

Section 9

IOFGA Standards for Health & Beauty Products

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IOFGA STANDARDS FOR ORGANIC FOOD AND FARMING IN IRELAND

9.1 What these standards apply to:

9.1.1 These standards cover health and beauty products that are made from organic ingredients, including:

- herbal products
- natural and herbal medicine-like products
- toiletries
- body care products, and
- cosmetics and perfumery.

Note – toiletries include:

- foaming products
- blended oils
- emulsified products
- pastes
- salves
- gels
- toilet soaps
- aqueous products, and
- fragrances.

Note – a ‘cosmetic product’ shall be defined as under article 1 of the Eu Cosmetics Directive 76/768/EEC (as amended).

9.1.2 These standards define the criteria, treatments and practices of organic health and beauty products. They cover:

- processing of the raw materials
- manufacture
- labelling, and
- composition.

9.1.3 Health and beauty products are new areas for organic standards. These standards are evolutionary and may change as technology evolves, and more organic ingredients become available.

Currently, Eu ‘organic’ regulations (no. 889/2007 & 834/2008) do not include health and beauty products. This means there are no legal controls over the term organic for these products. However, if you wish to use the IOFGA symbol, then you must follow these standards.

9.1.4 These standards do not conflict with or attempt to replace the range of statutory requirements and industry codes of practice. We expect you to work to any other relevant codes as a matter of course. You must make sure your products meet all other relevant statutory regulations relating to:

- safety
- manufacturing and composition
- grade, quality and quantity
- product descriptions/labelling, and
- any other national, European and international legislation for food, medicines and/or cosmetics (as appropriate).

9.2 **PRINCIPLES**

9.2.1 In addition to the principles for organic production and processing in section 1, here we have defined more detailed principles for organic health and beauty products.

9.2.2 Organic health and beauty products should:

- be fit for their purpose
- have as high as possible proportion of organic ingredients
- be clearly identified, traceable and separate from non-organic products at all stages of manufacturing

- not be tested on animals
- not be harmful to human health and the environment in manufacture and use

- be produced in line with ethical trade standards, and
- be labelled to give clear and accurate information to the consumer.

9.3 RAW MATERIALS AND INGREDIENTS

General

- 9.3.1 You must only use ingredients, additives and processing aids that we allow in these standards.
- 9.3.2 You must not use ingredients produced using nanoscale processes where:
- the mean particle size is 200nm or smaller, and
 - the minimum particle size is 125nm or smaller.
- 9.3.3 You must not test raw materials, ingredients or products on animals except where required by law.

Agricultural ingredients

- 9.3.4 You should use agricultural raw materials that are fresh or minimally processed.
- 9.3.5 Your ingredients must be organic if available.
- 9.3.6 With our permission you may use non-organic agricultural ingredients that are not listed in standards 6.05.22. You must show us that the ingredient is not available as organic in sufficient quantity or quality for your product.
- 9.3.7 You must not use any ingredient derived from a species identified on the IuCN red list as Critically Endangered, Endangered or Vulnerable (www.redlist.org).

Water

- 9.3.8 You must use water that is potable (fit for drinking). you must tell us:
- where the water comes from, and
 - how you treat it.

Minerals

- 9.3.9 You may use these minerals:
- montmorillonite and kaolin clays
 - chalks
 - sand
 - salt
 - pumice, and
 - diatomaceous earth.
- Note – please see standard 9.10.2 for how you can label products containing minerals.
you should only use minerals from environmentally sound extraction processes.
- 9.3.10 The minerals may be treated by:
- washing
 - steam cleaning
 - ultra heat treatment
 - other mechanical cleaning methods, and
 - drying.
- Viscosity modifiers, thickeners, anti-oxidants and other additives
- 9.3.11 You may use:
- viscosity modifiers, thickeners and anti-oxidants listed in standard 6.05.21
 - processing aids listed in standard 6.05.21
 - other plant gums
 - other plant-derived anti-oxidants
 - sodium hydroxide and potassium hydroxide as pH adjusters, and
 - phytic acid as a chelating agent.
- 9.3.12 With our permission you may use other viscosity modifiers, thickeners and anti-oxidants, also fillers and binders not listed in standard 6.05.21. You must tell us why you need to use that particular ingredient and why those listed are not suitable for your product.
- 9.3.13 You must not use chelating agents based on ethylene diamine tetraacetic acid (EDTA) and its salts.

Anti-microbial agents

9.3.14 You may use the following anti-microbial agents:

- benzyl alcohol
- benzoic acid and its salts
- sorbic acid and its salts
- dehydroacetic acid
- sodium dehydro acetate
- agricultural raw materials or extracts, which may be modified by simple physical or chemical processes that do not change the active ingredients.

