CHRISTEYNS
LIFE SCIENCES

KLERCIDE 70|30 IPA
Water for injection

KLERWIPE 70|30 IPA
Water for injection

KLERCIDE 70|30 IPA
Deionised water

SCIENTIFIC PROFILE

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SUMMARY

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 will be 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 70|30 IPA

A. ADVANTAGES

Easy to use

Convenient range of comfortable and easy to use trigger sprays. The large droplet size reduces the risk of inhalation.

Cost effective

All the sterile alcohol can be dispensed from the bottle, so there is no wastage. Validation of the Sterile Delivery System (SteriShield Delivery System) demonstrates that the content remains 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.

Optimum surface coverage

The fully adjustable trigger spray allows the liquid to be dispensed as either a jet or spray, enabling thorough wetting of the surface so that disinfection procedures are effective.

More environmentally friendly

The product contains no propellants so does not require any special disposal procedures.

B. DESCRIPTION

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 (only for sterile reference).

Composition

Klercide 70|30 IPA is a blend of 70% v/v Isopropyl Alcohol with:

- Water for injection for the sterile version (1L / 500 mL / wipes)
- Deionised water for the filtered non-sterile version (1L).

Process

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

The filtered version is 0.2 micron filtered and filled in a grade A cleanroom and simple bagged in a grade B cleanroom.

2. PRESENTATION OF KLERWIPE 70|30 IPA

A. ADVANTAGES

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 alcohol 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 prepreg wipe eliminates the risk of over-spraying, reducing the risk of inhalation, especially in confined spaces.

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.

Suitable for direct product contact use

The Isopropyl Alcohol (IPA) will evaporate completely, the wipes contain no chemical binder, no chemical residue remains. Therefore, Klerwipe 70|30 IPA wipes are particularly recommended for use on surface in direct contact with the product, where residues are unacceptable.

B. DESCRIPTION

Composition

Klerwipe 70|30 IPA is a blend of 70% v/v isopropyl alcohol 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 70|30 IPA
Product composition	Klercide/Klerwipe 70|30 IPA consists of a v/v formulation of 70% isopropyl alcohol with 30% water (water for injection or deionised water according to the reference)
IPA content	68 – 72% v/v
Colour	Colourless
Odour	Alcohol-like
Clarity	Clear
Specific gravity (20°C)	0.872-0.883 g/cm^3
Refractive Index	24-26 % Brix
Endotoxin - sterile version only	<0.25EU/ml* (according to the reference)
Production and packaging	• The sterile version is 0.2 micron filtered, sterile filled and double bagged in a grade A cleanroom • The filtered version is 0.2 micron filtered and filled in a grade A cleanroom and simple bagged in a grade B • Wipe pouches are filled with the 0.2 micron filtered blend, sealed and double bagged in a grade A cleanroom
Sterility - sterile version only	Gamma irradiation of consumables and sterile fill confirmed by standard sterility testing
Production expiry	2 years 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/m²	TAPPI T-410
THICKNESS	264	µm	TAPPI T-411
FIBERS (≥100µm)	160	fibers/cm²	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.2
PARTICLES (≥0.5µm)	10	x103/m²	IEST-RP.CC004.3, Sec 6.1.3 / Sec 6.2.1
ABSORBENCY CAPACITY RATE	320 2	ml/m² seconds	IEST-RP.CC004.3, Sec 8.1 modified, Sec 8.2 modified
NON-VOLATILE RESIDUE DESIONISED WATER ISOPROPYL ALCOHOL	0.028 0.0038	g/m²	IEST-RP.CC004.3, Sec 7.1.2
IONS Na^+ K^+ Ca^{++} Mg^{++} Cl^-	62 5.9 22 5.0 31	ppm	IEST-RP.CC004.3, Sec 7.2.2

4. PRODUCT PACKAGING

Item Code	Product Name	Unit of Sale	Sterile	Water Quality	Endotoxin	Bagging
3078560	Klercide 70|30 IPA	12x500 ml	STERILE	WFI	<0.25EU/ml	Double
3078540	Klercide 70|30 IPA	6x1 L	STERILE	WFI	<0.25EU/ml	Double
3079330	Klerwipe 70|30 IPA	20x15 wipes	STERILE	WFI	NA	Double
3078430	Klercide 70|30 IPA	6x1 L	FILTERED	DI	NA	Simple

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

Apply the ready-to-use solution directly onto non-porous surfaces using a cleanroom low particulate wipe to ensure complete coverage.

