Supplier Questionnaire for Cosmetic Ingredients

SCHÖNHEITSPFLEGE"

KOMPETENZPARTNER IM IKW

IKW 2019

IKW"

Explanations

IKW developed this comprehensive supplier questionnaire for cosmetics manufacturers in consultation with member companies.

The questionnaire is intended to assist cosmetics manufacturers to obtain the required information from their raw material suppliers to ensure the quality of the final cosmetic product and to fulfil the regulatory requirements. Furthermore the questionnaire may enable the cosmetics manufacturer and the supplier to identify areas of improvement.

This questionnaire is provided as a basis for discussion and should be handled in a flexible manner. Companies are free to adapt the questionnaire to company or ingredient specific requirements by deletions or additions. This tool can be especially helpful in cases where the suppliers' own documentation does not adequately cover the needs of the cosmetic manufacturer.

The suppliers questionnaire should be regularly reconfirmed (e. g. in two year intervals) to ensure the inclusion of new scientific findings, studies and legal requirements. Raw material suppliers should provide their customers automatically and without delay with information on new developments impacting the contents of the supplier questionnaire.

The questionnaire is formulated for raw materials containing one main component. For multicomponent systems the corresponding pages can be copied.

The questionnaire was generated from an EU perspective and is essentially based on the EU cosmetics legislation (EC 1223/2009) concerning human health aspects and the REACH Regulation (EC 1907/2006) with regard to environmental issues. Some international aspects are addressed in Annex II.

Please note:

The supplier questionnaire for cosmetic ingredients was prepared with the greatest possible care. Nonetheless the authors do not take over any liability for the accuracy of information, instructions, advice or possible printing errors. Claims can hence not be asserted against the authors based on any possible consequences. This does not apply if the damage has been caused intentionally or in a grossly negligent manner by the publisher or persons performing duties for the latter.

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1 Identity – General Information

Trade name	
Trivial name	
Manufacturer of raw material (address)	
Production site (city, country)	
Supplier (address), if not identical with manufacturer	
The product is manufactured by a contract manufacturer according to our company specification	◯ Yes ◯ No
Article number / commodity code	
Function(s) of the cosmetic ingredient	
Please specify	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Please enclose	
Declaration on conformity with EU cosmetics legislation (EC 1223/2009)	
Declaration on conformity with REACH Regulation (EC 1907/2006)	
Analysis certificate	
Raw material specification	
EU materials safety data sheet	

2 Manufacturing

Origin of starting materials	
Animal	◯ Yes ◯ No
Plant (for plant extracts see Annex I)	◯ Yes ◯ No
Microorganism	◯ Yes ◯ No
Petrochemical	◯ Yes ◯ No
Mineral	◯ Yes ◯ No
Other	◯ Yes ◯ No
	If YES, please specify
For animal, plant or microorganism derived materials	
Is the component in scope of the access and benefit-sharing obligations laid down in the Regulation (EU) No. 511/2014?	◯ Yes ◯ No
	If No, list reasons (such as species or activities exempted)
	If YES, is compliance with the Regulation (EU) No. 511/2014, Nagoya Protocol on Access and Benefit Sharing, ensured and documented? ◯ Yes ◯ No
Does the component fall within the scope of ABS (access and benefit sharing) requirements (laws and regulations) of the provider country?	◯ Yes ◯ No
	If No, list reasons (such as species or activities exempted)
	If YES, is compliance with the laws and regulations of the provider country on ABS ensured and documented? ◯ Yes ◯ No