9.3.15 With our permission you may use:

- phenoxyethanol
- lactoperoxidase
- phenylethyl alcohol
- any other anti-microbial agent that meet criteria.

For us to give permission, you will need to show us why you need to use these anti-microbials instead of the ones we allow.

Note – we understand that cosmetic products may support the growth of micro-organisms. Anti-microbials can protect products from contamination, especially after purchase and during use. We also appreciate that using them in combination can be more effective due to them working synergistically.

We have considered issues such as toxicity, biodegradability, origin of source material and allergic potential when we developed these lists. We also incorporated some of the principles of ‘green chemistry’.

However, unlike surfactants, we found it very difficult to screen antimicrobials through any established and accepted criteria. We have therefore assessed them on the principles and criteria in these and other related standards.

9.4 Extracting and preserving raw materials

9.4.1 You should:

- extract as much of the herb as possible, and
- use extraction methods that extract the biologically active parts of the plant material while retaining maximum activity.

9.4.2 You must:

- use extraction ratios (solvent to plant) to recognised standards, where they exist
- tell us which standards you are using
- justify the extraction ratio you use, where there are no recognised standards.

9.4.3 You may only use the following substances for extraction:

- solvents of organic origin (for example, alcohol, glycerol, lactose, sugar, vinegar)
- potable (drinking) water
- carbon dioxide, either as liquid CO₂ or in supercritical fluid extraction (SCFE).

9.4.4 For alcohol extraction you must:

- use denaturants for alcohol where they are legally required
- tell us which denaturant you are using.

9.4.5 For alcohol extraction you must not use denatured alcohol for tinctures.

9.4.6 With our permission you may use:

- non-organic glycerol providing it is not from animals and organic glycerol is not available
- non-organic herbs extracted in an organic solvent, if the herb is not available in organic form.

You must indicate that these are non-organic in the ingredients/INCI list.

9.4.7 To extract components from organic ingredients, you may use:

- maceration (hot or cold)
- expression
- percolation
- juicing
- solar extraction (for example of flower remedies)
- cold extraction
- pressing
- pressure
- vacuum
- distillation using water or steam at low pressure
- decoction
- infusion (hot or cold), and
- microbial digestion/fermentation.

Post-extraction

9.4.8 After extraction, you may use:

- filtration with non-bleached filtering papers
- micro filters
- depth filters
- concentration by evaporating, vacuum distilling or spray drying
- nitrogen flushing, and
- clarifying and precipitating agents listed in standard 6.05.22

9.4.9 With our permission you may use:

- ultrasound
- rectification
- post packaging sterilisation (for example: UV irradiation)
- pasteurisation
- standardisation.

Note – we understand that it is important to guarantee the percentage of an active ingredient for the quality of a product. Plant chemistry is so complex that it may not always be best to standardise the concentration of one ingredient without considering the others. Therefore, you must justify why you need to standardise.

9.4.10 You may not use:

- aroma enhancers
- ionising radiation, or
- electron beaming.

Preserving

9.4.11 You may prepare and preserve ingredients by:

- air drying with natural hot air or heated air
- freezing/individually quick freezing, and
- storing with modified atmosphere (for example, using nitrogen).

9.4.12 With our permission you may use other ways to preserve ingredients, such as freeze-drying. You must send us an explanation of why you wish to use a particular method and how it will affect the product.

9.5 Physical and chemical processing of ingredients

9.5.1 You should only process an organic ingredient if this is needed for it to work.

9.5.2 For processing organic ingredients, you may use:

- physical methods (including heating and cooling)
- mechanical techniques
- biological processes, such as fermentation, but not using GMOs or their derivatives, and
- saponification of organic materials using sodium hydroxide or potassium hydroxide.

9.5.3 You may chemically process agricultural ingredients using:

- the additives and processing aids listed in standards 6.05.22.
- petrochemical and synthesised chemicals as reagents, if the resulting substance complies with toxicity and biodegradability criteria.

Note – chemically processed ingredients that meet these criteria include:

Ingredient Examples

- soaps sodium palm kernalate, sodium olivate
- glyceryl esters of fatty acids, glyceryl mono stearate, glyceryl mono stearate SE, glyceryl di stearate
- alkylpolyglucosides, decyl glucoside, lauryl glucoside
- alkylglucosides, sucrose cocoate, sucrose stearate
- fatty acids and alcohols cetyl alcohol
- esters of fatty acids and alcohols cetearyl olivate
- alkybetaines coco betaine cocamidopropyl betaine

Maximum levels for impurities in both organic and non-organic alkyl betaines are:

- | | |
|----------------------------------------------|--------|
| • monochloroacetic acid | 5 ppm |
| • dichloroacetic acid | 10 ppm |
| • free amidoamine | 0.3% |
| • 3-aminopropyldimethylamine (DMAPA) = 15ppm | |

The levels must be measured in the betaine ingredient ‘as used’ to formulate the end product.

