

BỘ Y TẾ
CỤC AN TOÀN THỰC PHẨM

Số: 646 /ATTP-SP
V/v cảnh báo 02 sản phẩm bán online
có chứa lượng lớn tadalafil

CỘNG HÒA XÃ HỘI CHỦ NGHĨA VIỆT NAM

Độc lập – Tự do – Hạnh phúc

Hà Nội, ngày 07 tháng 3 năm 2019

Kính gửi:

BAN QUẢN LÝ ATTP

ĐẾN

Số: 883

Ngày: 07/3/2019

Chuyển: SS: Lan

Lưu hồ sơ:

Chi cục An toàn vệ sinh thực phẩm các tỉnh, thành phố trực thuộc

Trung ương

Ban Quản lý An toàn thực phẩm các tỉnh, thành phố: Hồ Chí Minh,
Đà Nẵng, Bắc Ninh

Cục An toàn thực phẩm nhận được cảnh báo từ Cơ quan Khoa học Y tế Singapore (HSA) đối với 02 sản phẩm không an toàn “Hickel” và “Solomon Island - Soloco Traditional Candy (gọi tắt là Soloco)” được quảng cáo là “kẹo” và bán online có chứa hàm lượng tadalafil (cao gấp 30 lần so với liều dùng hàng ngày cho phép), đây là dược chất không được sử dụng trong thực phẩm chỉ sử dụng điều trị rối loạn cương dương (có bản photo đính kèm), Cục An toàn thực phẩm đề nghị:

1. Kiểm tra rà soát việc tự công bố và đăng ký bản công bố đối với 02 sản phẩm nói trên, trường hợp đã tiếp nhận bản công bố và đăng ký bản công bố sản phẩm thì thực hiện các biện pháp thu hồi sản phẩm theo quy định đồng thời gửi báo cáo về Cục An toàn thực phẩm.

2. Không tiếp nhận bản tự công bố, đăng ký bản công bố, phối hợp với các cơ quan chức năng trên địa bàn giám sát việc lưu thông trên thị trường đối với 02 sản phẩm nêu trên.

3. Thông báo rộng rãi trên các phương tiện thông tin đại chúng để người tiêu dùng được biết và không sử dụng các sản phẩm này. *Nguyễn*

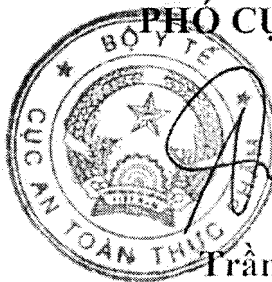
Trân trọng./.

Nơi nhận:

- Như trên;
- Cục trưởng (để b/c);
- Trang TTĐT Cục;
- Lưu: VT, SP.

KT.CỤC TRƯỞNG *[Signature]*

PHÓ CỤC TRƯỞNG



[Signature]
Trần Việt Nga



FOR IMMEDIATE RELEASE

**HEALTH SCIENCES AUTHORITY
PRESS RELEASE
26 FEBRUARY 2019**

**HSA ALERT: TWO PRODUCTS SOLD ONLINE AS CANDIES
CONTAINED VERY HIGH LEVELS OF POTENT ERECTILE
DYSFUNCTION MEDICINE**

The Health Sciences Authority (HSA) is alerting members of the public not to purchase or consume two unsafe products, 'Hickel' and 'Solomon Island Soloco Traditional Candy ('Soloco')' sold online. HSA's laboratory detected very high levels of tadalafil, an undeclared potent medicinal ingredient used in the treatment of erectile dysfunction in these products. The amount of tadalafil was up to 30 times higher than the usual prescribed daily dose. Consuming such high levels of tadalafil is dangerous and would increase the risk of serious adverse effects, including heart attacks, stroke, vision and hearing loss.