Is the starting material derived from genetically modified organisms (GMOs)?	◯ Yes ◯ No
	If YES, is the supplied material free from detectable DNA of GMOs? ◯ Yes ◯ No
In case of animal origin	
Species	
Country of origin	
Body parts used	
Compliance with the Regulation (EC) No.1069/2009 (replaces former Regulation 1774/2002) on animal byproducts and Regulation (EC) 1223/2009 (Annex II/419)?	*Please attach BSE / TSE-Certificate*
In case of plant origin	
Are the plants from sustained cultivation of plantations?	◯ Yes ◯ No
Species	
Country of origin	
Plant parts used	
Is the starting material derived from a species which is listed in the "Convention of International Trade in Endangered Species of Wild Fauna and Flora"(WA / CITES)?	◯ Yes ◯ No
	If YES, please attach import permission from appropriate authorities
For powders, dispersions or aerosols containing solid particles	
Particle size distribution (range)	
Volume specific surface area	
Fraction of particles in an unbound state or as aggregates or agglomerates which have one or more external dimensions in the size range 1 nm - 100 nm	% number % mass
Is the component an intentionally manufactured nanomaterial?	◯ Yes ◯ No
Is the component a nanomaterial according to the EC Recommendation 2011/696/EU?	◯ Yes ◯ No
Is the component a nanomaterial according to Regulation (EC) No. 1223/2009?	◯ Yes ◯ No

For quartz containing products	
Does the particle size distribution reaches alveolar fraction < 10 µm?	◯ Yes ◯ No
Manufacturing process	
Starting materials	
Solvent(s)	
Catalyst(s)	
Description	
Purification process	
Additive(s)	
Description	

3 Additives

Please specify all additives in the final product (preservatives, antioxidants etc.)	
Additive 1	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Function	
Additive 2	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Function	

Additive 3	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Function	
Additive 4	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Function	

4 Impurities and Byproducts

Does the product contain any of the following substances?		
Metals in ppm		
Metal	Method/LOQ (Limit of Quantification)	ppm
Aluminium (Al)		
Antimony (Sb)		
Arsenic (As)		
Barium (Ba)		
Cadmium (Cd)		
Chromium (Cr)		
Cobalt (Co)		
Copper (Cu)		
Lead (Pb)		
Mercury (Hg)		
Nickel (Ni)		

Selenium (Se)		
Zinc (Zn)		
Other heavy metals *Please specify*		

Solvents in ppm	
Methanol	
Phenol	
Toluene	
Other solvents *Please specify*	
Monomers in ppm	
Acrylamide	
Acetaldehyde	
N-Vinyl-2-Pyrrolidone	
Styrene	
Other monomers *Please specify*	
Nitrogen compounds or nitrosating agents in ppm	
Alkyl amido amines	
Dimethylaminopropyl amine	
Nitrosamines (NDELA, NDMA etc) *Please specify*	
Nitrite	
N-Vinyl-2-Pyrrolidone	
Other Nitrogen compounds or nitrosating agents *Please specify*	
Others in ppm	
1,4-Dioxane	
Dioxines	
Ehylene oxide	
Glyoxal	
Mycotoxins	
Pesticides	
Phthalates	

Polycyclic aromatic hydrocarbons	
Propylene oxide	
Any CMR substances (according to classification in Regulation (EC) No. 1272/2008)	◯ Yes ◯ No
	Comments
Cyclosiloxanes (D4, D5, D6)	◯ Yes ◯ No
	If Yes, please specify
Any other toxicological relevant impurities (please see especially Annex II and Annex III of the Regulation EC 1223/2009)	◯ Yes ◯ No
	If Yes, please specify
Main food allergens, like peanuts etc.	◯ Yes ◯ No
	If Yes, please specify

Please list the concentration of the following 26 fragrance ingredients (according to EU Cosmetics Regulation, Annex III) - if contained - in ppm	
Alpha-Isomethyl ionone	
Amyl cinnamal	
Amylcinnamyl alcohol	
Anise alcohol	
Benzyl alcohol	
Benzyl benzoate	
Benzyl cinnamate	
Benzyl salicylate	
Butylphenyl methylpropional	
Cinnamal	
Cinnamyl alcohol	
Citral	
Citronellol	
Coumarin	
Eugenol	
Evernia prunastri extract	
Evernia furfuracea extract	
Farnesol	
Geraniol	
Hexyl cinnamal	
Hydroxyisohexyl 3-cyclohexene carboxaldehyde	
Hydroxycitronellal	
Isoeugenol	
Limonene	
Linalool	
Methyl 2-octynoate	
Comments	