9.5.4 With our permission you may use processed ingredients other than those

listed in standard 6.05.22. You must show us that:

- you need to use that ingredient in your product, and
- the ingredient meets our requirements for toxicity and biodegradability

Note – you must send us test results for the ingredient to prove that it meets these requirements.

9.5.5 You must ensure that side reactions do not cause unwanted by-products, such as nitrosamines, when you make ingredients from raw materials and reagents.

9.5.6 You must not use:

- sulphonation
- ethoxylation, or
- propoxylation.

9.5.7 You must not use:

Ingredient Examples

- alkyl sulphates sodium lauryl sulphate sodium coco sulphate ammonium lauryl sulphate

Note – the scientific evidence for and against these substances is still not clear. As a precaution we do not allow them. We will continue to watch developments and may change standards if new evidence is available.

- alkyl ether sulphates sodium laureth sulphate ammonium laureth sulphate
- polysorbates polysorbate 20
- ethanolamides cocamide DEA, cocamide MEA

Requirements for toxicity and biodegradability

9.5.8 You must be able to demonstrate that each chemically processed ingredient meets all of the following requirements:

- aquatic toxicity – the EC50 and LC50 for algae, crustaceans and fish must be at least 1mg/kg
- aerobic bio-degradability - must be ‘easily degradable’, as defined in OECD document 301A-F
- anaerobic bio-degradability – must be ‘easily degradable’ as defined in ISO 11734
- bio-accumulation – the log Pow value must be no more than 3.

Note – we have used information from the Nordic Ecolabeling Scheme for personal care products to draw up these requirements, primarily group C2.

9.6 Labelling and composition

9.6.1 You should label your products:

- clearly and accurately to give information to the consumer so they can make informed buying decisions, and
- with a list of English, as well as International Nomenclature on Cosmetic Ingredients (INCI) names.

9.6.2 You may label your product as 'organic' if more than 95% of the ingredients are organically produced.

You must calculate the organic percentage as follows:

- the calculation is of the finished product
- you must exclude any added water from the calculation, including floral waters
- for an ingredient that itself includes water, you must exclude the water part from the calculation, and
- for an ingredient of mixed organic and non-organic origin, either as a mixture or arising from a chemical reaction, you must use the relative proportions in the calculation.

Example: soap

Ingredients: saponified organic oil 80%
organic herbs and essential oils 20%
Saponified oil = 94% organic oil and 6% NaOH

Organic percentage in product from saponified oil 94

$$80 \times = 75.2\%$$

Organic percentage of final product

$$75.2\% + 20\% = 95.2\%$$

Therefore, it may be labelled as 'organic soap'.

9.6.3 You must label your products as ‘made with x% organic ingredients’ where at least 70% of the ingredients are organically produced.

This percentage must be calculated on the same basis for ‘organic’, above.

Example: shampoo

Ingredients: water 50%
surfactant made with organic oil 47.5%
organic herbs and essential oils 2.5%

Percentages without water: surfactant 95%
herbs and essential oils 5%

Surfactant: organic oil 75%
NaOH 5%
non-organic reagent 20%

Organic percentage in product from surfactant 75%

$95 \times 75 = 71.25\%$

100 Organic percentage of final product

$71.25\% + 5\% = 76.25\%$

Therefore, it may be labelled as ‘made with 76% organic oil and herbs’.

9.6.4 Your labels must also show:

- the percentage of organic ingredients (which must be in the product title for a 70%+ product)

Note – we interpret ‘in the product title’ to be within or right under the product name and in the same (or similar) size and style.

- full ingredient breakdown in descending order by weight – down to 1%

Note – we may give you permission to use a reduced ingredient listing in the case of complex fragrances.

- processing aids
- percentage of added water including flower water/infusion/decoction, and
- percentage of all mineral components in the product.

9.6.5

You must label:

- ingredients as ‘organic’ only when the whole of that ingredient is of organic origin, and
- the organic ingredients transformed by chemical processes as ‘made with organic ingredient’ or similar. You may indicate this by using an asterisk or similar mark following the name of the ingredient which then refers to a statement elsewhere on the label.

9.7 Inspection and certification

9.7.1 If you want to label the products that you produce, make or sell with our symbol, you must hold a valid certificate of registration from us for that product.

