

Long Lasting Insecticidal Nets - Target Product Profile

Measure	Criteria
EFFICACY	
WHO PQ threshold	To demonstrate that the next-generation LLIN is non-inferior to the current benchmark in the product class. Achieves WHO PQ criteria for a Long-Lasting Net.
Wash resistance (lab)	In laboratory trials retains activity in WHO cone Bioassays after 20 washes.
Wash resistance (huts trials)	LLIN is non-inferior to standard net after 20 washes in experimental huts trials (in terms of BFI and mortality). The time between two consecutive washes should correspond to the regeneration time determined in laboratory studies.
Field efficacy	In large scale field studies, 80% of the distributed nets should achieve 80% mortality in WHO cone bioassay after 3 years. This is based on ability to meet the efficacy criteria for at least one outcome measure in laboratory testing (i.e. mortality, blood-feeding inhibition, or reduction in reproductive output).
Target species	Effective against <i>Anopheles gambiae</i> s.str. and <i>Anopheles arabiensis</i> including existing resistant strains. Resistant strains to include: Kdr, Mace, Rdl, Metabolism (oxidative; esterase; GST)
Formulation	Final formulation produced in easy to use packaging. Net suitable for manufacturing in existing plant on standard equipment.
Other benefits	Demonstrates rapid knock down
MANUFACTURING	
Cost of implementation	Market Cost competitive for an LLIN
TGAI production	Technical specifications of a.i. are defined
Supply chain	Active ingredients are available to the company developing the product. There is a reliable manufacturing process to ensure consistency between batches.
Commerciality	Use rates are commercially acceptable at launch
Net durability	Final product to meet WHO requirements for net durability and fabric integrity.
SAFETY AND REGULATORY	
International standards	All active ingredients used must hold a registration in a stringent regulatory authority (e.g. EPA, EU, Japan) or WHO CAGR approval
WHO PQ	Product meets WHO LLIN safety requirements

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Risk Assessment	Product passes WHO PQ risk assessment for LLINs
Toxicology	For all major categories of toxicological importance, risks are understood and considered to be manageable.
Non-target species	Risks to non-target species in line with accepted standards for PHPs at the time of registration submission. It is expected that environmental exposure will be minimal for LLINs.
Product chemistry	Manufacturer can satisfy all product chemistry regulatory requirements.
MARKET	
Competitiveness	Product is a competitor for comparable products on the market
IRM	Product is sustainable and part of a wider insecticide resistance management strategy (e.g. GPIRM) and will be used as part of a rotation or a mosaic programme
END USER SUITABILITY	
Irritancy and skin sensitization	No classification for irritancy or skin sensitisation
Odour	No unacceptable odour
Staining	No staining
FREEDOM TO OPERATE	
FTO	Manufacturer has access to all product components, including formulations, and has freedom to manufacture in the intended geography.
Route of synthesis	Manufacturing route of synthesis is well defined and considered to be commercially robust.