

Summary of product characteristics for a biocidal product

Product name: Care Plus Anti Insect DEET Spray 20%

Product type(s): PT19 - Repellents and attractants (Pest control)

Authorisation number: 790-2

R4BP 3 asset reference number: DK-0013782-0000

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Administrative information

1.1. Trade names of the product

Care Plus Anti-Insect DEET Spray 20%
Insect Repellent Family Spray 20% DEET

1.2. Authorisation holder

Name and address of the authorisation holder	Name	Primmed BV
	Address	De Huchtstraat 14 1327 EE Almere Netherlands
Authorisation number		790-2
R4BP 3 asset reference number		DK-0013782-0000
Date of the authorisation		14/01/2015
Expiry date of the authorisation		24/12/2024

1.3. Manufacturer(s) of the biocidal products

Name of the manufacturer	Tropenzorg B.V.
Address of the manufacturer	De Huchtstraat 14 1327 EE Almere Almere Netherlands
Location of manufacturing sites	Niverpack BV 8239 DD Lelystad Netherlands

1.4. Manufacturer(s) of the active substance(s)

Active substance	23 - N,N-diethyl-meta-toluamide
Name of the manufacturer	Vertellus Performance Material Inc.
Address of the manufacturer	2110 High Point Road NC 27403 Greensboro United States
Location of manufacturing sites	2110 High Point Road NC 27403 Greensboro United States

2. Product composition and formulation

2.1. Qualitative and quantitative information on the composition of the biocidal product

Common name	IUPAC name	Function	CAS number	EC number	Content (%)
N,N-diethyl-meta-toluamide	N,N-diethyl-m-toluamide	Active Substance	134-62-3	205-149-7	20
Ethanol	Ethanol 2-propanol	Non-active substance	64-17-5	200-578-6	79,999

2.2. Type of formulation

AL - Any other liquid

3. Hazard and precautionary statements

Hazard statements	Highly flammable liquid and vapour. Causes serious eye irritation.
Precautionary statements	If medical advice is needed, have product container or label at hand. Keep out of reach of children. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. - No smoking. Do not breathe spray. Use only outdoors or in a well-ventilated area. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Dispose of contents to container.

4. Authorised use(s)

4.1 Use description

Use 1 - To repel mosquitoes and ticks from humans

Product type	PT19 - Repellents and attractants (Pest control)
Where relevant, an exact description of the authorised use	Repellent against mosquitoes and ticks on humans
Target organism(s) (including development stage)	Scientific name: Culicidae: Common name: Mosquitoes Development stage: Adults Scientific name: Ixodoidea Common name: Ticks Development stage: Adults
Field(s) of use	Indoor Outdoor For use indoors in well ventilated areas and outdoors
Application method(s)	Method: Spraying Detailed description: Apply sparingly to exposed body parts, divide the product evenly over the skin.
Application rate(s) and frequencies	Application Rate: Protects the user for a period of 4 hours against the bites of mosquitoes and 2 hours against ticks. The protection time against certain aggressive tropical tick species can be shorter. Dilution (%): 0 Number and timing of application: Protects the user for a period of 4 hours against the bites of house mosquitoes, malaria mosquitoes and yellow fever mosquitoes, and 2 hours against ticks. The protection time against certain aggressive tropical tick species can be shorter. Do not use on children younger than 2 years. Do not use more than once a day on children under 13 years. Use maximum two times a day on children of 13 years and older and adults.
Category(ies) of users	General public (non-professional)
Pack sizes and packaging material	100 mL HDPE bottle with spray attachment

4.1.1 Use-specific instructions for use

See general directions for use

4.1.2 Use-specific risk mitigation measures

See general directions for use

4.1.3 Where specific to the use, the particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

See general directions for use

4.1.4 Where specific to the use, the instructions for safe disposal of the product and its packaging

See general directions for use

4.1.5 Where specific to the use, the conditions of storage and shelf-life of the product under normal conditions of storage

See general directions for use

5. General directions for use

5.1. Instructions for use

- Apply Care Plus Anti-Insect DEET Spray 20% sparingly and carefully to parts of the body that are not covered by clothing; spread evenly.
- Wear long pants and/or long sleeved shirt.
- Do not apply under clothing.
- Keep the spray bottle at least 15 cm from the skin (do not spray directly on the face).
- When used in combination with sun block lotion, apply sun block first then wait 30 minutes before applying the Care Plus DEET product.
- To protect the face from insect bites, first spray or spread a small quantity of Care Plus Anti-Insect DEET Spray 20% onto the palm of the hand and then spread on the face.

Restrictions and warnings:

- Do not use on children younger than 2 years.
- Do not use more than once a day on children under 13 years.
- Use maximum two times a day on children of 13 years and older and adults.
- For adults and children over 12 years of age, the following areas can be treated twice a day: the face, neck, hands, wrists, forearms and on top of the feet, while the rest of the body is protected with clothing.
- For children 2-12 years old, the following areas can be treated once a day: the face, neck, forearms and on top of the feet, while the rest of the body is protected with clothing.
- Children must not apply the product themselves, the product must be applied by an adult.

- Avoid contact with eyes, mucous membranes, nose, lips and damaged skin.
- Do not apply Care Plus Anti-Insect DEET Spray 20% to areas around joints such as behind the knees or inside the elbows where skin folds normally occur.
- Avoid contact with food.
- Wash your hands thoroughly with soap and water before eating or drinking.
- Application of Care Plus Anti-Insect DEET Spray 20% is not advised for sensitive groups such as pregnant and breast feeding women.
- Wash the areas of skin that have been treated when protection is no longer needed or if side effects occur.
- Use only outdoors or in a well-ventilated area.
- Do not inhale the product.
- Keep this product away from children.
- Avoid contact with plastics (glasses), synthetic-/leather clothing and painted surfaces.