5 Microbiological Status

Do you accept a hygiene audit?	◯ Yes ◯ No
Antimicrobial treatment	
Gamma irradiation	◯ Yes ◯ No
Beta irradiation	◯ Yes ◯ No
Moist heat	◯ Yes ◯ No
Dry heat	◯ Yes ◯ No
Ethylene oxide	◯ Yes ◯ No
Electron beam	◯ Yes ◯ No
Other antimicrobial treatment	◯ Yes ◯ No
	If Yes, please specify
Microbiological specification	
Total viable count of bacteria and fungi	(target < 10 cfu/g)
Test method used: DAB/EP (Deutsches Arzneimittelbuch/ European Pharmacopoeia)	◯ Yes ◯ No
Test method used: USP (United States Pharmacopoeia)	◯ Yes ◯ No
Test method used: ISO method	◯ Yes ◯ No
	If Yes, please specify
Other	◯ Yes ◯ No
	If Yes, please specify

If above target cannot be fulfilled	
Total viable count < 100 cfu/g	◯ Yes ◯ No
	Is it a natural ingredient? ◯ Yes ◯ No
	Comments
Please confirm the absence of pathogenic microorganisms	
Candida albicans	◯ Yes ◯ No
Escherichia coli	◯ Yes ◯ No
Pseudomonas aeruginosa	◯ Yes ◯ No
Staphylococcus aureus	◯ Yes ◯ No
Others	◯ Yes ◯ No
	If Yes, please specify
Comments	
Preservative challenge test of a freshly prepared and an aged production sample	
Test conducted	◯ Yes ◯ No
	If Yes, please specify test method
Comments	

6 Storage Recommendations

Recommended storage temperature		
Please describe temperature effects		
Storage under special conditions	◯ Yes ◯ No	
	If Yes, please specify	
Shelf life		
Recertification date	At temperature of	Time
Storage class		
Dust explosion class		
Comments		

7 Toxicology

Information on toxicology data (according to "The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and their Safety Evaluation 10 th Revision") is enclosed	
Acute Toxicity: oral	◯ Yes ◯ No
Acute Toxicity: dermal	◯ Yes ◯ No
Acute Toxicity: inhalation	◯ Yes ◯ No
Skin irritation	◯ Yes ◯ No
Mucous membrane (eye) irritation	◯ Yes ◯ No
Skin sensitisation potential	◯ Yes ◯ No
Chronic or subacute toxicity	◯ Yes ◯ No

Carcinogenicity	◯ Yes	◯ No
Reproductive toxicity (fertility and teratogenicity)	◯ Yes	◯ No
Genotoxicity	◯ Yes	◯ No
Dermal absorption / penetration	◯ Yes	◯ No
Photoirritation	◯ Yes	◯ No
Photosensitisation	◯ Yes	◯ No
Toxicokinetics (absorption, distribution, metabolism, elimination)	◯ Yes	◯ No
Any data on human experience (allergies, skin irritation, sensitisation)	◯ Yes	◯ No
	If Yes, please specify	
Other *in vitro* or *in vivo* studies	◯ Yes	◯ No
	If Yes, please specify	
Any other test or studies	◯ Yes	◯ No
	If Yes, please specify	

8 Ecotoxicology Data

Enclosed information on ecotoxicology data		
Biodegradability according to OECD 301 (A-F) / OECD 302 B	◯ Yes	◯ No
Data on bioaccumulation potential (e. g. octanol / water partition coefficient or BCF fish)	◯ Yes	◯ No
Data on water solubility	◯ Yes	◯ No
Data on aquatic toxicity: Algae	◯ Yes	◯ No
Data on aquatic toxicity: Daphnia	◯ Yes	◯ No

Data on aquatic toxicity: Bacteria	◯ Yes	◯ No
Data on aquatic chronic toxicity: Fish	◯ Yes	◯ No
Water hazard class (WGK, Germany)	◯ Yes	◯ No
	If Yes, please specify	
Additional information		

Animal Testing

The following questions relate to Art. 11.2 (e) of Regulation (EC) 1223/2009. Please only make entries if the testing was performed after 11 September 2004.

