



TECHNICAL REGULATIONS FOR ORGANIC AND NATURAL BEAUTY PRODUCTS CERTIFICATION

Bios s.r.l., via Montello, 6 - 36063 Marostica (VI), Italy
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Document	Revision No	Date	Edited by	Verified by	Approved by
BCos01	01	03/03/2016	A. Spadoni	RCV	CSI



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1.GENERAL

The present Technical Regulations describe the requirements to produce cosmetic products that can be certified by the BIOS s.r.l. (BIOS) certification body. The technical regulations outlined here are the only ones that BIOS recognises. These regulations can be reviewed and updated and are to be seen as complimentary to the Certification Rules for BIOS Organic and BIOS Natural Beauty Products (D240).

The applicant company must comply with all current applicable regulations related to the production and sales of cosmetic products.

Cosmetic products, as defined in UE Reg. 1223/2009, can contain certified organic raw materials.

These BIOS technical regulations have the following objectives:

1. To promote the diffusion of cosmetic products containing natural and organic certified raw materials.
2. To increase the consumer's protection through information and education.
3. To contribute to environmental protection, and safeguarding biodiversity.
4. To add value to the diversity of organic farming so that it is seen not just as a source of raw materials.

2.REFERENCE DOCUMENTS

- ☐ Reg. CE 834/2007
- ☐ Reg. CE 889/2008
- ☐ Reg. CE 1223/2009
- ☐ Reg. CE 1830/2003
- ☐ UNI EN ISO 22716:2007

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- ☐ UNI CEI EN ISO 17065:2012 - Conformity assessment, requirements for bodies certifying products and services.
- ☐ UNI CEI EN 45020:1998 – General terms and definitions relating to the regulation and its activities.
- ☐ UNI EN ISO 19011:2002 – Guidelines for quality and/or environmental management systems auditing.
- ☐ D240 Certification Rules for BIOS Organic and BIOS Natural Standard for Beauty Products.

The above references were the ones valid for when these Technical Regulations were drafted. During the certification process, all of the references cited above must be applied using their most up to date versions.

3.DEFINITIONS

COMPANY SUBJECT TO THE CONTROL SCHEME: A company applying for the certification that is voluntarily asking to be subject to the BIOS control scheme for natural and organic beauty products.

PRODUCT TRACEABILITY: the process of tracing all the elements included in the product.

FULL TRACEABILITY: the process that involves going back in the production chain to identify an event that has caused an unexpected outcome.

NON-COMPLIANT INGREDIENT: A raw material that is not present in the Technical Regulations Annexes.

4. SCOPE AND FIELD OF APPLICATION

The present Technical Regulations define the requirements and the rules the observance of which are necessary to certify organic and natural cosmetics, and are applied to :

- A. cosmetic products as defined in the UE Reg. 1223/2009;
- B. cosmetic ingredients
- C. animal products such as aids, ingredients, raw materials, auxiliary or simple natural substances that may be used in cosmetics as well as animal products;
- D. packaging for the above.

This control system applies to certified cosmetics production, preparation and distribution, as well as labelling, packaging and/or intermediates.

5. GENERAL PRINCIPLES

Certified cosmetics production is based on the following principles:

- 5.1. A prohibition on the use of genetically modified ingredients.
- 5.2. The use of only naturally derived or organic raw materials in their production.
- 5.3. A minimum use of non-renewable sources.
- 5.4. The recycling of production waste wherever possible and the proper disposal of it.
- 5.5. Only ingredients allowed in the present Annexes should be used as they respect the environment and human health.

The present Technical Regulations define the compliance requirements in relation to:

- ☐ Suppliers Qualifications (6.)
- ☐ Raw Materials Delivery (7.)
- ☐ Production, Preparation, Stock Sites (8.)
- ☐ Used Raw Materials (9.)
- ☐ Packaging (10.)
- ☐ Labelling (11.)

6.SUPPLIERS QUALIFICATIONS

The company subject to the control scheme related to these Technical Regulations will have to ensure that any raw material is compliant via supplier documents that declare it's conformity prior to purchase.

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In particular the following aspects need to be verified:

- ☐ Raw materials and packaging need to satisfy (add ISO Documents) acceptance criteria related the quality of the finished product.
- ☐ The business name and address of the supplier.
- ☐ The validity of the certificate of organic raw material.

7. RAW MATERIAL DELIVERY

7.1. When the raw material that is declared organic is received, the company subject to the control scheme must verify that the pack is sealed (to avoid adulteration or damage) and before using it, must in addition verify compliance via the following documents:

- a) The raw materials organic certificate;
- b) The invoice and delivery note;
- c) The labelling and technical data sheet.

