Diversey™ | Life Sciences

ClearKlens® IPA

Technical Dossier

BPR APPROVED

ClearKlens IPA

Use description

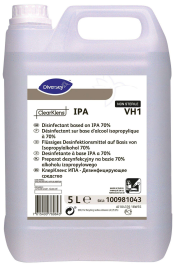
ClearKlens IPA is a ready to use product for the disinfection of non-porous hard surfaces and gloves.

It is ideal for the routine disinfection of all surfaces in pharmaceutical & cosmetics facilities, such as clean room work surfaces, process equipment, isolators and biosafety cabinets, etc. It is also recommended for decontamination of materials before entering the clean room, and for spraying on gloved hands.

ClearKlens IPA 12x1LBottle with a trigger: *The solution is a 0.2 micron filtered.* *(70% IPA/ 30% deionized water)* Clean and dry the surface before disinfection. • Cloth: Wet the cloth with the disinfectant and wipe the surface. • Spraying: Spray the surface, wipe if necessary to spread the product (14 sprays/m^2). • Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (3 sprays on two hands). Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room. Bottle has 81mm diameter (fits most of the bottle holders)	NON STERILE  flip top cap *+ trigger spray heads, packed separately* *Spray head: Spray/JET/Off* SKU (Grey label) 101105068/ 101105069 (depending on country)
ClearKlens IPA 12x500mLTrigger: *The solution is a 0.2 micron filtered.* *(70% IPA/ 30% deionized water)* Clean and dry the surface before disinfection. • Spraying: Spray the surface, wipe if necessary to spread the product (14 sprays/m^2). • Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (3 sprays on two hands). Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.	NON STERILE  *Spray head: Spray//Off* SKU (Grey label) 101105066/ 101105067 (depending on country)

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ClearKlens IPA

ClearKlens IPA 2x5L can: *The solution is 0.2 micron filtered.* *(70% IPA/ 30% deionized USP)* Clean and dry the surface before disinfection. Wet the cloth with the disinfectant and wipe the surface. Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.	NON STERILE  SKU (Grey label) 101105065
ClearKlens IPA 10x1Lbottle: *Compatible with dedicated touchless dispenser* *The solution is a 0.2 micron filtered produced under ISO 5, single bagged.* *(70% IPA/ 30% WFI USP water)* Clean and dry the surface before disinfection. • Cloth: Wet the cloth with the disinfectant and wipe the surface. • Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (3 sprays on two hands). Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.	NON STERILE  SKU (Grey label) 101104881 *flip top cap*

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ClearKlens IPA

ClearKlens IPA 4x5L can: *The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* Clean and dry the surface before disinfection. Wet the cloth with the disinfectant and wipe the surface. Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.	STERILE  SKU (Green label) 101104901/ 101104902/ 101104903/ 101104904 (depending on country)
ClearKlens IPA 10x1L bottle (glove disinfection): *Compatible with dedicated touchless dispenser* *The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* Clean and dry the surface before disinfection. • Cloth: Wet the cloth with the disinfectant and wipe the surface. • Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (3 sprays on two hands). Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.	STERILE  SKU (Green label) 101104905  Touchless dispenser for IPA (autoclavable): SKU 4400420
ClearKlens IPA Spray 6x 900mLTrigger: *The solution is a 0.2 micron filtered, gamma irradiated, sterile preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* **Antisuck system** (bag in bottle) to prevent contaminant to be sucked in. Clean and dry the surface before disinfection. • Spraying: Spray the surface, wipe if necessary to spread the product (16 sprays/m^2). • Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (3 sprays on two hands). Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room. Shelf life after opening : **5.5months**	STERILE  SKU (Green label) 101105062/ 101105063/ 101105064 (depending on country)

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ClearKlens IPA

ClearKlens IPA Airless spray 12x 250ml:

The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.
(70% IPA/ 30% WFI USP)
Clean and dry the surface before disinfection.

- Spraying: Spray the surface, wipe if necessary to spread the product (21 sprays/m^2).
- Glove disinfection: Apply 3ml of the product directly on clean gloved hands, distribute evenly (4 sprays on two hands).

