SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **PEACEFUL SLEEP INSECT REPELLENT CREAM**
(AND DOSAGE FORM) **(CREAM)**

COMPOSITION:

Each gram contains:

N,N-Diethyl-M-Toluamide	250 mg
Preservatives:	
Germaben II E	1,0 % (m/m)

The preservative Germaben IIE is comprised of:

Diazolidinyl Urea	20 %
Methyl parahydroxybenzoate	10 %
Propyl parahydroxybenzoat	10 %
Propylene Glycol	60 %

PHARMACOLOGICAL CLASSIFICATION:

A.34 Other (Insect Repellent)

PHARMACOLOGICAL ACTION:

Topical insect repellent

INDICATIONS:

For protection for up to 2 hours against bites/stings of mosquitoes, flies, fleas and ticks.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients.

WARNINGS:

For external use only. Do not apply near eyes or lips, on mucous membranes, broken skin or areas of skin flexion.

DOSAGE AND DIRECTIONS FOR USE:

Apply frequently to the entire area of the skin that is to be protected. Do not apply to eyes and mouth and do not apply to hands of young children.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Hypersensitivity. Harmful if swallowed. May cause eye injury. Use sparingly on small children as encephalopathy has been reported. Do not allow use by small children without close adult supervision. Do not apply to excessively sunburned or damaged skin. May cause skin reactions less frequently.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See "**SIDE EFFECTS AND SPECIAL PRECAUTIONS**". In case of accidental ingestion, treatment is symptomatic and supportive. If in eyes, flush with plenty of water. If irritation persists, get medical treatment. If swallowed, call a physician or poison control centre. Get medical attention. If you suspect that you or your child is reacting to this product, wash treated skin and call your doctor.

IDENTIFICATION:

Smooth white aqueous cream with characteristic odour.

PRESENTATION:

100 ml white pre-printed plastic tubes with blue flip-top caps.

STORAGE INSTRUCTIONS:

Store below 25 º C, away from heat and flames.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:

35/34/0130

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION:

Tiger Consumer Brands
2 Purlin Street
Isando
Kempton, 1600

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

SKEDULERINGSTATUS: **S0**

EIENDOMSNAAM: **PEACEFUL SLEEP INSECT REPELLENT CREAM**
(EN DOSEERVORM) **(ROOM)**

SAMESTELLING:

Elke gram bevat:

N,N Diëtiel-m-toluamied	250 mg
Preserveermiddel:	
Germaben IIE	1,0 % (m/m)

Die preserveermiddel Germaben IIE bestaan uit:

Diasolidiniel Ureum	20 %
Metielparahidroksibensoaat	10 %
Propielparahidroksibensoaat	10 %
Propileenglikool	60 %

FARMAKOLOGIESE KLASSIFIKASIE:

A.34 Ander (Insekweerder).

FARMAKOLOGIESE WERKING:

Topikale insekweerder.

INDIKASIES:

Vir die beskerming teen byte/steke van muskiete, vlieë, vlooie en bosluise vir ‘n tydperk van tot en met 2 ure.

KONTRA-INDIKASIES:

Hipersensitiwiteit teenoor enige van die bestanddele.

WAARSKUWINGS:

Vir eksterne gebruik alleenlik. Moenie naby die oë, lippe, op mukusmembrane, stukkende vel of areas van velbuiging aangewend word nie.

DOSIS EN GEBRUIKSAANWYSINGS:

Wend gereeld aan oor die hele area van die vel wat beskerm moet word. Moet nie aan die oë en mond aangewend word nie en moet ook nie aan die hande van jong kinders aangewend word nie.

NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREëLS:

Hipersensitiweiteit. Skadelik as ingesluk word. Mag oogbesering veroorsaak. Gebruik spaarsamig by klein kinders, omdat enkefalopatie al gerapporteer is. Moet nie gebruik deur klein kinders toelaat sonder volwasse toesig nie. Mag nie aangewend word op erge sonverbrande of beskadigde vel nie. Mag velreaksies veroorsaak, maar dit kom minder gereeld voor.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:

Sien "**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS**". In die geval van onopsetlike inname is die behandeling simptomaties en ondersteunend. As dit in die oë kom, was en spoel die oë met baie water. As irritasie voortduur, moet mediese behandeling verkry word. As dit gesluk word, moet 'n geneesheer of die gifbeheersentrum geskakel word. Verkry mediese aandag. As jy vermoed dat jy of jou kind 'n reaksie toon as gevolg van die produk, was die behandelde vel en skakel jou dokter.

IDENTIFIKASIE:

Gladde wit room met 'n waterbasis en 'n kenmerkende reuk.

AANBIEDING:

100 ml Wit voorafgedrukte plastiek buisies met blou oopknip doppies.

BERGINGSAANWYSINGS:

Berg benede 25 °C weg van hitte en flamme.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
35/34/0130

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Tiger Consumer Brands
2 Purlin Straat
Isando
Kempton Park
1600

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET: