



Health
Canada

Santé
Canada



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

Substance: Xi Xin

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):

- Xi Xin is a herb used in traditional Chinese medicine and does not contain any substances similar to those listed in the CDSA.

Prepared by: _____ Date: Sept 16th 2010
Evelyn Soo

Verified by: _____ Date: _____
Marianne Tang

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

This status was requested by: "third party information removed as per agreement with applicant"

Drug Status Report

Drug: Xi Xin

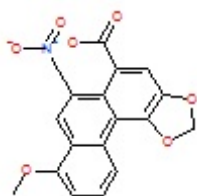
Drug Name Status: Xixin.

Chemical Name: *Radix et Rhizoma Asari* is the proper name.

Other Names: Saishin, Sesin, Manchurian Wildginger, Asarum spp.

Canadian Status:

Xixin is a herb that is used in Traditional Chinese Medicine and is not currently listed in the Schedules to the CDSA. The herb has been shown in the literature to contain aristolochic acids of which, aristolochic acid I is known to be nephrotoxic and a human carcinogen¹. While the emergence of aristolochic acid poisoning has promoted many countries to ban herbs, drugs and preparations containing the substance, the root of Xixin is believed to be void of aristolochic acid^{1,2,3}. Therefore, preparations of Xixin root are permitted in some countries if it can be demonstrated that aristolochic acid is absent in the final product². It is noteworthy that Health Canada has issued an advisory on products containing aristolochic acid and the importation of products containing the substance is prevented by the CBSA⁴. However, aristolochic acid is not listed in the CDSA and is not similar to any of the substances included in the Schedules to the CDSA.



Aristolochic acid I

Synonyms: 8-Methoxy-3,4-methylenedioxy-10-nitrophenanthrene-1-carboxylic acid; Aristolochic acid; Aristolochine; 8-methoxy-6-nitrophenanthro(3,4-d)-1,3-dioxole-5-carboxylic acid,
Molecular Formula: $C_{17}H_{11}NO_7$
CAS-RN: 313-67-7

Recommendation: Xixian is not included in the Schedules to the CDSA and is not a controlled substance.

September 16th 2010

¹Hsu, Y-H. *et al.* (2009) Analysis of aristolochic acid in asarum (Xixin) and its preparations by liquid chromatography/tandem mass spectrometry, *J. Food Drug Anal.* **17**:274-281.

²Hsieh, S-C. *et al.* (2010) Is Duhuo Jisheng Tang containing Xixin safe? A four-week safety study, *Chinese Medicine*, **5**:art 6.

³Zhao, ZZ. *et al.* (2008) Comparative study on the aristolochic acid I content of Herba Asari for safe use, *Phytomed.* **15**:741-748.

⁴http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2004/2004_43-eng.php