2 HSA was alerted to 'Hickel' by a journalist, while 'Soloco' was detected by the Immigration & Checkpoints Authority at the Woodlands Checkpoint when a 29-year old woman tried to bring the product into Singapore. Investigations showed that both products were sold on various local e-commerce and social media platforms including Facebook. Both products were advertised online to be "100% natural" and "pure plant formula" with "no side effects". They were also marketed in a manner to mislead consumers into thinking that they were candies, with exaggerated claims to improve cardiovascular and kidney health, diabetic conditions, vitality, fertility and immunity. HSA is working with the administrators of the local online platforms to remove the product listings.

3 In 2017, a similar illegal product, 'Candy B', was seized and tested by HSA to contain tadalafil¹. 'Hickel' and 'Soloco' were promoted to be "better than Candy B". Both products' contents were packaged individually in attractive wrappers inside tin containers or boxes. "Nutritional information", and food or quality certification marks

¹ https://www.hsa.gov.sg/content/hsa/en/News_Events/Press_Releases/2017/operationpangea2017.html

like the UK Food Standards Agency logo and the Good Manufacturing Practice (GMP) logo respectively, were also printed on the packaging. 'Soloco' was also affixed with a QR verification code for authenticity checks. These characteristics were likely intended to mislead consumers into thinking that the products are safe and of good quality.

Please refer to **Annex A** for photos of the two products.

DANGERS OF THE ILLEGAL PRODUCTS SOLD ONLINE

4 Tadalafil is a potent prescription medicine used to treat male erectile dysfunction and it should only be used under medical supervision. Inappropriate use of tadalafil without medical supervision would put consumers at increased risk of serious adverse effects. They include low blood pressure, stroke, heart attack and priapism (painful and exceedingly long erections). Tadalafil can pose serious risks to certain patients, including those with heart-related problems. It should not be used by patients who are on heart medications such as nitrates as it can cause potentially life-threatening low blood pressure, which may lead to death. Patients with heart problems are also at increased risk of cardiovascular adverse effects such as heart attack, stroke and chest pain.

ADVISORY TO CONSUMERS

5 Consumers are advised to:

- Stop taking 'Hickel' and 'Soloco' immediately and consult a doctor if you feel unwell. If you experience any adverse effects or are concerned about your health after using the affected product, please see a doctor as soon as possible.
- Be wary of health products that promise miraculous effects, carry exaggerated claims, or are marketed to be "100% natural" with "no side effects". Such products may contain undeclared potent ingredients or prescription medicines that should be used under medical supervision.

- Exercise caution when purchasing health products online, especially from unfamiliar websites. Anyone can be a seller on these e-commerce platforms. You cannot be certain where and how these products were made. They may be well-packaged or appear certified to meet international standards, but in fact contain undeclared ingredients which can seriously harm your health.

6 HSA has produced a short video on the risks associated with buying health products online. This video can be viewed at https://youtu.be/dmjI_bSqJgA.

WARNING TO SELLERS AND SUPPLIERS

- 7 All sellers and suppliers must stop selling 'Hickel' and 'Soloco' immediately.
- These are illegal products which contain potent medicinal ingredients.
 - Anyone who supplies illegal health products is liable to prosecution and if convicted, may be imprisoned for up to 3 years and/or fined up to \$100,000.

8 Members of the public who have any information on the sale and supply of these illegal products may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: hsa_is@hsa.gov.sg.

**HEALTH SCIENCES AUTHORITY
SINGAPORE
26 FEBRUARY 2019**

About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit <http://www.hsa.gov.sg/>.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

