

# **COSMOS-standard**

## **Technical Guide**

**Version 2.10**  
**25/11/2016**

**COSMOS-standard AISBL**

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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**

*Cf COSMOS Standard – 4. Definitions*

### **“Soap”**

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

### **“Organic” precision**

- Considered as complying with Regulation No. (EC) 834/2007 are those countries/standards/certifiers that have been accepted as compliant or equivalent through the mechanisms set out in that regulation.
- Considered as using as their reference point the Codex Alimentarius GL 32 are those national standards (ie recognised by or within national legislation) where Codex Alimentarius GL 32 is clearly referenced within the standard.

In all cases, the certification to such standards must be carried out by a certification body or authority that is duly authorised and/or independently accredited for the standard in question. In addition, the standard and/or respective product must not be in conflict with the relevant provisions of the COSMOS-standard.

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Examples:

- National Program for Organic Production (NPOP)
- National Organic Program (NOP)
- Canada Organic Regime (COR)
- Australian National Food standards
- Brazilian Organic Regulation
- Japanese Agricultural Standard (JAS)

### **3. General**

*Cf COSMOS Standard – 5. General*

#### **Article 5.1.1 Nanomaterials**

Particles with a coating (eg. TiO<sub>2</sub> 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.

TiO<sub>2</sub> and ZnO used as UV filters are acceptable if the following conditions are met:

- As per chapter 2 of the standard, the raw material must fulfil the requirements of the Cosmetic Regulation (EC) 1223/2009 (namely the regulations (EU) 2016/11431 and (EU) 2016/6212 amending Annex VI of Regulation (EC) 1223/2009 for TiO<sub>2</sub> and ZnO respectively)
- The particle size distribution (number of particles) under 100 nm must be less than 50%
- The mass distribution (weight of particle fraction) under 100 nm must be less than 10%.

<sup>1</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R1143>

<sup>2</sup> <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32016R0621>

#### **Article 5.1.2 GMOs**

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.

The Regulation that COSMOS is referring to when discussing Genetic Modification, is Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. Article 2 gives definitions of GMO. Annex 1A summarizes what techniques are included as genetic modification.

#### **Article 5.2 Animal testing**

Animal tests are allowed only if mandatorily requested by law for ingredients.

## **4. Origin and processing of ingredients**

*Cf COSMOS Standard – 6.1 Ingredients categories*

### **Article 6.1.3 Ingredients of animal origin**

Milk, honey, beeswax, etc. are ingredients of animal origin that are allowed (as long as the 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.

Bee venom is prohibited.

Snail slime is prohibited when produced using salt and electricity, but is permitted otherwise if the details are checked by the 'Independent Expert of Snails'.

Mother of pearl can be accepted if it is collected from naturally dead shells. Wild harvest is compulsory.

### **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 used 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 Aquatic 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 and 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
- 6) Salts of naturally occurring molecules (obtained by solvent/physical extraction and salification to obtain associated salt). However, data for zinc salts has to be provided
- 7) Poorly soluble esters (polyesters included) resulting from esterification between acid and alcohol that meet the COSMOS ecological criteria.

