

Deltamethrin-based tablet for bed net impregnation

K-O TAB[®]

A small, detailed illustration of a mosquito is positioned over the letter 'O' in the product name "K-O TAB".

The easy to use unit dose insecticide tablet for the treatment of mosquito nets.



K-OTAB[®] is a concentrated tablet (1.6 g tablet contains 0.4 g of deltamethrin), designed for treatment of mosquito nets to provide a long lasting repellent and killing effect against mosquitoes, sand flies and other arthropods

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Efficacy

K-O TAB[®] contains deltamethrin (0.4 g per tablet), amongst the most active synthetic pyrethroids ever developed commercially. It requires very low doses (20-25 mg/m²) of active ingredient to give effective control over a 12 month period and up to three washes.

K-O TAB[®] is also effective against a wide range of nuisance insects.

K-O TAB[®] treated bed nets are welcomed by people as they get less annoyance from Culicine mosquitoes, bedbugs, and lice. Trials carried out by the World Health Organization have also shown that use of bed nets treated with deltamethrin reduces the impact of cutaneous leishmaniasis, a disease transmitted by sand flies.

(Tayeh, A. et al, 1997)

Excellence

K-O TAB[®] when added to water, forms a suspension of deltamethrin with a particle size of circa one micron. This provides millions of small, active particles which distribute all over the netting surface and lodge firmly between the multi-filament fibres making them less easy to remove by abrasion or washing.

K-O TAB[®] gives more than 90% kill (after 3 minutes exposure) of *Anopheles* mosquitoes even after 12 months and 3 washes. (Hunt, R.H., 1998)

K-O TAB[®] offers excellent stability under various climatic conditions



Acceptability

The acceptability of the K-O TAB[®] formulation has been demonstrated in trials in Africa. The results were overwhelmingly more favourable than the use of liquids (Jones, C.).

Each K-O TAB[®] tablet is packed in an easy-to-tear foil sachet and can be dropped from the sachet directly into water. The tablet disperses in 30 seconds and then, after stirring, the product suspends perfectly and the solution is ready for dipping the net.

One K-O TAB[®] tablet is a precise unit dose.

The product is odourless and there will be no oily residues on the net which may attract dust.

K-O TAB[®] contains no solvents, making it a safer formulation for bed net impregnation than EC formulation. K-O TAB[®] is easier to transport than competitor products.

K-O TAB[®] in its individual foil sachet is easy to handle, transport and store with less risk of accidental spillage (Zaim M., et al., 2000).

K-O TAB[®] can be easily included in a net treatment kit or a re-treatment kit. The empty sachet can be disposed of very easily by burning as there is no residue left behind.

Reliability: K-O TAB[®] successfully evaluated by WHO

The World Health Organization operates the WHO Pesticide Evaluation Scheme (WHOPES). This scheme has 4 major stages from laboratory to field trial evaluations and the development of technical specifications:

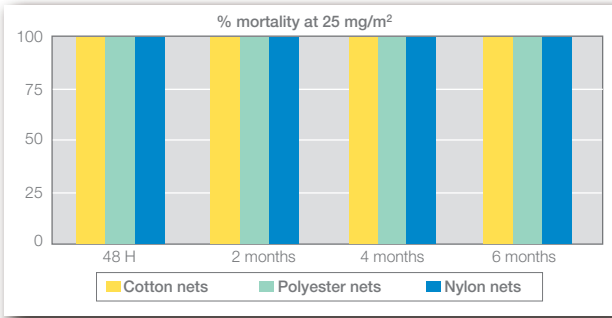
- laboratory trials
- small scale field evaluation
- full village scale field study
- establishment of specifications for the formulation

K-O TAB[®] was submitted to WHO for evaluation and was successfully evaluated by the WHOPES in field trials for the treatment of mosquito nets for malaria control. In addition, it is manufactured in accordance with WHO specifications. This assures customers, that they are purchasing a proven product manufactured to the highest quality specifications.

Field efficacy

- WHOPEs trials of K-O TAB® at Institut Pierre Richet (Cote d'Ivoire - Darriet, F. et. al, 1999)

Nets hung in test huts were evaluated regularly using the standard WHO cone test with 3 minute exposure of wild caught *Anopheles*. Three different types of bed nets were used to evaluate the performance of K-O TAB®. The results are shown below. It can be seen that the performance was excellent on all types of bed net materials.

