



Third Board
 Management of Hygiene, Perfume, Cosmetics and Sanitizing Products
 Sanitation Coordination
 SIA Stretch 05, Special Area 57, Brasília/DF, CEP 71205-050
 Telephone: 0800 642 9782 - www.anvisa.gov.br

Office nº 27/2021/SEI/COSAN/GHCOS/DIRE3/ANVISA

THE
 INCOCRYL INDÚSTRIA E COMÉRCIO DE TINTAS LTDA

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Subject: **VARNISH - REVITARE NANO IS-47.**

Reference : If you respond to this Ofício, expressly indicate Process No. 25351.927747/2020-18.

In response to the request for authorization to sell varnish with sanitizing action called **VERNIZ - REVITARE NANO IS-47** , I position it below.

Considering that varnishes / varnishes do not require registration as sanitizers in this Agency, according to the guidelines of the Technical Report - INF-022/2015 , but due to sanitizing action announced on the label, the technical dossier of the product sent to Anvisa was evaluated.

After technical evaluation by the Sanitation Agents on toxicological studies and considering that:

1. The ingredient used by Silver (Silver Clean 800) is in accordance with the ones used for products Disinfectants;
2. the label presented for free sale meets the specific requirements; and,
3. the following tests and information were presented:
 - qualitative composition;
 - physicochemical data;
 - accelerated stability test;
 - effectiveness tests, acute and residual (under conditions of accelerated stability);
 - oral acute toxicity test.

The toxicological suitability and the bacterial and virucidal efficacy of **VERNIZ - REVITARE NANO IS-47** , in the form of **FREE SALE** .

It is recommended that the company also maintain the studies presented within the scope of its facilities for inspection purposes or new requests from the National Health Surveillance System (SNVS).

The company is not authorized to use the Anvisa logo on packaging, labeling, or other prospectuses, or even in advertisements, as established by Law No. 6,360, of September 23, 1976.

We would like to inform you that the matter is a matter of ongoing regulation (**topic 9.6 of the Anvisa's Regulatory Agenda 2017/2020**), in the consolidation phase of the Public Consultation, which intends to establish the obligation to register the requested product, and may even establish to submissions of new tests and other obligations of a registered product, as soon as the standard specific to complete.

This manifestation does not support an indication in disagreement with the documentation technique presented.

Graciously,



Document signed electronically by **Webert Goncalves de Santana , Product Manager for Hygiene, Perfumes, Cosmetics and Substitute Sanitizers** , on 04/26/2021, at 15:44, as Brasília's official time, based on art. 6, § 1, of Decree No. 8.539, of October 8, 2015 [hp://www.planalto.gov.br/ccivil_03/ Ato2015-2018/2015/Decreto/D8539.htm](http://www.planalto.gov.br/ccivil_03/ Ato2015-2018/2015/Decreto/D8539.htm).



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Reference: If you respond to this Official Letter, expressly indicate Process No. 25351.927747/2020-18

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