For wipes, apply the ready-to-use solution directly onto non-porous surfaces to ensure complete coverage.

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.

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

4. EFFICACY AND MODE OF ACTION

Klercide 70|30 IPA is a good broad-spectrum biocide.

The purpose of this section is to summarise the efficacy data available to support its use in cleanroom applications.

1. MODE OF ACTION OF BIOCIDES

Alcohols have been shown to be effective antimicrobials. Amongst them, ethyl alcohol, isopropyl alcohol, and n-propanol are the most widely used. In general, the antimicrobial efficacy of alcohols is optimal in aqueous solution at concentrations in the 60 to 90% range and significantly lower below 50%. Thereby, both alkyl chain length and the degree of branching affect their antimicrobial activity (McDonnell and Russell, 1999).

Alcohols represent the group of antimicrobial substances that most rapidly and efficiently reduces the number of micro-organisms on the skin. They are known to exhibit a broad-spectrum antimicrobial activity against vegetative bacteria including mycobacteria, fungi, and lipid containing (enveloped) viruses. In contrast, alcohols are not active against spores and less against non-lipid containing (non-enveloped) viruses.

Mode of action of Klercide 70|30 IPA

Alcohols such as Klercide 70|30 IPA owe their antimicrobial activity to their ability to denature cell proteins leading to a disruption of cellular function and to a minor extend to their ability to cause membrane damage (McDonnell and Russell, 1999).

Denaturation of proteins by alcohols

Proteins are biological macromolecules that are essential components of all living organisms and take part in virtually every single biochemical process within the cell.

Alcohols efficiently lead to a change in the configuration of these proteins and as such prevent them from performing their specific functions. Enzymes that catalyse the chemical conversion of a specific substrate into a product become inactivated as a result of exposure to >60% alcohols at their binding site. In consequence, the substrate and enzyme interaction is altered in such a way that binding is prohibited. This is supported by studies in the early 1950s that revealed an inhibitory activity of alcohols on the production of metabolites essential for cell division in Enterobacter aerogenes (Dagley et al., 1950).

Alcohols also target the cell envelope resulting in a damage of the cytoplasmic membrane and the subsequent leakage of intracellular contents. Various studies on different antimicrobials support this observation (Pulvertaft and Lumb, 1948; Cheeseman et al., 2009). One might speculate that in the presence of an aqueous alcohol solution the surface tension of the membrane is reduced allowing extracellular water present in the surrounding environment to cross the membrane via osmosis resulting in bacterial lysis.

Literature:

K.E. Cheeseman, S.P. Denyer, I.K. Hosein, G.J. Williams, and J.Y. Maillard, J Hosp Infect 2009, 72, 319-325

Dagely S, Dawes EA, and GA Morrison, J Bacteriol 1950, 60, 369-378

McDonnell G and AD Russell, Clin Microbiol Rev 1999, 12, 147-179

Pulvertaft RJV and GD Lumb, Journal Hygiene 1948, 46, 62-64.

2. THE EFFICACY OF KLERCIDE 70|30 IPA

Efficacy testing of all biocide products is performed to the following standards.

At the time of product testing, the most recent version of the EN standard is followed as indicated in the individual test report.