It is recommended that users of products based on DEET consult the instructions of the National Coordination Centre Travellers Information (LCR) when travelling abroad.

5.2. Risk mitigation measures

See general instructions for use

5.3. Particulars of likely direct or indirect effects, first aid instructions and emergency measures to protect the environment

Description of first aid measures:

After inhalation: Move person to fresh air and keep at rest in a position comfortable for breathing. Consult a physician if the person feels unwell.
 After contact with eyes: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 After ingestion: Drink 1 or 2 glasses of water, rinse the mouth and induce vomiting by touching the back of the throat with a finger. Do not induce vomiting or give anything by mouth to an unconscious person. Get medical attention if the person feels unwell.
 After contact with open wounds: Wash with plenty of water. If irritation persists, consult a physician.

5.4. Instructions for safe disposal of the product and its packaging

Do not reuse the container for any other purpose.
 Dispose any remaining product small chemical waste collection to a waste recycling centre as hazardous waste rather than to domestic waste .

5.5. Conditions of storage and shelf-life of the product under normal conditions of storage

The shelf-life of the product is expected to be 5 years in its commercial container.

6. Other information

Etiketten skal indeholde nedenstående oplysninger. Oplysninger i citationstegn skal angives ordret:

1) I hovedfeltet:
"Afskrækningsmiddel (PT19)

Må kun anvendes som afskrækningsmiddel mod myg og flåter."

2) I advarselsfeltet:
"FARE
Meget brandfarlig væske og damp (H225)

Forårsager alvorlig øjenirritation (H319)

Ved brand: Anvend [udfyldes af ansøger] til brandslukning.
Hold beholderen tæt lukket.
Indånd ikke damp.

Vask huden med vand og sæbe når beskyttelse ikke længere er nødvendig eller hvis der opstår bivirkninger.

For påføring i ansigtet, spray produktet i hænderne og påfør det i ansigtet.
Undgå at produktet kommer i kontakt med øjnene, slimhinder, næsen, læberne og beskadiget hud.

Vask hænder før du spiser eller håndterer fødevarer.

Undgå indånding af spray.

Undgå at produktet forurener fødevarer, service eller overflader der er i kontakt med fødevarer.

Hvis der anvendes solcreme, vent da 30 minutter med at påføre Care Plus anti insect DEET spray 20%

Overtrædelse af nedenstående særligt fremhævede forskrifter kan medføre straf:

Må kun anvendes som afskrækningsmiddel mod myg og flåter.
Må ikke anvendes mod andre skadevoldere og ikke i højere doseringer end de i brugsanvisningen nævnte.

Må ikke anvendes til børn under to år.

For voksne og børn over 12 år kan følgende steder behandles to gange om dagen: ansigtet, halsen, nakken, hænder, håndled, underarme og oversiden af fødderne, mens resten af kroppen beskyttes med beklædning.

For børn, der er 2-12 år gamle, kan følgende steder behandles en gang om dagen: ansigtet, halsen, underarme og oversiden af fødderne, mens resten af kroppen beskyttes med beklædning.

Børn må ikke selv påføre produktet, produktet skal påføres af en voksen.

Holdes væk fra varme/gnister/åben ild/varme overflader. Rygning forbudt.

Brug kun udendørs eller i et rum med god ventilation.

Opbevares utilgængeligt for børn.

Må ikke opbevares sammen med fødevarer, drikkevarer og foderstoffer."

Farepiktogrammerne GHS02 for fysiske farer og GHS07 for sundhedsfare.

Miljøstyrelsen henleder opmærksomheden på, at godkendelsesindehaver skal anføre oplysninger om førstehjælp. Herunder: Hvis der er behov for lægehjælp, medbring da beholderen eller etiketten. (P101)

VED KONTAKT MED ØJNENE: Skyl forsigtigt med vand i flere minutter. Fjern eventuelle kontaktlinser, hvis dette kan gøres let. Fortsæt skylning. (P305+P351+P338)
Ved vedvarende øjenirritation: Søg lægehjælp.

3) I deklarationsfeltet:
a) Teksten "Insektmiddel BPR-reg. nr. 790-2. Aktivstof og biocidholdigt produkt er godkendt efter biocidforordningen (Forordning (EU) nr. 528/2012)".

- b) Oplysning om præparattype: "væske" for dette præparat.
- c) Indholdet af aktivstof i vægtprocent (% w/w) og g/L ved 20 °C.
- d) Sætningen: "Indeholder ethanol".
- e) Udløbsdatoen skal anføres. Denne dato må højst være 5 år efter produktionsdatoen. Etikettens dato kan udformes som en henvisning til en produktionsdato andetsteds på emballagen.
- f) Batchnummer eller – betegnelse skal anføres.
- g) Pakningsstørrelse i L.
- h) Godkendelsesindehavers navn og adresse.

4) Brugsanvisningen:

Oplysninger om skadevoldere, anvendelsesområde og doseringer.

Brugsanvisningen skal rettes til efter den vedlagte effektivitetsvurdering fra Institut for Agroøkologi, Aarhus Universitet, AGRO.

Følgende retningslinjer gælder i forhold til bortskaffelse:

Der skal mærkes med sikkerhedssætning P501: "Indholdet/holderen bortskaffes i overensstemmelse med kommunale regler for affaldshåndtering."

Derudover skal mærkningen ske efter retningslinjerne:

Rester skal afleveres til den kommunale affaldshåndtering for farligt affald. Tom emballage kan bortskaffes som dagrenovation.