

## Technical Data Sheet

Product: LORIS10% PVP-I Solution (Bottle 500 ml, E/F)

Product Code: 109-08

NPN 80008372 (Canada)

### Product Packaging

Solution content: 480 – 520 mL

Number of bottles per corrugate: 12

### Product Label


**Intended use:** Antiseptic solution for wound cleansing.

**Directions:** Apply to wound once or twice daily.

**Warnings:** For external use only. Avoid contact with the eyes. If contact occurs, flush eyes with water. Discontinue use and consult a health care practitioner if irritation develops.

**Caution:** Store at 30°C or below.

### Label view

<p>Product No. / No de produit : 109-08      NPN 80008372</p>		
<p><b>USAGE :</b> Solution antiseptique pour le nettoyage des plaies.</p> <p><b>MODE D'EMPLOI :</b> Appliquer sur les plaies une ou deux fois par jour.</p> <p><b>MISE EN GARDE :</b> Pour usage externe seulement. Éviter tout contact avec les yeux. Le cas échéant, rincer abondamment les yeux avec de l'eau. Si une irritation apparaît, cesser d'utiliser le produit et consulter un praticien de soins de santé.</p> <p><b>INGRÉDIENTS NON-MÉDICINAUX :</b> Eau purifiée, phosphate dibasique de sodium heptahydraté, acide citrique, Glycérol, Éthoxylate de nonylphénol 9 mole, hydroxyde de sodium</p> <p><b>PRÉCAUTIONS :</b> Garder hors de la portée des enfants.</p> <p><b>ENTREPOSAGE :</b> Entreposer à 30° C ou moins.</p> <p><b>LERNAPHARM (LORIS) Inc.</b> 2323 Halpern, Saint-Laurent Montréal (Québec), Canada H4S 1S3 1-866-322-4634 • www.lernapharm.com</p> <p>Made in Canada Fabriqué au Canada</p>	<p><b>Solution antiseptique de Povidone Iodée 10% P/V, USP</b> (équivalent à 1% d'iode disponible)</p> <p><b>LORIS<sup>TM</sup>-10% PVP-I Solution</b></p> <p><b>Antiseptic solution with 10% W/V Povidone Iodine, USP</b> (equivalent to 1% available iodine)</p> <p><i>Usage externe seulement For external use only</i></p> <p><b>500 ml</b></p>	<p><b>INTENDED USAGE:</b> As an antiseptic solution for wound cleansing.</p> <p><b>DIRECTION:</b> Apply to wound once or twice daily.</p> <p><b>WARNING:</b> For external use only. Avoid contact with the eyes. If contact occurs, flush eyes with water. Discontinue use and consult a health care practitioner if irritation develops.</p> <p><b>NON-MEDICINAL INGREDIENTS:</b> Purified Water, Sodium phosphate, dibasic heptahydrate, Citric Acid, Glycerol, Nonyl Phenol 9 Mole Ethoxylate, Sodium Hydroxide</p> <p><b>CAUTION:</b> Keep out of reach of children.</p> <p><b>STORAGE:</b> Store at 30°C or below.</p> <p>R2811 Rev. 2 / 06-2014</p> 

## Technical Data Sheet

### In-Process Quality Controls on Finished Products

Test	Method	Specification
Fill volume	S-MAN-003	Minimum 480 mL
Seal Integrity	Visual	No leaks found when a bottle is shaken upside down

### Chemical / Biological Analysis

Test	Method	Specification
Description	TL-S-QUA-012	Bottle containing brown liquid
Visual inspection	TL-S-QUA-012	The solution is free of dirt, hair, precipitates, and other foreign matter
pH	USP<791>	1.5 - 6.5
Available iodine	TL-S-QUA-012	0.85% w/v - 1.20% w/v
Identification (A)	TL-S-QUA-012	A deep blue color is produced
Identification (B)	TL-S-QUA-012	No blue color appears within 60 seconds
Total Aerobic Microbial Count (TAMC)	TL-S-QUA-028	Report < 10 cfu/mL
Total Combined Yeast and Molds Count (TYMC)	TL-S-QUA-028	Report < 2 cfu/mL
<i>S.aureus</i>	TL-S-QUA-053	Absence
<i>P.aeruginosa</i>	TL-S-QUA-053	Absence
<i>B.cepacia</i>	TL-S-QUA-053	Absence