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
Pseudomonas aeruginosa	ATCC 15442
Escherichia coli	ATCC 10536
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	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 ± 1) °C for 5 minutes ± 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 standar	Test Results – log reduction in Clean conditions	Pass/ Fail
Pseudomonas aeruginosa	ATCC 15442	Log 5 reduction in 5 mins	>5.19	PASS
Escherichia coli	ATCC 10536	Log 5 reduction in 5 mins	>5.33	PASS
Staphylococcus aureus	ATCC 6538	Log 5 reduction in 5 mins	>5.33	PASS
Enterococcus hirae	ATCC 10541	Log 5 reduction in 5 mins	> 5.21	PASS

Test Report Reference : Chelab 15/2010

→ According to EN 1276 Klercide 70|30 IPA 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
Candida albicans	ATCC 10231
Aspergillus brasiliensis (niger)	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 ± 1) °C for 15 minutes ± 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* (yeasticidal 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
Candida albicans	ATCC 10231	Log 4 reduction in 15 mins	≥4.49	PASS
Aspergillus brasiliensis (niger)	ATCC 16404	Log 4 reduction in 15 mins	≥4.36	PASS

Test Report Reference: Chemila D178/2013

→ According to EN 1650 Klercide 70|30 IPA 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
Pseudomonas aeruginosa	ATCC 15442
Escherichia coli	ATCC 10536
Staphylococcus aureus	ATCC 6538
Enterococcus hirae	ATCC 10541
Candida albicans	ATCC 10231
Aspergillus brasiliensis (niger)	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°C ± 1°C and 25°C ± 1°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 13697

Organism	Strain	Pass Criteria According to standard	Test Results – log reduction in Clean conditions	Pass/ Fail
Pseudomonas aeruginosa	ATCC 15442	Log 4 reduction in 5 mins	>6.15	PASS
Escherichia coli	ATCC 10536	Log 4 reduction in 5 mins	>6.02	PASS
Staphylococcus aureus	ATCC 6538	Log 4 reduction in 5 mins	>6.61	PASS
Enterococcus hirae	ATCC 10541	Log 4 reduction in 5 mins	>6.72	PASS
Candida albicans	ATCC 10231	Log 3 reduction in 15 mins	≥6.26 in 5 mins*	PASS
Aspergillus brasiliensis (niger)	ATCC 16404	Log 3 reduction in 15 mins	3.46*	PASS

Test Report Reference: Chelab 17/2010 & *Chemila D178/2013

According to EN 13697 Klercide 70|30 IPA demonstrates a bactericidal and fungicidal efficacy.

Table 3: Modified EN 13697 - Reduced Contact Time

Organism	Strain	Pass Criteria According to standard	Test Results – log reduction in Clean conditions	Pass/ Fail
Pseudomonas aeruginosa	ATCC 15442	N/A	5.2 in 1 min	N/A
Escherichia coli	ATCC 10536	N/A	5.0 in 1 min	N/A
Staphylococcus aureus	ATCC 6538	N/A	6.9 in 1 min	N/A
Enterococcus hirae	ATCC 10541	N/A	5.4 in 1 min	N/A

Test Report Reference: Bactimm P3721201 16-02

→ According to Modified EN 13697 Klercide 70|30 IPA demonstrates a bactericidal efficacy.

D. 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
Staphylococcus aureus	ATCC 6538 / DSM 799
Pseudomonas aeruginosa	ATCC 15442 / DSM 939
Enterococcus hirae	ATCC 10541 / DSM 3320
Candida albicans	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 4: Result and efficacy testing for EN 16615*

Organism	Strain	Pass Criteria According to standard	Test Results – log reduction in Clean conditions	Pass/ Fail
P. aeruginosa	DSM 939	Log 5 reduction between 1 & 60 mins	>5.74 in 1 min	PASS
S. aureus	DSM 799	Log 5 reduction between 1 & 60 mins	5.2 in 5 mins	PASS
E. hirae	DSM 3320	Log 5 reduction between 1 & 60 mins	>5.73 in 5 mins	PASS
C. albicans	DSM 1386	Log 4 reduction between 1 & 60 mins	>4.59 in 1 min	PASS

