



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

Substance: Whole Cell Pneumococcal Vaccine

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

Controlled []
Not Controlled [x]

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

- The substance is not similar to any of those included in the CDSA.

Prepared by: Evelyn Soo Date: Jan 18th 2011

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

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

Drug Status Report

Drug: Whole Cell Pneumococcal Vaccine

Drug Name Status: Whole Cell Pneumococcal Vaccine is the common name.

International status:

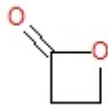
US: Whole Cell Pneumococcal Vaccine is not currently listed in the Schedules to the US *Controlled Substances Act* and is not mentioned anywhere on the DEA website.

United Nations: The substance is not listed on the Yellow List - List of Narcotic Drugs under International Control, the Green List - List of Psychotropic Substances under International Control, nor the Red List - List of Precursors and Chemicals Frequently Used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances Under International Control.

Canadian Status: Whole Cell Pneumococcal Vaccine is not currently listed in the CDSA. The substance is a vaccine containing *Streptococcus pneumoniae*, inactivated with β -propiolactone and stored in Lactated Ringer's solution.

Streptococcus pneumoniae is a Gram-positive, pathogenic bacterium and the major causative agent of pneumonia. The bacterium is not similar to any of the substances listed in the Schedules to the CDSA.

β -propiolactone is mainly used as a disinfectant against micro-organisms and for the gaseous sterilization of pharmaceutical and surgical materials. The substance is not listed in the CDSA and is not similar to any of the substances listed in the Schedules to the CDSA.



Common Name: β -propiolactone

Chemical Name: 2-oxetanone

Other Names: 3-Hydroxypropionic acid lactone, hydroxylic acid beta-lactone; BPL;

CAS-RN: 57-57-8

Molecular Formula: $C_3H_4NO_2$

Lactated Ringer's solution is an isotonic, sterile solution consisting of chloride, potassium chloride, sodium chloride, and sodium lactate in water and does not contain any substances similar to those included in the Schedules to the CDSA.

Recommendation: Whole Cell Pneumococcal Vaccine is not included in the schedules to the CDSA and is not a controlled substance.

Date: 18 January 2011