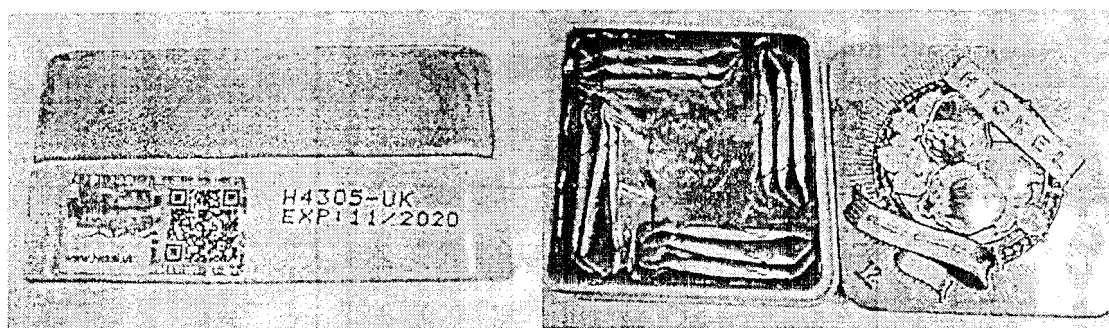
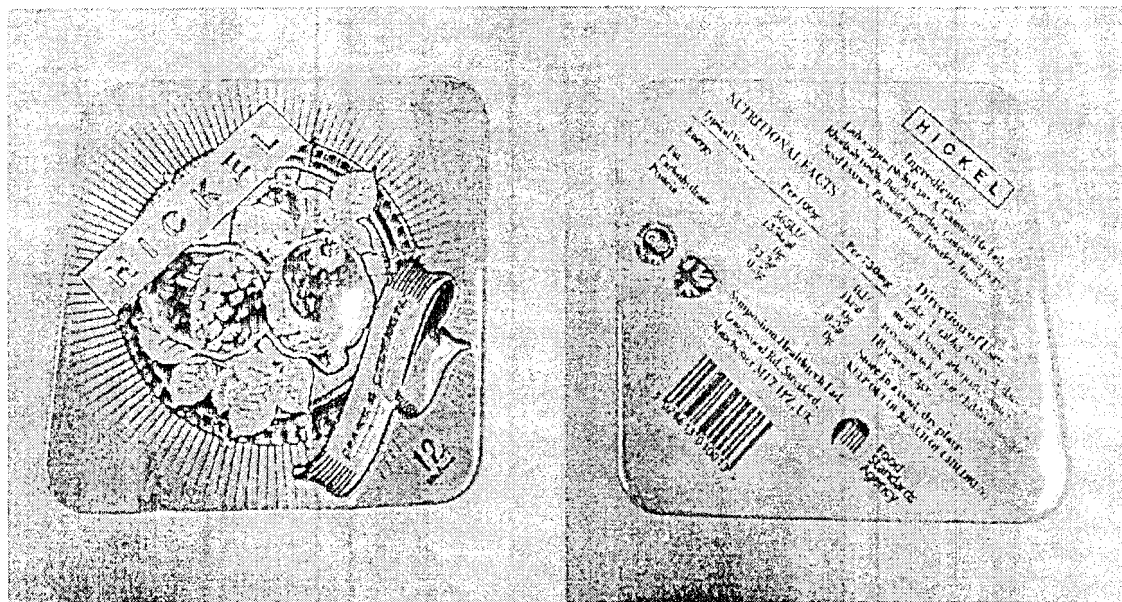
About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

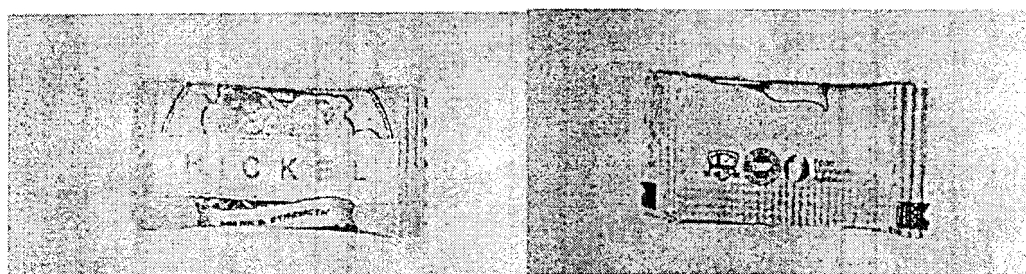
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Hickel

