APPLICANT	**:Reckitt Benckiser Pharmaceuticals (Pty) Ltd**	**Submitted: October 2023**
PROPRIETARY NAME (DOSAGE FORM)	**:Dettol Antiseptic Liquid**	**MODULE 1**
STRENGTH	**:4.8 g Chloroxylenol per 100 ml**	**1.5.5**

PROFESSIONAL INFORMATION

SCHEDULING STATUS:

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1. NAME OF THE MEDICINE:

DETTOL ANTISEPTIC LIQUID

Chloroxylenol 4,8 g/100 ml liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

Chloroxylenol 4,8 g/100 ml

3. PHARMACEUTICAL FORM:

Liquid.

4. CLINICAL PARTICULARS:

4.1. Therapeutic indications:

FOR EXTERNAL USE ONLY. DO NOT SWALLOW.

DETTOL ANTISEPTIC LIQUID is indicated as:

Antiseptic for wounds, cuts, abrasions and insect bites.

Surface disinfection for floors and hard surfaces.

Dettol Antiseptic Liquid is not recommended as a hand sanitiser for the Covid-19 virus.

4.2. Posology and method of administration:

For external use only. Do not swallow. Use diluted.

DIRECTION FOR ANTISEPTIC USE: wounds, cuts, abrasions and insect bites

Wash with diluted Dettol Antiseptic Liquid 3 medicine measures (15 ml) in a glass of water (300 ml). (one medicine measure = 5 ml).

Adhere to recommended dilutions, avoid usage in hypersensitive persons.

Do not apply repeatedly. Repeated application may give rise to hypersensitivity.

DILUTION FOR SURFACE USE: **Floors and hard surface disinfection**: dilute 20 ml in 100 ml of water. Apply to surface and leave on for 3 minutes. Remove by wiping the surface.

Method of administration:

For external use only. Do not swallow. Use diluted.

4.3. Contraindications:

Hypersensitivity to chloroxylenol or to any of the other ingredients.

Do not use on eczematous conditions.

Not for use in children under 1 year of age.

Not for use around eyes, ears, nose or mouth.

Do not use undiluted on your skin as severe irritation may occur

DO NOT SWALLOW.

4.4. Special warnings and precautions for use:

If contact is made with eyes, wash thoroughly with cold water and seek medical advice immediately.

If accidentally swallowed, wash out mouth and drink plenty of water or milk. Seek medical advice immediately.

If inhaled move to fresh air.

Wear gloves and eye protection when performing surface disinfection cleaning.

Eating, drinking and smoking is prohibited in areas where this material handled, stored and processed. Wash hands, forearms and face after handling, before eating, drinking, smoking, or using the lavatory. Remove contaminated clothing and protective equipment before entering eating areas.

4.5. Interactions with other medicines and other forms of interaction:

The are no known drug interactions with topical chloroxylenol

4.6. Fertility, pregnancy and lactation:

Pregnancy

No effects during pregnancy are anticipated, since systemic exposure from topical chloroxylenol is negligible.

DETTOL ANTISEPTIC LIQUID should be used with caution during pregnancy.

Lactation

It is unknown whether chloroxylenol or its metabolites are excreted into human milk. A risk to the newborns/infants cannot be excluded. Application of DETTOL ANTISEPTIC LIQUID to the breast is not recommended during breastfeeding.

Fertility

No data on human fertility are available.

4.7. Effects on ability to drive and use machines:

DETTOL ANTISEPTIC LIQUID has no or negligible influence on the ability to drive or use machinery.

4.8. Undesirable effects:

Adverse events which have been associated with chloroxylenol, tabulated by system organ class and frequency.

Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100);

Rare (≥1/10000 and <1/1000); Very rare (<1/10000); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order

System organ class	Frequency	Adverse events
Immune system disorders	Not known	Hypersensitivity
Skin and subcutaneous tissue disorders	Not known	Skin sensitisation, contact dermatitis[1], skin discolouration

[1]Contact dermatitis can be associated with pruritus, erythema, skin scaling, itching, stinging and depigmentation.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

4.9. Overdose:

Over-exposure signs/symptoms: Eye contact: pain, watering, redness. Skin contact: pain or irritation, redness or blistering may occur.

Accidental ingestion: vomiting and diarrhoea. Large quantities may cause respiratory distress, respiratory depression and cardiovascular collapse. Treatment is symptomatic and supportive. Administer a demulcent drink eg milk. Contact your doctor, poison treatment centre or hospital immediately.

5. PHARMACOLOGICAL PROPERTIES:

5.1. Pharmacodynamic properties:

Pharmacological classification: *A 13.1 Antiseptics*

DETTOL ANTISEPTIC LIQUID is active against gram-positive and gram-negative, but species of *Staphylococcus* and *Pseudomonas*, particularly the latter are relatively less susceptible. The medicine is inactive against bacterial spores.

Chloroxylenol is a substituted phenol and it is known to be bactericidal, in low concentration, to a wide range of Gram positive and Gram-negative bacteria. It has proven efficacy against a range of harmful micro-organisms including bacteria *E. coli, Salmonella, Listeria*, MRSA,

E Hirae, vibrio cholera; fungi and viruses H1N1, H5N1, Influenza A2, corona virus 229E, SARS-CoV-2 (COVID-19 Virus).

DETTOL ANTISEPTIC LIQUID is compatible with soap.

The activity of the product is reduced by organic matter.

No data on corrosiveness of the product is available.

5.2. Pharmacokinetics properties

Chloroxylenol is well-absorbed when applied to the skin. It is extensively metabolised in the body, probably by the liver, and rapidly excreted, mainly in the urine, as sulphate and glucuronide conjugates. Chloroxylenol has a low systemic toxicity, even at dosage levels many times higher than those likely to be absorbed during normal usage of DETTOL ANTISEPTIC LIQUID.

6. PHARMACEUTICAL PARTICULARS:

6.1. List of excipients:

- Pine oil
- Caramel
- Isopropyl alcohol
- Castor oil soap
- Water

6.2. Incompatibilities:

Not applicable

6.3. Shelf-life:

36 months

6.4. Special precautions for storage:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

STORE AWAY FROM FOOD STUFFS.

Containers that have been opened must be carefully resealed and kept upright to prevent leakage.

Chloroxylenol has been reported to be incompatible with nonionic surfactants and methylcellulose.

6.5. Nature and contents of the container:

Clear amber liquid with pine oil odour free from particulate matter.

DETTOL ANTISEPTIC LIQUID is marketed in 50 ml, 125 ml, 500 ml, 750 ml or 1 litre of liquid contained in clear polypropylene bottles

6.6 Special precautions for disposal:

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road,

Elandsfontein, 1601

8. REGISTRATION NUMBER:

G/13.1/2345

9. DATE OF FIRST AUTHORISAITON/ RENEWAL OF THE AUTHORISATION:

Date on the registration certificate: 20 April 1983

10. DATE OF REVISION OF THE TEXT:

Date of the revised professional information: 22 January 2024

NRCS Registration: NRCS/8054/294116/1240