Test Report Reference: Henkel 15-04680

**Test performed using Klerwipe 70|30 IPA 100% Polyester Pouch Wipe 115gsm*

According to EN 16615 Klercide 70|30 IPA demonstrates bactericidal and yeasticidal efficacy

Organism	Strain	Pass Criteria According to standard	Test Results – log reduction in Clean conditions	Pass/ Fail
A. brasiliensis (niger)	DSM 1988	N/A	>3.57 in 5 mins	N/A

Test Report Reference : Henkel 15-12507-2

**Test performed using Klerwipe 70|30 IPA, Product code 3079330, Low Particulate Pouch Wipe*

→ According to Modified EN 16615 Klercide 70|30 IPA demonstrates fungicidal efficacy.

E. TEST DVV/RKI GUIDELINE 2005: TO DEMONSTRATE EFFICACY AGAINST ENVELOPED VIRUSES

Guideline of the German Association for the Control of Viral Diseases (DVV) eV and the Robert Koch Institute (RKI) for testing chemical disinfectants for effectiveness against viruses in human medicine.

DVV/RKI guideline 2005 employs the following test viruses and appropriate host cells

Virus Type	Strain	Host Cell Type
Bovine Viral Diarrhoea Virus (BVDV)	Type 1, NADL	BELK cells
Vaccinia Virus (VACV)	Elstree	Vero 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 for four different contact times, but no longer than 60 minutes.
2. After specified contact time aliquots are taken and the virucidal activity is immediately suppressed by ice cold cell culture medium. A dilution series is immediately prepared in ice cold medium.
3. Subsequently the diluted samples are to be inoculated in cultures. 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 log virus titres before and after treatment with the product.

Table 5: Result and efficacy testing for DVV/RKI guideline 2005

Virus	Pass Criteria	Test Results (Test Conc. 80%[1]) log reduction		Test Results – log reduction in Clean conditions		Infectivity Method Used
		CLEAN	DIRTY	CLEAN	DIRTY	
BVDV	Log 4 Reduction	≥4 log	≥4 log	1 min	1 min	Quantal Test
VACV	Log 4 Reduction	≥5 log	≥5 log	1 min	1 min	Quantal Test

Test Report Reference: Henkel 08.00441

[1] *Final concentration of the ready to use product that corresponds to the maximum possible test concentration according to the standard.*

→ According to DVV/RKI Klercide 70|30 IPA demonstrates virucidal efficacy.

F. INACTIVATING / NEUTRALIZING AGENT FOR KLERCIDE 70|30 IPA

The following solution is validated in the above-mentioned efficacy testing and may therefore be used when seeking to inactivate/ neutralize Klercide 70|30 IPA:

Lecithin	0.3%
Tween 80	3.0%
Sodium thiosulfate	0.5%
L-histidine	0.1%
Saponin	3.0%
In phosphate buffer 0.25 mol/l at	1%

Neutralization will usually not be necessary if treated surfaces are sampled because the alcohol will have evaporated.

However, if deemed appropriate the above-mentioned solution can be used for neutralization.

CONCLUSION

In conclusion, Klercide 70|30 IPA clearly demonstrates bactericidal, fungicidal and virucidal efficacy and is therefore suitable for surface disinfection.

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 70|30 range of alcohols are compatible with the Klercide range of cleanroom biocides.

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

The Klercide 70|30 range of alcohols should not be mixed with Klercide Sporicidal Low Residue Peroxide as the oxidising nature of hydrogen peroxide means there is a risk of combustion. At a surface level this does not present a problem.

Test procedure

Klercide 70|30 IPA was tested against the others in turn. Equal amounts of the two products were mixed. Changes in pH and temperature were recorded as well as any observed physical changes.

