Rein Product

VDA 6.2
ESAD II
G M P

DIN EN ISO 14001

DIN EN ISO 9001

SGS

Purity 4 25

Multi-Purpose

Disinfectant

Technical Data Sheet

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Introduction

Disinfection is an essential aspect of today's world . we all expect germ-free and absolutely safe manufacturing and packaging of processed foods and drinks, impeccable handling of foods in restaurants, and drinking water of indisputable quality. We expect microbiologically irreproachable surroundings in the ever increasing healthcare sector, in clinics and old age homes, in the cosmetics and pharmaceutical in descries, in all public buildings, swimming pools , sanitary installations ,air conditioning systems. the list is endless.

In this highly competitive market intensive research has been in progress for decades. New scientific evidence is constantly being gained and new products and methods are being developed to help us all fighting our "smallest" yet most dangerous enemies.

Today's challenge for a disinfectant is to be effective and safe and ecological!

Disinfectants on a chemical basis are generally one component products, intended for a specific application field, depending on the properties of the component used. However, narrow specificity has resulted in a multitude of similar products; the market has actually been flooded with virtually identical products by numerous manufacturers, all fiercely competing with one another.

The registered chemical disinfectants are divided in several groups The most common are the aldehydes, the Alcohols, the phenols, the Halogens and the quats . The application fields for every single product are reduced to a limited number of situations. The purity4 concept for efficient disinfection envisions one single product for all applications. Consequently, just to take one example, a brewery would not have to use up to seven different disinfectants to do a proper disinfection job, but just one universal purity4 disinfectant for a perfect job!

Rein product GmbH has succeeded in developing a multi-component, ecological, i.e. . Fully degradable disinfectant that is high effective against bacteria, fungi, algae, viruses and amoebae, without contaminating the environment a remarkable advantage over traditional disinfectants.

PRODUCT DESCRIPTION

Purity 4: is a mixture of several disinfectants:

Purity 4 is a highly effective disinfectant based on three active ingredients with two different action mechanisms, oxidation potential effect of stabilized H_2O_2 up to 24% and peracetic acid and Oligodynamic effect of silver ions – in addition to corrosion inhibitor food grade substances

- Peracetic acid: a strong oxidizing agent (classified after Ozone) able to penetrate organic maters and destroy microbes by oxidizing cell membrane and cytoplasm.
- Hydrogen peroxide: an oxidizing agent which is stabilized with silver for long term efficacy.
- Silver ions: have an Oligodynamic effect (covalent linkage with Microbial protein leads to protein precipitation & prevent DNA Duplication) - catalyst for Hydrogen peroxide
- Hydrogen peroxide and silver ions have a synergetic effect as a disinfectant.

