

SAFEGUARDS

SGS CONSUMER TESTING SERVICES

COSMETICS, PERSONAL CARE AND HOUSEHOLD

NO. 004/13 JAN 2013

US FINAL RULE ON SUNSCREEN PRODUCTS COMES INTO FORCE

US Food and Drug Administration (FDA) has published the sunscreen final rule 'Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-the-Counter Human Use'¹ in mid 2011. After a 6-month delay of compliance dates of the final rule, products with annual sales of more than US\$ 25,000 have to comply with the final rule as of 17 December 2012. For other products, the deadline is extended until 17 December 2013.



Reference:

¹ [Guidance for Industry, Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use – Small Entity Compliance Guide](#)

² [Guidance for Industry: Enforcement Policy – OTC Sunscreen Drug Products Marketed Without an Approved Application](#)

³ [Q&A: FDA announces new requirements for OTC sunscreen products marketed in US](#)

⁴ [The final rule 2011: Labeling and Effectiveness Testing: Sunscreen Drug Products for Over-The-Counter Human Use](#)

A **Broad Spectrum claim** is newly introduced. Two tests can be conducted to make claims on sunscreen products. In vivo Sun Protection Factor (SPF) test measures the ability of the product to protect against sunburn, while in vitro Broad Spectrum Test measures the ability of the product to protect against both UVA and UVB.

	PRODUCT CLAIMS
SPF value 15 or higher with Broad Spectrum claim	Reduce the risk of skin cancer and early skin aging if used as directed with other sun protection measures
<ul style="list-style-type: none">• SPF value 15 or higher without Broad Spectrum claim, or• SPF value 2 to 14 with Broad Spectrum claim	Help prevent sunburn

Water Resistance claim for 40 minutes or 80 minutes is allowed. Claim could be substantiated if a sunscreen product remains effective for certain period of time while swimming or sweating, based on standard testing but claims which may overstate the effectiveness of the product are not allowed.

Misleading claims (NOT allowed)	<ul style="list-style-type: none">• Water-proof• Sweat-proof• Sun block• Protection immediately after application
---------------------------------	--

SGS

Requirements on Drug Fact sheet have to be followed for all sunscreen products which are considered as over-the-counter (OTC) drugs in US. It must be included on the information panel (side or back panel) of the container to indicate proper use based on the requirements from 21 CFR 201, (especially 21 CFR 201.66 and 201.327). FDA strongly recommends using the exact wordings and language provided in the regulation to deliver truthful and non-misleading statements to the consumers.

WHAT IS STILL UNDER DISCUSSION?

Since there is still no adequate information to support claims that products with SPF values higher than 50 can provide additional sun protection compared to products with SPF value of 50, SPF 50+ labeling is still subject to finalization². FDA is now working on the safety of spray products since there is a safety concern when the product is inhaled unintentionally³.

For products with annual sales more than US\$ 25,000, failure to comply with the final rule may lead to regulatory action⁴.

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](#).

FOR ENQUIRIES:

Global Competence Support Centre: gcsc@sgs.com

HK- Ivan Tsui. Tel: +852 2204 8374 (ext 1374) or Ivan.Tsui@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: gcsc@sgs.com

If you wish to unsubscribe to this technical bulletin, go here: [Unsubscribe](#)

© 2013 SGS SA. All rights reserved. This is a publication of SGS, except for 3rd parties' contents submitted or licensed for use by SGS. SGS neither endorses nor disapproves said 3rd parties contents. This publication is intended to provide technical information and shall not be considered an exhaustive treatment of any subject treated. It is strictly educational and does not replace any legal requirements or applicable regulations. It is not intended to constitute consulting or professional advice. The information contained herein is provided "as is" and SGS does not warrant that it will be error-free or will meet any particular criteria of performance or quality. Do not quote or refer any information herein without SGS's prior written consent.