Results

Klercide 70|30 IPA was mixed with each product from the Klercide range. The results are as follows:

Klercide 70|30 IPA with	Comparison product pH	Combined pH	Temp Change ºC	Comments
Klercide 70|30 Denatured Ethanol	5.5	5.5	0	No apparent reaction or precipitation.
Klercide Sporicidal Low Residue Peroxide	6	4.6	+5	Exothermic reaction due to dilution of alcohol. No apparent reaction or precipitation.
Klercide Sporicidal Active Chlorine	8.23	12.91	+2.2	Exothermic reaction due to dilution of alcohol. No precipitation noted.
Klercide Low Residue Quat	8.83	7.2	+0.5	Exothermic reaction due to dilution of alcohol. No reaction or precipitate noted.
Klercide Neutral Detergent	7	6	+6	Exotherm due to dilution of alcohol. No apparent reaction or precipitation.

Conclusion

The above results indicate that no significant adverse reactions were observed when these products are combined and that no precipitates or gels are formed. An exothermic reaction was noted with the non-alcohol products. This is due to dilution of the Klercide 70|30 IPA alcohol by addition of the other product. However, this is a very stringent test not truly representative of the real-life use of the products. The amount of product contact at a surface level 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 disinfection should always be used. The standard best practice of a disinfect, wipe and rinse routine should always be used as efficacy may be adversely affected.

2. CORROSION STUDIES

Testing has been carried out to determine the interaction between Klercide 70|30 IPA and a number of materials commonly encountered in cleanrooms.

Test procedure

The test procedure comprised of a two-week immersion test. Nine different materials were tested against Klercide 70|30 IPA.

Materials:

1. 316 stainless steel
2. Zinc galvanised mild steel
3. Anodised aluminium
4. Polypropylene
5. PVC
6. Polycarbonate
7. Cast acrylic
8. Extruded acrylic
9. Laminate (type used for flooring)

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

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

The full test method for this investigation is available in *Technical Report TR10021R 'Investigation into the effect of Klercide products on commonly encountered materials'*.

Result

The table below shows the changes in weight and thickness, expressed as percentages. Where there were any visible changes to the material, these were also recorded. The results below are for Klercide 70|30 IPA blended with deionised water. These results apply to all formats of Klercide 70|30 IPA.

Test Material	Stress	Weight Change (%)	Thickness Change (%)	Comments
316 Stainless steel	0	0.00	0.0	None
	+	0.00	0.0	None
Galvanised steel	0	0.00	0.0	None
	+	0.00	0.0	None
Anodised aluminium	0	0.00	0.0	None
	+	0.00	0.0	None
Polypropylene	0	+ 0.05	0.0	None
	+	+ 0.05	0.0	None
PVC	0	+ 0.02	0.0	None
	+	+ 0.01	0.0	None
Polycarbonate	0	+ 0.11	+ 0.3	Surface tacky
	+	+ 0.10	+ 0.1	Surface tacky
Cast acrylic	0	+ 0.26	+ 0.5	None
	+	+ 0.28	0.0	Cracks formed
Extruded acrylic	0	+ 0.26	0.0	None
	+	+ 0.35	+ 0.1	Cracks formed
Laminate	0	+ 6.28	+ 29.0	None
	+	+ 6.20	+ 0.25	None

All metals and PVC exhibited no adverse effects on immersion in IPA. Polypropylene recorded a significant weight increase. However, if contact was restricted to the upper surface, it is unlikely any change would be recorded.

Polycarbonate, acrylic and laminate exhibited significant absorption. In the case of acrylic this was accompanied by stress cracking.

The large level of liquid absorption in the case of laminate appeared to occur just from the underside surface. It is quite possible that if liquid contact were restricted to the upper surface few effects would be observed.