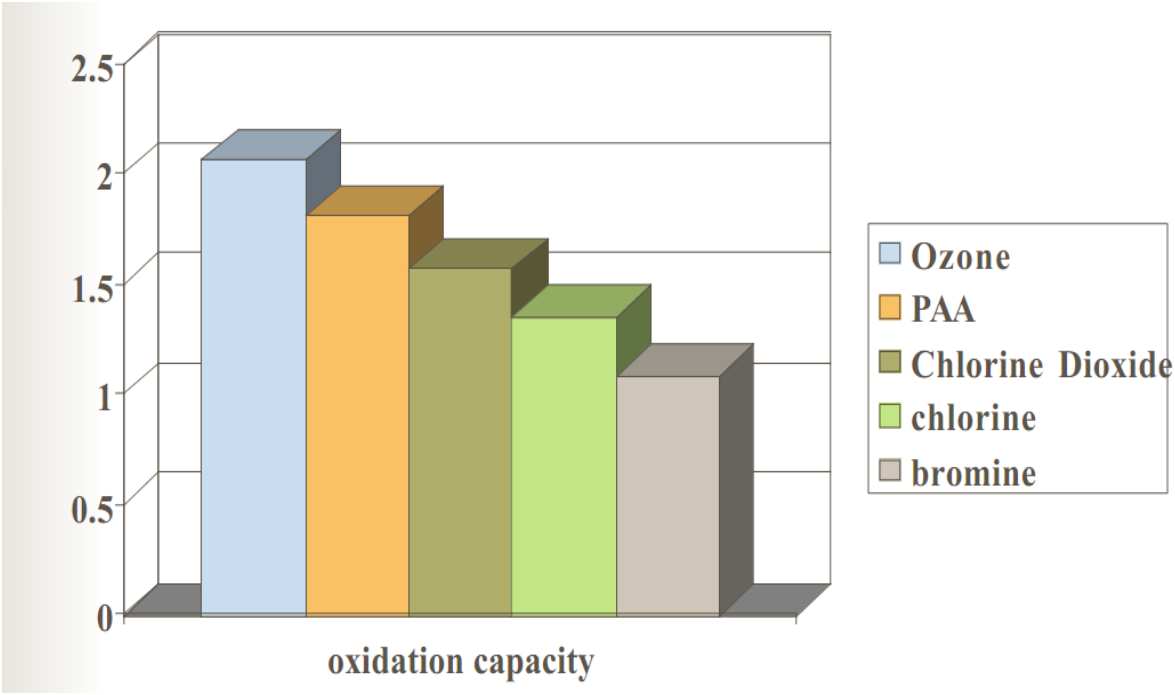
Advantages and properties of the purity4 disinfectants

- ✓ Universal range of application
- ✓ No gaps
- ✓ Long-term effect
- ✓ Hinders a renewed contamination
- ✓ No danger of bacterial resistance
- ✓ effective at water temperatures of 0°C -95°C
- ✓ effectiveness and long-term effect are guaranteed even at high water Temperatures
- ✓ no danger in case of overdosing
- ✓ does not create any odour
- ✓ has no toxic effect in its diluted state
- ✓ no carcinogenic or mutagenic effect
- ✓ in its diluted state it does not cause irritation to skin, eyes and mucous membranes
- ✓ does not alter the taste of foodstuffs treated
- ✓ no need to rinse after application
- ✓ neutralization after use not necessary
- ✓ practically not detrimental to waste water and environment
- ✓ does not enter into chemical combination with any other chemical element
- ✓ the PH value is not alter by the application in the recommended concentration
- ✓ storage of up to years possible
- ✓ own measuring and regulating equipment
- ✓ all raw material and equipment suppliers as well as well as the purity4
- ✓ manufacturing plants satisfy the norms ISO 9001
- ✓ VAH/DGHM certificate

PAA Sanitation-Regulatory

- FDA approved for direct food contact
  - 21 CFR 173.315 (fruits, vegetables)
  - 21 CFR 173.370 (meat, poultry, seafood)
- FDA approved as sanitizer on food contact surfaces
  - 21 CFR 178.1010