7.2. When raw materials that are at risk of GMO contamination are purchased, and they are not compliant with the Reg. CE 1830/03 (i.e. they do not have traceability and the required compulsory GMO labelling), it will be necessary to ask the supplier for an explicit declaration, stating that the raw materials supplied are not derived from GMO crops.

7.3. Only when points 7.1 and 7.2 are met successfully, the raw material in question can be used to produce products certified according to the BIOS Standard for Beauty Products and complying with this Technical Regulations (BCos01). In case of incomplete documentation and/or doubts regarding the real conformity of the raw material, it is necessary to segregate and identify the product, notifying the Certification Body.

8. PRODUCTION, PREPARATION AND STORAGE SITES

8.1. All organic raw materials stored in warehousing must be strictly managed, so that the identification of incoming lots are guaranteed, and any potential contamination with products that are non compliant with the Technical Regulations is avoided.

8.1.1. All organic raw materials must be clearly distinguishable from products of other nature.

8.1.2. Validated hygiene procedures must be in place. The applicant company must have a program in place to manage warehouse procedures and to identify any potential pollution sources.

8.1.3. The storage units and the preparation of raw materials must satisfy the requirements related to current Cosmetic Regulation. The way the product is stored needs to give the opportunity to take samples if needed in order to perform analytical tests.

8.1.4. The company subject to the control scheme establishes and updates suitable procedures to identify the critical phases of the product preservation and processing.

8.2. The certified product manufacturing areas need to be separate in time and space in relation to conventional production. If it is not possible to separate the areas/sites, it is then possible to use the same area/site providing it is used at a different time and proper cleaning procedures are in place.

8.2.1. The applicant company should establish a program for periodical site/plant verification, and identify any possible source of pollution, and remove it. Site /plant cleaning procedures need to be recorded and monitored for efficacy.

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8.2.2. Precautions must be taken to avoid any cross contamination.

8.2.3. Suitable measures must be taken so that non-compliant products are not released onto the market claiming compliance with these Technical Regulations.

8.3. All operators handling organic raw materials must have relevant training.

8.5. The production, preparation and storage need to employ product sampling routines to allow performance of analytical tests.

8.6. All invoices and delivery notes need to be made available for inspection by the certification body.

9. COMPOSITION REQUIREMENTS

There are two possible BIOS certificates for cosmetics:

9.1. Natural Cosmetic

9.2. Organic Cosmetic

9.1. Natural Cosmetic

A cosmetic product made from the following:

- ☐ 95 % (by weight) of the total (including added water) must be either natural ingredients, or naturally derived ingredients, or synthetic ingredients present in nature.
- ☐ 5 % (of total weight) can be permitted additives. The permitted additives are listed in Annex 6.

Natural ingredients are:

- a) Ingredients derived from plants through farming production or wild cropping;
- b) Ingredients derived from farmed animals, without chemical modification. Annex 3.
- c) Mineral derived ingredients. Annex 4.
- d) Ingredients that are naturally derived and have undergone the processes outlined in Annex 1 and 2

The percentage of natural ingredients must be not less than 10% of the total formulation. In this calculation the added water is excluded.

9.2. Organic Cosmetic

A cosmetic product must be made up of the following:

- ☐ 95 % (by weight) of the total (including added water) must be either natural ingredients, or naturally derived ingredients, or synthetic ingredients present in nature.
- ☐ 5 % (of total weight) can be permitted additives. The permitted additives are listed in Annex 6.
- ☐ The presence of the same organic raw material in *conventional* grade, is not permitted in the *same* finished product. Either one or the other can only be used.

The percentage of the organic raw materials must be at least 25% of the total weight.

10. ALL PACKAGING

10.1. None of the packaging material should release harmful substances into the cosmetic product.

10.2. Packaging and packing material must be reduced to a minimum in terms of weight and volume, and whenever possible must be made from materials that are biodegradable, recyclable (or recycled), eco-compatible and that are from renewable sources. The same applies to secondary and tertiary packaging.

10.3. Wherever possible packaging should be used that can be reused by the consumer.

10.4. Packaging must be cleaned for possible contamination before being used for the product, and needs to be stocked in dry and clean sites, away from heat and other contaminatory sources.

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10.5. Cosmetics that are pressurised can only make use of natural gases.

10.6. Packing materials that are not permitted are: polyvinyl-chloride, polystyrene, and halogenated plastic.

11. LICENSEE LABELLING

Licensees may use the certification logos displayed below, depending on the type of certification acquired. The logo must always relate to the certified product complying with the Standard.

