



KLERCIDE SPORICIDAL LOW RESIDUE PEROXIDE Water for injection

KLERWIPE SPORICIDAL LOW RESIDUE PEROXIDE Water for injection

SCIENTIFIC PROFILE



SUMMARY

1. INTRODUCTION AND COMPANY PROFILE	1
1. CERTIFICATION	1
2. PRODUCT DESCRIPTION	2
1. PRESENTATION OF KLERCIDE SPORICIDAL LOW RESIDUE PEROXIDE	2
A. Advantages	2
B. Description	3
C. Activity	3
2. PRESENTATION OF KLERWIPE SPORICIDAL LOW RESIDUE PEROXIDE	4
A. Advantages	4
B. Description	4
3. TECHNICAL SPECIFICATIONS	5
4. PRODUCT PACKAGING	7
5. BATCH CERTIFICATION	7
3. APPLICATION	8
4. EFFICACY AND MODE OF ACTION	9
1. MODE OF ACTION OF BIOCIDES	9
2. THE EFFICACY OF KLERCIDE SPORICIDAL LOW RESIDUE PEROXIDE	10
A. EN 1276: to demonstrate bacterial efficacy	10
B. EN 1650: to demonstrate fungicidal efficacy	12
C. EN 13697: to demonstrate bactericidal and fungicidal efficacy	13
D. EN 13704: to demonstrate sporicidal efficacy	14
E. EN 16615: to demonstrate bactericidal, yeasticidal efficacy	15
F. EN 14476: to demonstrate virucidal efficacy	17
Conclusion	18
5. COMPATIBILITY DATA	19
1. COMPATIBILITY WITH OTHER KLERCIDE PRODUCTS	19
2. CORROSION STUDIES	20
6. PRODUCTION PROCESS	22
1. PROCESS FLOW CHART: STERILE BOTTLES	22
2. PROCESS FLOW CHART: STERILE WIPES	23

1. INTRODUCTION AND COMPANY PROFILE

CHRISTEYNS Life Sciences is a major player in the French market for environmental decontamination in clean rooms, notably through the Klercide range, manufactured under Ecolab license.

In 2022, the production of these references is done in France by the company CHRISTEYNS, with the will to develop a partnership based on expertise, high standards and reliability.

As close as possible to our customers, this geographical proximity allows us to simplify our logistics management in order to best meet the needs of users.

SIMAGEC and SIMA PHARMA are major players in the field of conditioning and packaging in clean rooms for the medical sector (SIMAGEC) and for the pharmaceutical industries (SIMA PHARMA).

The Klercide range is produced at their site, based in Rousset in Bouches-du-Rhône.

SIMAGEC and SIMA PHARMA have:

- 15 clean rooms spread over 1,000m² including 250m² of grade A to D for SIMA PHARMA activities
- Their own production of water for injection in bulk
- All the specific equipment necessary for production (up to 3 500L, ATEX zone from 50mL to 5L).

1. CERTIFICATION

CHRISTEYNS France has EN ISO 9001:2008 and EN ISO 14001:2015 certifications.

SIMA PHARMA has EN ISO 9001:2008 certification.

Certificates are available on request.

2. PRODUCT DESCRIPTION

1. PRESENTATION OF KLERCIDE SPORICIDAL LOW RESIDUE PEROXIDE

A. ADVANTAGES

Very low residue

Klercide Sporicidal Low Residue Peroxide is a blend of hydrogen peroxide and water for injection, so it is very low residue with very low endotoxin levels (<0.25 EU/ml).

Very effective, including sporicidal activity

Klercide Sporicidal Low Residue Peroxide will control most risks of contamination including difficult bacterial spores. It can be used safely and effectively as part of a rotation with any other Christeys Life Sciences biocide.

Easy and safe to use

Klercide Sporicidal Low Residue Peroxide is classified as non-corrosive, so it can be used safely in most cleanroom applications. The fully adjustable trigger spray allows liquid to be dispensed as either a jet or a spray, which is particularly useful in critical areas.

Alternatively, a 5-litre ready-to-use product is available for use in large areas.

Cost effective

All the biocides can be dispensed from the bottle so there is no wastage. Validation of the Sterile Delivery System (SteriShield Delivery System) demonstrates that the contents remain sterile. An in-use shelf life of six months is supported with the data, enabling a long in-use shelf life to be applied by the end user.

Environmentally friendly packaging

The packaging does not contain any propellant so does not require any special disposal procedures.