OXIDATION POTENTIAL OF PAA VS OTHER OXIDANTS

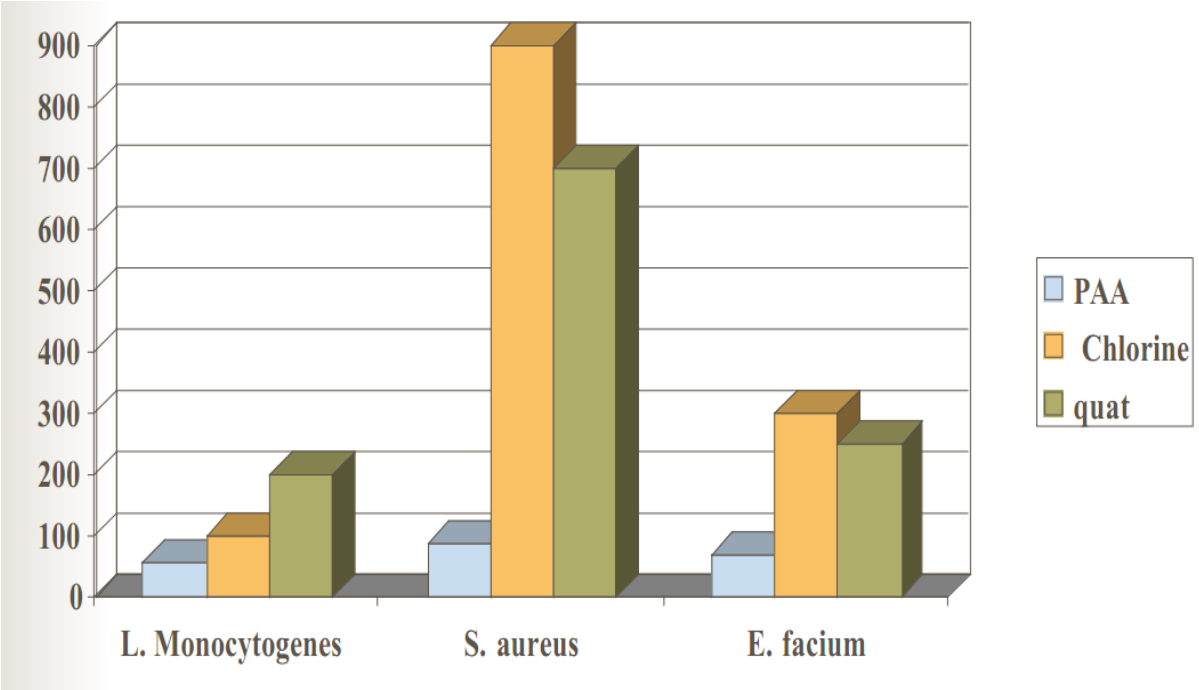


Disinfectants	ORP value
Ozone	2,07
Peracetic acid	1,81
Chlorine dioxide	1,57
Sodium hypochlorite	1,36

TECHNICAL DATA:

State of aggregation:	Clear liquid
Density:	1.095 kg/dm3
Boiling point:	107°C at 1013 mill bar
Freezing point:	-31°C
pH:	1.5
Foaming activity:	Not foaming
Forming of coatings:	Not forming
Corrosion properties:	Corrosion-resisting are aluminum 99.5 % (free of iron), 316L- stainless, 304stainless ,Teflon ,polypropylene, polyethylene, polyvinylchloride. Varnish coatings and lining materials which are used in swimming pools or storage containers for instance should be tested in pre-experiments.
Bleaching:	Bleaching shouldn't appear at the recommended concentrations.
Neutralization:	By any Reducing agent like (sodium thiosulfate $Na_2S_2O_3$) or (Sodium hydrogen sulfate $NaHSO_4$)

PPM required for lethality in five minutes



TOXICITY

-Please note the warning information on the packaging.

-Hydrogen peroxide is classified as relatively harmless according to HODGE and STEINER, Ind.Hyg.Quar.1949, 10.93-96 CIVO-TNO 03.11.1980 JvH. LD_{50} > 2000 mg/kg.

-all ***Purity 4*** Components are food grade

List of Pathogens Tested up to Date

Gram negative bacteria

Acinetobacter Iwoffii
Aeromonas salmonicida
Agrobacterium radiobacter
Burkholderia cepacia
Campylobacter jejuni
CDC gr. IV c-2 (Ralstonia sp.)
Chryseomonas luteola
Comamonas acidovorans
Enterobacter aerogenes
Erwinia carotovora
Eschericia coli
Flavobacter/Cytophaga
Flavobacterium indologenes
Gallionella sp.
Klebsiella oxytoca
Klebsiella pneumonia
Legionella pneumophila
Naumaniella sp.
Neisseria meningitidis
Ochrobactrum anthorpi
Pasteurella sp.
Proteus mirabilis
Proteus vulgaris
Pseudomonas aeruginosa
Pseudomonas alcaligenes
Pseudomonas chlororaphis
Pseudomonas fluorescens
Pseudomonas sp.
Pseudomonas syringae pv. Tomato
Ralstonia pickettii
Salmonella enteritidis
Salmonella paratyphi
Salmonella sp.
Salmonella typhi
Salmonella typhimurium
Salmonella typhosa
Vibrio cholerae (Colera)
Vibrio parahaemolyticus
Xanthomonas campestris
Yersinia pestis (Pestis)

Acid-fast bacteria

Mycobacterium phlei
Mycobacterium smegmatis
Mycobacterium spez.

Algae

Asterionella Formosa
Stephanodiscus hantzschii
Fragilaria sp.
Chroomonas norstedtii
Chlamidomonas sp.
Melosira var.
Nitzschia sp.

Gram positive bacteria

Bacillus anthracis (Anthrax)
Bacillus cereus
Bacillus circulants (vegetative and spores)
Bacillus licheniformis
Bacillus mesenterious
Bacillus sp.
Bacillus subtilis
Bacillus subtilis spore
Clostidrium novyi
Clostidrium perfringens
Clostridium sporogenes
Corynebacterium
Enterococcus faecalis (Streptococcus faecalis)
Enterococcus faecium
Enterococcus hirae
VRE (Vancomycin resistant Enterococcus)
Lactobacillus brevis
Lactobacillus lindneri
Lactobacillus plantarum
Lactobacillus sp.
Lactococcus lactis (Streptococcus lactis)
Leuconostoc mesenteroides
Listeria innocua
Listeria monocytogenes
Micrococcus candidu
Micrococcus pyogenes
Micrococcus roseus
Mycobacterium Tuberculosis (tuberculosis)
Pedicoccus damnosus
Pedicoccus sp
Sarcina Lutea (Micrococcus Luteus)
Staphylococcus agalactiae
Staphylococcus albus
Staphylococcus aureus
MRSA
Staphylococcus Coagulase +ve
Staphylococcus faecium
Staphylococcus marcescens
Streptococcus pyogenes

Yeast

Saccaromyces cerevisiae
Saccharomyces uvarum
Saccharomyces cereivisia var. uvarum
Saccharomyces carlsbergensis
Candida albicans

Fungi

Absidia corymbifera
Alternaria alternate
Aspergillus fumigatus
Aspergillus niger
Aspergillus niger spores
Botrytis cinerea
Cladosporium cladosporioides
Flagellata apochromatica
Fusarium spp.
Geotrichum candidum
Microsporum gypseum
Mucor
Penicillium digitatum
Penicillium roqueforti
Penicillium sp.
Penicillium verrucosum
Pichia membranaefaciens
Trichophyton mentagrophytes

Virus

Adenovirus
ECBO virus
Hepatitis B
Hepatitis C surrogate
Herpes simplex type 1
HIV-1
Influenza A (H5, H7 and H9)
Influenza A (H5N1)
Influenza A virus
Newcastle Disease virus
Orthopoxvirus
Papovavirus SV-40
Paramyxo virus
Poliovirus 1
Pseudorabies virus
Vaccina virus

Protozoa

Trophozoite
Amoebae
Ciliata g. sp.
Cryptosporidium parvum
Cryptomonas sp.
Nagleria fowleri

Arthropoda

Dermatophagoides pteronyssinus

Notes for direction of applications

- ## Sanitation processes:

When using purity 4 for sanitation we have to consider four parameters:

1-load of contamination (vegetative or spore)

2-contact time

3-concentration

4-temprature (high temp. equal reducing for contact time & conc.)

- ## Application for fogging:

Environmental sanitation require purity 4 diluted (3-5%) with cold fogging. for critical area like production and packaging areas in food industries, sterile & clean area in pharmaceutical industries and operation rooms, ICU in hospitals and poly clinic.