Have you carried out animal testing in the development of this cosmetic raw material in terms of Art. 11.2 (e) of Regulation (EC) 1223/2009?	◯ Yes	◯ No
	If Yes, please state	
	Date and type of test	
	The test was performed in which country?	
Year of last *in vivo* testing		
Purpose of the study		
REACH Regulation (EC) No 1907/2006	◯ Yes	◯ No
Non-EU chemical legislation	◯ Yes	◯ No
EU-Cosmetic legislation (76/768/EEC) / Regulation (EC) No 1223/2009	◯ Yes	◯ No
Non-EU cosmetic legislation	◯ Yes	◯ No
Other	◯ Yes	◯ No
	If Yes, please specify	
Comments		

10 Regulatory Information

Are any possible import / export restrictions applicable for EU?	◯ Yes ◯ No
Does the supplier confirm REACH-Compliance?	◯ Yes ◯ No
Are there any ingredients on the Candidate List of Substances of Very High Concern (SVHC) of the ECHA	◯ Yes ◯ No *If Yes, please specify*
Quality/Safety standards	
Is the raw material manufactured according to EFfCI-GMP Standard for Cosmetic Ingredients?	◯ Yes ◯ No
Does the raw material comply with IFS HPC Standard?	◯ Yes ◯ No
Does the raw material comply with Food Standards (ISO 22001, HACCP etc.)?	◯ Yes ◯ No *If Yes, please specify*
Other	◯ Yes ◯ No *If Yes, please specify*
Intellectual Property	
Is the raw material a patented product by the manufacturer?	◯ Yes ◯ No
Additional information (e.g. licence agreement)	

Annex I: Plant Extracts

Plant name	
Scientific name	
Plant part(s) used	
Risk of adulteration with other plants	
Place of cultivation (Country / Region)	
Method of harvesting / collection	
Period of harvesting	
Stage of harvesting	
Pre-treatment of plant material	
Purification process Description	
Extraction method Description	
Solvent(s) (type and amount)	
Is the plant extract screened for pesticides?	◯ Yes ◯ No
Does the raw material contain any denatured alcohol?	◯ Yes ◯ No
	If Yes, please specify the denaturants
Physico-chemical parameters	
Description of control and quality assurance measures applied to the starting plant material, process and final product	
Absence of toxicologically relevant natural secondary components (pyrrolizidine alkaloids etc)	◯ Yes ◯ No
Comments	

Description of the extract: Main components, active ingredients	
Component A	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Biological / toxicological profile of action for active ingredients	
Desired effect	
Mechanism of action	
Evidence of action	
Profile of side effects	
Component B	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Biological / toxicological profile of action for active ingredients	
Desired effect	
Mechanism of action	
Evidence of action	
Profile of side effects	
Component C	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Biological / toxicological profile of action for active ingredients	
Desired effect	
Mechanism of action	
Evidence of action	
Profile of side effects	
Component D	
Chemical name (IUPAC)	
INCI name (EU)	
INCI name (US)	
CAS No.	
EINECS/ELINCS No.	
Concentration (-range) [% w/w]	
Molecular weight (for polymers approx.)	
Biological / toxicological profile of action for active ingredients	

Desired effect	
Mechanism of action	
Evidence of action	
Profile of side effects	

Annex II International / Non-EU Aspects

Are any of the ingredients or impurities listed by California Proposition 65?	◯ Yes	◯ No
Are any of the ingredients declarable by California`s Senate Bill 484?	◯ Yes	◯ No
Does the raw material contain ingredients, which are classified as Volatile Organic Compounds (VOC) according to the US-American VOC-Regulations?	◯ Yes	◯ No
Registration / Notification according to chemical legislation		
US	◯ Yes	◯ No
Canada	◯ Yes	◯ No
China	◯ Yes	◯ No
Japan	◯ Yes	◯ No
Korea	◯ Yes	◯ No
Australia	◯ Yes	◯ No
Taiwan	◯ Yes	◯ No
Other	◯ Yes	◯ No
	If Yes, please specify	
Taxation		
Does the raw material contain a Volatile Organic Compound (VOC) which is an object of taxation according to the Swiss "Ordinance on the Incentive Tax on Volatile Organic Compounds" (VOCV, AS 2008 1765)?	◯ Yes	◯ No

Annex III Specific Requirements

Kosher	◯ Yes	◯ No
Halal	◯ Yes	◯ No
Vegan	◯ Yes	◯ No
Comments		