Conclusion

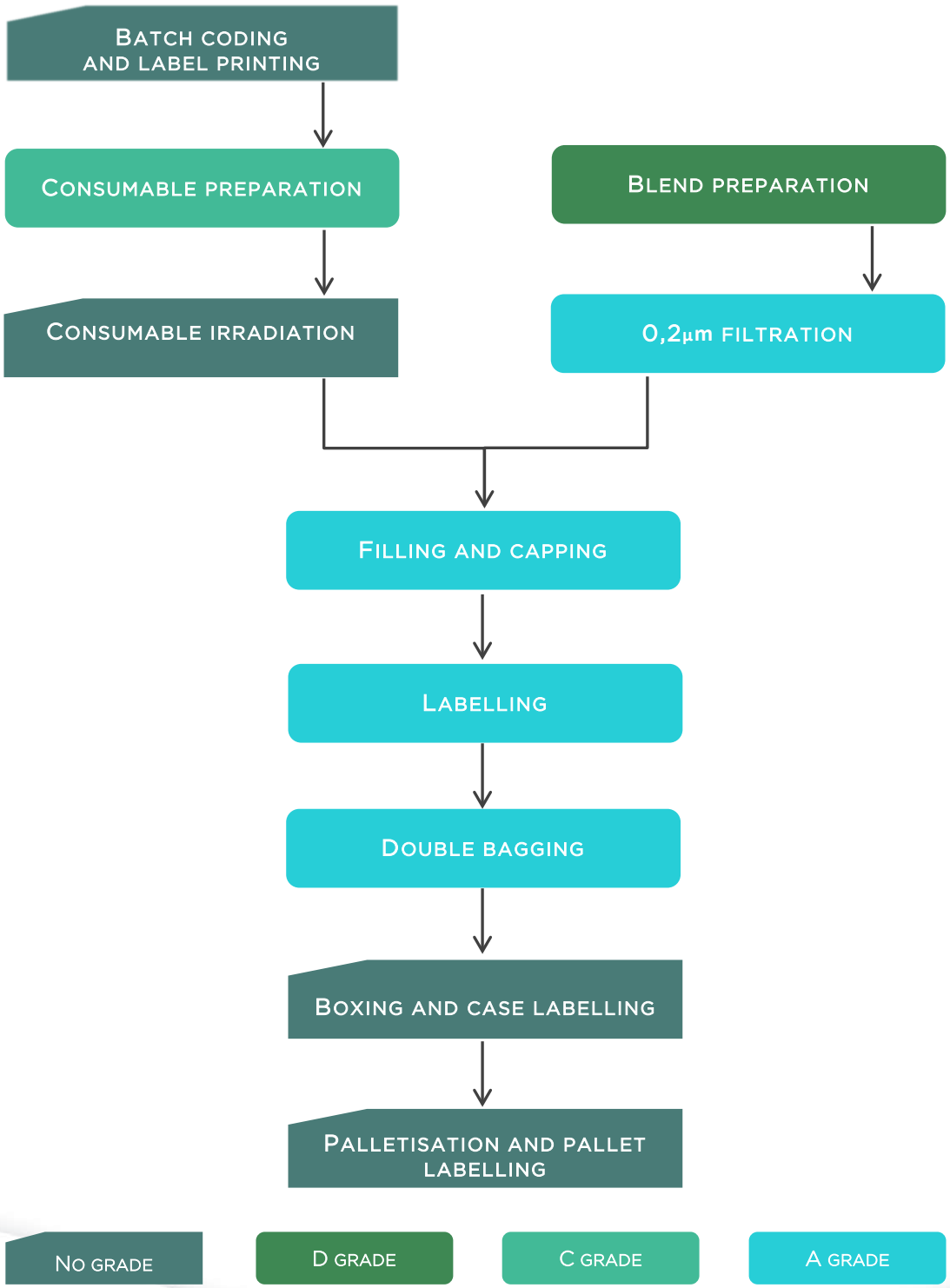
The above results show that Klercide 70|30 IPA products will perform as anticipated and adequately against materials frequently utilised in cleanroom construction.

Normal conditions of surface application and 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 represent a worst-case scenario.