12. CERTIFICATION LOGOS

The logos that identify the two types of certified products are displayed below and must be used in strict accordance with the specific rules set out in Technical Regulations (BCos01) and D240.

NATURAL COSMETIC



ORGANIC COSMETIC



ANNEX NO. 1 - PHYSICAL PROCESSES ALLOWED FOR THE PRODUCTION OF COSMETIC RAW MATERIALS

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- ☐ Absorption
- ☐ Atomisation
- ☐ Calcination of vegetable residues
- ☐ Centrifugation
- ☐ Decantation e sedimentation
- ☐ Decolorisation
- ☐ Decoction
- ☐ Deodorisation
- ☐ Deterpenetion
- ☐ Digestion
- ☐ Distillation
- ☐ Molecular distillation
- ☐ Dessication
- ☐ Extraction
- ☐ Fermentation
- ☐ Filtration
- ☐ Grinding
- ☐ Hydration
- ☐ Hydrolysis (via micro-organisms or enzymes)
- ☐ Infusion
- ☐ Lyophilization
- ☐ Maceration
- ☐ Mixing
- ☐ Homogenisation
- ☐ Percolation
- ☐ Pulverising
- ☐ Refining
- ☐ Rettificazione
- ☐ Heating
- ☐ Sifting
- ☐ Squeezing

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- ☐ Sterilisation
- ☐ Roasting

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- ☐ Alkylation
- ☐ Amidation
- ☐ Amphoterics
- ☐ Carbonisation
- ☐ Condensation
- ☐ Esterification
- ☐ Esterification
- ☐ Phosphorylation
- ☐ Hydrolysis
- ☐ Neutralisation
- ☐ Oxidation/Reduction
- ☐ Saponification
- ☐ Sulphatation (only for hair products given the high skin irritation potential)
- ☐ Glycosylation
- ☐ Hydrogenation
- ☐ Trans-Esterification
- ☐ Fermentation
- ☐ Polymerisation of Natural Molecules
- ☐ Refining

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ANNEX 3 - INGREDIENTS OF ANIMAL ORIGIN ALLOWED

INCI	CAS	EINECS ELINCS	Restrizioni	Nome comune	Funzione
CERA ALBA	8012-89-3	232-383-7		Cera d'api	EMOLLIENT EMULSIFYING FILM FORMING PERFUMING
CI 75810	11006-34-1 / 8049-84-1	234-242-5 / 232-471-5	IV/116	Carminio	COSMETIC COLORANT DEODORANT
MILK	8049-98-7			Latte	SKIN CONDITIONING
MEL	8028-66-8			Miele	EMOLLIENT HUMECTANT MOISTURISING
ROYAL JELLY	8031-67-2			Pappa reale	
PROPOLIS EXTRACT	85665-41-4	288-130-6		Propoli	SKIN CONDITIONING
SERICIN	60650-88-6 / 60650-89-7			Sericina	ANTISTATIC HAIR CONDITIONING SKIN CONDITIONING SMOOTHING

