SUMMARY

Description of revisions

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Revision	Date	Description of the modification	Comments
01	12/2009	Initial Version	
02	03/2013	Include Normative reference GECA 22-2008 and Required documents items (e) until (k).	

Preparation	Verification	Approval
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0 Introduction

ABNT's Environmental Labeling program has been developed to support a continuing effort for improving and/or maintaining environmental quality via reduced energy and material consumption, along with the minimization of pollution impacts brought on through production, use and final disposal of products and services.

This document has been prepared based on an overview concerning the life cycle evaluation of the product and in information on specifications for similar products from other environmental ecolabeling programs developed by other members of the Global Ecolabelling Network (GEN).

1 Objective

This procedure establishes the requirements that shampoos, corporal hygiene products and both solid and liquid soaps, available on the Brazilian market, shall adhere to in order to obtain a license for the use of the ABNT Environmental Quality Mark (ABNT Ecolabel).

This document encompasses criteria on the classification of substances used, on degradability and bioaccumulability, fragrances and coloring agents, packaging and also product efficiency. Because these products are released into the water after use, properties such as biodegradability, bioaccumulation and toxicity in aquatic environments are considered key factors. This applies in particular to surfactants, which are the most important components of the product, in terms of quality and function. Therefore the environmental charge of certified products is less than those that are not certified when they are compared.

Skin sensitizers agents and other hazardous substances are also considered in this document. Therefore, this document not only recognize shampoos, corporal hygiene products and both solid and liquid soaps that are environmentally preferable, but also those products that are less harmful to consumers health.

2 Normative references

The documents listed below contain dispositions which, when cited in this text, constitute valid requirements for this procedure. The editions indicated where valid at the time of this publication. Because the documents are subject to revision, it is recommended to those who use this procedure investigate the utilization of the most recent edition of the documents indicated. ABNT maintains a registry of all valid documents.

- ABNT NBR ISO 14001:2004 - Environmental management systems - Requirements with guidance for use
- ABNT NBR ISO 14020:2002 - Enviromental labels and declalrations - General principles
- ABNT NBR ISO 14024:2004 - Environmental labels and declarations - Type I environmental labelling - Principles and procedures
- ABNT NBR ISO 14040:2009 - Environmental management - Life cycle assessment - Principles and framework
- GECA 22-2008 - Shampoos and Soaps - The Australian Ecolabelling Program
- PG-11 - General Procedure for ABNT Environmental Quality Label
- PG-12 - Guidelines for preparing ABNT Environmental Quality Label criteria

3 Definitions

3.1 Active content

This is the quantity in weight of all organic substances present in the product, excluding water contained in the components. Abrasive agents present in hand cleaning agents are not included.

3.2 Bioaccumulative

A substance is classified as potentially bioaccumulative if its partition coefficient for octanol-water participation is greater than 1000, when measured conforming to the following:

OECD 107 Guidelines for the Testing of Chemicals / Section 1: Physical-Chemical properties Test No. 107: Partition Coefficient (n-octanol/water): Shake Flask Method.

OECD 117 Guidelines for the Testing of Chemicals / Section 1: Physical-Chemical properties Test No. 117: Partition Coefficient (n-octanol/water), HPLC Method

Note: The OECD 107 shall not be used for surfactants. Other test methods may be accepted, such as the OECD 305 - Guidelines for the Testing of Chemicals / Section 3: Degradation and Accumulation Test No. 305: Bioconcentration: Flow-through Fish Test.

3.3 Surfactants or tensoactive agent

Any substance whose purpose is to reduce superficial tension, thereby helping the water to encompass and remove dirt from surfaces.

3.4 Acute toxicity

a) A deleterious effect caused by the sample in the mobility of test-organisms, in a 48 hours of exposure time (ABNT NBR 12713:2004).

b) A deleterious effect caused by the sample in the survival of the test-organisms, during the exposure of test time (ABNT NBR 15088:2004 and ABNT NBR 15308:2005).