Tin box packaging

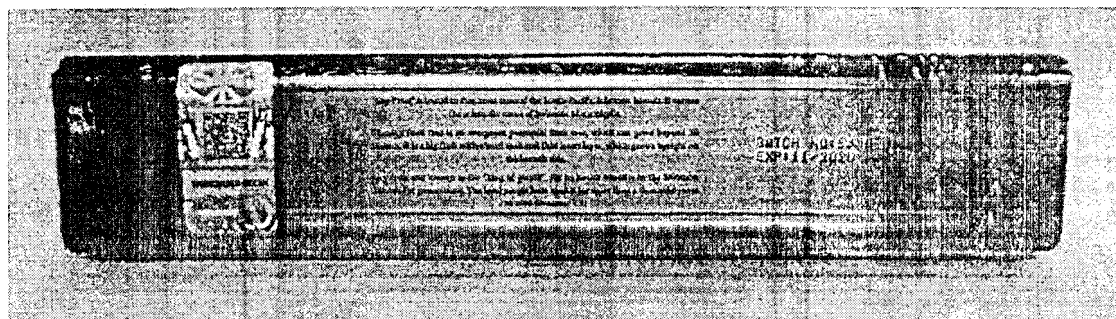
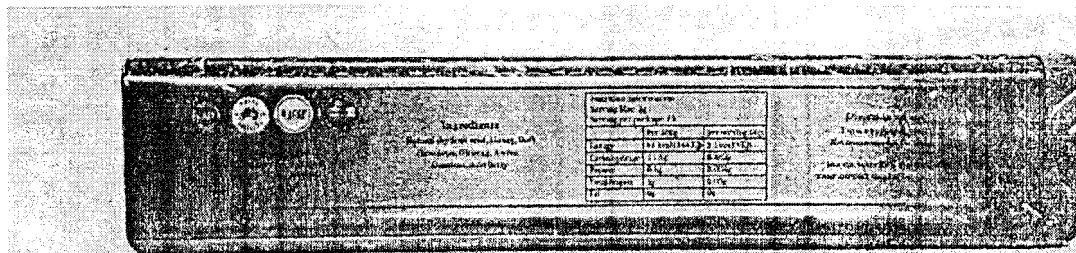


Product in individual wrapper



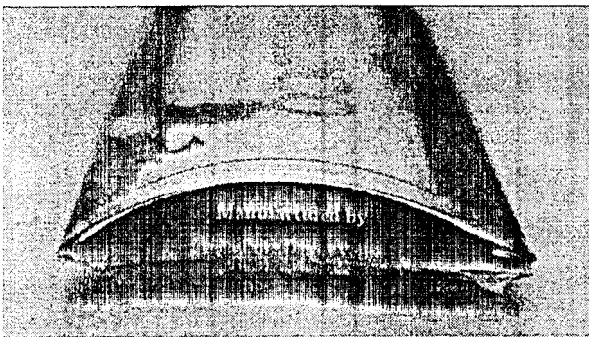
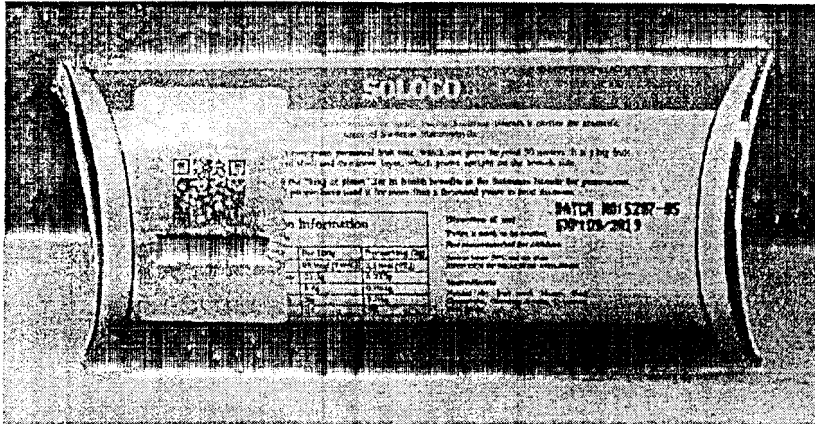
Soloco

Tin tube packaging



Box packaging





Product in individual wrapper

