



Quality standard of Minitube's QuickTip® semen bags 100% sperm safe

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Porcine artificial insemination (AI) is an important part in pig production worldwide. More than 95% of all sows worldwide are inseminated (Knox, 2016). Each AI dose needs to be temporarily stored in some sort of semen container until the insemination takes place. In many cases, the semen dose is transported and stored in a semen container for many days.

The semen container must therefore absolutely guarantee non-toxicity in terms of semen fertility. Minitube's QuickTip® semen bags meet this essential requirement through compliance with numerous regulations, a rigorous quality control and not least, design.

Safety through design

Minitube's QuickTip® semen bags are designed for sperm friendliness and safety. An innovative plastic foil is used to manufacture the bags. Like many plastic foils, it consists of several layers to combine certain physical properties for the final product. While other manufacturers use a three to four layer structure with at least one adhesive layer to keep the plastic films together, Minitube has opted for an innovative compound foil concept entirely free from any adhesive.

The following illustration shows a cross section of a typical foil of a commercially available semen bag. The image was produced with polarization microscopy. Next to the outer layer you find the adhesive or glue layer which can contain repro-toxic substances. The glue layer is separated from the diluted semen by so-called supporting layers. These layers suffer from technically unavoidable variations in thickness. If the thickness of the layers between glue and semen decreases below a certain value, the risk that toxins from the glue layer migrate into the semen solution, increases exponentially. This occurrence has been documented in the past (Nerin et al., 2015) with severe consequences for sow fertility. Variations in the thickness of these layers are system-inherent and cannot realistically be detected 100% in any quality control system.

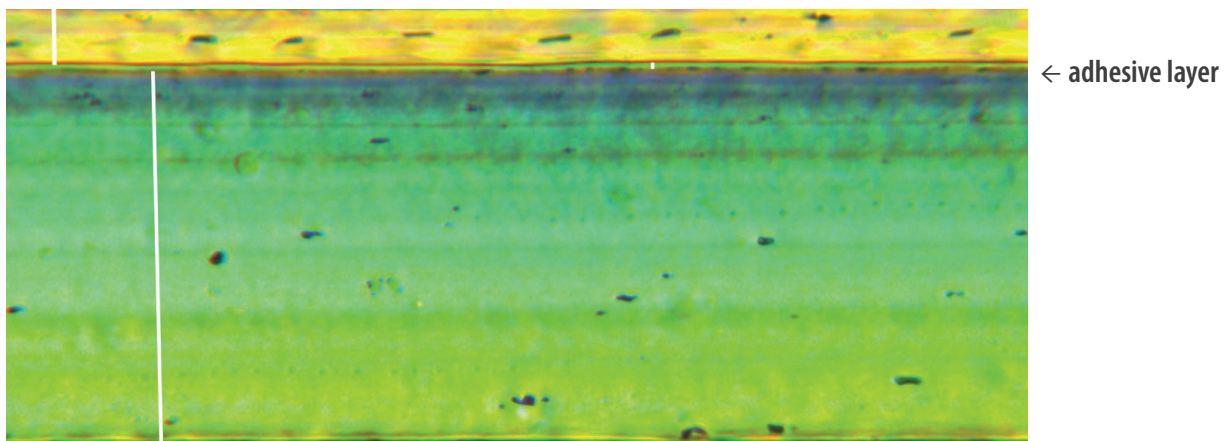


Figure 1: Typical layer structure with adhesive of a plastic foil used for semen bags - NOT Minitube (Fraunhofer IVV)

The foil used to manufacture Minitube's QuickTip® semen bags is designed to eliminate the risk of toxins being released into the semen. The foil for the QuickTip® semen bags is made solely of PET (polyethylene terephthalate) and PE (polyethylene) and does not use any potentially toxic additives. Figure 2 shows the layered structure of a QuickTip® semen bag.

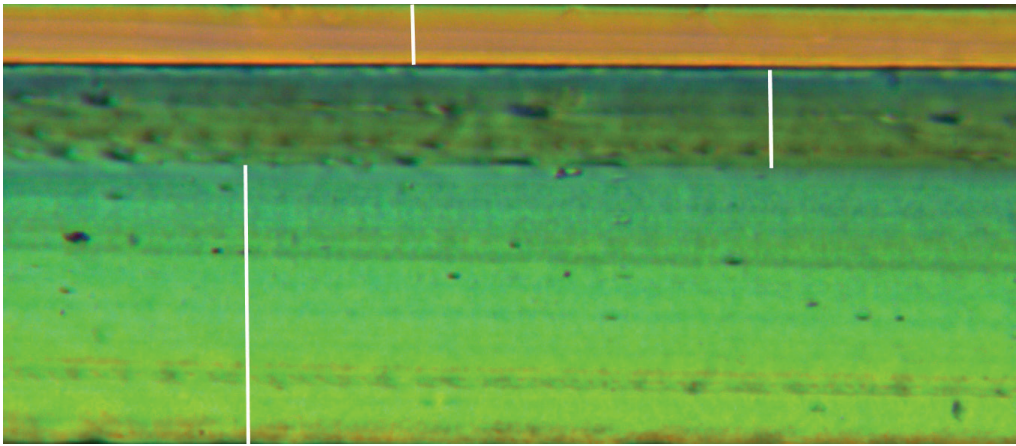


Figure 2: Layer structure of Minitube's QuickTip® semen bag (Fraunhofer IVV)

The Minitube foil structure uses PET as outside layer and binds the inner bilaminar PE film to the outer layer with purely physical forces. The QuickTip® semen bag is free from any adhesive chemicals and therefore cannot contain any substances toxic to reproduction. This is an exclusive safety insurance that is only provided by Minitube QuickTip® semen bags. The foil design for Minitube QuickTip® bags is unique in the boar semen bag market and ensures a systemically safe product.