4 Acronyms

The acronyms used in the text of this procedure are the following:

- ABNT - Brazilian Association for Technical Standards
- CA - Active content
- CT - Technical Coordination
- GSI - Systems Certification Management
- IARC - International Agency for Research on Cancer
- IFRA - International Fragrance Association
- ISO - International Organization for Stantardization
- OECD - Organization for Economic Co-operation and Development

5 Scope of product category

This document covers the cosmetic products that are mainly used for hair and skin cleaning, and are removed using water afterwards. The list includes:

- Shampoos
- Soaps, both solid and liquid
- Corporal cleansers
- Shampoos and both liquid and solid soaps for animals

6 Criteria for performance

6.1 Fitness for purpose

The product shall be suitable for its intended purpose .Certain quality and durability patterns may be inherent to the product itself.

The manufacturer shall demonstrate sufficient quality of the product, through test reports obtained from laboratories selected in conformity with item 7 of this procedure, which has to demonstrate the fitness for purpose of the product. In case the product is destined for exportation, it shall comply to the requirements of the standards and regulations that are applicable and required in the target market.

6.2 Specific requirements for the products

6.2.1 The products shall not have been tested on animals.

6.2.2 The products shall be easily bio-degradable. The compliance to this requirement shall be verified through testing according to test method 301-b (OECD 1997) or another equivalent test.

6.2.3 The products shall not present acute toxicity. The compliance to this criteria shall be verified through testing, according to test method presented in one of the following standards:

a) ABNT NBR 12713:2004 - Aquatic Ecotoxicology - Acute toxicity - Test method using Daphnia spp (Crustacea, Cladocera);

b) ABNT NBR 15088:2004 - Aquatic Ecotoxicology - Acute Toxicity - test method with using fish;

c) ABNT NBR 15308:2005 - Aquatic Ecotoxicology - Acute Toxicity – Test method with using] mysidacea (crustacean).

6.2.4 The products must substitute components of animal origin by means of extract with vegetable base.

6.2.5 Prohibited substances:

a) Chemical substances which are included on lists of proven (group 1) or probable (group 2) carcinogenics, from IARC:
(see http://www.absoluteastronomy.com/topics/International_Agency_for_Research_on_Cancer);

b) Phosphates;

c) Linear alkylsulphonates (LAS);

d) Nitrilotriacetic acid or any of its salts (NTA);

e) Boric acid, borates and perborates (including as pH regulators);

f) Substances classified as R23 – R29 inclusive;

g) Substances classified as R45 – R49 inclusive;

h) Substances classified as R60 – R68 inclusive;

i) Chelating agent ethylenediaminetetraacetic acid (EDTA) – except solid soap – see item 6.2.5.a;

j) Alkylphenol ethoxylate (APEO);

k) Halogenated organic solvents or butoxiethanol.

6.2.6 Restricted substances

a) The complexing agent, EDTA (CAS No. 64-02-8), its salt and phosphonates may be present only in solid soap, with the total quantity ≤ 0.6 mg/g CA.

b) Aerobic and anaerobic non-biodegradable organic substances (aNBDO & anNBDO), with the exception of surfactants, must not exceed the limits in Table 1. These limits also apply for products intended for animals.

Table 1: Aerobic and anaerobic non-biodegradable organic substance limits.

SUBSTANCE	LIMIT
Shampoo, body washes, liquid soap	15 mg/g CA
Solid soap	10 mg/g CA
Conditioner	30 mg/g CA

6.2.7 Surfactants

a) All surfactants must be readily biodegradable. In testing biodegradability, test method N° 301 B - Guidelines for the Testing of Chemicals / Section 3: Degradation and Accumulation Test N°. 301: Ready Biodegradability, or other equivalent test method.

b) All surfactants must also be anaerobically biodegradable. For testing anaerobic biodegradability, ISO 11734 – “Water quality — Evaluation of the "ultimate" anaerobic biodegradability of organic compounds in digested sludge — Method by measurement of the biogas production”, or other equivalent test method, shall be used. The requirement is a minimum of 60% ultimate degradability under anaerobic conditions.