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

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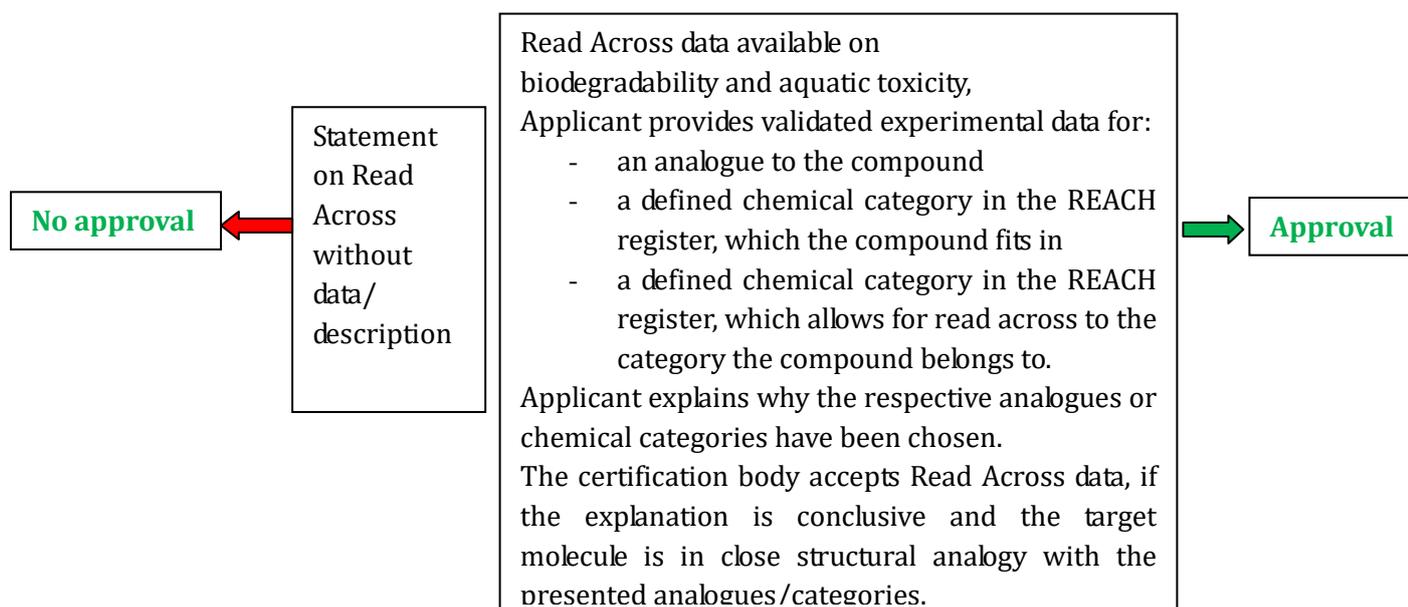
- Follow this link for available data of compounds registered for REACH:  
<http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

### **What to do if no data is available:**

Performing new animal tests to evaluate the ecological profile of a COSMOS ingredient is prohibited.

If the required ecological data (biodegradation and aquatic toxicity) is not available in the literature (ECHA database or other publication sources), the following alternative methods can be used:

#### **-Analogy approach - read across:**



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.

#### **-QSAR (Quantitative Structure-Activity Relationship)-**

Data coming from QSAR computational approach can be accepted under the following conditions:

- the results provided are derived from a validated model ([link](#) to Reach guidance)

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- the chemical falls under the applicability domain of the validated model

Both alternative methods have to be well documented to be accepted.

### **Stem cells**

Stem cells, used as active ingredients only, are allowed as long as the culture media is also 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. A specific statement from the supplier has to be provided.

### **Ingredients from biotechnology**

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.

Defoamers and other auxiliaries can be used in biotechnology (as long as there are removed in final raw material).

## **5. Calculation rules and examples**

*Cf COSMOS Standard – 6.2 Calculation rules for organic percentages*

### **Article 6.2.3 Physically processed agro-ingredients**

#### **Dry to fresh plant ratios to be used:**

Watery fruit: 1:8 (eg. pineapple, orange)

Other fruits: 1:5 (eg. apricot, grape)

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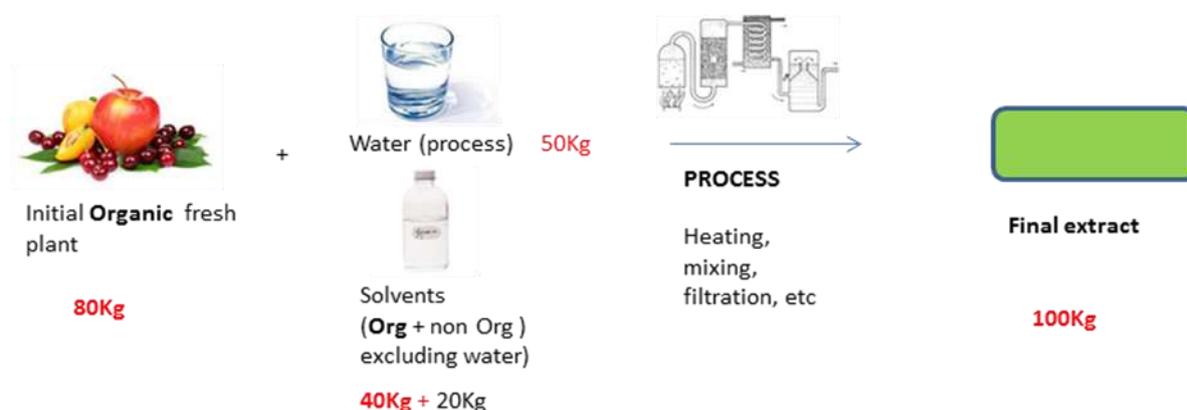
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### Alcohol in extracts:

Organic alcohol (even if completely removed) has to be used in organic extracts. If conventional alcohol is used during the process, the ingredient cannot have an organic contribution.

Alcohol and extracts have to respect Appendix VI and VII for COSMOS ORGANIC certification.

### Aqueous extract



#### Standard:

Ratio = [organic fresh plant / (final extract - solvents)]

If the ratio is greater than 1, then it is counted as 1.

% organic = {[ratio x (extract - solvents) / extract] + [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 x (100 - 60) / 100] + [40 / 100]} x 100 = 80%

### Non aqueous extract

For non-water based extracts, the organic percentage is calculated as follows:

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

\*fresh or dried plant



#### Standard:

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

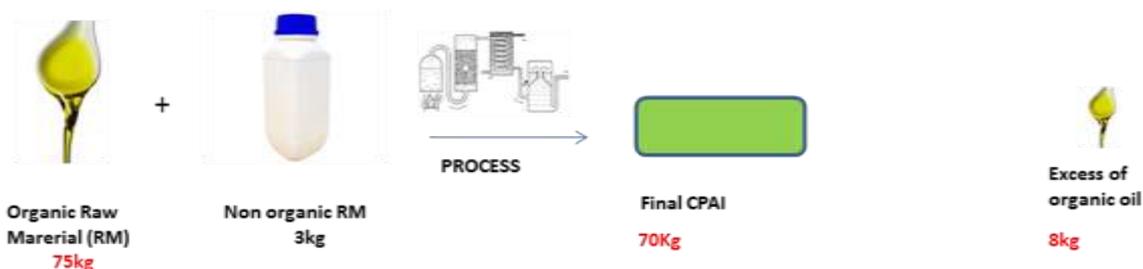
•Organic alcohol in organic extract  
•No mixture of organic and non organic quality of the same plant

Example:

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

## Article 6.2.4 Chemically processed agro-ingredients

### General case



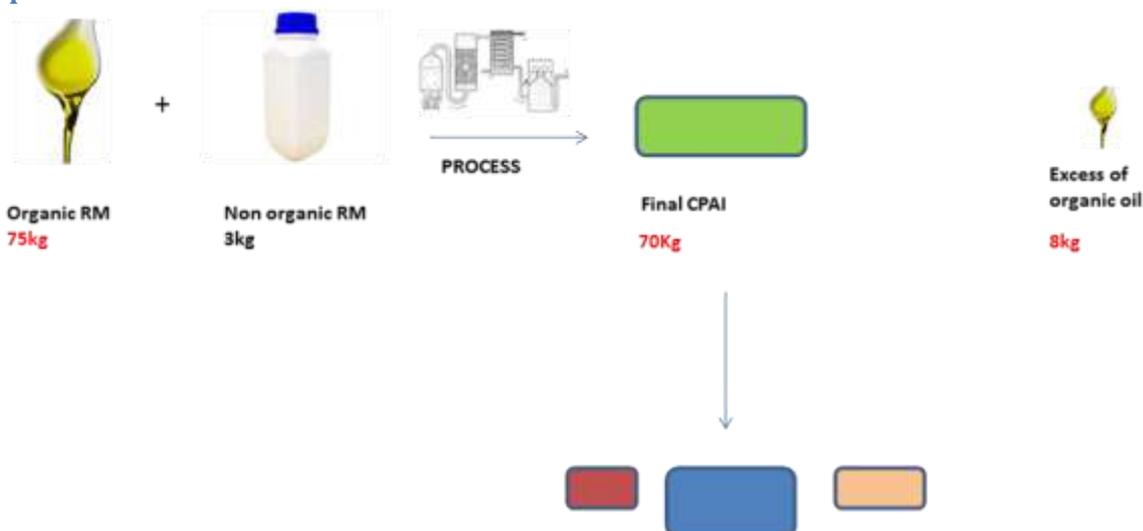
Standard:

$$\% \text{ organic} = [( \text{all organic starting primary raw materials} - \text{organic starting primary raw materials in excess} ) / ( \text{all starting primary raw materials} - \text{all starting primary raw materials in excess} )] \times 100$$

Example:

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

### Specific case



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

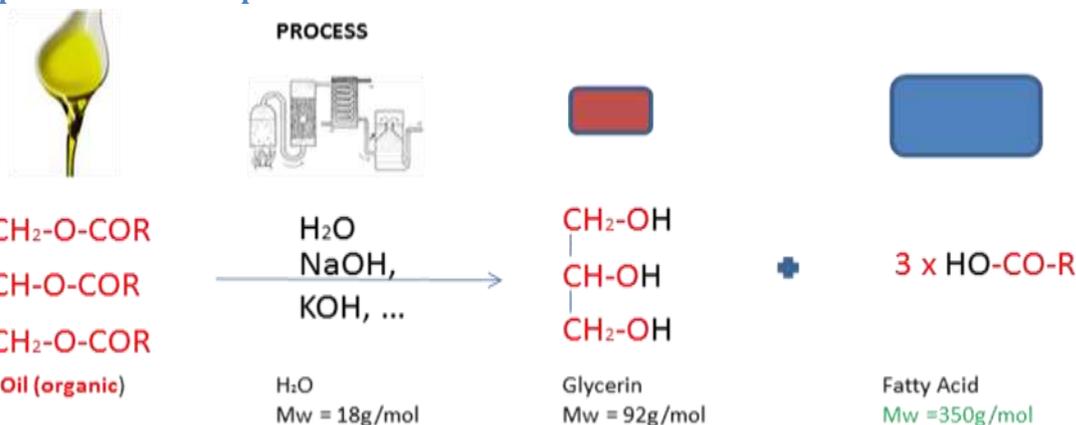
The main CPAI calculation can be used if the final product is a single ingredient, OR if the resulting mixture is not separated.

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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:

$$\begin{aligned} \% \text{ organic Glycerin} &= \text{Organic part} / \text{total} = (\text{Mw Glycerin} - \text{Mw 3 hydrogen}) / \text{Mw Glycerin} \\ &= (92 - 3) / 92 \\ &= \mathbf{96.7\%} \end{aligned}$$

$$\begin{aligned} \% \text{ organic Fatty Acid (FA)} &= \text{Organic part} / \text{total} = (\text{Mw FA} - \text{Mw OH}) / \text{Mw FA} \\ &= (350 - 17) / 350 \\ &= \mathbf{95.1\%} \end{aligned}$$

## 6. Composition of total product

*Cf COSMOS Standard – 7. Composition of total product*

### Article 7.1 Rules for cosmetic products under organic certification

Due to the composition of soaps, alcohol spritzers and perfumes (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 is 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), organic alcohol spritzer products and perfumes, 95% of the certifiable ingredients must be organic.
- The remaining physically processed agro-ingredients must be organic if they are listed in Appendix VI.

## **Article 7.2 Rules for cosmetic products under natural certification**

Complex bulk ingredients (eg. shampoo bases, soap bases) without organic content cannot go through the standard approval service for COSMOS. It can be certified under COSMOS Certified for COSMOS NATURAL applications only. In such cases, an inspection on site is required.

## **7. Environmental management**

*Cf COSMOS Standard – 9. Environmental management*

### **Article 9.2 Cleaning and Hygiene**

Plant based cleaning products certified by one of the following organic certification bodies may be used: Ecocert, Ecogarantie, ICEA, Nature & Progress, 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. Changes after 2016**

*Cf COSMOS Standard – 12. Implementation of this Standard*

### Precision of 12.2 (founders)

Products certified under private standard and application for certification received before 31/12/2016 can remain under that standard after this date.