Quality assurance system

All materials used in the manufacture of QuickTip® semen bags must be tested and proven to be biologically inactive and sperm friendly. Minitube as a specialized and ISO 9001:2015 certified producer of semen bags has a quality control program in place which consists of a three-level concept for the quality assurance and testing of raw materials and finished products that come into contact with semen.



Figure 3: Three-level concept for quality assurance (NIAS: non-intentionally added substances)

Sperm tolerance testing

Quality assurance tests are regularly performed at the Unit of Reproductive Medicine of the University of Veterinary Medicine Hannover, Foundation, which operates a DAkkS* accredited GLP laboratory in accordance with the international ISO/IEC 17025 norm. Each new raw material must pass the tests before it can enter the production line for boar semen bags. For these tests, boar semen from at least three different boars is extended with Androstar® Plus, divided into split samples and incubated in the QuickTip® boar semen bags to be tested and in glass vials as a control. Semen is evaluated over a semen storage period of at least 6 days. All split samples are stored in a semen storage unit at 17° C. The following tests are performed:

- Total and progressive motility (CASA) after 24, 72 and 144 h
- Acrosome integrity and membrane integrity (flow cytometry, H33342/PNA/PI) after 24 and 144 h
- Thermo-resistance test after 144 h storage at 17°C (incubation at +38°C for 120 min), then analysis of progressive motility (CASA)
- Mitochondria membrane potential (flow cytometry, H33342/PI/JC-1) after 24 and 144 h
- Membrane fluidity (flow cytometry, H33342/Yo Pro 1/Merocyanin (M540)) after 24 and 144 h
- Complete morphology (wet mount, phase contrast microscopy 1000x) after 24 and 144 h

Absence of non-intentionally added substances (NIAS)

The QuickTip® semen bag foil does not contain substances like heavy metals, endocrine disruptors and plasticizers like Bisphenol A, Phthalates and Adipates per its formulation and certification. NIAS are any substances that might have been non-intentionally added to the raw material during production or transport and are potentially harmful. These substances can cause adverse biological effects in the event they are added non-intentionally. Most importantly in the context of boar semen preservation, these substances can cause damage to the sperm during storage and diminish fertility and productivity of the inseminated sows. The test for NIAS verifies compliance with these requirements.

Therefore, in the third level of the Minitube quality assurance program, the absence of NIAS is controlled with routine testing of the raw materials for endocrine disruptors and plasticizers like Bisphenol A, phthalates and adipates as well as heavy metals. It is a matter of principle for Minitube, as a manufacturer of semen packaging material, to take full responsibility for using only substances and raw materials that are not harmful to animals or sperm.

Physical quality control

In addition, all batches of QuickTip® boar semen bags are subject to physical quality control and are only released for sale after approval by Minitube's quality control management. Tests performed include sealing tests, leak tightness, functionality of the QuickTip® and the accuracy of the dimensions and grid of holes for transporting the bags on the filling machine. The samples used for these tests are randomly drawn from each production batch in accordance with ISO 2859-1-204.

Specifications and compliance

Minitube QuickTip® semen bags are made from polyethylene terephthalate (PET) and polyethylene (PE). PET and PE are known for its inactivity and biocompatibility. They are free from any toxic ingredients like Bisphenol A, heavy metals, phthalates or adipates as these substances would impair the necessary product features. Each batch of the raw material that is assigned for the production of QuickTip® boar semen bags at Minitube's manufacturing plant, must be accompanied by a batch certificate. Unlike certain other manufacturers' semen bags, Minitube's QuickTip® semen bags are free from the disinfectant Triclosan which has been demonstrated to have a negative effect on mammalian cells, including porcine spermatozoa (Ajo et al., 2015).

The raw materials used in Minitube's QuickTip® semen bags meet all of the following standards:

- EC Regulation 1907/2006/EC and amendments (referred to as REACH regulation), and further EC regulation 1272/2008/EC on classification, labelling and packaging of substances and mixtures
- EC Directive (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food
- EC Directive (EC) No 2016/1416 amending and correcting regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food
- EC Directive (EC) No 10/2011 on plastic materials and articles intended to come into contact with food

* DAkkS = National accreditation body for the Federal Republic of Germany

- Commission Regulation (EU) No. 10/2011 of January 14, 2011, including its amendments (EU) No. 1282/2011 of November 28, 2011, (EU) No. 1183/2012 of November 30, 2012, (EU) No. 202/2014 of 3 March 2014, (EU) No. 2015/174 of 5 February 2015, (EU) No. 2016/1416 of 24. August 2016 and (EU) 2017/752 of 28. April 2017
- Empfehlung III „Polyäthylen“ von Kunststoffen im Lebensmittelverkehr: Empfehlungen des Bundesinstituts für Risikobewertung (BfR) (former BgVV)., latest amendment February 15, 2016 (BGBl. I S. 198)
- Code of Federal Regulations, issued by the Food and Drug Administration (FDA), paragraph 21 CFR 177.1520 (olefin polymers)

Literature

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