COSMOS-standard

Technical Guide

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COSMOS-standard AISBL

Rue du Commerce 124 1000 Brussels Belgium

E: <u>info@cosmos-standard.org</u> W: www.cosmos-standard.org

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1. Introduction

This information is intended to give guidance on interpreting technical points and criteria of the COSMOS-standard.

2. Definitions

"Soap": is considered as the product (liquid or solid) obtained through a saponification reaction.

3. General

Article 5.1.1 Nanomaterials

Particles with coating (eg: TiO_2 with coating) are allowed when the minimum particle size is above 100 nm. Otherwise, all nanomaterials, whether required to be labelled or not according to European cosmetic regulations, are not allowed.

Pending further technical information, TiO_2 and ZnO are not allowed as UV filter in any certified products or approved ingredients. This decision will be reconsidered when additional data is available.

4. Origin and processing of ingredients

Article 6.1.3 Ingredients of animal origin

Milk, honey, beeswax, etc. are ingredients of animal origin allowed (as long as processes comply with appendices I and II and criteria of the standard).

Other ingredients of animal origin may be approved after submission of additional documents (i.e. snail slime, etc.).

Article 6.1.4 Chemically processed agro-ingredients

Atom economy - Reaction mass efficiency

If several products are obtained (i.e. the oil is saponified into glycerol and fatty acid) and all products are valorized at the end of the manufacturing process, the weight of each of the products must be considered for the calculation, even if only one item is submitted as the raw material.

Biodegradability and Aqua toxicity

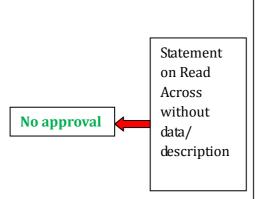
This data is not required for:

- 1) Naturally occurring molecules obtained by fermentation (e.g. hyaluronic acid)
- 2) Molecules resulting from a cleavage of a molecule existing in nature (e.g. maltodextrin obtained by hydrolysis of starch) allowed cleavage reactions are enzymatic hydrolysis, hydrolysis with mineral acids or bases
- 3) Polymers, only obtained by esterification of monomers, which are readily biodegradable and non-toxic to aquatic systems
- 4) Hydrogenated oils and butters
- 5) Perfumes.

For other ingredients, if no test is done, there is the possibility to submit written (bibliographic) data or to apply alternative methods such as <u>Read Across approach</u>.

- Follow this link for available data of compounds registered for REACH: http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances

What to do if no data are available:



Read Across data available on biodegradability and aquatic toxicity, Applicant provides validated experimental data for:

- an analogue to the compound
- a defined chemical category in the REACH register, which the compound fits in

Approval

 a defined chemical category in the REACH register, which allows for read across to the category the compound belongs to.

Applicant explains why the respective analogues or chemical categories have been chosen.

The certification body accepts Read Across data, if the explanation is conclusive and the target molecule is in close structural analogy with the presented analogues/categories.

Structural analogy of molecules can be determined based on:

- The functional groups present in a molecule
- The chemical class the molecule belongs to
- The carbon skeleton of the molecule the most reactive functional group in the molecule determines the chemical class membership.

With the same functional groups present, properties do not differ too much with slight changes in the carbon skeleton (4 to 8 carbons).

For Read Across data, only really close analogues based on the above basic criteria will be accepted.

Example:

Myristyl Myristate: REACH category: Fatty acids, C10-18 and C12-22-unsaturated, C14-18 and C16-18-unsaturated alkyl esters.

Case of stem cells

Stem cells, used as active ingredients only, are allowed as long as the culture media is as well compliant with the standard. The following must be from natural or microbiological origin (and not be synthetic): substrates, culture mediums. The use of inputs (eg. hormones, growth factors or similar components) at low levels (ppm scale) is permitted in stem cell culture mediums. These

inputs have to be metabolized/removed and not detectable in the final product. Aspecific statement from the supplier has to be provided.

Appendix I and II

Allowed decolorizing agents: bentonite, activated charcoal, bleaching earth, hydrogen peroxide, ozone.

Neutralization processes are allowed to obtain Na, Ca, Mg, K salts.

Ammonia is allowed in neutralization process to form Ammonium Lauryl Sulphate and Ammonium Glycyrrhizate.

Fermentation processes: ammonia/ammonium salts and other N sources are allowed.