Certification of a new product made after 01/01/2017 has to be according to COSMOS Standard.

### Precision of 12.3 (other certification bodies)

Other certification bodies need to certify products according to COSMOS-Standard and/or according to existing own standard which has to be fully in accordance with the COSMOS-Standard. If necessary they have to ask for a transitional period to the AISBL.

## **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](http://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.

## 10. Non organic raw materials available on the database

Compliant non-organic raw materials are available on [www.cosmos-standard-rm.org](http://www.cosmos-standard-rm.org). Ingredients published on the COSMOS database are recognized and accepted by all certification bodies.

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.

Re assessment of non-organic raw materials need to be made at least every 3 years (or as soon as any change) in order to confirm any change on process and origins of accepted raw materials. It can be done through a declaration.

## 11. Appendixes

### Appendix I and II

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

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

Ammonia is allowed in the neutralization process to form Ammonium Lauryl Sulphate and Ammonium Glycyrrhizate (and any other ammonium salt – as long as the other criteria including biodegradability and ecotoxicity are fulfilled).

**Fermentation processes:** ammonia/ammonium salts and other nitrogen 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.

### Appendix III

All caustic sodas and potashes (INCI: Sodium Hydroxide, Potassium Hydroxide) are allowed. The decision will be reviewed depending on any technical developments.

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### **Ingredients changing of status**

For several reasons (change in process, error, etc), ingredients may change status (become non-compliant or remain compliant but with different percentages that may affect the final ingredients/products percentages). These cases are studied by the technical committee who may decide to allow a transition period depending on the context, impacts and potential alternative. Non-compliant ingredients will be removed from the database and cannot be used in any new formula.

## **Appendix IV**

Phosphate ingredients of mineral origin, other than those listed in Appendix IV, are permitted for anticaking properties.

Magnesium phosphate can be accepted as ingredient of mineral origin with the restriction of being used in association with Zinc Oxide.

Potassium thiocyanate can be accepted as ingredient of mineral origin with the restriction of additive for preservative/anti-oxidant systems, maximum concentration 1%.

Potassium Alum can be accepted as ingredient from mineral origin.

## **Appendix V**

### **Appendix V.1**

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

### **Appendix V.2**

Tocopherol includes tocotrienol.

Addition to V.2:

Phytosterol

### **Appendix V.3**

Cocoamidopropyl Betaine includes Coco Betaine.

Additions to V.3:

<b>Ingredient</b>	<b>Restrictions</b>
Olive Amidopropyl Betaine	
Alkyl Methyl Glucamide	
Cocodimonium Hydroxypropyl Hydrolyzed Wheat Protein	Hair products only

### **Appendix V.4**

<b>Ingredient</b>	<b>Restrictions</b>
Caramel	Compliant reactants and process

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### **Calculation of synthetic moieties**

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

Molecular weight of the whole molecule = 342 g/mol

Molecular 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.**

### **Appendices VI and VII**

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

- No mixture (one component):
  - o Ingredients must be used in organic quality according to Appendix VI (example: Sunflower oil or Wax)
  - o 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) – Hydrolates with two plants would enter in the category:
  - o 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):
  - o Exemption from Appendix VI/VII (except when all certifiable ingredients of the mixture are listed in Appendixes VI/VII).

In the case of a shortage of an organic raw material listed in appendix VI or VII:

The client needs to inform the certification body that none is available, why and, if known, provide details of how long (e.g. poor harvest for certain year). The certification body needs to check their records and with the other partners that none is available. The client/company then needs to provide three written confirmations from reputable organic suppliers that the material is not available organically. Labels and promotional materials have to be changed temporarily so that it is clear at point of sale that the material's organic status has changed (for example by over-stickering of product labels, or a clear indication on the client's website for the product etc.). These indications must be verified by the certification body. Provided all of the above has been followed permission can be granted for a certain period.