Checklist for Applicants submitting Nanomaterial Characterisation Information on SCPN.

In order to comply with Article 16 of the domestic (GB) version of the Cosmetic Regulation 2009, it is advised that applicants complete and submit the following checklist along with the supporting documents.

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Nanomaterial is defined as: **"an insoluble or biopersistant and intentionally manufactured material with one or more external dimensions, or an internal structure, on the scale from 1 to 100 nm".**

Please see the guidance linked here for more information on nanomaterials in cosmetic products[1].

If your product does not meet the definition above, it is **NOT classified as** a nanomaterial under UK cosmetic regulations, therefore you do not need to continue with your submission.

Checklist:

It is recommended that the following checklist be followed, as appropriate, when submitting information on a nanomaterial.

All information and data provided on the nanomaterial **MUST** be submitted in English. If you cannot provide/submit specific data, please state why in the tables below.

1. International Union of Pure and Applied Chemistry (IUPAC) name and other descriptors e.g. CAS number, EC Number etc.
2. The quantity expected to be placed on the market each year (please include the units).
3. The specification, including the size of particles, physical and chemical properties:

Nanomaterial Specification	**Additional Notes**	**Provided**	**Notes on Submission (for RP)**	**Notes on Submission (for Responsible Authority ONLY)**
Chemical Identity				
Chemical Composition				
Particle Size	For any spray products, size distribution of the droplets after spraying as well as of the dried residual particles should be provided			
Morphology				
Surface Characteristics				
Solubility				
Surface Area				
Catalytic Activity				
Concentration	For dry powder products only			
Dustiness				

[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.

Density and pour density	For granular materials only			
Redox Potential				
pH	For aqueous solutions			
Viscosity	For liquid dispersions			
Stability				
UV Absorption				
Other				

For details on these parameters see Table 2 in the guidance document here.

4. The toxicological data*:

Nanomaterial Information Required	**Additional Notes**	**Provided**	**Notes on Submission (for RP)**	**Notes on Submission (for Responsible Authority ONLY)**
Likelihood and extent of internal exposure via skin, lung or oral route considering the use type				
Dermal Absorption	For dermally applied products			
Biokinetic behaviour, aggregation/agglomeration considered during tests?				
Acute Toxicity				
Irritation and Corrosivity				
Skin Sensitisation				
Mutagenicity/ Genotoxicity**				
Repeated Dose Toxicity				
Phototoxicity	For products intended for use in sunlight-exposed skin			
Reproductive Toxicity				
Carcinogenicity				
Human Data				
Other relevant Information				

*Guidance on addressing each of these pharmacokinetic and toxicology endpoints can be found here.

**The Ames test is not considered appropriate for nanomaterial mutagenicity assessment. The following guidance, found here , proposes a scheme based on *in vitro* assays.

5. The information on exposure:

Nanomaterial Exposure Information Required	**Provided**	**Notes on Submission (for RP)**	**Notes on Submission (for Responsible Authority ONLY)**
Category of cosmetic products in which the ingredients is intended for use			
Concentration of the ingredients 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.			

In the absence of information, default values for some of the parameters may be used (details can be found here).