EU Cosmetic Ingredients Glossary - Commission Decision (EU) 2019/701 of 5 April 2019 establishing a glossary of common ingredient names for use in the labelling of cosmetic products¹

Frequently Asked Questions

- 1. What are the purpose and scope of the Glossary ?
 - The only purpose of the Glossary is to provide companies and control authorities with the reference list for ingredient names that must be used for labelling purposes in the cosmetic product ingredient list. In compiling and updating the Glossary the Commission takes account of internationally recognised nomenclatures including the International Nomenclature of Cosmetic Ingredients (INCI). The Glossary replaces the Inventory of Cosmetic Ingredients (Commission Decision

96/335/EC and Commission Decision2006/257/EC) which has been the reference list for ingredient labelling since 1996, updated in 2006 but by now severely outdated. Part of the information in the Inventory was also taken over into the ingredient information database COSING (see question 5)

- The Glossary is not a list of authorized or safe cosmetic ingredients and does not provide information on the regulatory status or function of ingredients. Presence of the substance name in the Glossary does not necessarily mean that substance may be legally used in cosmetic products. Depending on the updating frequency, it may occur that substances are listed in the Glossary that are no longer allowed for use in cosmetics. The EU Cosmetics Regulation 1223/2009² (Annex II to VI) is the only legally binding reference with regard to the regulatory status of ingredients (approval, ban, limitations, use conditions, etc.).
- In order to ease the publication of further updates, the Glossary does not contain any information (i.e. ingredient functions, chemical names) that would require translation in the official languages of Members States.

(cf. Cosmetics Regulation Article 19 - Labelling, Article 33 – Glossary of Common Ingredient names and Commission Decision (EU) 2019/701).

2. What is the interlink between INCI Dictionary and Handbook, EU Cosmetics Regulation, EU Glossary and CosIng ?

INCI is an International Nomenclature of Cosmetics Ingredients. INCI names are assigned by the International Nomenclature Committee and published in the INCI Dictionary and Handbook. These names are internationally recognized and provide the primary source of ingredients names for labelling requirements, in the EU Cosmetics Regulation, the European Glossary and well as the (non-binding) EU information database CosIng. EU labelling names of ingredients are therefore based on INCI names and are (in general) consistent with them. In case of discrepancies between INCI and the EU Cosmetics Regulation / Glossary, the EU names are legally binding.

- 3. What is the legal status of the Glossary ?
 - The Glossary is legally binding. If a Glossary name exists for an ingredient, this name must be used in the ingredient list. (cf. Cosmetics Regulation, Article 19 Labelling)

- 4. What is the difference between the Glossary and the European Commission's ingredient database COSING⁴ ?
 - COSING is a free online consultation tool maintained by the EU Commission describing cosmetic ingredients but has no legal value. It is developed from the information generated by the *International Cosmetic Ingredient Dictionary and Handbook* and contains the substance identification(CAS#, EC#, Chemical name, INCI name) as well as typical function(s), the regulatory status under the EU Cosmetics Regulation and, if pertinent, reference to the scientific opinions of the EU Scientific Committee for Consumer Safety (SCCS). The INCI name of a substance in COSING usually corresponds to its Glossary name.
 - Although COSING can be considered as a very useful information tool, it should be reminded that COSING is not a legally binding reference. In general the Glossary list (which is legally binding) is based on information available in CosIng (and originally in INCI list) and it is therefore consistent, however, sparse discrepancies may occur. In case of discrepancies between COSING and the Glossary, it is the latter which shall be considered, keeping in mind that, in case of inconsistencies between the Glossary and the EU Cosmetic Regulation, the INCI names listed in the Cosmetic Regulation annexes are the final regulatory reference (cf. <u>http://ec.europa.eu/growth/tools-databases/cosing/</u>)
- 5. When will the Glossary become applicable ? What happens to products on the shelve that are still labelled according to the 1996 Inventory ?
 - The Glossary applies to products placed on the market as of 19 April 2020. Products placed on the market before that date can be made available with an indefinite selling out period.
 - Given that the Glossary names are mostly in line with common industry practice (*International Cosmetic Ingredient Dictionary and Handbook*³ and where applicable EU INCI), the practical impact on products on the market should be minor. (*cf. Cosmetics Regulation Article 19 -Labelling , Article 33 Glossary of Common Ingredient names*)
- 6. I have already printed my labels for a product which I will place on the market after 19 April 2020. Some ingredient names are not in line with the Glossary names. Do I need to reprint ?
 - In principle yes. Product placed on the market after 19 April 2020 need to comply with the Glossary nomenclature. However, corrective actions imposed by the authorities will depend, in a case-by-case approach, on the type of ingredient concerned, its safety profile, the level of difference between the labelled name and the Glossary name (e.g. whether it is in line with the international Cosmetic Ingredient Dictionary) and the actions already taken by the company to bring the product into compliance in the future. The Cosmetics Regulation stipulates that corrective actions imposed by the authorities have to be commensurate with the nature of risk created by the non-compliance.
 (cf. Cosmetics Regulation Article 19 Labelling, Article 33 Glossary of Common Ingredient names, Article 25 Non-compliance by the responsible person, Article 37 Penalties)