- ## Direction for vegetables and fruits:

Index	Application field	Concentration
1	cauliflower - Artichokes	150-200 ppm
2	Beans	150-200 ppm
3	Spinach - mallow	300 : 600 ppm
4	Okra	150 : 400 ppm
5	Apricot - Strawberry	100 : 200 ppm
6	Fig	300 : 700 ppm

COMPARISON OF PERACETIC ACID , HYDROGEN PEROXIDE AND SILVER WITH PURITY 4

	PAA	H2O2	Ag+	Purity 4
UNIVERSAL USAGE	No	No	No	Yes
GAPS OF effect	Yes	Yes	Yes	No
Long term effect	No	No	Yes	Yes
Efficiency against bacteria	Rapid	Slow	v. Slow	Rapid
Efficiency against algae	good	few	good	good
Efficiency against fungi	good	few	good	v. good
Prevention of re-germination	Yes	No	Yes	Yes
Long shelf-life	No	No	Yes	Yes
Efficiency in organic waste water	Yes	Yes	No	Yes
Efficiency against biofilms	Yes	No	No	Yes
Necessary dose	high	high	v. high	v. high

APPLICATION FIELDS

1. FOOD INDUSTRY

- Milk industry (Packaging, dairies, cheese-dairies, etc.)
- Mineral water production, fruit juice and lemonade production, etc..
- Pickles production
- Others:

Canning factories, butchers, bakers, mills, farinaceous paste production, finished Product producers, fish processing, chocolate factories, vegetable oil and Margarine producers, aromas and essence producers etc.

2. AGRICULTURE

- Animal farms
- Disinfection of stables and slaughterhouses.

3. AIR-CONDITIONERS AND COOLING TOWERS

- Disinfection of humidifier, cooling towers, air-conditioners, removal of algae.

4. HOSPITALS AND PUBLIC BUILDINGS

- Hospitals, nursing homes and old-age homes

  Disinfection of surfaces, linen etc.
- Disinfection of sanitary facilities.

  Hotels, restaurants, kitchens, warehouses, schools, showers, lavatories etc.

5. MEDICINE AND COSMETICS

- Surgery

  Disinfection of surfaces, equipment, humidifiers, sanitation etc.
- Chemical and pharmaceutical industry.

  Disinfection of surfaces, production equipment for pharmaceuticals, perfumes, extracts, colors etc.

6. TOURISM AND HOUSEHOLD

- Drinking water, sanitary facilities, camping, hobby, containers for drinking water and waste water (caravans, ships).

  Disinfection of bath rooms, showers, lavatories, glass, carpets etc.

7. SWIMMING POOLS

- Private and public pools, hotel pools, thermal baths, whirlpools, fitness

Centers, saunas, solar banks etc.

Recommended does for purity4

Branch	Application field	Concentratation (%)
Food and beverages	Equipment, CIP Walls/floors, Bottle washing, Crown corks, filling	2% 0.2% 3-4% 20 ppm 2.5% 2.5%
Milk industry	equipment, CIP Walls/floors Transport vehicles	2.5% 0.2% 2.5% 2.5%
Animal & poultry farms	Wall/floors, equipment, drinking water	5% 2.5% 20 ppm
Hatching eggs	Hatching eggs	2-3%
Hatching lab	Walls/floors Equipment,	2-3%
Fruits , vegetables	Equipment, Before harvest, After harvest	20 ppm 2-3% 2-3%
Air -conditioners	Filters, pipes	40 ppm 1.5%
Cooling towers	Cooler	30-50 ppm
Swimming pool	Private pools, Floors, Against fungi, sauna	20-80 ppm 2.5 % 2.5% 50-80 ppm
Drinking water	Pipe disinfection, Drinking water Treatment, Wells, Drinking water in tanks	100-150 ppm 40 ppm 40 ppm 40 ppm
Chemical and pharmaceutical industry	Equipment, Walls/floors, conservation	2.5% 2.5% 80 ppm

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Client number: 10106365
Sample number: 120726132
Order number: 2393091

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Consumer Testing Services
Personal & Homecare

SGS INSTITUT FRESENIUS
Im Maisel 14
65232 Taunusstein

Taunusstein, 06th November 2012

Test Report: 2393091-01

Examination of the disinfection effect

Sample entry:	04.10.2012
Test conditions:	see page 2
Results:	see page 3
Sample description:	Rein Product Purity 4 Prod. 01/2012 Exp. Date 01/2015

