



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

Substance: Nalbuphine-6-glucuronide, Nalbuphine-3-glucuronide, Nalbuphine-3-sulfate

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

Controlled [checked]
Not Controlled [unchecked]

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

- The substances are derivatives of nalbuphine and are not excluded from item 10 of Schedule I to the CDSA.

Prepared by: Evelyn Soo Date: Sept 16th 2010

Verified by: Marianne Tang Date:

Approved by: DIRECTOR, OFFICE OF CONTROLLED SUBSTANCES Date:

This status was requested by: Nacer Silarbi

Drug Status Report

Drug:

- I** - Nalbuphine-6-glucuronide
- II** - Nalbuphine-3-glucuronide
- III** - Nalbuphine-3-sulfate

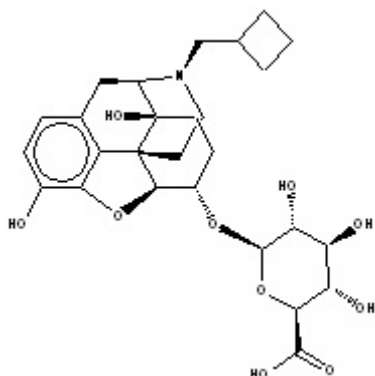
Drug Name Status:

- I** - Nalbuphine-6-glucuronide
- II** - Nalbuphine-3-glucuronide
- III** - Nalbuphine-3-sulfate are common names.

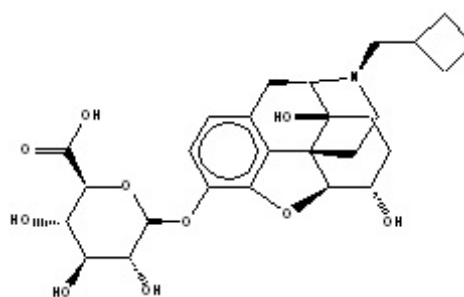
Chemical Name:

- I** - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-3,14-diol-6-beta-D-glucopyranuronic acid
- II** - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-6,14-diol-3-beta-D-Glucopyranuronic acid
- III** - 17-(Cyclobutylmethyl)-4,5alpha-epoxymorphinan-6,14-diol-3-sulfate

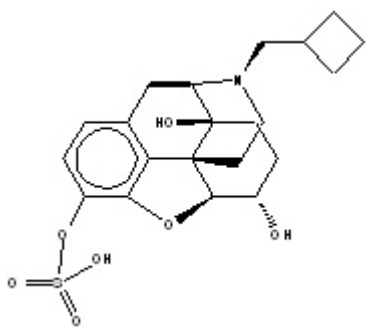
Chemical structure:



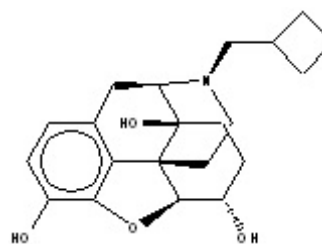
I



II



III



Nalbuphine

Molecular Formula: I - $C_{27}H_{15}NO_{10}$; II - $C_{27}H_{15}NO_{10}$; III - $C_{21}H_{27}NO_7S$

Pharmacological class / Application: Pharmaceutical-related substances

CAS-RN: NONE

International status:

US: The substance is not listed specifically in the 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 nor the Green List - List of Psychotropic Substances under International Control.

Canadian Status: Nalbuphine-6-glucuronide, nalbuphine-3-glucuronide and nalbuphine-3-sulfate are metabolites of nalbuphine. While nalbuphine is explicitly excluded from the heading "Morphinans, their salts, derivatives and salts of derivatives" as sub-item 15 of item 10 of Schedule I to the CDSA, these substances are morphinans and are not considered to fall under the "but not including" heading of item 10 of Schedule I. A review of other related substances of nalbuphine including for example bis-nalbuphine and N-(cuclo-methyl)noroxymorphone also determined them to be controlled under item 10 of Schedule I to the CDSA.

Recommendation: Nalbuphine-6-glucuronide, nalbuphine-3-glucuronide and nalbuphine-3-sulfate are included under item 10 of Schedule I to the CDSA and are controlled substances.

Date: 16 September 2010