- 7. My ingredient corresponds to more than one Glossary names. Which one should I chose ?
 - If an ingredient justifiably fits more than one Glossary name, you are in principle free to choose.
 - However, there are some restrictions to this principle:
 - Although the Glossary lists two names for perfuming and flavouring mixtures ("fragrance" / "parfum" and "aroma"/"flavor"), the Cosmetics Regulation prescribes in Article 19 that the terms "parfum" or "aroma" have to be used.
 - Likewise, ingredients used as cosmetic colorants (other than hair colouring) have to be labelled with their CI (Colour Index) nomenclature, even if the same substance may also be listed in the glossary with another name.
 - If one of the Glossary names is the INCI name listed in the annexes of the cosmetics Regulation, it should be used.
- 8. I have a new ingredient which is not yet listed in the Glossary, which name should I use for labelling?
 - In the absence of a Glossary name, a generally accepted nomenclature has to be used. The Cosmetics Regulation does not specify what is considered by 'generally accepted nomenclature'. However, given that the Glossary names derive from the *International Cosmetic Ingredient Dictionary and Handbook*, it can be inferred that INCI names listed in this publication can be used in the absence of a Glossary name.
 - In the absence of such an INCI name, use of nomenclature conventions¹ given in the International *Cosmetic Ingredient Dictionary and Handbook* are recommended, although such name should be considered as temporary expedient. The manufacturer of the cosmetic product is recommended to take the necessary steps to ensure that an INCI name is applied for and allocated, and, when it becomes available, it should be used in the ingredient declaration without unnecessary delay.
 - Also IUPAC *Chemical* names should be considered as valid temporary alternatives. (cf. Cosmetics Regulation Article 19 - Labelling, Article 33 - - Glossary of Common Ingredient names)
- 9. What should I do if the name for my ingredient is misspelled in the Glossary
 - Considering the big amount of data included in the Glossary and despite the efforts of the Commission in the review of the Glossary, a number of mistakes have already been identified, including typos, hyphens missing, etc. In case of a company suspecting a mistake, it should check the Glossary name against the name in the INC dictionary. If it is confirmed that the Glossary name is wrong, the company should without delay inform the EU Commission. A record of the mistake and the actions taken by the company should be included in the Product Information File.

cf. Cosmetics Regulation Article 19 - Labelling; International Cosmetic Ingredient Dictionary and Handbook)

- 10. The Glossary name of an ingredient I am using in products on the market has changed, do I need to change my labels ? / An ingredient that I had to label using a specific INCI Name for the USA (e.g. cosmetic colorants, some botanical names and trivial names) (see Q 3 & 4) has now been included in the Glossary with a different name. Do I need to change my labels ?
 - It is not yet clear with what frequency the glossary will be updated. It can be expected, however, that transition times will be granted for every update that are similar to the original implementation of the glossary (i.e. applicable to products placed on the market 12 months after publication).
- 11. I have an international packaging with a combined EU/US ingredient list. For ingredients that have a different labelling name in the EU Glossary compared to the specific INCI names for the USA (e.g. cosmetic colorants, some botanical names and trivial names), can I use a dual name, e.g. EU and US name separated by "/" or using "()" or asterisk form "*" linking to additional information?
 - The Cosmetics Regulation does not provide a specific guidance on this topic. The only explicit requirement under the Cosmetics Regulation is that the Glossary name has to appear in the ingredient list. The Regulation does not preclude that additional information can be added into the ingredient list (e.g. US INCI names, trivial names or information on natural/biological origin). It should be noted that dual labelling has been accepted in the EU since many years and the Glossary has not set out to change that practice.
- 12. Since the INCI names of the raw materials are written in capitals in the Glossary, is this type format mandatory on the cosmetics product label?
 - No. ingredient labelling has to be in "easily legible and visible lettering" but the EU Regulation does not prescribe a specific type format. In practice, most companies use capital lettering, but this is not an obligation.
 - According to international nomenclature conventions given in the International Cosmetic Ingredient Dictionary and Handbook, "in order to facilitate clarity and ease of use when labeling, INCI names have been designed to require a minimum of punctuation and capitalization"cf. Cosmetics Regulation Article 19 - Labelling; International Cosmetic Ingredient Dictionary and Handbook)⁵
- 13. How can I check if the ingredient name provided by my supplier is correct ?
 - The Glossary itself does not provide information on the chemical identity of the ingredients that are listed. In order to check the correctness of an ingredient name provided by a supplier, the cosmetic company should first use the information received on the chemical idendity of the ingredient (Chemical Name, CAS#, etc.) and identify the corresponding INCI name based on the INCI dictionary and COSING. In a second step, the listing of this INCI name in the glossary should be checked. In case of the INCI name not being listed inthe glossary, see Question 8.

- 14. My supplier provided me an incorrect INCI name in the information materials provided with the raw material. What INCI name should I use?
 - For each cosmetic product placed on the market, the responsible person shall ensure compliance with the relevant obligations set out in this Regulation including labelling. If the supplier provides the incorrect name, the responsible person is required to check the correct INCI name and to apply it or establish the INCI name according to the international nomenclature conventions.

REFERENCES

¹<u>https://eur-lex.europa.eu/legal-</u> content/EN/TXT/?uri=uriserv:OJ.L_.2019.121.01.0001.01.ENG&toc=OJ:L:2019:121:TOC

² https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02009R1223-20180801

³<u>https://www.personalcarecouncil.org/resources/inci/</u>

⁴<u>https://ec.europa.eu/growth/sectors/cosmetics/cosing_en</u>

⁵ <u>https://pcpcouncilstg.wpengine.com/wp-content/uploads/2018/11/INCI-Nomenclature-</u> <u>Conventions.pdf</u>
