

SAFE GUARDS

SGS CONSUMER TESTING SERVICES

COSMETICS, PERSONAL CARE & HOUSEHOLD

NO. 084/13 MAY 2013

NEW COSMETIC REGULATION APPROVED IN BRAZIL- RDC N° 15/2013

The new Technical Regulation that establishes a "List of Substances for Cosmetic Use: Lead Acetate, Pyrogallol, Formaldehyde and Paraformaldehyde" was approved on the 26th of March, 2013. This Regulation incorporates the Regulation GMC Mercosur n° 48/2010.

Pyrogallol, used as a dye for hair oxidation, is included in the restricted substance list as is already the case in the EU since 1976. The use of pyrogallol is allowed within the optimal concentration (the maximum concentration of 5% in hair dyes), however the label on the packaging of products containing pyrogallol in its formulation must include a warning indicating the presence of this component and restrictions on use.

The use of Formaldehyde and Paraformaldehyde as preservatives was already forbidden in aerosols. The maximum allowed concentration is now 0,1% for hygienic products; 0,2% for other products and 5% for formaldehyde in nail hardeners.

The RDC no. 15/2013 approves Lead Acetate in hair dye with a maximum concentration of 0,6% (calculated as lead)

The following table provides a comparison between the previous legislation and the new regulations:

LEGISLATION REPEALED	NEW RESOLUTION - RDC N°15, FROM MARCH 26, 2013
Prohibition was on the provisory list II of RDC 215/05 (provisory list II was revoked).	Approves the lead acetate for hair dye with maximum concentration of 0,6% calculated as lead. With limited purity higher as 99% Lead Acetate and insoluble material in water not more than 0,02%. Conditions of use and warnings which must appear on the label: <ul style="list-style-type: none">• Keep away from children;• Avoid contact with eyes;• Do not use if pregnant;• Wash hands after use;• Contains lead acetate;• Do not use to dye face hair;• In case of irritation, discontinue use and seek medical advice;• Do not use onin irritated and injured scalp;• Read and follow all the directions ;• The use of gloves during the use is recommended;

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The logo for SGS, consisting of the letters 'SGS' in a bold, sans-serif font. A vertical orange line is positioned to the right of the 'S', and a horizontal orange line is positioned below the 'S'.

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LEGISLATION REPEALED	NEW RESOLUTION - RDC N°15, FROM MARCH 26, 2013
It was on the item number 5 (revoked) of RDC 162 from 09/11/2001 the same maximum permitted concentration and the ban of only aerosols. It was added in the resolution the prohibition in sprays and mandatory labeling with the conditions of use and warnings.	Formaldeyhde and Paraformaldeido (used as preservatives) Maximum concentration allowed: 0,1% - in oral hygiene products 0,2% - other products not intended for oral hygiene (expressed as free formaldehyde) Banned in sprayable systems (such as aerosols and sprays) Conditions of use and warnings that must appear on the label: Contains formaldehyde (only for concentrations above 0,05% in the final product)
It was on the item 13 (revoked) of RDC 215/05 the same maximum permitted concentration.	Formaldehyde (used as nail hardener) Maximum concentration allowed: 5% calculated as formaldehyde Conditions of use and warnings that must appear on the label: 1) Protect the cuticle with oil 2) Contains formaldehyde (only for concentration above 0,05% in the final product)
There was nothing defined in the current legislation	Pyrogallol used as hair dye Maximum concentration allowed: 5% at pH 5 Conditions of use and warnings which must appear on the label: <ul style="list-style-type: none"> • It can cause allergic reactions • Contain Pyrogallol • Keep away from children; • Do not use to dye face hair; • The use of gloves during the use is recommended;

It is crucial for all cosmetic, personal care and household products to be safe effective and stable. SGS provides testing, inspection, auditing and consulting services to manufacturers, distributors and importers to ensure a high level of product quality in every area. Our state of the art laboratories offer custom-made solutions for chemical, biophysical, microbiological, stability and biological aspects. We also have extensive capabilities in performance testing, claim support studies and consumer panels. Our testing is conducted according to customer specific or recognised standard methods, some of which were developed by SGS. Our cosmetic safety assessors and other technical experts can support customers by making sure new products comply with regulatory requirements.

Please do not hesitate to contact us for further information or [visit our website](#).

Source of information:

<http://www.in.gov.br/visualiza/index.jsp?jornal=1&pagina=55&data=27/03/2013>

FOR ENQUIRIES:

Global Competence Support Centre: gccsc@sgs.com
BR—Adriana Moreira, Tel: +55 11 3883 8807 or adriana.moreira@sgs.com

Asia – Hong Kong. Tel: +852 2334 4481 Fax: +852 2144 7001 mktg.hk@sgs.com
Australasia – Perth. Tel: +61 (0) 3 9790 3418 Fax: +61 (0) 3 9701 0988 au.cts@sgs.com
Europe – London – UK. Tel: +44(0) 203 008 7860 Fax: +44 (0) 203 00 7870 gb.cts.sales@sgs.com
Africa & Middle East – Turkey. Tel: +90 212 368 40 00 Fax: +90 212 296 47 82 sgs.turkey@sgs.com
Americas – USA. Tel: +1 973 575 5252 Fax: +1 973 575 7175 uscts.inquiries@sgs.com

www.sgs.com/cts Global Competence Support Centre: gccsc@sgs.com

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