564/15	
Phototoxicity - for products intended for use in sunlight-exposed skin	Section 3-4.9 of SCCS/1564/15	
Reproductive Toxicity [(b)]	Section 3-4.6 of SCCS/1564/15	
Carcinogenicity [(c)]	Section 3-4.8 of SCCS/1564/15	
Human data (where available)	Section 3-4.10 of SCCS/1564/15 and SCCNFP/0633/02	
Other relevant information		

(a) The Ames test is not considered appropriate for nanomaterial mutagenicity assessment. The following scheme based on in vitro assays is proposed (SCCS/1564/15).

1. An in vitro mammalian cell gene mutation test (e.g. hprt, tk or xprt tests).
2. Mammalian cell chromosome aberration/clastogenicity – determined either by in vitro chromosome aberration test or micronucleus test. The micronucleus test can be performed by the mononucleate or cytokinesis blocked protocols. In the cytokinesis blocked micronucleus assay, co-exposure to both cytochalasin B and the test nanomaterial for the duration of the experiment is not considered acceptable.

   Additionally, other alternative tests, such as the Comet assay, may be included as further weight of evidence. New in vitro approaches such as cell transformation assays or toxicogenomic approaches may also be useful for identification of genotoxic as well as non-genotoxic carcinogen nanomaterials.
3. In vitro genotoxicity studies should be accompanied by an assessment of cellular and nuclear uptake to demonstrate target exposure.

[(b)] Where point 1 and 2 of the above table indicate significant systemic uptake

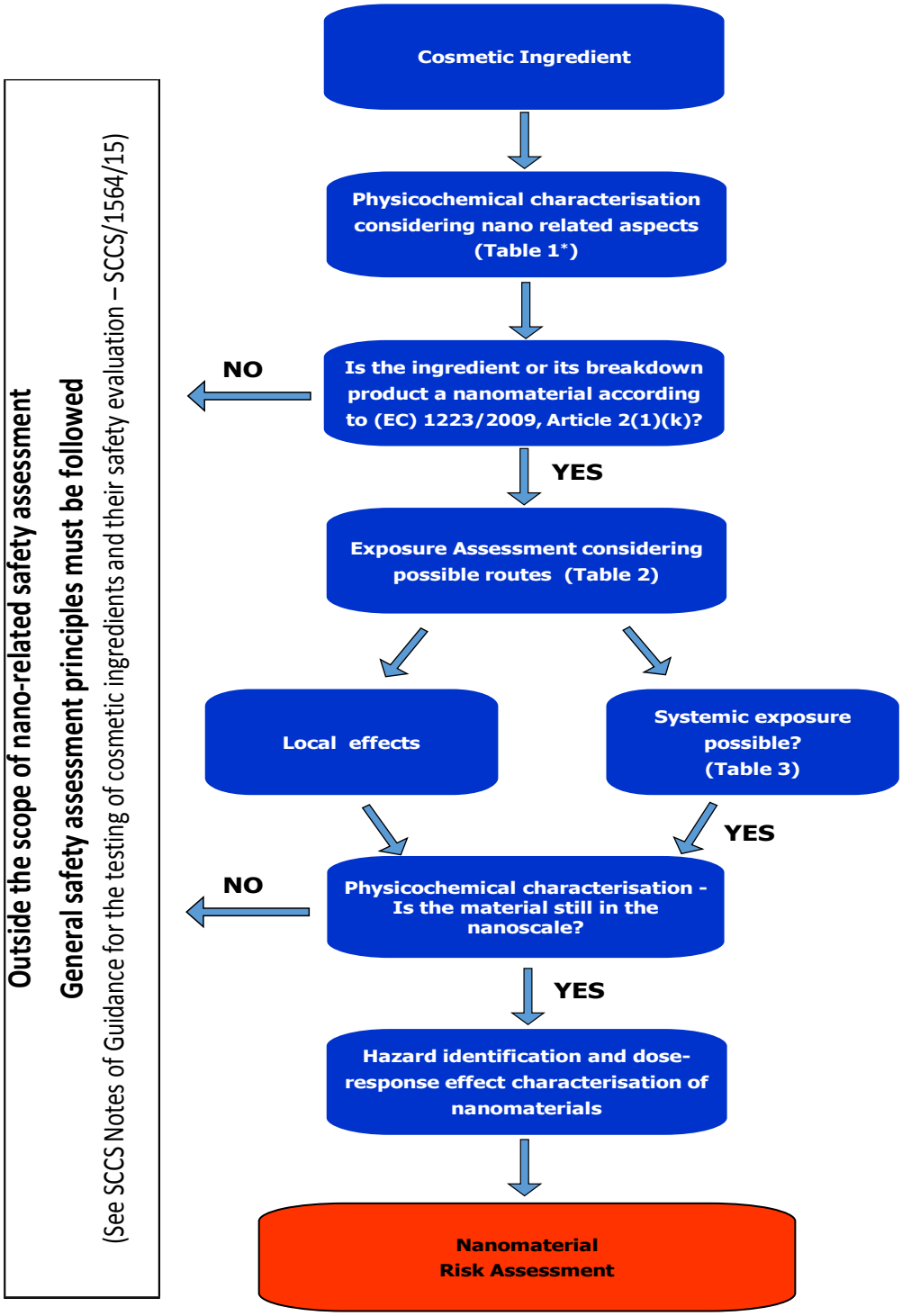
[(c)] Where point 1 and 2 of the above table indicate significant systemic uptake and/or bioaccumulation

Table 3.3: Checklist for Information on Exposure (for details see page 19 of SCCS 1484/12)

Information required [(a)]	Provided?
Category of cosmetic products in which the ingredient is intended for use	
Concentration of the ingredient in the finished cosmetic product	
Quantity of the product used at each application	
Frequency of use	
Total area of skin contact	
Duration of exposure	
Foreseeable uses which may increase exposure	
Consumer target groups (e.g., children, people with sensitive, damaged or compromised skin) where specifically required	
Quantity likely to enter the body (fraction absorbed) for each target group	
Application on skin areas exposed to sunlight	
Estimated dermal exposure based on the intended use of the product	
Estimated oral exposure based on the intended use of the product	
Estimated inhalation exposure based on the intended use of the product	
Exposure calculation for each target group	
Other relevant information	

(a) In the absence of information, default values for some of the parameters may be used (SCCS Notes of Guidance SCCS/1564/15)

Figure 3.1: Schematic outline for the safety assessment of nanomaterials in cosmetics:



* i.e. in raw material, final formulation and as used for toxicological investigations and exposure assessment;