6.2.8 Colourants

a) All colourants used must be included 1n the “List of Colouring Agents Allowed for Use in Cosmetic Products” in Annex IV of European Commission Directorate 76/768/EEC.

b) Organic colouring agents must not be bioaccumulative. In testing bioaccumulativity, test method ISO 11734 Water quality - Evaluation of the "ultimate" anaerobic biodegradability of

organic compounds in digested sludge - Method by measurement of the biogas production, or other proved equivalent test methods shall be used

6.2.9 Fragrances

a) Fragrances used must comply with the International Fragrance Association's (IFRA) Guidelines as described in Code of Practice, available in the site of IFRA (www.ifraorg.org).

b) The fragrances/substances in table 3 represent a potential effect of dermic sensitivity. The presence of these substances in the product shall be clearly indicated in the list of ingredients referred to if their concentration exceeds:

– 0.001% for products that remain on the skin;

– 0.01% for rinsable products.

Table 3: Fragrances with potential to produce dermic sensitivity

NAME	CAS no
Amyl cinnamal	122-40-7
Benzyl alcohol	100-51-6
Cinnamyl alcohol	104-54-1
Citral	5392-40-5
Eugenol	97-53-0
Hydroxycitronellal	107-75-5
Isoeugenol	97-54-1
Amylcinnamyl alcoho	101-85-9
Benzyl salicylat	118-58-1
Cinnamal	104-55-2
Coumarin	91-64-5
Geraniol (rhodinol)	106-24-1
Methyl heptine carbonate	31906-04-4
Anisyl alcohol	105-13-5
Benzyl cinnamat	103-41-3
Farnesol	4602-84-0
2-(4-tert-butylbenzyl)-propionaldehyd (Lilial)	80-54-6
Linalool	78-70-6
Benzyl benzoate	120-51-4
Citronellol	106-22-9
Hexyl cinnamaldehyd	101-86-0
d-Limonen	5989-27-5
Methyl heptin carbonat	111-12-6
3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-on	127-51-5

Table 3: Fragrances with potential to produce dermic sensitivity (cont.)

NOME	N° CAS
Oak moss	90028-68-5
Tree moss	90028-67-4
Musk Ketone	81-14-1

6.3 Manufacturers requirements

6.3.1 Packaging requirements

a) Halogenated or chlorinated plastics shall not be used in products' packaging;

b) Plastic packaging with a weight higher than 50g shall be marked with a appropriate resin identity code promulgated by the Plastics and Chemical Industry Association [http://www.pacia.org.au] or in conformity with ISO 11469.

c) Packaging shall not be impregnated, labeled, coated or treated in such a manner which may impede its recycling (metaLlic labels, for instance).

6.3.2 Environmental requirements

a) The manufacturer shall establish a plan for continuous reduction of energy and water consumption and a process for control and revision of reduction goals:

a.1) The manufacturer shall establish a program for the re-use of water used in cooling systems, steam generation, as well as in procedures for cleaning and sanitizing of machines, equipments, transfer pipes and hoses.

a.2) The manufacturer shall establish a program for the reduction of waste generation and for an adequate destination for the waste that is generated, including those that are recyclable;

b) The manufacturer shall qualify its suppliers of raw materials and services (such as transporters). The criteria for qualification shall include desirable environmental criteria.Suppliers who comply to these criteria shall be given priority in choice;

c) The manufacturer shall encourage its distributers (if any) to adhere to the same desirable environmental requirements established for the qualification of suppliers (see item "b" above);

d) The manufacturer shall plan the implementation of an environmental management system in accordance to ABNT NBR ISO 14001 (in case it has not yet been done);;

e) The products shall be manufactured in such a manner as that the material used in can be recycled.

6.3.3 Product information

a) The product shall be accompanied by instructions for proper and adequate use in order to maximize its performance and minimize waste.

b) Certified products shall show a list of the ingredients contained in the product, in the packaging box.

7 Using test laboratories

7.1 ABNT is responsible for laboratory selection for the performance of tests which will be used in the process of concession and maintenance of ABNT's Environmental Quality Mark – ABNT Ecolabel.

7.2 When using laboratories accredited by Inmetro or laboratory accredited by Accreditation Bodies from other Countries with which Inmetro has Mutual Recognition Agreement, the laboratories need not be evaluated.

7.3 When non accredited laboratories are used, they shall be evaluated in accordance to item 7.5 of PG-11 - General Procedure for ABNT Environmental Quality Label.

7.4 In case of using a first part laboratory (laboratory owned by a manufacturer), ABNT shall accompany the execution of all tests for concession and maintenance of certification, regardless the laboratory be accredited or not.

