Netprotect: a "Biocidal product" or a "Treated article"?

1. Background
Applications for the authorisation of existing biocidal products containing deltamethrin have to be submitted at the latest by 1/10/2013. In case this is not done, the products will be removed from the market.

Question and purpose of this document
Currently, Bestnet is investigating whether an application should be submitted or not.

The question relevant herein in first instance whether Netprotect is a "biocidal product" or a "treated article".

I understand that if Netprotect is a "treated article", there is no need to apply for a biocidal product authorisation, be it under the current Directive 98/8/EC or under the future Regulation on biocidal products.

The insecticide deltamethrin has been approved for inclusion in Annex I of Biocide Directive 98/8/EC.

The company Bestnet is currently marketing and selling Netprotect in EU (for example in Denmark) and will expand sales in Europe in 2012. Bestnet will sell Netprotect via Amazone.com. Currently, registration of Netprotect in Europe is following local national laws and guidelines (Netherlands, United Kingdom, Spain, France, Belgium, Italy, Portugal, Luxemburg, Germany and Denmark). The Netherlands answered us that no registration is needed on the basis that Netprotect is considered as a treated article. The same was true in Sweden. Denmark required registration and an evaluation and after 2½ years was registered as a biocide.

2. Netprotect
This document provides the basic product information on Netprotect. Please find all product information also on www.bestneteurope.com under 'Products'.

Netprotect is a textile net made of polyethylene yarns knitted into a textile net. The polyethylene yarns contain deltamethrin to an amount of 68 mg/m² or 1.8 g/kg textile. The PE master batch (further explained below) follows a special proprietary recipe developed and invented by Bestnet AS. This recipe is licensed out to textile producers in China and India.

Netprotect is a WHO approved product for the prevention of malaria infections in humans. It is used as a bed net, tugged under mattresses or sleeping mats or generally covering sleeping and resting areas. The malaria infected mosquitoes trying to bite humans, lands on the textile net and is thereafter killed by a sufficient amount released deltamethrin which is present on the surface of the yarns. Netprotect has been tested in large field trials in Africa and India as a part of the WHOPES approval scheme to obtain such approval from WHO. Without this approval suppliers of such nets can not participate in tenders for such malaria prevention programs mostly funded programs by global fund or other malaria prevention health programs around the world.

Further specifications are:

Fabrication: Warp knitted
Fabric: 100% polyethylene
Yarn size: 118 denier (0.13 mm), monofilament
Mesh: 136 (holes per inch²), 21 (holes per cm²)
200 (holes per inch²), 31 (holes per cm²)
Weight: 136 mesh: 38 g/sqm - 200 mesh: 44 g/sqm
Dimensional stability: 30° +/-5% (8A) or 40° +/-10% (6A)
Dimensional tolerance: Size deviation less than 10%
Bursting strength: 136 mesh: 400 Kpa 200 mesh: 500 Kpa
Colours: Standard in white, light/dark green and light/dark blue - (other colours available upon request)

2.1. Product information
Below detailed information on the manufacturing of Netprotect. See details in Annex I below.

Netprotect is a knitted textile net. The yarns of the textile net are made of polyethylene (hereafter PE). The polyethylene is HDPE and LDPE which are standard types available in the trade.

Basic steps are;

2.1.1. PE Masterbatch production–Polyethylene pellets
The company Alok Industries India buys deltamethrin approved by WHO for public health usage from the company Tagros India.

Bestnet AS has commercial agreement in place including the "letter of access" from Tagros India. Alok industries have a licence agreement with Bestnet AS on the formulation of master batch polyethylene.

Bestnet has intellectual property on how to formulate deltamethrin into PE so that is slowly released on the surface of the PE yarn in an amount sufficient to kill mosquitoes according to the WHOPES approval scheme. Netprotect is a long lasting insecticidal net approved by WHO. The approval was given in 2008 and since that date Netprotect was sold worldwide to protect people against malaria infections.

A master batch is a solid formulated polyethylene product mostly in the form of a pellet and is made by melting Polyethylene to a temperature, so that PE becomes fluid (around 180C). The insecticide deltamethrin together with other standard plasticizers are than added to the molten polyethylene. This mix is lowered in temperature and pressed through a mesh, so to obtain solid pellets. These pellets are then shipped to a textile manufacturer to make PE yarns.

2.2.1. PE Yarns to Textile net
The textile manufacturer receives the pellets from the master batch producer herein Alok India. The pellets are melted again to a modest temperature and extruded to obtain yarns of a defined thickness (denier). The yarns are collected and rolled on standard rolls.

Once the yarns are available on these rolls, the net is than obtain by standard knitting process. The knitted textile net is then stored in rolls and is available in long meters on the roll with a defined length per role and width. The net is than further cut and sown to make a net of different shapes; circular net, rectangular net or others depending on the need in the country of sales.