9.7.2 You must allow us to:

- inspect your operation and premises (annually)
- carry out unannounced inspections, and
- take samples for residue testing if we or our inspector think there may be a risk of contamination or as a back up to the certification process.

Note – we will use laboratories that are qualified to carry out tests to these standards.

The organic ingredients you buy must be certified. However with our permission, if you are a manufacturer of surfactants, you do not need inspection and certification. However, for the products concerned you must:

- meet all other relevant parts of these standards, and
- give us full details of:
 - i. the proof of the status of the organic ingredients
 - ii. the chemical processes involved
 - iii. any other inputs you use
 - iv. the waste products produced, and
 - v. the organic percentage in the final substance.

Glossary

A

Active –the active ingredient or substance in a health and beauty or pharmaceutical product that produces or contributes to the effectiveness of a product.

Aerobic bio-degradability – how easily a substance is broken down by micro-organisms when oxygen is available.

Anaerobic bio-degradability – how easily a substance is broken down by micro-organisms when oxygen is not available, for example in sludge.

Anti-microbial agents – a material that will kill or inhibit the growth of microbes such as bacteria, yeasts and moulds. They are commonly used to extend the life span of a wide variety of consumer products.

Aroma enhancers – an aroma enhancer is a synthetic additive which improves or strengthens the smell of a product.

B

Binders – a material used to hold particles together to ensure uniform consistency or solidification; typical binders are resin, gum, silicate and casein.

Bio-accumulation – a substance’s ability to be accumulated in an organism.

C

Chelating agents – compounds able to bind metal ions and make them chemically inactive.

Chemically purified – the ingredients in the product are isolated or separated by various chemical reactions.

Clarifying agents – clarifying agents are natural or chemical substances that are used to remove suspended particles or sediments from liquids. This means that the final product has a translucent or clear appearance.

Precipitating agents – precipitating agents cause suspended solid particles in a liquid to drop out of suspension. These solids are then removed leaving behind the liquid.

Cold extraction – methods that include vacuum extraction or cold pressed extraction.

D

Decoction – a herbal preparation made by boiling a plant part in water to make an extract.

Dispersants – usually a detergent or surfactant that is used to produce a stable distribution of an oil or solid in a liquid.

E

EC50 – measure of a substance's toxicity to specific organisms. The effective concentration which affects or kills half of the population tested.

Electron beaming – subjecting a material or product to a beam of electrons to kill micro-organisms. This technology is used in food and medical sterilisation, packaging, and to increase the shelf life of products.

Essential oil – an aromatic volatile substance usually extracted by distillation or expression from a single botanical species. Once the primary process of distillation or expression has been completed, nothing further should be added.

Ethoxylation – a chemical process in which ethylene oxide is added to long chain molecules in order to make them more soluble in water. An example is the ethoxylation of sodium lauryl sulphate to form sodium laureth sulphate, which is used as a foaming agent in non-organic shampoos and toothpaste, and as an industrial detergent.

Excipients – substances added to formulas which have no activity and are used to deliver active ingredients at a desired level in an appropriate form.

Expression – the process of extracting an essential oil by mechanical methods.

Extraction – the process of separating the essential or active part of a plant into a solvent.

F

Fillers – ingredients that add bulk to a product.

Flower waters (hydrolats or hydrosols) – waters resulting from the steam distillation of aromatic plants. These waters may either be a by-product of the extraction process for essential oils (steam distillation) or may be the primary objective of the distillation process. They are distillates and are not manufactured by the addition of any odorous material or a further solvent. These are sometimes known as hydrolats and hydrosols.

I

INCI – International Nomenclature on Cosmetic Ingredients.

Infusion (hot or cold) – tea made by steeping herb leaves, bark or flowers in hot (or cold) water.

Ionising radiation – radiation which has enough energy to cause atoms to lose or gain electrons and become ions. Alpha and beta particles, gamma and x-rays are all examples of ionising radiation.

J

Juicing – to extract the liquid from a fruit or vegetable by mechanical methods.

L

LC50 – measure of a substance's toxicity to specific organisms. The lethal concentration which affects or kills half of the population tested. Liquid CO₂ extraction – otherwise known as supercritical CO₂ extraction. Extraction of plant material using liquid CO₂ under pressure.

M

Maceration (hot or cold) – the process of soaking.

Microbial digestion – the aerobic or anaerobic breakdown of a substance by micro-organisms.

Microbial fermentation – anaerobic growth of microorganisms to produce or break down ingredients.

N

Nitrogen flushing – packaging products using a nitrogen flush removes oxygen from inside the packaging.

P

Pasteurisation – the reduction of micro-organisms using a carefully controlled heating process.

