

18 April 2017

Original: English

(17-2102) Page: 1/2

Committee on Technical Barriers to Trade

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: BRAZIL

If applicable, name of local government involved (Article 3.2 and 7.2):

2. Agency responsible: Brazilian Health Regulatory Agency (Anvisa)

Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:

National Institute of Metrology, Quality and Technology (INMETRO)

Telephone:+(55) 21 2563.2765 Telefax: +(55) 21 2563.5637

Email: <u>barreirastecnicas@inmetro.gov.br</u>

Web-site: www.inmetro.gov.br/barreirastecnicas

The comments to this Draft Regulation shall be sent to

http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=30771.

- 3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
- 4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Hair products
- **5. Title, number of pages and language(s) of the notified document:** Draft Technical Resolution n. 323, 21 March 2017. 6 pages, Portuguese.

6. Description of content:

This Draft Resolution:

- Establishes technical requirements for authorization of products to modify hair format by changing its chemical structure;
- Creates the List of Allowed Active Ingredients in such products, establishes the conditions for its use; and
- Establishes criteria for approval of new active ingredients.

For this Resolution, the cosmetic products to modify the shape of the hair by changing chemical structure are those that modify the chemical structure of hair to relax, smooth or curl the hair after rinsing. The products referred in this Resolution should only contain ingredients in the List of Active Ingredients Allowed in Cosmetic Products to Modify the Hair Format by altering its chemical structure published as a normative instruction.

The labelling of cosmetic products shall contain the following warnings: "This product should only be used for its intended purpose, being DANGEROUS to any other use" "Do not apply if the scalp is irritated or injured"; "keep out of the reach of the children"; "Do not use in children"; "For use in pregnant women and nursing mothers, consult a Doctor or physician"; "Perform the test on a lock of hair before use it".

The companies holding products already regularized by ANVISA will have twelve months from the date of publication of this Resolution for adequacy. This resolution comes into force on the date of its publication.

- 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of Human Health
- 8. Relevant documents: Brazilian Official Journal (Diário Oficial da União), 22 March 2017; Section 1 page 71/72. Draft Resolution (Consulta Pública) number 323, 21 March 2017, issued by the Brazilian Health Regulatory Agency Anvisa; when adopted, it will be published at Brazilian Official Journal. Available in Portuguese
- 9. Proposed date of adoption: To be determined after the end of the consultation period.
 Proposed date of entry into force: To be determined after the end of the consultation period.
- 10. Final date for comments: 29 May 2017
- 11. Texts available from: National enquiry point [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

Agency Responsible Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF/Brazil

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http://portal.anvisa.gov.br/documents/10181/3317277/CONSULTA+P%C3%9ABLICA+N+

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