At any step of the manufacturing process:

- Aqueous solutions of mineral acids (hydrochloric acid, sulphuric acid, phosphoric acid, etc.)
 are allowed as manufacturing auxiliaries for neutralization, purification and extraction.
 They are not allowed as reactants (raw material or ingredient);
- Manufacturing auxiliaries are therefore not listed in the INCI list of the ingredient or cosmetic finished product;
- There are exemptions for sulphuric acid which is allowed for sulphation/sulphatation reactions, and for phosphoric agents which are allowed to produce phosphorylated ingredients, for leave on products only.

5. Calculation rules and examples

Article 6.2.3 Physically processed agro-ingredients

Aqueous extract



Standard:

Ratio = [organic fresh plant / (final extract - solvents)] If the ratio is greater than 1, then it is counted as 1.

% organic = $\{[\text{ratio } x \text{ (extract - solvents) / extract]} + [\text{organic solvents / extract]}\} x 100.$

 Organic alcohol in organic extract

*No mixture of organic and non organic quality of the same plant

Example:

Ratio: 80 / (100 - 60); Ratio > 1, counted as 1

% Organic = $\{[1 \times (100 - 60) / 100] + [40 / 100]\} \times 100 = 80\%$

Non aqueous extract



Standard:

% organic = (organic fresh plant + organic starting solvents) / (fresh plant + all starting solvents) x 100

 Organic alcohol in organic extract

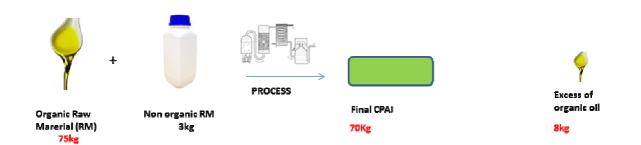
•No mixture of organic and non organic quality of the same plant

Example:

% Organic = $(80 + 40) / (80 + 60) \times 100 = 85.7\%$

Article 6.2.4 Chemically processed agro-ingredients

General case



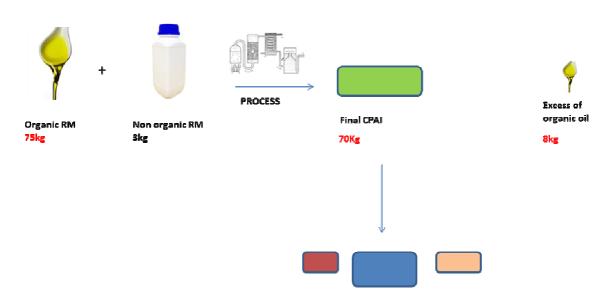
Standard:

% organic = [(all organic starting primary raw materials - organic starting primary raw materials in excess) / (all starting primary raw materials - all starting primary raw materials in excess)] x 100

Example:

% Organic = $[(75 - 8) / (75 + 3 - 8)] \times 100 = 95.7\%$

Specific case

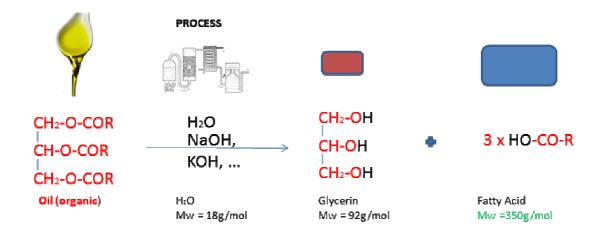


If the final CPAI obtained contains several different molecules, the organic % of each molecule can be different.

The main CPAI calculation can be used if the final product is a single ingredient, OR if the resulting mixture is not separated.

If the result produces more than one material, specific calculations are made based on the molecules obtained (considering the molecular organization, see below).

Saponification example



Example:

Article 7.1 Rules for cosmetics products under organic certification

Due to the composition of soaps and alcohol spritzer products (high majority of CPAI), where it is not possible to meet the >95% organic PPAI requirement, this criteria is not compulsory for these products if it can be proved that as much organic CPAI as possible has have been used (the criteria about the total organic content remains unchanged).

7.1.1 Ingredients

- At least 95% of the physically processed agro-ingredients must be organic
- For organic soaps (bars and liquid) and organic alcohol spritzer products, 95% of the certifiable ingredients must be organic
- The remaining physically processed agro-ingredients must be organic if they are listed in Appendix VI

6. Article 8 Packaging

Primary and secondary packaging must meet the criteria, and any fabric components. Accessories sold with products, such as brushes or applicators do not have to comply.