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ANNEX 4. INGREDIENTS DERIVED FROM MINERAL EXTRACTION

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INCI	CAS	EINECS ELINCS	Restrizioni	Nome comune	Funzione
CALAMINE	8011-96-9			Calamina	ABSORBENT OPACIFYING SKIN PROTECTING
KAOLIN	1332-58-7	310-194-1	IV/119	Caolino	ABRASIVE ABSORBENT ANTICAKING BULKING COSMETIC COLORANT OPACIFYING
ZINC CARBONATE	3486-35-9	222-477-6		Carbonato di Zinco	OPACIFYING
CI 77000	7429-90-5	231-072-3	IV/117	Alluminio	COSMETIC COLORANT
CI 77004	1302-78-9 / 1327-36-2 / 1332-58-7	215-108-5 / 215-475-1 / 310-194-1	IV/119	Bentonite	COSMETIC COLORANT
CI 77007	12769-96-9 / 1302-83-6 / 57455-37-5	235-811-0 / 215-111-1 / -	IV/120	Azzurrite ultramarines	COSMETIC COLORANT
CI 77120	7727-43-7	231-784-4	IV/122	Solfato di bario	COSMETIC COLORANT
CI 77220	471-34-1	207-439-9	IV/124	Carbonato di Calcio	ABRASIVE BUFFERING BULKING OPACIFYING ORAL CARE
CI 77268:1	1339-82-8	215-669-6	IV/128	Carbone vegetale	COSMETIC COLORANT
CI 77400	7440-50-8	231-159-6	IV/132	Rame	COSMETIC COLORANT
CI 77480	7440-57-5	231-165-9	IV/133	Oro	COSMETIC COLORANT
CI 77489	1345-25-1	215-721-8	IV/134	Ossidi di Ferro	COSMETIC COLORANT
CI 77491	1309-37-1 / 1317-61-9 / 1345-27-3 / 52357-70-7 / 1345-25-1	215-168-2 / 215-277-5 / 215-722-3 / 257-870- 1 / 215-721-8	IV/135	Ossidi di Ferro	COSMETIC COLORANT
CI 77492	51274-00-1 / 1345-27-3 / 20344-49-4 / 52357-70-7	257-098-5	IV/136	Ossidi di Ferro	COSMETIC COLORANT
CI 77499	12227-89-3 / 1309-37-1 / 1317-61-9 / 1345-25-1 / 1345-27-3 / 52357-70-7	235-442-5 / 215-168-2 / 215-277-5 / 215-721- 8 / 215-722-3 / 257- 870-1	IV/137	Ossidi di Ferro	COSMETIC COLORANT
CI 77510	14038-43-8 / 12240-15-2 / 25869-00-5	237-875-5 / - / 247- 304-1	IV/138	Blu di Prussia	COSMETIC COLORANT
MAGNESIUM OXIDE	1309-48-4	215-171-9		Ossido di Magnesio	ABSORBENT BUFFERING OPACIFYING
CI 77713	546-93-0 / 7757-69-9	208-915-9 / 231-817-2		Carbonato di Magnesio	COSMETIC COLORANT
CI 77742	10101-66-3	233-257-4	IV/140	Ammonium manganese difosfato	COSMETIC COLORANT
CI 77745	10124-54-6 / 14154-09-7	233-341-0 / 237-997-9	IV/141	Bis ortofosfato di Manganese	COSMETIC COLORANT
CI 77820	7440-22-4	231-131-3	IV/142	Argento	COSMETIC COLORANT
CI 77891	13463-67-7	236-675-5	IV/143 VI/27	Biossido di Titanio	COSMETIC COLORANT OPACIFYING UV ABSORBER UV FILTER
CI 77947	1314-13-2	215-222-5	IV/144	Ossido di Zinco	BULKING SKIN PROTECTING UV ABSORBER COSMETIC COLORANT
SILVER CHLORIDE	7783-90-6	232-033-3	V/52	Cloruro di Argento	PRESERVATIVE
MAGNESIUM CHLORIDE	7786-30-3	232-094-6		Cloruro di Magnesio	VISCOSITY CONTROLLING
SODIUM CHLORIDE	7647-14-5	231-598-3		Cloruro di Sodio	BULKING MASKING ORAL CARE VISCOSITY CONTROLLING
DICALCIUM PHOSPHATE DIHYDRATE	7757-93-9 / 7789-77-7	231-826-1		Fosfato bicalcico diidrato	ABRASIVE OPACIFYING ORAL CARE
ALUMINUM HYDROXIDE	2164-01-2				COSMETIC COLORANT EMOLLIENT HUMECTANT OPACIFYING SKIN PROTECTING
MICA	12001-26-2			Mica	VISCOSITY CONTROLLING OPACIFYING

