



## SpermSafe label

### 100 % safety standard of plastic products for use with live semen

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Minitube International tests all materials which come into direct contact with semen. Split ejaculate samples are exposed to the surface of test materials and incubated. Standard sperm functionality is evaluated after incubation.

Look for the SpermSafe label! All plastic products intended for the use with semen and produced by Minitube will be labelled and provide 100 % certainty, that they will not adversely affect the quality of the semen.



#### The SpermSafe label

One of the benefits of artificial reproductive technologies is the highly increased availability of superior genetics, due to the increased number of semen doses that can be produced from one individual ejaculate. In order to ensure and take full advantage of these benefits, a number of quality procedures must be adhered to; most importantly hygienic collection conditions, diligent processing of ejaculates, suitable storage containers and the application of single-use and sperm-safe materials.

Many substances and materials that come into direct or indirect contact with sperm cells can affect the sperm fertility. Adequate testing for adverse effects on spermatozoa is therefore necessary for products that will be in contact with semen or extender, within the scope of their intended use, before the product or product batch is released for sale in the AI market. It is a matter of principle for manufacturers and suppliers of plastic materials which are recommended for semen processing and insemination, to use only materials that will not harm spermatozoa.

Minitube's extenders for semen are tested according to GMP protocols: each ingredient is tested separately, before it is used in the extender production. The final composition repeatedly undergoes several quality control steps before it is released for sale. For more details on semen extenders please read our document describing the procedure in detail ("Why are Minitube extenders safer", available on our website ). The SpermSafe label applies to plastic materials used for Minitube products. As such, Minitube extenders are sperm safe and consequently not provided with the SpermSafe label.

#### Quality of raw plastic material

Minitube International uses only original and certified raw materials provided by certified suppliers. The granulate material used for the production of our plastic products is formulated and manufactured in accordance with the latest regulations. The raw material batches comply with the mandatory Minitube standard of full traceability.

Unique batch numbers allow each production lot to be traced back to the single raw material batch and to the details of production, storage and other treatment conditions. Audits of suppliers are performed on a regular basis. Each granulate batch is confirmed to contain no harmful substances including Arsenic, Cadmium, Mercury among many others. Biological inactivity is guaranteed.

#### The SpermSafe test procedure

Minitube International conducts regular internal tests for sperm safety of the following product groups:

- Boar semen collection gloves, bags, filters and similar products
- Semen straws for fresh and frozen semen
- Boar semen tubes, bottles, caps and similar products
- Plastic products for insemination of all species

Raw materials are always tested for sperm safety before a new batch can enter regular production, or when a new material batch is sourced. Samples are taken from a normal large-scale manufacturing process to test the ultimate product which will reach the end customer under real-life conditions.

Product samples are submitted to material-to-sperm contact tests according to the following protocol: Either the sample or parts of the sample, are incubated with extended semen. Incubation time and temperature are set to concur with the purpose of the product:

1. An incubation time of 5 days is used for products which are destined for storing semen.
2. Products to be used for semen collection, like disposable semen filters, and insemination materials are incubated with the semen for one hour and then removed.

The analysis is performed 24 hours after removing the samples from the semen.

For validation, a split sample aliquot of the same extended semen is incubated with control samples of the same product type that have been proven to be sperm safe. Semen quality assessments are made from both the samples and the controls. After the required incubation time, semen motility, viability and morphology parameters are measured with the CASA system AndroVision®. The test results are then analysed and the tested product batch is released as sperm safe, if the required quality parameters have been met by the test sample.

All products produced by Minitube International, which have been successfully tested are marked with the SpermSafe label which is clearly visible on the original shipping box or bag in which the product is packed.

### Example for a SpermSafe test protocol

	<h2 style="margin: 0;">SpermSafe Test Protocol</h2>	<small>Page 1 of 1</small>
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<b>Analysis of Sperm compatibility No.: 015/2014</b>																		
<b>Ref. / Material:</b> 13203/4001 <b>Batch no.:</b> 1451925/1-1 <b>Description:</b> Mixing and dispensing bag for boar semen, 3.5 l																		
Motility:	Control		Sample		Repetition - sample													
	Total Motility	Progressive Motility	Total Motility	progressive Motility	Total Motility	progressive Motility												
Prior to incubation	93,2%	84,3%	93,6%	85,7%	94,3%	86,1%												
After incubation	91,5%	83,4%	92,8%	82,2%	93,8%	84,3%												
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th style="width: 20%;">Viability Membrane intact sperm cells</th> <th style="width: 20%;">Control</th> <th style="width: 20%;">Sample</th> <th style="width: 40%;"></th> </tr> <tr> <td style="text-align: center;">Prior to incubation</td> <td style="text-align: center;">98%</td> <td style="text-align: center;">98%</td> <td></td> </tr> <tr> <td style="text-align: center;">After incubation</td> <td style="text-align: center;">97%</td> <td style="text-align: center;">98%</td> <td></td> </tr> </table>							Viability Membrane intact sperm cells	Control	Sample		Prior to incubation	98%	98%		After incubation	97%	98%	
Viability Membrane intact sperm cells	Control	Sample																
Prior to incubation	98%	98%																
After incubation	97%	98%																
<b>Duration of sample incubation / temperature:</b> 1 hour / +17° C																		
<b>Result:</b> The tested material complies with the intended application.																		
<b>Comment:</b> none																		