B. DESCRIPTION

Klercide Sporicidal Low Residue Peroxide is suitable for use on most types of hard surfaces in cleanrooms and controlled environments, isolators, LAFs, equipment exteriors and production. Klercide Sporicidal Low Residue Peroxide is especially suitable for areas where a low residue product is required and due to the grade of hydrogen peroxide is compatible with gassing isolators.

All trigger spray bottles incorporate the patented Sterile Delivery System (SDS) and an adjustable trigger spray. The unique way in which the SDS works as a closed system, ensures that the sterility of the contents is preserved throughout use.

Ready to use product is available in 1 liter trigger spray and 5 liters capped bottles.

Composition

100 g contains 6 g hydrogen peroxide in water for injection.

Klercide Sporicidal Low Residue Peroxide is a sterile cleanroom biocide, which is a blend of 6% hydrogen peroxide with water for injection. Its broad-spectrum activity includes troublesome bacterial spores.

Process

The blend is 0.2 micron filtered, sterile filled and double bagged in a grade A cleanroom.

C. ACTIVITY

Broad-spectrum activity including:

Bactericidal activity	<i>S. aureus</i> , <i>E. coli</i> , <i>E. hirea</i> , <i>P. aeruginosa</i>
Fungicidal activity	<i>C. albicans</i> , <i>A. brasiliensis</i> (<i>niger</i>)
Sporicidal activity	<i>B. subtilis</i>
Virucidal activity	<i>Human Adenovirus C</i> (HAdVC), <i>Human Polyovirus</i> (HPV-1)

2. PRESENTATION OF KLERWIPE SPORICIDAL LOW RESIDUE PEROXIDE

A. ADVANTAGES

Very effective biocides with good sporicidal activity

Klerwipe Sporicial Low Residue Peroxide can control most of the risks of contamination including the most difficult bacterial spores.

Rapid and effective application

The highly absorbent wipes allow rapid disinfection of surfaces equipment, and production tools. The wipes remain wet throughout use ensuring a consistent application of biocide to the required surface area. Wiping with a damp wipe improves the efficiency of the cleaning and disinfection procedure.

Easy to use

Klerwipe wipes are folded to make them easily removable from the pouch, even when wearing gloves. Using a pre-impregnated wipe eliminates the risk of over-spraying, reducing the risk of inhalation, especially in confined spaces.

All biocides are non-toxic and non-corrosive under normal conditions of use and therefore can be used in most clean room applications. The use of wipes in critical areas, such as isolators, reduces the risk of corrosion, as the biocide is almost completely removed from the surface.

Ideal for sterile environments

Each sterile, double bagged, resealable pouch contains only 15 low particulates wipes, which is sufficient for most uses without compromising sterility.

B. DESCRIPTION

Composition

Klerwipe Sporicial Low Residue Peroxide is a blend of 6% hydrogen peroxide with water for injection.

Process

Klerwipe pouches are filled with the 0.2 micron filtered blend, sealed and double bagged in a grade A cleanroom.

3. TECHNICAL SPECIFICATIONS

Physical Properties	Klercide/Klerwipe Sporicidal Low Residue Peroxide
Product composition	Klercide/Klerwipe Sporicidal Low Residue Peroxide is a blend of 6% hydrogen peroxide with water for injection
Content of H ₂ O ₂	5.5% - 6.5%
Colour	Colourless
Odour	Slight, pungent
Clarity	Clear
Specific gravity (20°C)	1.020 - 1.023 g/cm ³
Filtration	To 0.2 micron
Endotoxin	< 0.25 EU/ml*
Production and packaging	- The biocide is 0.2 micron filtered, sterile filled and double bagged in a grade A cleanroom - Wipe pouches are filled with the 0.2 micron filtered blend, sealed and double bagged in a grade A cleanroom
Sterility	Gamma irradiation of consumables and sterile fill confirmed by standard sterility testing
Production expiry	
Klercide Sporicidal Low Residue Peroxide	1 year from date of manufacture
Klerwipe Sporicidal Low Residue Peroxide	6 months from date of manufacture