Make sure to wet the surface completely. Allow to take effect for at least 30 seconds. The product may be applied only in a sufficiently ventilated room.
Ergonomic design, reducing risk of repetitive strain injury.

STERILE



SKU (Green label)
100899521

please note that this item is not available at the moment)

Certificate of analysis/ Irradiation/Sterility and endotoxins available *www.clearklens.com*

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BPR

Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) controls the sale and use of all types of biocidal products which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the biocidal product.

These substances and biocidal products have to be authorized before being used or sold on the European Union market.



Our dossier was submitted for consideration in July 2016 and was finally granted a Union approval in August 2020.

As a result, ClearKlens IPA products in all packaging formats can be sold in every EU country, Norway, Switzerland, Iceland and the United Kingdom without a country-specific registration.
The products can be recognized by our **European authorization number: EU-0022128-0000.**

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ClearKlens IPA

ClearKlens® Trigger Sterile

Our sterile trigger spray “Bag in Bottle” technology maintains sterility for 5.5 months within use area.



How does it work?

When the sprayer is operated, air is sucked inside the bottle through an external opening and the bag contracts when the liquid is distributed. This allows the pressure of the air inside the bottle to be in equilibrium with that of the environment, preventing any air, which is potentially contaminated, from coming into contact with the product.
Ergonomically designed for ease of use, the bottle is designed to reduce operator fatigue:

- A long handle trigger to reduce stress
- Designed to be held easily, even with wet gloves

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ClearKlens IPA

ClearKlens® IPA Airless

Ready for Cleanroom

All components are sterile before the filling stage.

- The solution is filtered at 0.2µm and filled under a class A laminar flow in a Class B environment.
- The double bagged system warrants the sterility of the full system and allows a direct entry in cleanrooms.



Design

Sustainable Solution:

Easily 'recyclable' materials

Transparent pouch allows complete usage of the solution

Pharmaceutical Quality guaranteed along the cleaning process

No contact with metal part

No contamination from microorganism, Endotoxins nor Particles:

From the packaging itself: Pouch is cleaned

From the environment: Pouch is hermetic



Ergonomic design allows reducing the risk of musculoskeletal disorders associated with regular use.



Pressure force is not only based on one finger
Gesture can be varied to not be repetitive

Airless versus aerosol:

Aerosol cans are really expensive to dispose:

- Nitrogen content being explosive leading to a specific waste collection
- Produced with different materials (aluminum, plastic parts)
- Large volume to be collected by the waste treatment company

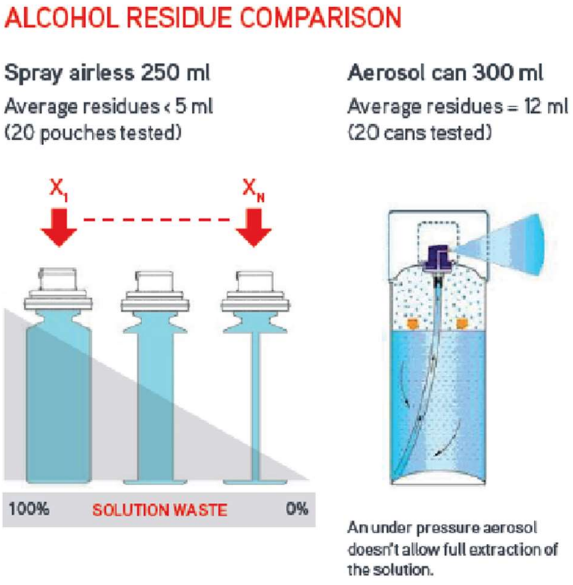
Airless Spray:

