



SLOVENSKI STANDARD
oSIST prEN 17487:2020
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Varovalna obleka - S permetrinom obdelana varovalna oblačila za zaščito pred klopi

Protective clothing - Protective garments treated with permethrin for the protection against tick bites

Schutzkleidung - Mit Permethrin behandelte Schutzkleidungsstücke zum Schutz gegen Zeckenbisse

Habillement de protection - Vêtements de protection traités à la perméthrine pour la protection contre les morsures de tiques

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Protective clothing - Protective garments treated with permethrin for the protection against tick bites

Habillement de protection - Vêtements de protection traités à la perméthrine pour la protection contre les morsures de tiques

Schutzkleidung - Mit Permethrin behandelte Schutzkleidungsstücke zum Schutz gegen Zeckenbisse

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 162.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (prEN 17487:2020) has been prepared by Technical Committee CEN/TC 162 “Protective clothing including hand and arm protection and lifejackets”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of Regulation (EU) 2016/425 and Regulation (EU) No 528/2012.

For relationship with EU Regulation, see informative Annex ZA, which is an integral part of this document.

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Introduction

By preventing tick bites, a range of tick-borne infectious diseases can be prevented. This document refers to protection against all biting stages of the tick *Ixodes ricinus*, hereafter named wood tick, the tick species with the largest occupational and public health relevance in Europe.

The most prevalent disease transmitted by the wood tick is Lyme borreliosis, which can affect the skin, nervous system, joints and heart. In some EU countries, Lyme borreliosis is regarded as an occupational disease. Employers are then obliged to make the best possible effort to prevent occupational diseases among employees. Employees are also obliged to reasonably abide by the measures offered.

The garments help protect people who can come into contact with ticks during their work. Wood ticks lay in ambush in the lower vegetation and cling on to passers-by with whom they come in to contact. They then crawl over skin or clothing to find a site where they can consume a blood meal. The protective effect of the garment against tick bites is primarily determined by the extent to which the garment covers the skin, and this effect will increase as a larger part of the body is covered. It is important here that those body parts (legs, waist, torso and arms) are covered that have contact with vegetation in which ticks can be present (up to a height of 1,5 m). With usual untreated covering garments, ticks are able to crawl over the fabric for minutes up to several hours and reach bare skin to bite. In addition to the protective effect of covering the body, the permethrin on or in the fabric offers extra protection. Ticks that come in contact with permethrin are immobilized, and as a result they are no longer able to reach bare skin and transfer pathogens through a bite. Protection against tick bites may be one of the functions of a garment. Examples of other functions may be maintaining body heat, preventing exposure to UV light, camouflage, preventing skin irritation or injury by plants or working conditions, or representation and recognizability.

The body covering garment can also help other target groups such as volunteers and recreationists (such as hunters) to offer protection against tick bites. However, the choice of using the garments is ideally based on a professional risk assessment which includes exposure to ticks, and factors such as age and pregnancy. Instructions for use and warnings for tick bite risks also apply to these users and it is important that these are provided to these groups by manufacturers of these garments.

The body covering garment industrially treated with permethrin can also help to protect against other arthropods that can transmit diseases, such as different tick and mosquito species [6]. However, this document only applies to the protection against bites by the wood tick, and specifically the most relevant developmental stage (nymphs).

Some general statements for the development of the protective clothing according to this document are:

- this document applies to body covering garments (with long trouser legs and/or sleeves) where the protection against ticks provided by covering the body is reinforced by industrial treatment with the biocide permethrin;
- the WHO states limits to the daily uptake of permethrin by the human body. This document states requirements to ensure that these limits will not be exceeded by wearing the protective garment;
- this document states requirements that safeguard the health of the user and at the same time safeguard that the additional protective effect of the permethrin treatment is maintained as long as possible during use. These two factors are, with the current state of technology, inseparable, as permethrin release rate from the garment determines uptake of permethrin by the user;
- the standard formulates requirements that ensure that the health of the wearer will not be burdened by other agents which are used as additives to, for example, bind permethrin to the fabric or other as a result of manufacturing processes;

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- the biological activity (bioactivity) against ticks is decisive for the protective effect of the permethrin-treated garments. Bioactivity is determined by the degree of contact between the tick and the permethrin (and to lesser extent by the level of the permethrin content);
- the number of standardized launderings that are required to reach the minimal permethrin content stated in this document may differ from the number of launderings under practical use including conditions during domestic laundering.

A detailed description of the requirements is given in Clause 4 of this document.