*Endotoxin Units/ml

Klerwipe	Value	Unit	Test Method
MATERIAL COMPOSITION	55% cellulose / 45% polyester hydroentangled nonwoven blend		
COLOR	White		
BASIS WEIGHT	68	g/m ²	TAPPI T-410
THICKNESS	264	μm	TAPPI T-411
FIBERS (≥100μm)	160	fibers/cm ²	IENT-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2
PARTICLES (≥0.5μm)	10	x10 ³ /m ²	IENT-RP.CC004.3, Sec 6.1.3 / Sec 6.2.1
ABSORBENCY CAPACITY RATE	320 2	ml/m ² seconds	IENT-RP.CC004.3, Sec 8.1 modified, Sec 8.2 modified
NON-VOLATILE RESIDUE DESIONISED WATER ISOPROPYL ALCOHOL	0.028 0.0038	g/m ²	IENT-RP.CC004.3, Sec 7.1.2
IONS Na ⁺ K ⁺ Ca ⁺⁺ Mg ⁺⁺ Cl ⁻	62 5.9 22 5.0 31	ppm	IENT-RP.CC004.3, Sec 7.2.2

4. PRODUCT PACKAGING

Item Code	Product Name	Unit of Sale	Sterile	Water Quality	Endotoxin	Bagging
3079100	Klercide Sporicidal Low Residue Peroxide	6x1L	STERILE	WFI	<0.25EU/ml	Double
3079120	Klercide Sporicidal Low Residue Peroxide	4x5L	STERILE	WFI	<0.25EU/ml	Double
3079320	Klerwipe Sporicidal Low Residue Peroxide	20x15 wipes	STERILE	WFI	NA	Double

5. BATCH CERTIFICATION

For all batches, a certificate of analysis is generated.

Batch coding is given as following:

DDMMYY corresponding to the date of the blend

DD = day

MM = month

YY = last two digits of the year

Example:

The mix is prepared the 15th of January 2021. The batch number will be 150121

If more than one batch is produced the same day, a letter (A, B, C...) will be added to the initial batch coding.

Example:

Two batches are produced the 15th of January 202. The batch numbers will be 150121A and 150121B

The expiry date is given as following:

MM/YYYY

MM = month

YYYY = year

3. APPLICATION

To ensure complete coverage, apply the ready to use product directly onto non-porous surfaces using a cleanroom wipe or mop of suitable quality. Always ensure the whole surface is in contact with the liquid. For best results, after the required contact time, wipe down the surface first to physically remove any contamination.

Allow a contact time of at least 5 minutes for bactericidal activity and then wipe dry. This contact time is a guide.

As current cGMP guidance suggests that contact times should be revalidated in each facility as they can be affected by surfaces, temperature and air change rate.

Klercide Sporicidal Low Residue Peroxide can be used as part of a rotational regime with any other Christeyns Life Sciences biocide.

Standard best practice of a disinfection, wipe and rinse routine should always be used and note should be taken of the safety datasheet which gives conditions and chemicals to avoid for each product.

Use biocides safely. Always read the label and product information before use.

4. EFFICACY AND MODE OF ACTION

1. MODE OF ACTION OF BIOCIDES

Biocides inhibit microorganisms in a variety of ways. Some alter the permeability of the cell walls interfering directly with the life processes of the microbe. Others penetrate the cell wall and enter the cytoplasm, destroying protein groups essential for life.

Mode of action of hydrogen peroxide

It is believed that the oxidising biocide hydrogen peroxide works by inflicting multiple cell damage to cells and removal of protein, ending in cell death.

Hydrogen Peroxide decomposes in contact with living tissue, evolving oxygen.

Hydrogen peroxide chemical reaction



This reaction takes place over the whole pH range and has a non-contaminating by-product. It decomposes to oxygen and water. As a result of this action, Klercide Sporicidal Low Residue Peroxide produces virtually no residues, making it particularly suitable for use in direct product contact areas.

2. THE EFFICACY OF KLERCIDE LOW RESIDUE PEROXIDE

Klercide Sporicidal Low Residue Peroxide is a broad-spectrum biocide, with sporicidal activity. The purpose of this section is to summarize the efficacy data available to support its use in cleanroom applications.

The intended uses for Klercide Sporicidal Low Residue Peroxide are pharmaceutical cleanrooms where clean conditions are applicable. Therefore, the subsequent efficacy testing is performed under clean conditions according to the corresponding standard.

A. EN 1276: TO DEMONSTRATE BACTERIAL EFFICACY

Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of bactericidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

EN 1276 is a quantitative test method used to assess the ability of liquid chemicals to inactivate bacteria. The standard evaluates the level of viable survivors, after treatment, as compared to control solution suspensions to quantitatively determine log reduction. The standard includes critical controls such as neutralization validation and side-by-side untreated control suspensions to ensure study validity. The standard is written to evaluate the efficacy of a disinfectant against selected microorganisms in the planktonic state.