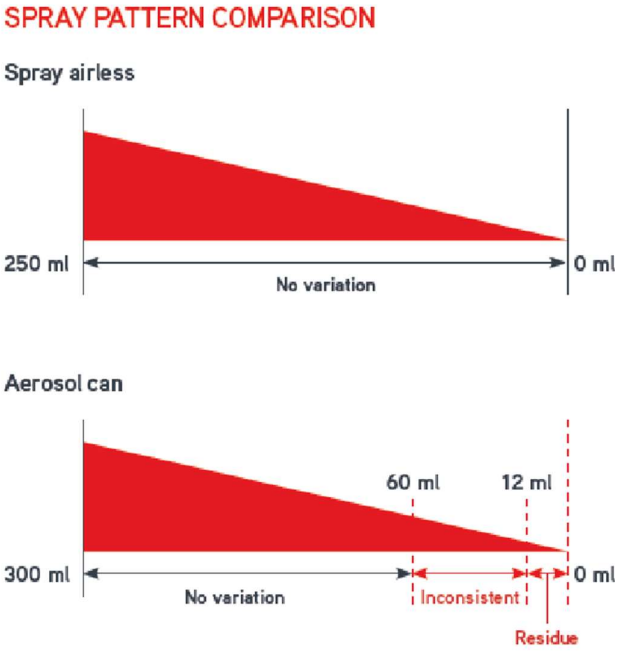
- Totally flat when emptied : x5 less volume
- Plastic based components: x3 less weight

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Airless versus aerosol:

	AEROSOL CAN	AIRLESS SPRAY
Alcohol residue level	≈ 12ml	**< 0.5ml**
Water quality	Demin water	WFI (USP pharmacopea)
Spraying pattern homogeneity	Instability when ≈ 60ml remains	Stability along the usage
Recycling	Different material part, including aluminum and nitrogen residues => Cost treatment increase	x5 less volume x3 less weight **> 80% of wastage cost reduction**
Production contamination	Not always produced in cleanroom Many production steps ☣contamination risk	A&B class cleanroom production All components cleanliness management Aseptically produced





ClearKlens IPA

Compatibility

Applications solutions, when used as directed, will not affect materials normally encountered in the aforementioned industries.



Barbara Pospišil
Global Formulation Manager Life Sciences | R&D F&B Europe
2021-01-22

ClearKlens IPA

Safe handling and storage information

Do not use more than 18.4 mL product/m2.

The product may be applied only in a sufficiently ventilated room. The minimum air change rates required are
- 8/h in laboratories;
- 60/h in pharmaceutical and cosmetics manufacturing facilities;
- 150/h in cleanrooms

The following personal risk mitigation measure can be considered for wiping disinfection unless it can be replaced by technical and / or organizational measures: The use of eye protection during handling of the product is recommended.

Avoid contact with eyes.

ClearKlens IPA

Residues

Our product ClearKlens IPA doesn't leave any residues.
(Study report done on February 15, 2016)

Composition

Composition:

70% volume/volume (63.1% w/w +/- 2.5%) IPA
30% volume/volume de-ionized water for non sterile
30% volume/volume USP WFI for sterile

ClearKlens IPA does not contain any surfactant.

Water used:
Demineralized

Chemical-physical data

Color	Clear liquid free from insolubles
Specific gravity (20°C) g/cm3	0.870 – 0.880
pH	6-9

The above data is typical of normal production and should not be taken as a specification.

ClearKlens IPA

Microbiological efficacy Summary

BACTERICIDAL ACTIVITY						
TEST METHOD	**TYPE OF ORGANISM**	**ORGANISMS**	**SOIL CONDITIONS**	**TEMPERATURE**	**CONC./ CONTACT TIME**	**LOG REDUCTION REQUIRED TO PASS**
EN 1276 (2010)	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	clean	20°C	*80% 30 sec*	≥5 log
EN 13697 (2015)	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa			*undiluted 30 sec*	≥4 log

Issue Date Test Reports: EN 1276-March 2017/EN 13697-Feb 2016

YEASTICIDAL ACTIVITY						
TEST METHOD	**TYPE OF ORGANISM**	**ORGANISMS**	**SOIL CONDITIONS**	**TEMPERATURE**	**CONC./ CONTACT TIME**	**LOG REDUCTION REQUIRED TO PASS**
EN 1650 (2013)	Yeast	Candida albicans	clean	20°C	*80% 30 sec*	≥4 log
EN 13697 (2015)	Yeast	Candida albicans			*50% 30 sec*	≥3 log