8 Compliance to legal requirements

8.1 Compliance to environmental regulations

The manufacturer shall comply to the applicable regulations and legislation at the federal, state and municipal levels considering also, but not limited to, aspects related to emissions, effluents and waste. Whenever a manufacturer operates in a foreign jurisdiction, the Environmental regulations of that jurisdiction apply.

In case the manufacturer has a product line exclusively destined to exportation, the product may comply only to the target market regulation, provided the following premises are met:

a) The manufacturer shall clearly state on the packaging that the product is destined exclusively for exportation;

b) The regulations relating to the production process shall be complied considering the site where the production takes place.

8.2 Compliance to regulations related to workers, anti-discriminatory and safety

The manufacturer shall demonstrate that all workers are covered by a work situation that is in conformity with Brazilian legislation (see annex 1), whether by CLT(Working Law Consolidation) or other legally accepted working contract. General conformity to federal, state or municipal legislation relative to the security and occupational health of the workers shall also be demonstrated.

Whenever a manufacturer operates in a foreign jurisdiction the regulations for non-discrimination, security, occupational health and work legislation of said jurisdiction apply.

9 Certification process description

9.1 Required documents

The manufacturer shall forward the documents listed below to ABNT for analysis:

a) Project/detailed specifications for each product to be certified with photo;

b) Documentation of the environmental management system, if existing;

c) Copy of the contract registered under Commercial Official Department;

d) Copy of Official Register of Real State;

e) Site floor plan;

f) Geographical Location updated (specifying the area surrounding the site - rivers, conservation areas, communities, industries, among others);

g) List of the main raw materials used in the production process;

h) List of key inputs that are needed to carry out the production process;

i) Environmental Permits;

j) Schematic flowchart of the production process, from raw material input to the output of the finished product;

k) Internal flow of water, energy, waste, effluents and emissions, with regard to manufacturing the product under concession.

9.2 Preliminary analysis of the process

The documentation shall be analyzed by ABNT to verify its adequacy and content, resolving any eventual outstanding together with the manufacturer.

9.3 Pre-audit

After approval of the documents presented, ABNT will carry out a pre-audit at the manufacturer's facilities, with the following objectives:

a) Evaluate the manufacturer's location and the specific conditions of the local and discuss with the manufacturer to verify the level of preparedness for the certification audit;

b) Evaluate the manufacturer's understanding considering the criteria that must be complied with in order to obtain the certification;

c) Collect necessary information related to the processes and manufacturer's location, legal and regulatory aspects;

d) Evaluate the allocation of resources for the certification audit, as well as facilitate the certification audit planning.

9.4 Certification audit

Once all irregularities and outstanding issues have been eliminated from the documents and having found solutions for any comments made during the pre-audit, the certification audit will take place and shall encompass the following aspects:

9.4.1 Evaluation of the projects/specifications

ABNT will evaluate at the manufacturers facilities if the products to be certified are being manufactured in accordance with the projects/specifications that have been presented, along with

the manner in which the manufacturer controls the production process in order to ensure compliance to the requirements.

9.4.2 Evaluation of the compliance to performance criteria and legal requirements

ABNT will verify if the manufacturers' product and/or processes, which are the object of certification, are in compliance to the requirements of items 6 and 7 of this procedure. The requirements which cannot be evaluated during the audit, for example those which needs laboratory testing for proof, the manufacturer shall demonstrate the manner in which the production process is controlled, as well as its relationship with suppliers, distributers and customers, in such a manner as to comply to the requirements.

9.5 Sample collection

ABNT will collect from the Manufacturers' expedition area the quantity of samples necessary for the completion of tests. Samples of all products that are the object of certification shall be collected.

The samples for testing shall be composed of proof, counter-proof and testimony. The samples shall be sealed by ABNT. The identification of the seals will be registered on the form for sample collection. The proof samples shall be sent to the testing laboratory indicated by ABNT, accompanied by a copy of the form for sample collection. The samples for counter-proof and testimony shall be stored for a minimum period of 6 (six) months, for the purpose of possible contestation. The manufacturer shall take the necessary precaution measures in order to preserve the seals on the samples sent to the testing laboratory, as well as those stored for the purpose of possible contestation.