EN 1276 employs the following standard organisms:

Organism	Strain
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Escherichia coli</i>	ATCC 10536
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Enterococcus hirae</i>	ATCC 10541

Test method summary

1. A sample of the product as delivered and/or diluted with hard water is added to a test suspension of bacteria in a solution of an interfering substance. The mixture is maintained at $(20 \pm 1) ^\circ\text{C}$ for 5 minutes $\pm$ 10 seconds (obligatory test conditions).
2. At the end of this contact time, an aliquot is taken, and the bactericidal and/or the bacteriostatic activity in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used.
3. The numbers of surviving bacteria in each sample are determined and the reduction is calculated. The test is performed using vegetative cells of *Pseudomonas aeruginosa*, *Escherichia coli*, *Staphylococcus aureus* and *Enterococcus hirae* as test organisms.

Table 1: Result and efficacy testing for EN 1276*

Organism	Strain	Pass Criteria (according to standard)	Test Results – Log reduction in Clean conditions	Pass/ Fail
<i>P. aeruginosa</i>	ATCC 15442	Log 5 reduction in 5 mins	> 5.25**	PASS
<i>E. coli</i>	ATCC 10536	Log 5 reduction in 5 mins	> 5.29**	PASS
<i>S. aureus</i>	ATCC 6538	Log 5 reduction in 5 mins	>5.21**	PASS
<i>E. hirae</i>	ATCC 10541	Log 5 reduction in 5 mins	> 5.30	PASS

Test Report Reference: Chemila D124-1/2015

*Tests were conducted on liquid as expressed from Klerwipe Sporicidal Low Residue Peroxide

**Tested at 97% test concentration

→ According to EN 1276 Klercide Sporicidal Low Residue Peroxide demonstrates a bactericidal efficacy.

B. EN 1650: TO DEMONSTRATE FUNGICIDAL EFFICACY

Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants and antiseptics used in food, industrial, domestic and institutional areas.

EN 1650 is a quantitative test method used to assess the ability of liquid chemicals to inactivate yeast and fungi. The standard evaluates the level of viable survivors, after treatment, as compared to control solution suspensions to quantitatively determine log reduction. The standard includes critical controls such as neutralization validation and side-by-side untreated control suspensions to ensure study validity. The standard is written to evaluate the efficacy of a disinfectant against selected microorganisms in the planktonic state.

EN 1650 employs the following standard organisms:

Organism	Strain
<i>Candida albicans</i>	ATCC 10231
<i>Aspergillus brasiliensis (niger)</i>	ATCC 16404

Test method summary

1. A sample of the product as delivered and/or diluted with hard water is added to a test suspension of fungi (yeast cells or mould spores) in a solution of an interfering substance. The mixture is maintained at 20 ($\pm$ 1°C) for 15 minutes $\pm$ 10 seconds (obligatory test conditions).
2. At the end of this contact time, an aliquot is taken, and the fungicidal and/or the fungistatic activity in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used.
3. The numbers of surviving fungi in each sample are determined and the reduction is calculated. The test is performed using the vegetative cells of *Candida albicans* (yeast activity) and the spores of *Aspergillus brasiliensis (niger)* (fungicidal activity).

Table 2: Result and efficacy testing for EN 1650*

Organism	Strain	Pass Criteria (according to standard)	Test Results – Log reduction in Clean conditions	Pass/Fail
<i>C. albicans</i>	ATCC 10231	Log 4 reduction in 15 mins	4.08** (in 5 mins)	PASS
<i>A. brasiliensis (niger)</i>	ATCC 16404	Log 4 reduction in 15 mins	4.02** (in 5 mins)	PASS

*Tests were conducted on liquid as expressed from Klerwipe Sporicidal Low Residue Peroxide

**Tested at 97% test concentration

→ According to EN 1650 Klercide Sporicidal Low Residue Peroxide demonstrates a fungicidal efficacy.

C. EN 13697: TO DEMONSTRATE BACTERICIDAL AND FUNGICIDAL EFFICACY

Chemical Disinfectants and Antiseptics - Quantitative non-porous surface test for the evaluation of bactericidal and/or fungicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

EN 13697 is a quantitative test method used to assess the ability of liquid chemicals to inactivate bacteria, yeast and mould spores. The standard evaluates the level of viable survivors, after treatment, as compared to control solution-treated coupons to quantitatively determine log reduction. The standard includes critical controls such as neutralization validation and side-by-side untreated control coupons to ensure study validity. The standard is written to evaluate efficacy on hard, non-porous surfaces (stainless steel coupons), but can be adapted for other surface materials of similar size.

