



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6.

1. Notifying Member: <u>Brazil</u> If applicable, name of local government involved (Articles 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 2145.3817 Telefax: +(55) 21 2563.5637 Email: barreirastecnicas@inmetro.gov.br Web-site: www.inmetro.gov.br/barreirastecnicas
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): HS Code(s): 3402; 3808 (household cleaning products)
5. Title, number of pages and language(s) of the notified document: Draft Resolution number 970, 7 December 2020. Language(s): Portuguese. Number of pages: 18. Draft: http://antigo.anvisa.gov.br/documents/10181/6149455/CONSULTA+P%C3%9ABLICA+N+970+COSAN+GHCOS.pdf/0a6eba23-3be6-4707-a8f6-f250d0114f1b Comment form: http://formsus.datasus.gov.br/site/formulario.php?id_aplicacao=60785
6. Description of content: This draft resolution establishes the procedures and technical requirements for the registry of furniture paint with sanitizing action.
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health. Since 2011, after the identification of paints touting sanitising action in the market without proper proof, ANVISA sanitizing area began to receive requests for authorization of paints and other products that initially do not have this purpose, but that incorporated ingredients in the formulation that characterize them as sanitizing. Thus, it became necessary to request authorization from the Agency to inform consumers that the products, in addition to the purpose for which they are already known, also have a sanitising action such as antibacterial, antifungal, repellent, insecticide. In view of the increasing number of requests for authorization to market paints with sanitising action, the lack of its own rules, which generates legal uncertainty due to the adaptation of the situation to product standards with similar action, as well as the lawsuits perpetrated against ANVISA, it becomes imperative and urgent framing of paints and other

<p>products with disinfectant/disinfectant action, as sanitising products subject to registration, in accordance with law 6.360/1976.</p> <p>Thus, the aim is to regularize these products on the market, ensure their efficacy and safety, and, at the same time, contribute with greater legal certainty.</p>
<p>8. Relevant documents: 1) Brazilian Official Gazette 235 on 09 December 2020, section 1, page 374; 2) Impact Report 3) Resolution draft</p> <p>https://www.in.gov.br/web/dou/-/consulta-publica-n-970-de-7-de-dezembro-de-2020-293179534</p> <p>http://antigo.anvisa.gov.br/documents/10181/6149455/Relat%C3%B3rio+de+mapeamento+de+impacto+-+REMAI.pdf/9371a10c-49a1-4b74-aac9-d91303216215</p> <p>http://antigo.anvisa.gov.br/documents/10181/6149455/CONSULTA+P%C3%9ABLICA+N+970+COSAN+GHCOS.pdf/0a6eba23-3be6-4707-a8f6-f250d0114f1b</p>
<p>9. Proposed date of adoption: To be determined after the end of the consultation period.</p> <p>Proposed date of entry into force: To be determined after the end of the consultation period.</p>
<p>10. Final date for comments: 15 February 2021.</p>
<p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>Brazilian Health Regulatory Agency (Anvisa) SIA, Trecho 5, Área Especial 57 Brasília – DF / Brazil CEP: 71.205-050 Phone.: +(55) 61 3462.5402 Website: www.anvisa.gov.br</p>