Garments can be treated with permethrin to prevent tick bites. In accordance with the Biocidal Products Regulation (EU) 528/2012, such garments can be regarded either as 'treated articles' (if protection against ticks is part of a set of functionalities such as protection against weather conditions, camouflage, company representation, protection against stinging plants etc.) or as 'biocides' (if the primary function of the clothing is protection against tick bites). This document is applicable to garments that might be considered as biocides and garments that might be considered as treated articles. If a specific product is regarded as biocide, EU member states could require specific registration or legislation before the product can be made available on the market.

This document describes requirements and the tests to which clothing that is treated with permethrin complies in order to provide sufficient assistance in protection against tick bites, and to be durable and safe for the user. Optimal laundering conditions, which are determinative for a sustainable effect of permethrin treatment, are also referred to.

The following regulations were observed in composing this document:

- 2016/425 regarding personal protective equipment;
- 528/2012 EU regarding biocidal products regulation.

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1 Scope

This document formulates requirements for garments that support the protection against tick bites. The document applies to all types of garments where protection against tick bites, which is provided by garments as physical barriers, is reinforced by industrial treatment with the biocide permethrin prior to confection

NOTE Untreated garments covering the torso, arms and legs and feet offer some protection against tick bites but are insufficient under high exposure to ticks, which can crawl over the fabric to reach bare skin and bite. Garments that comply with this document and cover at least torso, arms and legs counter ticks from crawling over the fabric to reach bare skin and bite; such garments thereby provide substantial additional protection.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 6330:2012, *Textiles — Domestic washing and drying procedures for textile testing (ISO 6330:2012)*

EN ISO 13688:2013, *Protective clothing — General requirements (ISO 13688:2013)*

EN ISO 13934-1:2013, *Textiles — Tensile properties of fabrics — Part 1: Determination of maximum force and elongation at maximum force using the strip method (ISO 13934-1:2013)*

EN ISO 13937-2:2000, *Textiles — Tear properties of fabrics — Part 2: Determination of tear force of trouser-shaped test specimens (Single tear method) (ISO 13937-2:2000)*

EN ISO 13935-2:2014, *Textiles — Seam tensile properties of fabrics and made-up textile articles — Part 2: Determination of maximum force to seam rupture using the grab method (ISO 13935-2:2014)*

EN 13921:2007, *Personal protective equipment — Ergonomic principles*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1 accepted daily intake ADI

maximal allowed daily body intake of a substance (100%) before adverse health effects can be expected

Note 1 to entry: In this document, the substance is permethrin.

Note 2 to entry: Based on definition of the World Health Organization (WHO).

prEN 17487:2020 (E)**3.2****bio-activity**

degree to which permethrin in the test fabric affects the test animals that came into contact with the fabric in the test assay

Note 1 to entry: This value is determined by the degree to which the animal comes into contact with permethrin.

Note 2 to entry: Bio-activity is not by definition determined by the permethrin concentration in a fabric. It is determined by the availability of permethrin on contact surfaces of the fabric.

3.3**biocidal product**

any substance or mixture which, in the form in which it is supplied to the user, consists of, contains or generates one or more active substances, with the purpose of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on a harmful organism by any means other than mere physical or mechanical action

Note 1 to entry: Manufacturers, suppliers and users of biocidal products can find information about the authorization of biocides to the market, rules for labelling, use and monitoring within the EU on the websites of ECHA and the European Commission [1].

Note 2 to entry: According to the definitions set by the EU, products treated with permethrin can be considered as biocidal products or treated articles. This consideration could differ per product and depends on the primary function of the product. If the product is primarily intended to control harmful organisms or to prevent harmful effects, then the product is considered a biocide. If the biocidal effect through treatment with permethrin is only an additional property to the basic function(s) of the product, such product / object can be regarded as treated article [2].

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[SOURCE: 528/2012 EU regulation regarding biocidal products regulation, 2018-06-15] 67-b850-f68981bf3666/osist-pren-17487-2020

3.4**cytotoxicity**

effect of one or more components in a substance on growth of living cells in a cell culture

3.5**sensitization**

effect of one or more components in a substance on expression of specific membrane proteins of cells in a cell culture

3.6**cut-off value**

minimal effective concentration of permethrin per square meter that is required to support protection against tick bites sufficiently

Note 1 to entry: Concentrations below the cut-off value have adverse effects such as:

- the required contact time between the tick and the fabric is too long, which enables ticks to bite;
- a short immobilisation followed by recovery of the tick;
- insufficiently exposed ticks could show increased bite frequency before taking a blood meal (this was observed in tick species other than the wood tick).