EN 13697 employs the following standard organisms:

Organism	Strain
<i>Pseudomonas aeruginosa</i>	ATCC 15442
<i>Escherichia coli</i>	ATCC 10536
<i>Staphylococcus aureus</i>	ATCC 6538
<i>Enterococcus hirae</i>	ATCC 10541
<i>Candida albicans</i>	ATCC 10231
<i>Aspergillus brasiliensis</i>	ATCC 16404

Test method summary

1. A test suspension of bacteria, yeast or fungal spores in a solution of interfering substances is inoculated onto a test stainless steel surface and dried. A prepared sample of the product under test is applied in a manner which covers the dried film. The surface is maintained at temperature between $18^{\circ}\text{C} \pm 1^{\circ}\text{C}$ and $25^{\circ}\text{C} \pm 1^{\circ}\text{C}$ for a defined period of time.
2. The surface is transferred to a previously validated neutralisation medium so that the action of the disinfectant is immediately neutralized.
3. The number of surviving organisms which can be recovered from the surface is determined quantitatively. The number of bacteria, yeast or fungal spores on a surface treated with hard water in place of the disinfectant is also determined and the reduction in viable counts attributed to the product is calculated by difference.

Table 3: Result and efficacy testing for EN 1650*

Organism	Strain	Pass Criteria (according to standard)	Test Results – Log reduction in Clean conditions	Pass/ Fail
<i>C. albicans</i>	ATCC 10231	Log 3 reduction in 15 mins	>5.83	PASS
<i>A. brasiliensis (niger)</i>	ATCC 16404	Log 3 reduction in 15 mins	3.28	PASS

Test Report Reference: Chelab 62/2010

→ According to EN 13697, Klercide Sporicidal Low Residue Peroxide demonstrates a fungicidal efficacy.

D. EN 13704: TO DEMONSTRATE SPORICIDAL EFFICACY

Chemical Disinfectants and Antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants used in food, industrial, domestic and institutional areas.

EN 13704 is a quantitative test method used to assess the ability of liquid chemicals to inactivate bacterial spores. The standard evaluates the level of viable survivors, after treatment, as compared to control solution suspension to quantitatively determine log reduction. The standard includes critical controls such as neutralization validation and side-by-side untreated control suspensions to ensure study validity.

EN 13704 employs the spores of one standard test organism:

Organism	Strain
<i>Bacillus subtilis</i>	ATCC 6633

Test method summary

1. A test suspension of bacterial spores in a solution of interfering substance is added to a prepared sample of the product under test diluted in hard water. The mixture is maintained at 20 °C ± 1 °C for 60 minutes ± 10 seconds (required test conditions).
2. After this contact time, an aliquot is taken; the sporicidal action in this portion is immediately neutralized or suppressed by a validated method. The method of choice is dilution-neutralization. If a suitable neutralizer cannot be found, membrane filtration is used.
3. The number of surviving bacterial spores in each sample is determined and the reduction in viable counts is calculated.

Table 4: Result and efficacy testing for EN 13704

Organism	Strain	Pass Criteria (according to standard)	Test Results – Log reduction in Clean conditions	Pass/ Fail
<i>B. subtilis</i>	ATCC 6633	Log 3 reduction in 60 mins	>1 x 10 ³	PASS

Test Report Reference: Chelab 63/2010

→ According to EN 13704, Klercide Sporicidal Low Residue Peroxide demonstrates a sporicidal efficacy.

E. EN 16615: TO DEMONSTRATE BACTERICIDAL, YEASTICIDAL EFFICACY

Chemical disinfectants and antiseptics – Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4-field test).

EN 16615 is a quantitative carrier test for establishing whether a chemical disinfectant for use on surfaces administered with wipes has a bactericidal and yeasticidal activity. This test closely simulates practical conditions of application such as contact time, temperature and interfering substances, including pre-drying specified test organisms on a test-surface as carrier and wiping the product on the test-surface with a wipe.

EN 16615 employs the following organisms:

Organism	Strain
<i>Staphylococcus aureus</i>	ATCC 6538 / DSM 799
<i>Pseudomonas aeruginosa</i>	ATCC 15442 / DSM 939
<i>Enterococcus hirae</i>	ATCC 10541 / DSM 3320
<i>Candida albicans</i>	ATCC 10231 / DSM 1386

Test method summary

1. A test-surface is marked with 4 squares of 5 × 5 cm, the “test fields”, in a row. Test field 1 on the test-surface is inoculated with a test suspension of bacteria or yeast in a solution of interfering substances.
2. The inoculum is dried.
3. A wipe is soaked with a sample of the product as delivered and/or diluted with hard water. The test-surface is wiped with the soaked wipe across the four marked test fields, starting in front of test field 1, turning immediately after test field 4 and wiped back to the starting point.
4. In parallel a water control is performed: a wipe is soaked with water instead of the product. Temperature, soiling and contact time are employed as recommended by the manufacturer.
5. At the end of the contact time, the test organisms are recovered from each test field with moistened cotton swabs. The swabs are brought into a tube containing broth and neutralizer and the test organisms are to be removed from the swab by shaking.
6. The numbers of surviving test organisms in each sample are determined, and the reduction is calculated by comparing the results of the drying control and the results obtained with the product.