Percolation – the slow passage of a liquid through a medium for extraction or purification.

Petrochemicals – chemicals produced from fossil fuels.

Propoxylation – a chemical process in which propylene oxide is added to long chain molecules in order to make them more soluble in water.

POW (Partition coefficient between octanol and water) – a measure of the distribution of a material between oil and water. This predicts the likelihood of a material building up in body fat. A technical measure which helps predict the degree which oil dissolves in water.

R

Raw material – the original plant (or animal or mineral) material.

Reagents – the starting materials in a chemical reaction.

Rectification – a process of re-distillation to remove or isolate particular constituents.

S

Saponification – the process of converting a fat into soap by treating it with an alkali.

Solvent – liquid substance able to dissolve other substances.

Standardise – a term used in the herbal trade to describe an extract that has been prepared to ensure that it contains set levels of specified plant compounds.

Sulphonation – the process of introducing one or more sulphonic acid groups into a compound to make them more water soluble.

Surfactants – the name is derived from the term surface active agent. It is a compound that reduces the surface tension of a liquid. Its primary functions are cleaning, emulsifying or creating foam.

Supercritical fluid extraction (SCFE) using CO₂ – see liquid CO₂ extraction – above.

T

Thickeners/thinners – ingredients used to make a substance more or less runny.

U

Ultrasound – a method in which high frequency sound waves are used to extract or mix ingredients.

UV irradiation – exposure to ultraviolet radiation to sterilise.

V

Vacuum extraction – extraction under reduced pressure.

Viscosity modifiers – thickeners or thinners to make a substance more or less runny.

SPECIFIC HEALTH AND BEAUTY PRODUCTS

- 9.8 Specific health and beauty product types
- 9.9 Capsules and tablets
- 9.10 Products with a mineral content above 30%
- 9.11 Propellant products
- 9.12 Skin creams
- 9.13 Wet wipes
- 9.14 Water based products
- 9.15 Household products and candles

9.9 Capsules and tablets

9.9.1 Capsules and tablets containing organic herbs and other substances are foods and must therefore comply with our standards for processed foods (see sections 6 & 7).

9.9.2 You may label homeopathic tablets or pillules as organic if:

- they are made from organic ingredients, and
- these have been extracted and diluted according to these standards.

9.9.3 You must use organic carriers such as lactose, sucrose and other excipients that comply with these standards.

9.10 Products with a mineral content above 30%

9.10.1 Some products need a high proportion of minerals. With our permission, you may label these products in the same way as a product with 70-95% organic ingredients if:

- you can justify to us that the minerals are essential for the product,
- and
- your label states the organic percentage in the product title.

Example: toothpaste

Ingredients: chalk
organic glycerol
surfactant made with organic oil
organic essential oils
60%
30%
8%
2%
Surfactant: organic oil
NaOH
75%
5%
non-organic reagent 20%

The organic percentage in product from surfactant – 75%

$8 \times 6\% = 6\%$

Therefore, the organic percentage in the paste

$30\% + 6\% + 2\% = 38\%$

For instance, it may be labelled as ‘toothpaste made with 38% organic glycerol and herbs’.

9.11 Propellant products

9.11.1 You may use as propellants:

- carbon dioxide
- air
- nitrogen.

9.12 Skin creams

9.12.1 You may use:

- titanium dioxide
- zinc oxide
- silicon dioxide (as a surface treatment to aid dispersion)
- caprylic diglyceride (as a dispersant).

These ingredients may be chemically purified, others may not.

9.12.2 You must not use chemically synthesised sunscreens.

9.13 Wet wipes

9.13.1 You must use material and liquid components made from organic ingredients that comply with these standards.

9.13.2 You must calculate the percentage of organic ingredients based on the combined total weight of the tissue and liquid components (less any water).

9.14 Water based products

9.14.1 Where the product is over 90% water (for example toners, spritzers and flower waters), you may consider the water-based organic ingredients as organic in the percentage calculation.

Note – the standards requiring you to justify the ratio of plant material to water (standard 9.4.2).

9.14.2 You must not sell flower waters as organic unless they have been produced using distillation.

Water based products used as ingredients

9.14.3 You should use the following formulation to establish the percentage of organic ingredients in water extracts of herbs:

weight of herb x 100

weight of herb + weight of water

Example:

20 grams of herb x 100 = 0.2 x 100 = 20

20 grams of herb + 80 grams of water

This means that 20% of the extract, when used as an ingredient, can count towards the organic percentage of your product.

9.15 Household products and candles

9.15.1 We can certify household products and candles if they fully comply with these health and beauty product standards. Please contact us for more information.