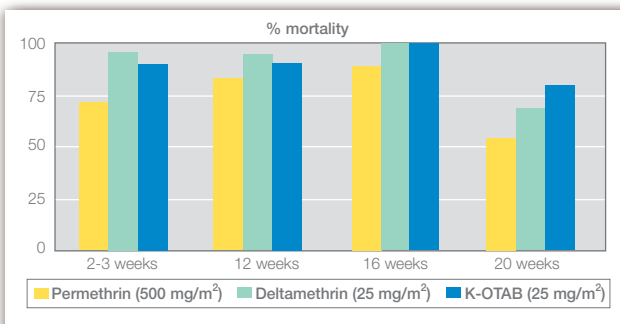


- Evaluation of K-O TAB® in MRC/WHOPEs trials, The Gambia (Pinder M. et. al., 1999)

K-O TAB® was compared with permethrin EC and deltamethrin SC liquid formulations. The dosage rates on the nets were checked by chemical analysis and the mean for permethrin nets was 446 mg/m², for deltamethrin SC was 23 mg/m² and for the K-O TAB® was 15 mg/m².

Therefore while the other two products were close to target dose, the K-O TAB® nets were for reasons unknown, under dosed underdosed.

However, despite being 40% under target dose, K-O TAB® was as effective as the other products for 16 weeks post-treatments but was superior by 20 weeks post-treatment. During this trial, in a village, the nets were washed as required and also subject to dust, dirt and regular handling.



Recommendations for use

- Dilution rates:

Fabric	Dilution
Synthetic	1 K-O TAB® in 0.5 litre of water
Cotton	1 K-O TAB® in 2.0 litres of water

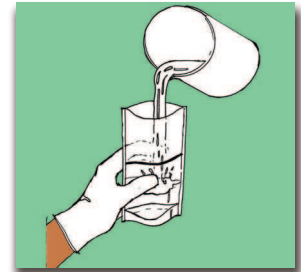
- Instructions for use:

Visual instruction drawings have been developed and

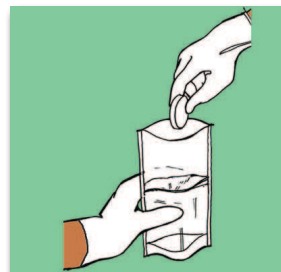
can be adapted and used in different commercial operations. Many donor funded programs have seen the advantages of and provide it with simple to follow pictogram instructions for home or "do-it-yourself" treatment



1. Put on gloves



2. Fill plastic bag with clean water up to the mark.



3. Remove K-O TAB® from pack and place in water.



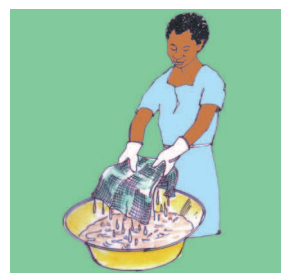
4. Seal pack tightly and shake until mixed thoroughly.



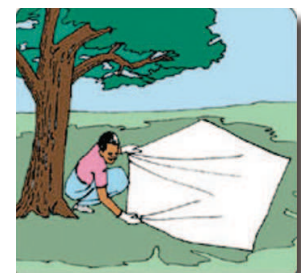
5. Pour solution over net in basin.



6. Turn net in solution until thoroughly wet (2 minutes).



7. Remove net and allow dripping over basin.



8. Lay net out flat to dry in the shade.



9. Pour left over solution into ground and cover with soil.



10. Wash hands with soap and water after treating net.

Toxicity

K-O TAB®		
Oral (rat)	LD ₅₀ (mg/kg bw)	1 965
Dermal (rat)	LD ₅₀ (mg/kg bw)	> 2 000
Skin irritation (rabbit)	Non-irritant	
Eye irritation (rabbit)	Non-irritant	
Skin sensitisation (pig)	Not a sensitizer	

Safety in use

One concern expressed concerning the use of tablets for bed net impregnation is that people may mistake them for a pharmaceutical and swallow them. Bayer Environmental Science has anticipated this and has added to K-O TAB® an extremely bitter agent; this makes the tablet totally unpalatable and minimizes the risk of accidental poisoning via the oral route.

Swallowing of a single whole tablet by an infant or child is considered unlikely to pose a threat to life (Barlow, S. et al., 2000, submitted to FCT).

There are however positive safety benefits from using the tablet formulation:

- less risk of accidental exposure to user due to splashes or spillage during treatment
- no risk of container or sachet leakage, odour or contamination
- solid presentation therefore the product is safer to transport and safer to store
- minimal packaging to dispose of, unlike drums/bottles which can be subsequently misused
- no solvents used so no flammability risk

Human exposure

(Reference: Risk Assessment of The Use of Deltamethrin on Bednets for the Prevention of Malaria - Susan Barlow, Frank Sullivan and Jo Lines, 2000, Food and Chemical Toxicology, in press)

Accidental swallowing or chewing of a whole tablet is considered unlikely since it is foil wrapped and not easily opened by a child. In addition it contains Bitrex, a bittering agent which should cause any person accidentally putting a tablet into their mouth to reject it. However if a 1-2 year old child accidentally swallowed a tablet then the dose absorbed is well below levels shown to cause toxicity. Swallowing a single tablet by a child or infant is therefore unlikely to pose a threat to life.