Table 5: Result and efficacy testing for EN 16615*

Organism	Strain	Pass Criteria (according to standard)	Test Results – log reduction in Clean conditions	Pass/Fail
<i>P. aeruginosa</i>	DSM 939	Log 5 reduction	5.7 in 1 min	PASS
<i>S. aureus</i>	DSM 799	Log 5 reduction	>5.59 in 5 mins	PASS
<i>E. hirae</i>	DSM 3320	Log 5 reduction	>5.55 in 5 mins	PASS
<i>C. albicans</i>	DSM 1386	Log 4 reduction	>4.39 in 1 min	PASS

Test Report Reference: Henkel 15-04677

*Test was performed on Klerwipe Sporicidal Low Residue Peroxide

- According to EN 16615, Klercide Sporicidal Low Residue Peroxide demonstrates bactericidal and yeasticidal efficacy.

Table 6: EN 16615 Modified for spores*

Organism	Strain	Pass Criteria (according to standard)	Test Results – log reduction in Clean conditions	Pass/ Fail
<i>A. brasiliensis (niger)</i>	DSM 1988	N/A	>3.99 (2 mins)	N/A
<i>Bacillus subtilis</i>	DSM 347	N/A	2.34 (2 mins)	N/A

Test Report Reference: Henkel 15-14764.3

**Test was performed on Klerwipe Sporicidal Low Residue Peroxide*

- According to modified EN 16615 Klercide Sporicidal Low Residue Peroxide demonstrates fungicidal and sporicidal efficacy.

F. EN 14476: TO DEMONSTRATE VIRUCIDAL EFFICACY

Chemical Disinfectants and Antiseptics – Quantitative suspension test for the evaluation of virucidal activity of chemical disinfectants and antiseptics used in human medicine.

EN 14476 employs the following test viruses and appropriate host cells:

Virus Type	Strain	Host Cell Type
Human Adenovirus C (HAdVC)	Type 5 Strain Adenoid 75	H.Ep.#2
Human Polyovirus (HPV-1)	Type 1 Strain LSC-2ab	RD cells

Test method summary

1. A test suspension of viruses in solution of interfering substances is added to the product test solution. The mixture is maintained at 20°C ±1°C for no longer than 60 minutes.
2. After specified contact time aliquots are taken and the virucidal activity is immediately suppressed by ice-cold cell maintenance medium. A dilution series is immediately prepared in ice-cold medium.
3. Subsequently the dilutions are transferred into cell culture units either using monolayer or cell suspension. Infectivity tests are done either by plaque assay or quantal tests.
4. After incubation, the titre of infectivity is calculated, whereas reduction of virus infectivity is determined from the differences of lg virus titres before and after treatment with the product.

Table 7: Result and efficacy testing for EN 14476

VIRUS	PASS CRITERIA	RESULTS (LOG REDUCTION)		CONTACT TIME	INFECTIVITY METHOD USED
		CLEAN	PASS/FAIL		
HAdVC	Log 4 Reduction	>4.0	PASS	60 min	Quantal Test
HPV-1	Log 4 Reduction	>4.0	PASS	60 min	Quantal Test

Test Report Reference: Henkel 08.00441

→ According to EN 14476 Klercide Sporicidal Low Residue Peroxide demonstrates virucidal efficacy.

G. INACTIVATING / NEUTRALIZING AGENT FOR KLERCIDE SPORICIDAL LOW RESIDUE PEROXIDE

Inactivating / neutralizing agent for Klercide Sporicidal Low Residue Peroxide

A neutralizer which is suitable for hydrogen peroxide is a universal one. The composition is as follows:

Tween 80	30 g
Egg Lecithin	3 g
Histidine	1 g
Potassium dihydrogen phosphate	3.6 g
Sodium thiosulphate	5 g
Made up to a litre in TSB	

If there is any problem validating the neutralizer, membrane filtration should be used.