9.6 Sampling conditions

The products shall be evaluated per production unit. This initial sampling shall take place at the factory, selecting products that are ready for expedition.

In the case that the products present in the expedition area do not represent a random sampling, ABNT shall communicate this fact to the manufacturer immediately in order to outline the collection of product samples from its clients or distributors.

9.7 Tests

For the evaluation of product conformity, the necessary tests for proof the compliance to the requirements established in item 6 of this procedure shall be held.

9.8 Initial evaluation

For the approval of the concession of the ABNT Environmental Quality Mark, the tested samples must succeed in the tests related in item 9.7 of this procedure, as well as the evaluation of the compliance to the requirements required in items 6, 7 and 8 shall demonstrate conformity throughout the entire process.

In case of failure of any of the tested products during this phase, the certification of non-conforming product will not be granted until the resolution of the problem.

After the implementation of the corrective action, ABNT shall schedule a new collection of samples and the completion of new tests. In this case the, quantity of samples for each product that has failed shall be double the quantity of the original sampling, if possible from different batches. If the tested samples succeed, the certification will than be granted to the product.

9.9 Certification concession

When all the previously steps have been completed, CT emits a conclusive opinion and send the process to GSI for analysis. In the case of approval by the GSI, ABNT will emit the Environmental ABNT Quality Mark Certificate, which is the license for use of the label on the product (Ecolabel).

In case of failure, the reasons will be communicated to the manufacturer so that the necessary corrective actions are taken and the product can return to the certification process. The corrective actions as well as the actions taken to return to the certification process shall be agreed with ABNT.

9.10 Certification maintenance

After the concession of the Certification, ABNT shall carry out the control for the verification of the manufacturers' maintenance of the techno-organizational conditions which gave origin to the certification. This verification will be completed through maintenance audits and sample collecting at the factory and from the market place.

9.10.1 Maintenance audits

The audits will be held annually at previously set times and dates agreed to by the manufacturer. In these audits the following aspects will be considered:

9.10.2 Evaluation of projects/specifications

ABNT will verify at the manufacturer's factory, whether the certified products continue to be manufactured according to the originally presented projects/specifications.

9.10.3 Evaluation of the compliance to performance criteria and legal requirements

ABNT will verify if the manufacturers' product and/or processes, which are the object of certification, are in compliance to the requirements of items 6 and 7 of this procedure. The requirements which cannot be evaluated during the audit, for example those which needs laboratory testing for proof, the manufacturer shall demonstrate the manner in which the production process is controlled, as well as its relationship with suppliers, distributers and customers, in such a manner as to comply to the requirements.

9.10.4 Sample collection

ABNT will collect samples of certified products every six months. This collection will be held alternately, one at the factory (during the maintenance audits) and the other on the market place. Will collect the amount of samples required for conducting the tests. The necessary quantity of samples needed for testing shall be collected for all certified products.

ABNT will inform the manufacturer of the date for the sample collection from the market place so as the manufacturer can accompany the sample collecting and substitute the products collected from

distributers or customers. The manufacturer shall provide ABNT with an updated list of distributers and customers as to let ABNT collect the samples in a random manner.

The samples for testing shall be composed of proof, counter-proof and testimony. The samples shall be sealed by ABNT. The identification of the seals will be registered on the form for sample collection. The proof samples shall be sent to the testing laboratory indicated by ABNT, accompanied by a copy of the form for sample collection. The samples for counter-proof and testimony shall be stored for a minimum period of 6 (six) months, for the purpose of possible contestation. The manufacturer shall take the necessary precaution measures in order to preserve the seals on the samples sent to the testing laboratory, as well as those stored for the purpose of possible contestation.
ABNT will send the test results to the manufacturer. In the case of non conformity being found during tests (non compliance to any requirement) the manufacturer shall present a action plan in up to 15 days for evaluation by ABNT.

9.11 Conformity evaluation

For certification maintenance, the tested samples shall succeed the tests related to item 9.7 of this procedure, as well as the evaluation of the requirements required in items 6, 7 and 8 shall demonstrate conformity throughout the entire process.

In case of failure in any tested products during this phase, the certification of the non conforming product will be suspended until the problem is resolved.