Issue Date Test Reports: March 2017

VIRUCIDAL ACTIVITY virucidal activity against enveloped viruses such as Coronavirus (SARS CoV-2)						
TEST METHOD	**TYPE OF ORGANISM**	**ORGANISMS**	**SOIL CONDITIONS**	**TEMPERATURE**	**CONC./ CONTACT TIME**	**LOG REDUCTION REQUIRED TO PASS**
EN 14476 (2013) +A1 :2015	Virus	Modified vaccinia virus Ankara /MVA	clean	20°C	*undiluted 30 sec*	≥4 log

Issue Date Test Reports: Dec 2015

ClearKlens IPA

Shelf life

ClearKlens IPA has a shelf life of 24 months.
ClearKlens IPA Sterile Trigger Spray has a proven shelf life of 5.5 months after the first use.

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ClearKlens IPA

ATE

The calculated Acute Toxicity Equivalent – Oral value (LD50) of **ClearKlens IPA (VH1) is**:

4000 mg/kg

TOC

Total Organic Carbon (TOC) value:
45.27%

Analysis by means
TOC- V.cph SHIMADZU.
Facultat de Farmàcia de la Universitat de Barcelona UB.

SDM (Servei de Desenvolupament del Medicament)

AOX, GMO or TSE declaration

Our product Clearklens IPA (VH1) does not contain AOX, GMO or TSE.

Barbara Pospišil
Global Formulation Manager Life Sciences | R&D F&B Europe
2021-01-22

ClearKlens IPA

PDE

Revision: 2017-06-15

Overall permissible daily exposure for ClearKlens IPA VH1

The permissible daily exposure of the undiluted mixture is best estimated by combining the contribution of the acceptable daily exposures (ADE) of each individual ingredient in the mixture. Assuming that the critical effects of all ingredients are additive may be considered as worst case. The permissible daily exposure of the mixture is then calculated according to the following equation:

$$PDE_{mixture} = \frac{100\ \%}{\sum_{i=1}^{n} \frac{\%_i}{ADE_i}}$$

i	components in mixture
$\%_i$	component percentage
ADE_i	component ADE

EMA/CHMP/ICH/82260/2006

Assuming such additivity, the permissible daily exposure of the undiluted mixture by the general public is then estimated to be 3.7 mg/kg BW/day assuming life time oral exposure.
The most conservative approach to establish the permissible daily exposure of mixtures is to assume that the mixture is only based on the component with the most critical acceptable daily exposure. In this case that is 2.4 mg/kg BW/day based on Isopropyl alcohol.

This product should only be used as directed. Please use the information provided in this document in combination with instructions provided in the safety data sheet and product information sheet. Data have been derived with care for the product as supplied and need to be interpreted for the circumstances in which the product is actually used.