The nets are packed in thin PE bags which contain labelling and user instructions. The nets are tested on the amount of deltamethrin available in the yarns according to approved CIPAC specifications and according to the WHOPES washing protocols.

Claims of Netprotect

Insecticidal product.
For use as a protection for the prevention of biting by mosquitoes and other insects.
Netprotect protects the user from biting insects, diseases transmitted by such insects and provides a secure and quiet nights sleep.
Content: insecticide incorporated mosquito net made of 100% polyethylene.
Durability: up to 5 years from production date, as printed on this label.
The net remains active after 20 washes.
Do not wash at a temperature above 30 deg C.
Netprotect manufacturing sites
Final Textile knitting and sewing is done in India and in China. Netprotect product will be imported into Europe from China and India.

Please advice us to what category Netprotect (a "biocidal product" or a "treated article") will belong, so that the company Bestnet can act accordingly in good time.

Best regards,

Bestnet A/S

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Annex I detailed production information

**Bestnet Production, KRT (India)**

For each step in the production process, several quality inspections are being performed. For all inspections, Standard Operation Procedures (SOP) are available. This is important for in order to make sure that all inspections are performed currently. The SOP is also an important tool for training.

**Receiving of raw material and Master Batch**

The raw materials used in polyethylene nets are HDPE and LDPE chips and Master Batches (MBs). HDPE and LDPE chips are produced from crude oil and are the basic component of the material. MB is an expression used for concentrated additives like colour, UV protectants and other additives mixed with polyethylene. MBs are used to secure the proper mixing of the additives with the HDPE/LDPE chips.

<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content of Deltamethrin</td>
<td>SOP 1</td>
</tr>
</tbody>
</table>

**Quality Matrix 1 Receiving of raw material and Master Batch**

**Extruding**

The production of polyethylene nets starts with the mixing of the HDPE chips with the MB (see picture 1).

This mixture is transferred to the extruder. The extruder is basically a heated cylinder with a screw inside (see picture 2).

The mixture of HDPE chips and MB is placed in one end of the cylinder and is transported through the cylinder by the screw. On the way through the cylinder the temperature and the pressure increase, melting and mixing the chips and the MB. The fluid plastic created in the cylinder is then pressed through the spindernet, creating the primary stage of the yarn. The yarn is immediately let through a water bath to cool down, thereby hardening the HDPE (see picture 3).
After cooling, the yarn is run through the first stretching section, where it is drawn longer and thinner (see picture 4). Subsequently, the yarn passes through a heating section where the temperature is raised to create a softer yarn that is then stretched one more time to achieve its final thickness (denier).

<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yarn thickness</td>
<td>SOP 3</td>
</tr>
<tr>
<td>Extruder temp</td>
<td>SOP 2</td>
</tr>
<tr>
<td>Denier</td>
<td>SOP 5–ISO2060</td>
</tr>
</tbody>
</table>

**Quality Matrix 2 Extruding**

**Knitting**
The yarn is now finished, and the final step on the extruder is the winding (see picture 5). The yarn is then transferred from the winding wheels to the hanks form (see picture 6).

<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mesh</td>
<td>SOP 9–WHO 2005</td>
</tr>
<tr>
<td>Fabric width</td>
<td>SOP 4</td>
</tr>
</tbody>
</table>

**Quality Matrix 3 Knitting**
The netting material is inspected for knitting faults and is transferred to the cutting and sewing department where it is made into nets.

<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bursting strength</td>
<td>SOP 6–ISO13938</td>
</tr>
<tr>
<td>Material weight</td>
<td>SOP 7–ISO3801</td>
</tr>
<tr>
<td>Dimensional stability</td>
<td>SOP 8–ISO6330</td>
</tr>
<tr>
<td>Mesh</td>
<td>SOP 9–WHO 2005*</td>
</tr>
<tr>
<td>Fabric width</td>
<td>SOP 4</td>
</tr>
<tr>
<td>Temperature at heat setting</td>
<td>-</td>
</tr>
</tbody>
</table>

**Quality Matrix 4 Heatsetting**

**Cutting & Sewing**

After the heat setting, the fabric is cut into different shapes depending on the type of nets that is going to be stitched.

![Picture 8 Sewing](image)

**Picture 8 Sewing**

After the nets are completed and inspected, they will be packed and baled.

<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Content of Deltamethrin</td>
<td>SOP 10–CIPAC/4673</td>
</tr>
<tr>
<td>Major &amp; minor defects (like dimensions, holes etc.)</td>
<td>SOP 11</td>
</tr>
</tbody>
</table>

**Quality Matrix 5 Cutting & Sewing**

**Packing & baling**

Each net are either packing in bags or bulks depending on the customer's requirements.