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ALUMINA	1344-28-1	215-691-6		Ossido di Alluminio (Allumina)	ABRASIVE ABSORBENT ANTICAKING BULKING OPACIFYING VISCOSITY CONTROLLING
TIN OXIDE	18282-10-5	242-159-0		Ossido di Stagno	ABRASIVE BULKING OPACIFYING VISCOSITY CONTROLLING
GOLD	7440-57-5	231-165-9	IV/133	Oro	COSMETIC COLORANT
PUMICE	1332-09-8				ABRASIVE BULKING VISCOSITY CONTROLLING
SILICA	7631-86-9 / 112945-52-5 / 60676-86-0	231-545-4 / 262-373-8 / -		Silica	ABRASIVE ABSORBENT ANTICAKING BULKING OPACIFYING
HYDRATED SILICA	10279-57-9 / 1343-98-2 / 7631-86-9 / 112926-00-8 / 63231-67-4	- / 215-683-2 / 231- 545-4 / - / -		Silica idrata	ABRASIVE ABSORBENT ANTICAKING BULKING OPACIFYING VISCOSITY CONTROLLING
MAGNESIUM ALUMINUM SILICATE	1327-43-1	215-478-8		Silicato magnesiano di Alluminio	ABSORBENT ANTICAKING OPACIFYING VISCOSITY CONTROLLING
CALCIUM SULFATE (CI 77231)	7778-18-9	231-900-3	IV/125	Solfato di Calcio	ABRASIVE BULKING OPACIFYING PEARLESCENT COSMETIC COLORANT
FERROUS SULFATE	7720-78-7	231-753-5		Solfato ferroso	ASTRINGENT
FERRIC SULFATE	10028-22-5	233-072-9		Solfato ferrico	HUMECTANT
MAGNESIUM SULFATE	7487-88-9	231-298-2		Solfato di Magnesio	BULKING HAIR CONDITIONING VISCOSITY CONTROLLING
POTASSIUM SULFATE	7778-80-5	231-915-5		Solfato di Potassio	VISCOSITY CONTROLLING
SODIUM SULFATE	7727-73-3 / 7757-82-6	231-820-9		Solfato di Sodio	BULKING VISCOSITY CONTROLLING
ZINC SULFATE	7446-19-7 / 7733-02-0 / 7746-20-0	- / 231-793-3 / -	III/24	Solfato di Zinco	ANTIMICROBIAL ANTIPLAQUE ASTRINGENT ORAL CARE
SILVER SULFATE	10294-26-5	233-653-7		Solfato di Argento	ANTIMICROBIAL
CALCIUM CHLORIDE	10043-52-4	233-140-8		Cloruro di Calcio	ASTRINGENT VISCOSITY CONTROLLING
POTASSIUM CARBONATE	584-08-7	209-529-3		Carbonato di Potassio	BUFFERING
SODIUM CARBONATE	497-19-8	207-838-8		Carbonato di Sodio	BUFFERING BULKING
POTASSIUM CHLORIDE	7447-40-7	231-211-8		Cloruro di Potassio	VISCOSITY CONTROLLING
MAGNESIUM SILICATE	1343-88-0	215-681-1		Silicato di Magnesio	ABSORBENT ANTICAKING BULKING OPACIFYING VISCOSITY CONTROLLING
SODIUM BICARBONATE	144-55-8	205-633-8		Bicarbonato di Sodio	ABRASIVE BUFFERING DEODORANT ORAL CARE SKIN PROTECTING
SODIUM SESQUICARBONATE	533-96-0	208-580-9		Sodio sesquicarbonato	BUFFERING BULKING CLEANSING
SULFUR	7704-34-8	231-722-6		Zolfo	ANTIDANDRUFF ANTISEBORRHOIC ANTISTATIC HAIR CONDITIONING SKIN CONDITIONING

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TECHNICAL REGULATIONS FOR ORGANIC AND NATURAL BEAUTY PRODUCTS CERTIFICATION

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ANNEX 5 - INGREDIENTS OF NATURAL ORIGIN

- ☐ Every plant, mineral and animal derivative ingredient must be obtained using the processes in Annex 1 and 2.

ANNEX 6 OTHER INGREDIENTS ALLOWED

Food preservatives are allowed, and must be evaluated in accordance with the principles of these Technical Regulations.

Natural perfumes complying with ISO/DIS 9235 are permitted. Synthetic perfumes that have been made without the listed forbidden aromatic substances can be used provided that the fragrance supplier can provide a suitable conformity statement. The list of forbidden aromatic substances can be supplied on request.

INCI	CAS	EINECS ELINCS	Restrizioni	Nome comune
BENZYL ALCOHOL	100-51-6	202-859-9	III/45 and V/34	Alcol benzilico
BENZOIC ACID	65-85-0	200-618-2		Acido benzoico e suoi sali ed esteri
DEHYDROACETIC ACID	520-45-6 / 771-03-9 / 16807-48-0	208-293-9 / 212-227-4 / -		Acido deidroacetico e suoi sali
PROPIONIC ACID	79-09-4	201-176-3	V/2	Acido propionico e suoi sali
SALICYLIC ACID	69-72-7	200-712-3	III/98 V/3	Acido salicilico e suoi sali
SORBIC ACID	110-44-1	203-768-7	V/4	Acido sorbico e suoi Sali
FORMIC ACID	64-18-6	200-579-1	V/14	Acido formico
UNDECYLENIC ACID	112-38-9	203-965-8	V/18	Acido undecilenico e suoi Sali
CI 77820	7440-22-4	231-131-3	IV/142	Argento e suoi Sali e composti inorganici
GUAR HYDROXYPROPYLTRIM ONIUM CHLORIDE	65497-29-2		Ammesso alla concentrazione massima dell' 1%	
ETHYLHEXYLGLYCERIN	70445-33-9	408-080-2		Etilsilglicerina
PIROCTONE OLAMINE	68890-66-4	272-574-2	III/61 V/35	

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