



SparMED ApS Phone: +45 39 40 25 03

E-m@il: info@sparmed.dk

www.sparmed.dk

Certificate of Analysis

Product: Oosafe® Disinfectant

Batch/LOT No.: 60465

Production date: 10/2016

Expiry date: 11/2019

Analyses / Method	Specification	Result
Appearance / Visual	Clear liquid	Clear liquid
Odor / Olfactive	Mild	Mild
pH-Rate (2% active substance in water) / pH meter (DIN EN 1262)	6.5 – 7.2	6.9
Density, 20 °C, gr/cm ³ / DIN 51757	1.001 - 1.010	1.005
Quaternary Ammonium Compounds / QUAT test stripe		2.6 mg/g
Sodium nitrite		≤ 0.1 mg/g
Additives		3.2 mg/g
Water		The rest

GOosafe with SparMED!

Qi Wei

Quality Control Manager

SparMED ApS

Date: 09.02.2017





SparMED Aps Ryttermarken 2 3520 Farum Denmark



ELI Accession Number: SPAR-6218-0217

Date of completion: 02-07-2017

Lot numbers: 60465, 63504

Reference numbers: OOMD/OOMDW

Description of test articles: Disinfectant, Disinfectant-Wipes

Assay system requested by customer: An incubator was cleaned with the test article (OOMDW). Post cleaning 1mL of test article (OOMD) was placed in a Petri dish and placed in the cleaned incubator. A culture plate was set up and one-cell mouse embryos were cultured in the cleaned incubator with the test article for 96-hours.

Control assay method and results: 15 one cell (B6C3F1 X B6D2F1) embryos were cultured in triplicate micro drops of culture medium in control incubator ELI-158:

15 / 15 (100 %)

1-cell to 2-cell within 24 hr

15 / 15 (100 %)

1-cell to expanded blastocyst within 96 hr

For a valid assay, <u>Embryotech™</u> requires at least 70% of one cell control embryos to develop to expanded blastocyst within 96-hours.

Test assay method and results: 21 one cell (B₆C₃F₁ X B₆D₂F₁) embryos were cultured in triplicate micro drops of culture medium while in incubator ELI-203 cleaned with test article OOMDW containing a Petri dish filled with the test article OOMD:

21 / 21 (100 %)

1-cell to 2-cell within 24 hr

21 / 21 (100 %)

1-cell to expanded blastocyst within 96 hr

Summary of observations: All test and control embryos were selected randomly from a common pool of freshly collected embryos. 100 percent of the control embryos developed to the expanded blastocyst stage within 96-hours. 100 percent of the embryos cultured in an incubator previously cleaned and containing the test articles developed to the expanded blastocyst stage within 96-hours.

Signature Study Director 02-07-201

Date

Signature Quality Reviewer Date



SparMED Aps Ryttermarken 2 3520 Farum Denmark



ELI Accession Number: S2843-0217SPAR Date of completion: 02-08-2017

Lot numbers: 60465, 63504 Reference number: OOMD, OOMDW

Description of test articles: Disinfectant, Disinfectant Wipes

Assay system requested by customer: An incubator was cleaned with the test article (OOMDW). Post cleaning the test article (OOMD) was added to a Petri dish and placed in the cleaned incubator. A prepared sperm sample was then placed in the cleaned incubator with the test articles for 24-hours. The forward progressive motility was read and recorded at 24-hours.

Results:

	Initial motility	24hour motility
Test Article (incubator ELI-203)	94 %	94 %
Control (incubator ELI-068)	94 %	94 %

Summary of observations: The motility of the sperm remained consistent in the incubator ELI-203 (that was cleaned with and that contained the test articles) and the incubator ELI-068 (the control sperm).

Signature Study Director Data

Signature Quality Reviewer 02-08-2017 Date