CONCLUSION

In conclusion, Klercide Sporicidal Low Residue Peroxide clearly demonstrates bactericidal, fungicidal, sporicidal and virucidal efficacy according to the corresponding EN efficacy test standards and is therefore suitable for surface disinfection. Klercide Sporicidal Low Residue Peroxide provides a log 2 reduction of spores on a surface tested in accordance with modified EN16615 satisfying the USP<1072>* pass criteria.

*United States Pharmacopoeia (USP) Chapter <1072> 'Disinfectants and Antiseptics'.

5. COMPATIBILITY DATA

1. COMPATIBILITY WITH OTHER KLERCIDE PRODUCTS

As rotation of disinfectants is recommended by certain authorities, testing has been performed to confirm that the components of the Klercide range of cleanroom biocides are compatible with each other and with the Klercide range of alcohols.

When used in rotation, it is possible that at the point of changeover, small quantities of different products could come into contact. This could possibly produce an adverse reaction or inhibit the efficacy of the product.

Test procedure

Klercide Sporicidal Low Residue Peroxide was tested against the others in turn. Klercide Sporicidal Active Chlorine Unit Dose Concentrate was tested in its diluted form. Equal amounts of the two products were mixed. Changes in pH and temperature were recorded as well as any observed physical changes.

Results

Klercide Sporicidal Low Residue Peroxide was mixed with each product from the Klercide range. The results are as follows:

Klercide Low Residue Peroxide mixed with	Comparison Product pH	Combined pH	Temp Change °C	Comments
Klercide 70/30 Denatured Ethanol	5.6	4.5	+5	Exothermic reaction
Klercide 70/30 IPA	6.0	4.6	+5	Exothermic reaction
Klercide Sporicidal Active Chlorine	11.0	9.4	0	Effervescent reaction
Klercide Low Residue Quat	6.3	4.4	0	No reaction
Klercide Neutral Detergent	6.5	4.7	0	No reaction

Conclusion

Hydrogen peroxide is an oxygen donor and should not be mixed with alcohol in large quantities as there is a risk of combustion. As observed, an exothermic reaction occurs when Klercide Sporicidal Low Residue Peroxide is mixed with alcohol.

Hydrogen peroxide will also neutralise chlorine dioxide and will therefore inactivate Klercide Sporicidal Active Chlorine.

However, this is a very stringent test and not truly representative of the real life use of the products. The amount of product contact on a surface when products are used in rotation should be minimal.

Care should always be taken when chemicals mix and SDS's should be consulted. Standard best practice of rinsing after.

2. CORROSION STUDIES

Testing has been carried out to determine the interaction between Klercide Low Residue Peroxide and a number of materials commonly encountered in cleanrooms.

Test procedure

The test procedure comprised of a two-week immersion test. Eight different materials were tested against Klercide Sporidical Low Residue Peroxide.

Materials:

1. 1316 stainless steel
2. 304 stainless steel
3. Aluminium
4. PVC coated mild steel
5. Acrylic
6. Vinyl
7. Trespa
8. PVC

The purpose of the test was to determine any interaction between the liquid and materials, in terms of weight and dimension changes, as well as any visible signs of degradation.

The use of an immersion test, as a test model, does not mimic anticipated routine material exposure. However, this method should accelerate any visible effects allowing us to record measurable changes under worst case conditions. The materials were tested under normal and stressed conditions.

Full details of the test method used are provided in *Technical Report TR1002R - 'Investigation into the Effect of Klercide Products on Commonly Encountered Materials.'*

Results

The results of the testing are summarised below:

PVC coated mild steel was the only metal sample to show any observable change. It showed some corrosion around the edges.

This was most probably due to exposure of the metal during cutting of the samples.

Weight changes were less than 0.01% for all the stainless steel and aluminium samples.

The vinyl, PVC and acrylic showed a slight increase in weight and thickness, but with no visible changes. The Trespa material showed the largest weight increase, but again with no visible change.

Test Material	Stress	Weight Change (%)	Thickness Change (%)	Comments
316 stainless steel	0	<0.1	0	None
	+	<0.1	0	None
304 stainless steel	0	<0.1	0	None
	+	<0.1	0	None
Aluminium	0	<0.1	0	None
	+	<0.1	0	None
PVC coated mild steel	0	<0.1	0	Slight corrosion at edges
	+	<0.1	0	Slight corrosion at edges
Acrylic	0	+0.28	+0.08	None
	+	+0.27	+0.08	None
Vinyl	0	+0.19	+0.05	None
	+	+0.22	+0.05	None
Trespa	0	+0.89	+0.25	None
PVC	0	+0.81	+0.65	None

Conclusion

The above results indicate that Klercide Sporicidal Low Residue Peroxide will perform as anticipated and adequately against materials frequently used in cleanroom construction.

