



Health
Canada

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

Substance: Sodium Propylparaben

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 substance is not similar to any of those listed in the CDSA.

Prepared by: _____ Date: Aug 23rd 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

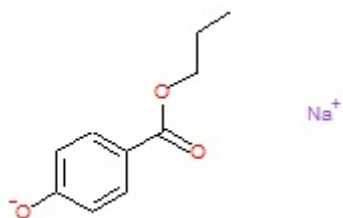
Drug: Sodium Propylparaben

Drug Name Status: Sodium Propylparaben is the common name.

Chemical Name: 4-hydroxybenzoic acid, propyl ester, sodium salt

Other Names: Sodium 4-propoxycarbonylphenoxide; sodium propyl hydroxybenzoate

Chemical structure:



Molecular Formula: C₁₀H₁₁NaO₃

Pharmacological class / Application: Antiseptic

CAS-RN: 35285-69-9

International status:

US: The substance is not listed specifically in the CDA 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: Sodium propylparaben is mainly used as a preservative and antiseptic in pharmaceutical products¹ and cosmetics². The substance is not currently listed in the CDSA and is not structurally similar to any of the substances included in the Schedules to the CDSA.

¹Safra, J. and Pospisilova, M. (2008) Separation and determination of ketoprofen, methylparaben and propylparaben in pharmaceutical preparation by micellar electrokinetic chromatography, *J. Pharm. Biomed. Anal.* **48**:452-455.

²Han, F. *et al.* (2008) On-line pretreatment and determination of parabens in cosmetic products by combination of flow injection analysis, solid-phase extraction and micellar electrokinetic chromatography, *Talanta*, **75**:1371-1377.

Recommendation: Sodium propylparaben is not similar to any of the substances included in the Schedules to the CDSA and is not a controlled substance.

Date: 23 August 2010