3.7**knock-down time**

time between first contact of the test animal with the permethrin-treated fabric, until the inability of the test animal to move (immobilisation)

3.8**permethrin**

active ingredient based on synthetic pyrethroid variant 25:75 cis:trans isomere ratio, non-racemic

Note 1 to entry: Permethrin is EU-registered under the biocide legislation and described by CAS number 52645-53-1.

Note 2 to entry: Permethrin is categorized as products used for the control of arthropods (e.g. insects, arachnids and crustaceans), by means other than repulsion or attraction in 528/2012 EU [3] (cat. PT18). This means that it does not have attractant or repellent properties (cat. PT19) to target animals without contact with the treated fabric.

3.9**permethrin migration rate**

velocity of permethrin molecules migrating through a substrate

3.10**biocide treated article****treated article**

any substance, mixture or article that has been treated with, or intentionally incorporates, one or more biocides

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[SOURCE: EU 528/2012 regarding biocidal products regulation, Article 3, sub Clause 1.a]

3.11**industrially treated**

treatment procedure by which fibres, yarns and /or fabrics are treated during production with permethrin on a large and mechanised scale before confection

Note 1 to entry: Retreatment of used garments is not included.

Note 2 to entry: A treated article that has a primary biocidal function is considered a biocidal product.

4 Performance requirements**4.1 General**

This clause covers the health, technical and maintenance requirements for garments that help to protect against tick bites, are industrially treated with permethrin and are marketed as a treated article or biocide.

If the garments are to be placed on the market as a biocide, an authorization procedure could be required according to the Biocides Regulation.

This document is to be applied in conjunction with EN ISO 13688:2013 and EN 13921:2007 for general ergonomic principles to be used in designing and specifying personal protective equipment. For general ergonomic requirements involving design and comfort, EN ISO 13688:2013 (4.3.1, 4.3.2, 4.3.3 and 4.4) shall be followed.

prEN 17487:2020 (E)**4.2 Innocuousness**

Protective clothing shall not adversely affect the health or hygiene of the user [source: EN ISO 13688:2013]. Permethrin per se may in certain concentrations pose a risk to human health. Several requirements stated in Annex A safeguard the users health and justify the application of permethrin in protective clothing in accordance with EN ISO 13688:2013 Annex B, Figure B.1 (flow chart acceptability of materials in protective clothing). If the requirements in these documents are met, the health benefits of preventing tick-borne disease outweigh potential health risks of for example minor temporal skin impairments that may occur.

Specific requirements and tests for permethrin incorporated in fibres or fabrics during the industrial treatment are described in Annex A.

4.3 Design

For general ergonomic requirements involving design and comfort, EN ISO 13688 (4.3.1, 4.3.2, 4.3.3 and 4.4 and Annex C) shall be followed.

Specifically regarding the protective effect of permethrin in preventing ticks to reach bare skin to bite, the following requirements are formulated:

- 1) The permethrin-free surface (for example, applications such as reflective striping in accordance with EN ISO 20471:2013, name badges etc.) shall comprise no more than 12 % of the outer surface of the garment.
- 2) The non-treated applications of fabric shall not be placed within 5 cm around the openings of a garment
- 3) Trousers shall have long trouser legs, where coverage of underlying skin or other garments at the openings at the end of the trouser-legs and the waist shall be retained during movement as described in EN ISO 13688:2013, Annex C.
- 4) The upper body garment shall have long sleeves. Coverage of the underlying skin or other garment at sleeve and waist openings shall be retained during movement as described in EN ISO 13688:2013, Annex C.

4.4 General technical requirements

- 1) The garment shall be made from materials industrially treated with permethrin.
- 2) Other treatments, for example to enhance fire resistance or water repellency, can be applied to the garment treated with permethrin. These applications shall not deteriorate or reduce the protective effect against ticks beyond the requirements stated in this document.

4.5 Permethrin requirements

- 1) The active ingredient with biocidal effects on ticks shall be: permethrin (m-phenoxybenzyl-3-(2,2-dichlorovinyl)-2-dimethyl-cyclopropanecarboxylate), CAS No. 52645-53-1.

The cis:trans isomere ratio of the permethrin shall be 25:75.

The biocide containing the permethrin needs to be registered according to the EU regulation in one of the member states.

- 2) Detailed requirements regarding permethrin content are described in A.1.