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Rein Product

VDA 6.2 ESAD II G M P DIN EN ISO 14001 DIN EN ISO 9001 SGS

SGS INSTITUT FRESENIUS

Order-No. : 2393091 06.11.2012
Test Report : 2393091-01
Sample : Rein Product Purity 4 Prod. 01/2012 Exp. Date 01/2015 (120726132)

Test conditions:

Evaluation of bactericidal and fungicidal activity in qualitative suspension test (DGHM-standard methods, 1.9.2001, Method 8)

10 ml of the appropriate dilution of the test product is mixed with 0.1 ml of test suspension and mixed well. After the required action times (see below), the mixture was mixed again.
Each 0.1 ml were removed and placed in 10 ml of CSL-bouillon without neutralizing agents.

Incubation of subcultures

Subcultures with bacterial suspension:	48 h at 36 ± 2 °C
Subcultures with yeast / fungi suspension:	48 h at 30 ± 2 °C
Test micro-organisms:	*Escherichia coli* ATCC 11229 *Staphylococcus aureus* ATCC 6538 *Proteus mirabilis* ATCC 14153 *Pseudomonas aeruginosa* ATCC 27853 *Candida albicans* ATCC 10231 *Aspergillus brasiliensis* ATCC 16404 *Salmonella enterica* DSM 554
Action time:	(5 min / 15 min / 30 min / 60 min)
Product concentration:	(0.5% / 1% / 2%/ 3% /4% / 5%)
Testing period:	01.11.2012 – 05.11.2012

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Rein Product

VDA 6.2 ESAD II G M P DIN EN ISO 14001 DIN EN ISO 9001 SGS

SGS INSTITUT FRESENIUS

Order-No. : 2393091 06.11.2012
Test Report : 2393091-01
Sample : Rein Product Purity 4 Prod. 01/2012 Exp. Date 01/2015 (120726132)

Results

Evaluation of *Escherichia coli* ATCC 11229 (1.77 x 10^8 cfu/ml)

End concentration of the test product	growth after			
	5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

Evaluation of *Proteus mirabilis* ATCC 14153 (1.70 x 10^8 cfu/ml)

End concentration of the test product	growth after			
	5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

Evaluation of *Salmonella enterica* DSM 554 (1.57 x 10^8 cfu/ml)

End concentration of the test product	growth after			
	5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

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VDA 6.2 ESAD II GMP DIN EN ISO 14001 DIN EN ISO 9001 SGS

SGS INSTITUT FRESENIUS

Order-No. : 2393091 06.11.2012
Test Report : 2393091-01
Sample : Rein Product Purity 4 Prod. 01/2012 Exp. Date 01/2015 (120726132)

Evaluation of *Aspergillus brasiliensis* ATCC 16404 (1.54 x 10^8 cfu/ml)

End concentration of the test product	growth after 5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

Evaluation of *Staphylococcus aureus* ATCC 6538 (1.51 x 10^8 cfu/ml)

End concentration of the test product	growth after 5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

Evaluation of *Pseudomonas aeruginosa* ATCC 15442 (1.87 x 10^8 cfu/ml)

End concentration of the test product	growth after 5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

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VDA 6.2 ESAD II G M P DIN EN ISO 14001 DIN EN ISO 9001 SGS

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Order-No. : 2393091 06.11.2012
Test Report : 2393091-01
Sample : Rein Product Purity 4 Prod. 01/2012 Exp. Date 01/2015 (120726132)

Evaluation of *Candida albicans* ATCC 10231 (1.59 x 10^8 cfu/ml)

End concentration of the test product	growth after			
	5 minutes	15 minutes	30 minutes	60 minutes
5 %	-	-	-	-
4 %	-	-	-	-
3 %	-	-	-	-
2 %	-	-	-	-
1 %	-	-	-	-
0.5 %	-	-	-	-
WSH Control	+	+	+	+

+: growth; -: no growth cfu: colony forming units

SGS INSTITUT FRESENIUS GmbH

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Teamassistant

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