![Picture 9 Baling](image)

**Picture 9 Baling**

The nets are then packing in bales with typically 25 or 50 nets in each bale. The bales are compressed to minimize shipping costs.
<table>
<thead>
<tr>
<th>Critical to Quality</th>
<th>Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dimensions, packing material, number of nets</td>
<td>SOP 111B</td>
</tr>
</tbody>
</table>

Quality Matrix 6 Packing & Baling
polyethylene mosquito net
moustiquaire en polyéthylène
mosquitero de polietileno
zanzariera di polietilene
polyethylene muggennet
polyethylen mückennetz
polyethylen myggenet

LONG LASTING INSECTICIDE INCORPORATED
MOSQUITO NET UP TO 5 YEARS PROTECTION
Moustiquaire incorporée d’insecticide à longue durée d’action jusqu’à 5 ans de protection
MOSQUITERO INCORPORADO CON INSECTICIDA DE LARGA DURACIÓN HASTA DE 5 AÑOS DE PROTECCIÓN
MOSQUITO INCORPORADO CON INSECTICIDA DE LONGA DURAÇÃO/PROTEÇÃO ATÉ 5 ANOS
ZANZARIERA CON INSETTICIDA INTEGRATA A LUNGA DURATA / DI PROTEZIONE FINO A 5 ANNI
Längdurch insekticide ingkorporerad muggennet tot 5 jaar bescherming
Langzeit haltbarem mückenetz mit eingearbeiteten insektizid, bis zu 5 Jahren haltbarkeit
Langtedsholdbart myggenet med indkorporeret insektmiddel - op til 5 års beskyttelse

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Registration Nos.
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B: xxx xxx xxx
NL: xx
FR: xxxx
E: x
I: xxx
D: x xxxxx xx
DK: xxx

MESH (HOLES PER INCH² / CM²) - 136/21

Rectangular
- 1 person - 160W X 180L X 150H cm - Striped Military Colours
- 2 persons - 190W X 180L X 150H cm - Dark blue

Circular
- 2 persons - 1050C X 220H X 56D cm - Dark blue
EN: INSECTICIDAL PRODUCT
For use as a protective treatment for the prevention of biting by mosquitoes and other insects.

• Very toxic to aquatic organisms.
• Use only as directed. May only be used by those trained to use insecticides and other pesticides. Wash not as required preferably during the season when biting insects are not active. After washing the net do not dispose of dirty water near rivers, lakes or water bodies. Store out of reach of children and not in the presence of food, drink or other consumables.

APPLICATION
Netprotect® protects the user from biting insects, diseases transmitted by insects and other insects. Netprotect® guarantees a safe night of sleep.

AFTER USE
• Clean the screens and insecticides after use to prevent the presence of residues and other chemicals.

AFTER USE:
• Determine the quality of the protection provided by the insecticide spray.
• Never dispose of the mosquito liquid near rivers, lakes or other water bodies. Store out of reach of children and not in the presence of food, drink or other consumables.

EN: PRODUCT INSECTICIDA
Se usa como protector para la prevención de picaduras de mosquitos y otros insectos.

• Muy tóxico para organismos acuáticos.
• Use sólo como indicado. Podrían verse usos por profesionales y no profesionales. Se usa preferiblemente cuando no se observan insectos. Después de lavar la red no se debe deshacer de la arena del rio, lago o depósito de agua. Después de lavar el mosquitero, no eliminar el agua suave cerca de ríos, lagos o depósitos de agua. Mantenga fuera del alcance de los niños y no en presencia de alimentos, bebidas o otros artículos de consumo.

AFTER USE:
• Determine the quality of the protection provided by spray insecticide.
• Never dispose of the mosquito liquid near rivers, lakes or other water bodies. Store out of reach of children and not in the presence of food, drink or other consumables.

FR: PRODUIT INSECTICIDE
Pour utilisation comme protecteur pour la prévention des piqûres de moustiques et autres insectes.

• Très toxique pour les organismes aquatiques.
• Utilisez uniquement tel que recommandé. Ne peut pas être utilisé comme protecteur pour la prévention des piqûres de moustiques et autres insectes. Netprotect® garantit une nuit de sommeil sûre et tranquille.

APLICACIÓN
Netprotect® protege al usuario de las picaduras de insectos, enfermedades transmitidas por insectos y otros insectos. Lasahy la red de dormir de manera segura.

DEFTER
• Entferne nach dem Verbrauch die Insektizide und andere Insekten nach dem Verbrauch.
• Keine Nahrungsmittel, getränke oder andere konsumierbare Gegenstände in der Nähe des Behälters aufbewahren.

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