

November 20, 2023

Sytenol®A is allowed for use in Chinese cosmetics: New notification #20230048 replacing old notifications #20220027 and #20230038

Dear Valued Customer,

We are pleased to announce that the extension of the scope of Sytenol® A (Bakuchiol)'s notification in China has been successfully accepted by NMPA since November 2023.

As a reminder, Sytenol® A has been notified as a new ingredient in China since August 2022.

Sytenol®A is now eligible to be used in cosmetic products for the Chinese marketplace with a wider scope of use. Thus, in the NMPA public platform you can find 3 notification numbers according to the following characteristics:

	(Old) notification number: #20220027	(Old) Notification number: #20230038	(New) Notification number: #20230048
Category	Low risk ingredient (scenario 3)	No change	No change
Chinese name	补骨脂酚	No change	No change
EC number	Incorrect EC #685-515-9	Corrected EC : #685-515-4	Corrected EC : #685-515-4
Use concentrations	0.1% to 2%; recommended 0.1 to 1%	No change	No change
Applications	face (excluding lips and eyes)	Lips, eyes, neck and hands (excluding face)	Extended to: face including lips and eyes, neck and hands
Claims	skin protectant, skin feeling regulator (in Chinese 肤感调节剂), skin moisturizer and antioxidant	No change	No change
Shelf life	3 years	Extended to: 4 years	Extended to: 5 years

If you have already applied with the old numbers #20220027 and #20230038, they are still effective, and you can continue to use them for your product notification/registration without needing a change if its application and claim remain the same (please refer to the table above).

However, we recommend you use the new number **#20230048** for any new application, since it has a broader scope.

We remind you that the notification dossier is strictly linked to Sytenol® A's purity (Bakuchiol ≥ 99% (w/w) HPLC assay, less than 25 ppm Psoralens/isopsoralens), analytical identification, specifications (refer to TDS), process and toxicology data. Developing cosmetics with this number while using another quality of bakuchiol is forbidden by the Chinese Regulation and is liable to severe penalties going up to the prohibition for the legal representative from engaging in cosmetics production and operation activities for life (Chapter V - art 59 of the CSAR Regulation).

Utilization of this document or parts thereof as well as product names for commercial or industrial applications is subject to explicit written approval by Sytheon. This information is based on our own experience to date and we believe it to be reliable. It is intended only as a guide to use at your discretion and risk. We cannot guarantee favourable results and we assume no liability in connection with its use, or the use of the methods or products described. None of this information is to be taken as a license to operate under, or a recommendation to infringe, patents.

There is an online approval process that Sytheon will need to sign prior to being able to use Sytenol®A to ensure it is the Bakuchiol in your formulations approved for commercialization in China. Please send us the information on your Chinese Responsible Person and your product to accelerate the process (a template of the information letter is available upon request).

When using Sytenol® A in your cosmetics products in China during the next three years there is a requirement to monitor for adverse reactions and report them to Sytheon. A yearly report of adverse effects linked to Sytenol® A will be prepared and sent by Sytheon to the NMPA according to the provision of the CSAR.

Please don't hesitate to reach out to us if you have any further questions.

Best regards,

Sophie DINAND

Regulatory Affairs and CSR Manager

CC: Ratan Chaudhuri -Sytheon Ltd President and CEO -ratan@sytheonltd.com François Marchio: Sytheon France Director - francois@sytheonltd.com Marie Delasson: Sytheon Asia-Pacific General Manager – marie@sytheonltd.com

Utilization of this document or parts thereof as well as product names for commercial or industrial applications is subject to explicit written approval by Sytheon. This information is based on our own experience to date and we believe it to be reliable. It is intended only as a guide to use at your discretion and risk. We cannot guarantee favourable results and we assume no liability in connection with its use, or the use of the methods or products described. None of this information is to be taken as a license to operate under, or a recommendation to infringe, patents.