Health Canada Santé Canada

STATUS DECISION OF CONTROLLED AND NON-CONTROLLED SUBSTANCE(S)

Substance: Indigo 3G

Based on the current information available to the Office of Controlled Substances, it appears that the above substance is:

Controlled	☐
Not Controlled	✓

under the schedules of the *Controlled Drugs and Substances Act* (CDSA) for the following reason(s):

- The ingredients in Indigo 3G are not similar to any of the substances included in the Schedules to the CDSA.

Prepared by: _____ Date: January 26th, 2012
Vincent Marleau

Verified by: _____ Date: _____
Mark Kozlowski

Approved by: _____ Date: _____
DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES

This status was requested by: Delano DeSilva

Drug Status Report

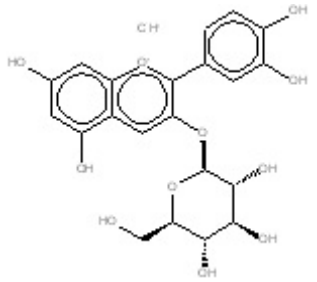
Drug: Indigo 3G

Drug Name Status: Indigo 3G is the brand name.

Indigo 3G is a dietary supplement manufactured by Biotest and is claimed to consist of the following ingredients:

- Cyanidin 3-glucoside
- Lauroyl macrogol-32 glycerides

Cyanidin 3-glucoside belongs to the anthocyanin group, which is the largest group of water-soluble pigments in plants[1]. This substance is not structurally similar to any of those listed in the CDSA and is not considered a controlled substance.



Name: Cyanidin 3-glucoside
Chemical Name: 1-Benzopyrylium, 2-(3,4-dihydroxyphenyl)-3-(beta-D-glucopyranosyloxy)-5,7-dihydroxy-, chloride
Synonyms: Cyanidin 3 glucoside; C3G; Cyanidin 3-O-glucoside; Cyanidin 3-monoglucoside; Cyanidin-3-glucoside chloride; Cyanidine 3-glucoside; Cyanidol 3-glucoside; 1-Benzopyrylium, 5,7-dihydroxy-2-(3,4-dihydroxyphenyl)-3-(beta-D-glucopyranosyloxy)-, chloride; Chrysanthemin (6CI,8CI); 2-(3,4-Dihydroxyphenyl)-3-(beta-D-glucopyranosyloxy)-5,7-dihydroxy-1-benzopyrylium chloride.
Molecular Formula: $C_{21}H_{21}O_{11}Cl$
CAS-RN: 7084-24-4

Lauroyl macrogol-32 glycerides is a polymer-based functional excipient that has a high tolerability for oral and for intraveinous intake and is generally used to increase the bioavailability of lipophilic drugs[2]. This substance is not structurally similar to any of those listed in the CDSA and is not considered a controlled substance.

Name: Lauroyl macrogol-32 glycerides

Chemical Name: Gelucire 44/14

Synonyms: Peg-32 glyceryl laurate

Molecular Formula: N/A
CAS-RN: 121548-04-7

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[1]Shipp, J. *et al.*(2010) Food Applications and Physiological Effects of Anthocyanins as Functionnal Food Ingredients. The Open Food Science Journal. pp.7-22.

[2]Li, P. and L. Zhao.(2007) Developing early formulations: Practice and perspective. International Journal of Pharmaceutics. **384(1-2)**: pp.1-19.

Recommendation: Indigo 3G does not contain any substances that are similar to those included in the Schedules to the CDSA and therefore is not a controlled substance.

Date: January 26th, 2012.