7. Article 9.2 Cleaning & hygiene

Plant-based cleaning products certified by one of the following organic certification bodies may be used: Ecocert, Ecogarantie, ICEA, Nature & Progres, Soil Association, United States National Organic Program (NOP), or Australian Organic Standards (AOS).

Products endorsed by labels including Nordic Swan or Ecolabel may be used if the natural origin of their ingredients can be checked.

Other standards for cleaning products can be submitted to the Technical Committee for assessment.

8. GMOs

Article 5.1.2

The COSMOS-standard does not allow the use of GMO plants to obtain cosmetic raw materials and ingredients. Therefore the manufacturer must indicate in the Raw Material questionnaire the name of the plant and the country of origin of the vegetable source which was used to produce that particular cosmetic raw material or ingredient.

Certification bodies will assess the GMO risk according to a common Geographical Risk Matrix developed by the Soil Association. If necessary, they may require additional information from the manufacturer.

Article 6.1.4

The culture medium must be in conformity with the COSMOS-standard. Therefore, each ingredient in the medium must be from mineral, vegetable, microbial, animal or marine origin (meeting the criteria of the Standard) and, where appropriate, must be guaranteed non-GMO origin.

Biotechnological processes are allowed as far as no genetically modified bacteria, fungi, yeast, etc. are used.

If enzymes derived from GMOs are used to produce the cosmetic ingredient, the manufacturer must prove they comply with the following conditions:

- Enzymes from GMO are purified before use
- The GMO must be used in closed vessel
- The GMO are deactivated after the process
- Risk assessment on GMO impact on environment is implemented
- Risk plan is established, if GMO is released in the environment
- PCR (-) or any other method must be provided to prove that no DNA of the GMO is present in the final raw material.

9. Raw material questionnaire

For all non-organic raw materials, each certification body will use a questionnaire based on common questions defined by the COSMOS-standard AISBL for raw material approval. The common questions are to be found on the www.cosmos-standard.org website but are there for reference only – the questionnaire used must be that supplied by the certification body concerned. Please note that not all certification bodies are accredited for the scope of approving non-organic raw materials.

Once an ingredient has been approved and published on the COSMOS database, all the other certification bodies will accept it.

10. Non organic raw materials available on the database

Compliant non-organic raw materials are available on www.cosmos-standard-rm.org.

Raw materials identified with an asterisk* relate to appendix II or appendix V article 2 (petrochemical solvents and/or halogenation processes in activating steps). The same INCI can be with or without this identification depending on the manufacturing process.

On periodical review of the raw material database these raw materials may be removed, when raw materials which do not use these processes become available in sufficient amounts.

Appendix V.3

Calculation of synthetic moieties

Example of a reference of cocoamidopropylbetaine at 30% in water:

Molar weight of the whole molecule = 342 g/mol Molar weight of the petrochemical part = 159 g/mol

- 1. % of petrochemical moiety of the molecule = $159/342 \times 100 = 46.4\%$
- 2. % of petrochemical moiety of the reference = $0.3 \times 0.464 \times 100 = 13.9\%$
 - → The reference would be considered 16.1% CPAI and 13.9% synthetic moiety.

Appendix III

All caustic sodas (INCI: Sodium Hydroxide) are allowed until 31/12/2016. The decision will be reviewed at this time depending on any technical developments.

11. Appendix II

For the chemical processing of organic agro-ingredients:

- -there must be no use of petrochemical solvent and/or petrochemical auxiliary (including catalyst, anti-foaming, etc)
- -halogenation process is not allowed (even as activating step).

12. Appendix V

Appendix V.1

Possibility to allow other denaturing agents for alcohol when required by law and no natural alternative.

13. Appendixes VI and VII

Clarification of ingredients that must be ORGANIC for COSMOS ORGANIC certification (which belong to the lists).

- No Mixture (one component)
 - Ingredients must be used in organic quality according to appendix VI (example: Sunflower oil or Wax)
 - This also applies to single ingredients which are stabilized with additives or contain preservatives (example: Sunflower oil, stabilized with Tocopherol)
- Non-complex/simple mixture (two components)
 - Ingredients must be used in organic quality according to appendix VI (example: Herbal extract/macerate with Sunflower oil)
 - o if one of the ingredients is added as a solvent to other active ingredients, to make them available, the ingredient does not need to be used in organic quality (example: Tocopherol dissolved in Sunflower oil)
- Complex mixture (three and more components)
 - Exemption from appendix VI/VII (except when all ingredients of the mixture are listed in appendixes VI/VII)