Should a child suck or chew a net (area of 50 cm²) or otherwise handle a net, and then transfer the active ingredient to its mouth, the maximum amount of deltamethrin absorbed results in a margin of safety of x75 for a newborn child and x250 for a two year old.

Exposure from treating a bed net, using gloves and following instructions, would give Margins of Safety of x 60 and x 30 for adults and children, respectively.

Any toxicity risk from inhalation by a person sleeping under a treated net is negligible. Short-term inhalation studies rats give a Non Observed Effect Level of 3 mg/m³, which is around 55000 times greater than the estimated maximum concentration under nets.

Environmental protection

Soil

Persistence and degradation when left-over or waste water from the washing of bed nets is disposed of:

Deltamethrin is rapidly degraded in most soils with DT₅₀ values of approximately 3 weeks. Deltamethrin is absorbed onto soil particles very rapidly and with high adsorption constants. The desorption is very low, therefore the risk of leaching of the parent compound into deep soil layers can be excluded.

Mobility:

Deltamethrin should be considered as non-persistent and immobile.

Ecotoxicity

Fish (96h) Rainbow trout	LC ₅₀ (µg/l)	0.91
Daphnia (48h)	LC ₅₀ (µg/l)	3.5
Worms (14d) Earthworm	LC ₅₀ (ppm)	1 290

No unacceptable risk to non-target aquatic organisms from and occasional off label washing of deltamethrin treated bed nets in natural water bodies. (Schaefer D., 2000).

Safety advice

- Wear rubber or plastic gloves when handling products or dipping nets.
- Allow treated nets to dry and air thoroughly before use.
- Wash splashes from skin or eyes immediately with plenty of water.
- Wash hands and exposed skin before meals and after work.
- Keep away from food, drink and animal feedstuffs stuffs.
- When using do not eat, drink or smoke.
- Keep out of reach of children.



First Aid measures in case of exposure

General advice:

Remove contaminated, soaked clothing immediately. Clothing must be thoroughly rinsed and washed.

Inhalation:

Remove the patient to fresh air and keep at rest. If symptoms persist, call a physician.

Skin Contact:

Take off all contaminated clothing immediately. Wash off immediately with plenty of water and soap. After skin contact, apply Vitamin E cream or toilet milks. When symptoms persist or in all cases of doubt, seek medical advice.

Eye contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Ingestion:

Do not induce vomiting. Wash out mouth with water. Keep at rest. Obtain medical attention.

Notes to physician

Symptoms:

Local. After skin contact: paresthesia (local), may cause skin and eye irritation. Inhalation may provoke the following symptoms: irritation, cough.

Symptoms:

Systemic. Excitement, gastrointestinal discomfort, tremor, dizziness, headache, listlessness, nausea and vomiting, epigastric pain, muscular fasciculation of limbs, unconsciousness, convulsions and coma (very high doses).

Risks:

This product/preparation contains a pyrethroid. Must not be confused with organophosphorus compounds!

Treatment:

Local: Initial treatment should be symptomatic and supportive.

After eye contact, instillation of local anesthetic drops e.g. 1% Amethocaine Hydrochloride eye drops. Give analgesics as necessary.

Treatment:

Systemic: Endotracheal intubation should be done and gastric lavage performed followed by administration of charcoal.

Monitoring of respiratory and cardiac functions ECG – control (electrocardiogram)

Check for pulmonary oedema in event of inhalation. Keep airway clear, administer artificial respiration if necessary.

Against convulsions, give Diazepam: for adults 5-10 mg intravenously as necessary until fully sedated. For children 2.5 mg i.v.

There is no antidote

Contraindication: Atropine, derivatives of adrenaline

Recovery: spontaneous.

Roll Back Malaria

Recognizing the deteriorating global malaria situation (about 2 mio. deaths per year) WHO launched the Roll Back Malaria (RBM) initiative in 1998.

RBM is a global partnership founded by the World Health Organization (WHO), the United Nations Development Programme (UNDP), the United Nations Children's Fund (UNICEF) and the World Bank with the goal of halving the world's malaria burden by 2010.

Bayer Environmental Science commitment:

Bayer Environmental Science as a partner in RBM has developed technical solutions, expertise and close working relationships with international organizations and Non Governmental Organizations, to control malaria on a national scale and for personal protection using impregnated bed nets, by:

- offering a large range of vector control products
- providing practical support and training
- assisting in promoting ITN's, insecticides and the use of mosquito nets

K-O TAB® offers the ideal product for the treatment and re-treatment of individual nets.

Bayer Environmental Science is therefore well placed to support the Roll Back Malaria initiative and ready to work closely with all stakeholders.





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