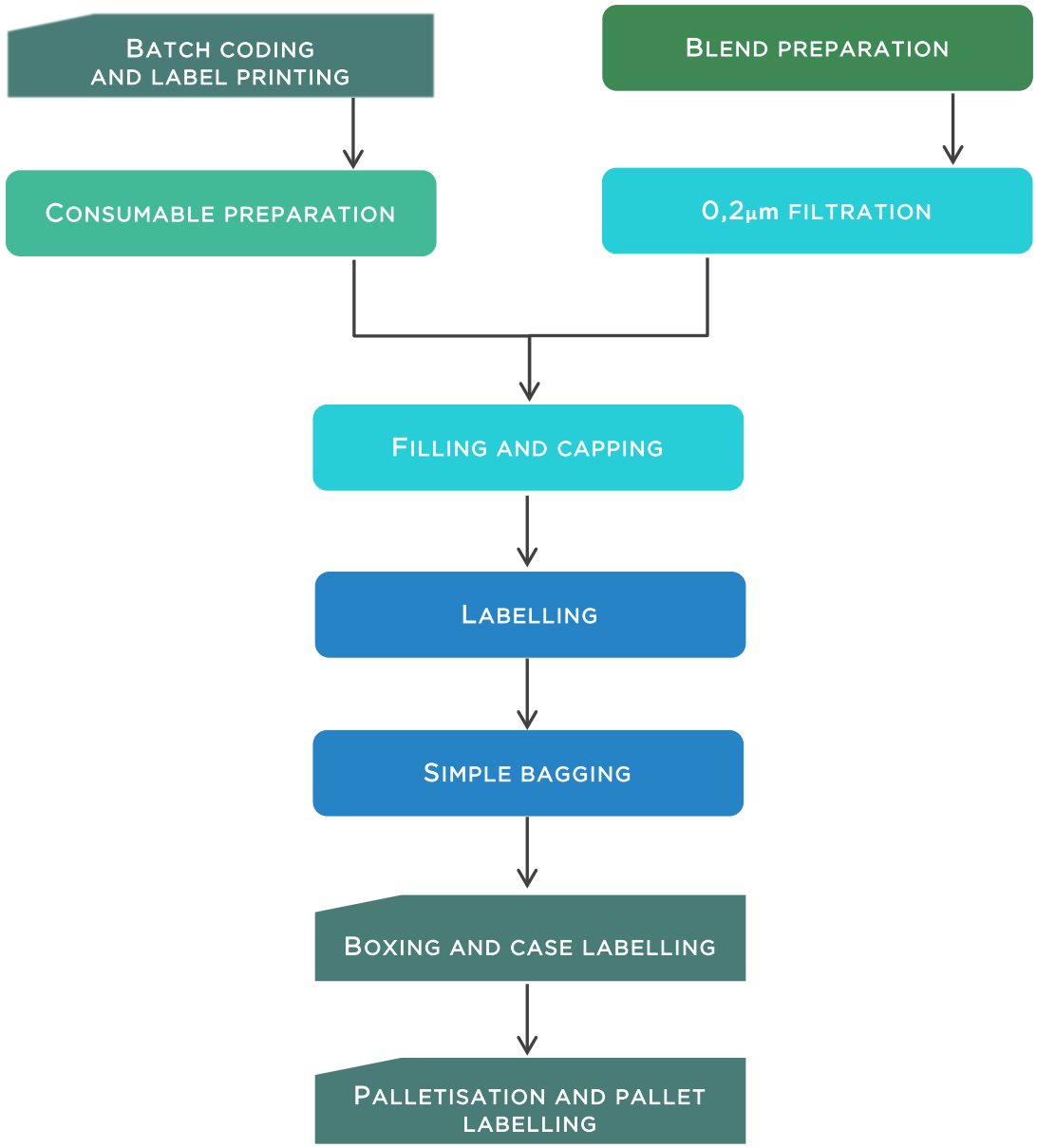
It should be noted that it is important to follow the directions for use for all products.

6. PRODUCTION PROCESS

1. PROCESS FLOW CHART: STERILE BOTTLES



2. PROCESS FLOW CHART: FILTERED BOTTLES



NO GRADE | D GRADE | C GRADE | B GRADE | A GRADE

3. PROCESS FLOW CHART: STERILE WIPES