After the implementation of the corrective actions, ABNT shall schedule a new audit and sample collection for testing. In case the manufacturer do not present any non-conformity and the tested samples succeed, the manufacturer may return to using the ABNT Conformity Mark on the product.

After this audit the test sampling for this product shall happen on a quarterly basis until its conditions have reached the conformity originally demonstrated, then the sampling period shall return to bi-annual.

9.12 Criteria modifications

If after the concession of the ABNT Conformity Mark, or during the process of concession, changes occur in the established criteria for the certification of the product, ABNT shall concede a period which will allow the certified manufacturers to adequate the products to the modified requirements.

9.13 Self-control

During the audits, the manufacturer shall demonstrate to ABNT how the production process is controlled so as to maintain the product in conformity with the established criteria of this procedure. This scheme will be subject to ABNT's approval and may be considered as a non-conforming item if not approved.

/Annex 1

Annex 1

Legislation pertinent to the sector

According to Brazilian sanitarian legislation, personal hygiene products, perfumery and cosmetics are defined and regulated in relation to the way and purpose to use through the law 6360 of September 23, 1976 and its updating, which establish the sanitary vigilance under which these products are subjugated, regulated by the Decree Law 79.094 of January 05, 1977 and other specific valid standards.

ANVISA - National Agency for Sanitary Vigilance, was created in order to regulate, control and supervise products, substances and services of health interest, which includes cosmetic products.

ANVISA published, on August 28, 2000, the resolution nº 79, in order to make national regulations compatible with the already harmonized instruments in the scope of Mercosul (GMC-110/94) adopting as definition of cosmetics, hygiene products and perfumes:

"Preparations constituted by natural or synthetic substances, for external use over the diverse parts of the human body, skin, capillary system, nails, lips, external genital organs, teeth, mucous membranes of the oral cavity, with the principal or exclusive objective of cleaning them, perfuming them, altering their appearance and/or correcting body odor and/or protecting them or maintaining them in a good state".

Law nº 6360 of September 23, 1976 – "Dispose about the sanitary vigilance under which are subjected medicines, drugs, pharmaceuticals inputs and correlates, cosmetics, cleansers and other products syrups and related products, cosmetics, cleansers and other products, and establishes other provisions".

Law nº 10.669 of May 14, 2003 – "Alters the law 6.360 of September 23, 1976 which dispose about the sanitary vigilance under which are subjected the medicines, drugs, pharmaceuticals inputs and correlated products, cosmetics, cleansers and other products".

Law nº 9.782 of January 26, 1999 – "Defines the National Sanitary Vigilance System, creates the National Agency for Sanitary Vigilance and establishes other provisions, in particular with respect to article 8th which assigns the Agency, respecting the valid legislation, to regulate, control and supervise the products and services which involve risks to public health.

§ 1st – III - Cosmetics, perfumes and personal hygiene products are goods and products which are considered to be under the control and sanitary supervision of the Agency.

Supplementary São Paulo state law n. 791 of March 9, 1995 (Health Code) –

"Article 1st – This code establishes standards for public order and social interest for the promotion, defense and recuperation of health, under the terms of the States' Constitution and Republics' Constitution, and disposes about the organization, the regulation, the supervision and the control of actions and of health services in the State and Municipal scope.

Article 17 – The state directory of SUS is also responsible for:

I - Coordination and, in a complementary situation, execute actions and services for:

c) sanitary vigilance;

§1st – The activities of sanitary vigilance and epidemiologic vigilance will be executed jointly and in integration with other sectors, which include those responsible for basic sanitation, energy, urban planning, public works, agriculture and environment.

§ 2nd - Sanitary vigilance will encompass the group of actions capable of eliminating, reducing or preventing health risks and to intervene in the sanitary problems resulting from the environment, including the work place, from the production and circulation of goods and rendered services of health interest.

Article 34 – Is responsibility of sanitary authority, through official letter or by means of health risk denunciation, proceed to the evaluation of the risk sourced in the environment, including the site and work processes, and determine the adoption of the providences in order to stop the motives which gave cause.

CONAMA Resolution 357, of March 17, 2005. Establishes that the industrial spills must be treated in order to the physicochemical characteristics of the effluents be in accordance to the patterns established in the Resolution.

São Paulo State Decree n° 8468/76. Regulation for releasing industrial effluents.