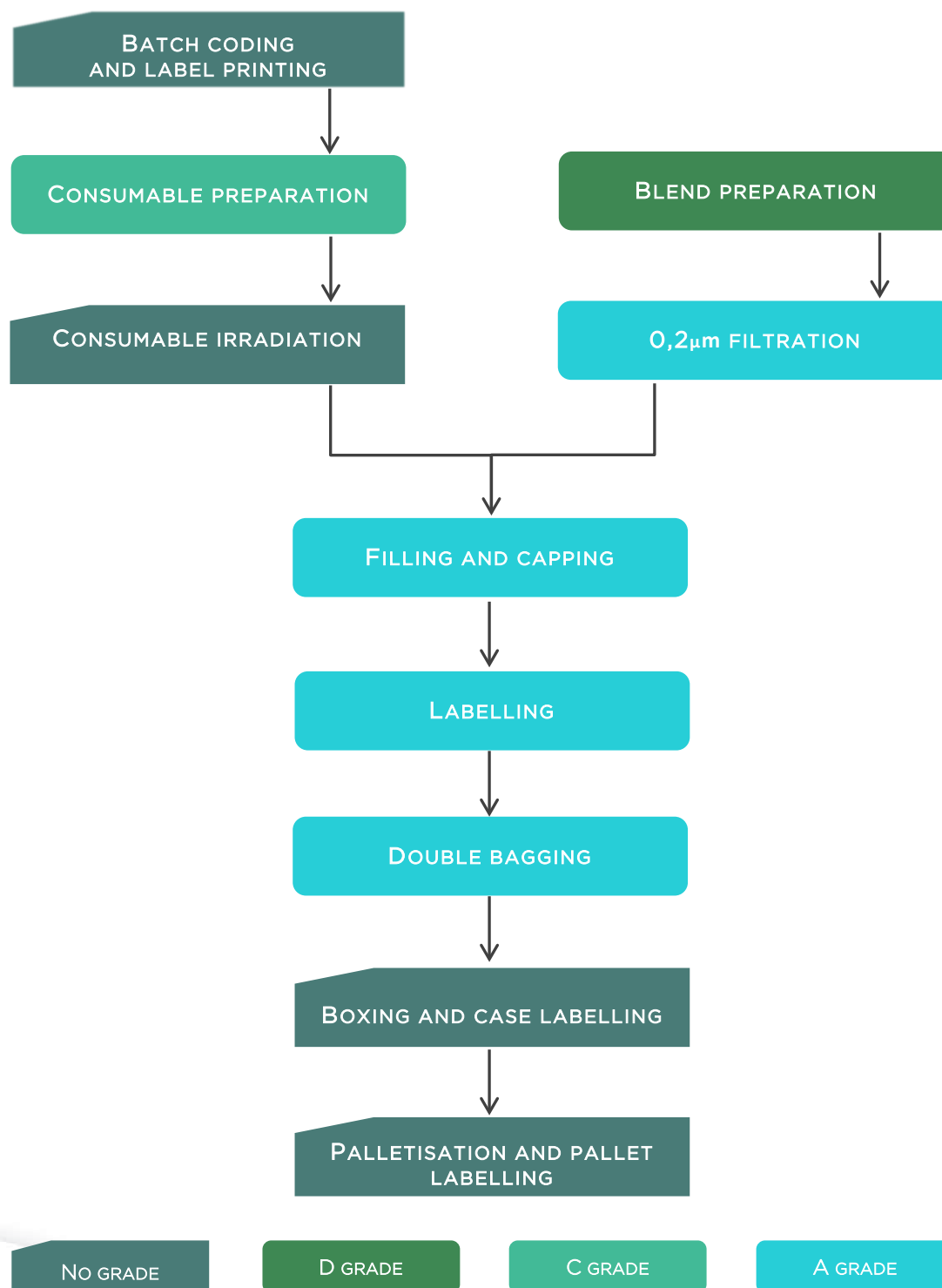
Normal conditions of surface application and then wiping should result in little, if any, significant interaction. In practice, surfaces would not be immersed for such a lengthy period and therefore the results above are a worst-case scenario.

It should be noted that it is important to follow the directions for use for all products.

6. PRODUCTION PROCESS



1. PROCESS FLOW CHART: STERILE BOTTLES



2. PROCESS FLOW CHART: STERILE WIPES