- - - - - End of Statement - - - - - -

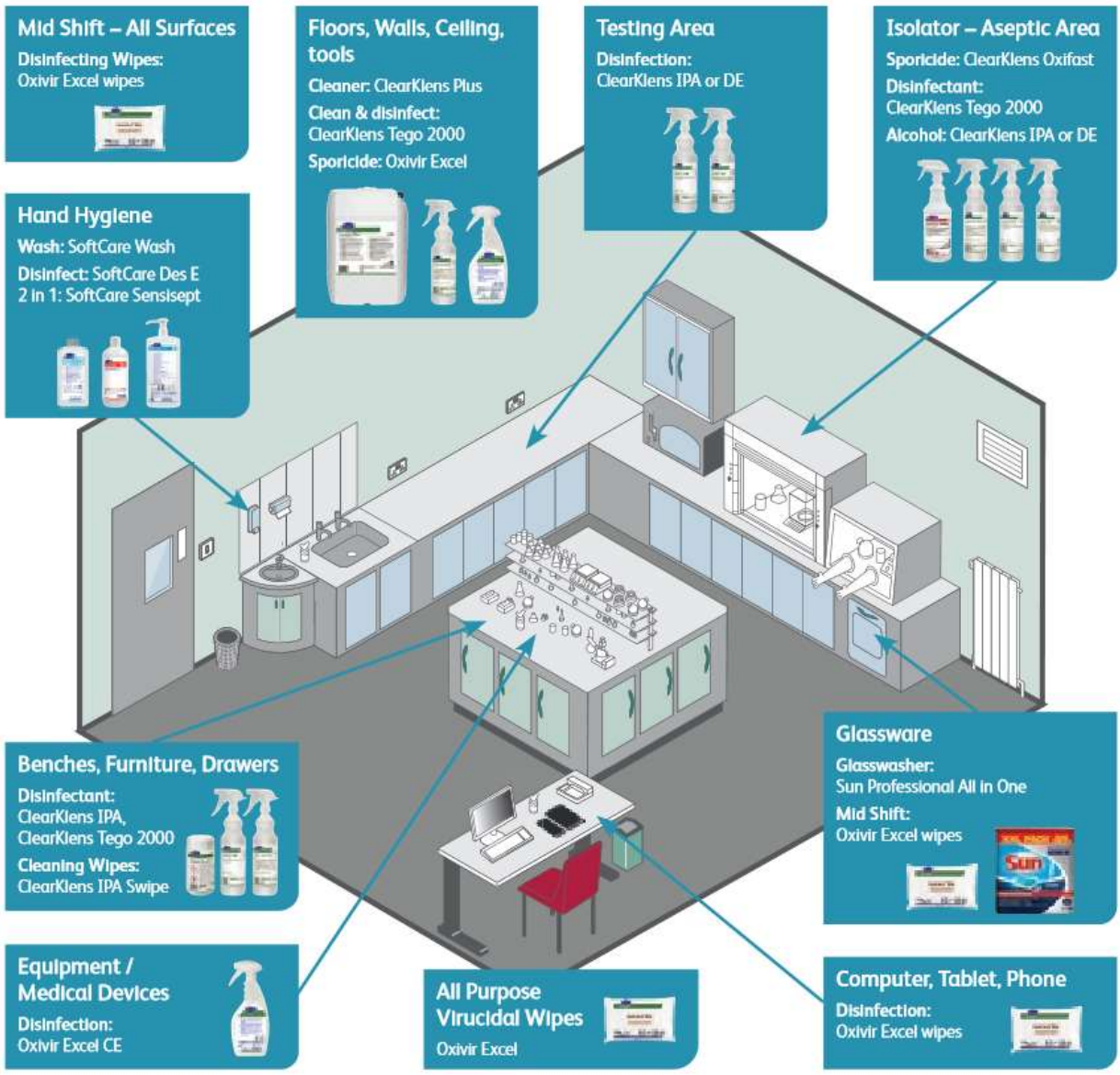
Please note that this is not a regulatory assessment and should not be interpreted as an endorsement of regulatory compliance.

MSDS5513

Full document is available upon request at ***pharma@diversey.com***

ClearKlens IPA

Laboratory use points



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ClearKlens IPA

ClearKlens range

Key features

HYGIENE ASSURED

The ClearKlens product range streamlines the validation process ensuring:



BPR Supported Formulation

The Biocidal Products Regulation (BPR) requires biocidal products to be registered with the European Union and will become the standard for all member states. As a significant investment per formulation you can be rest assured that Diversey ClearKlens is committed to the pharma sector and ensuring that we have a product range that is fit for the purpose.



Manufactured in a controlled environment to cGMP

The ClearKlens range is manufactured to cGMP principles (ISO 22716). Our sterile range is manufactured in cleanrooms accredited to the same standards as the cleanrooms the products are designed to be used in.



Tested to relevant standards

ClearKlens biocides are tested against relevant standards to prove efficacy against bacteria, fungi, yeasts, spores and viruses. Full test data is available on request.



Standard, protected worldwide formulations

The formulations of ClearKlens products are standard across the globe and are protected from change, ensuring no changes will be made unless for reasons beyond Diversey's control and with extended notice.



Supported with full technical documentation package

The ClearKlens range is supplied with a document package containing relevant documentation including: Certificate of Analysis, Certificate of Irradiation, Certificate of Sterility, Copies of the test data, TOC and ATE data, HPLC test methods for residues, manufacturing specifications and process and packaging specifications where applicable.



Packaging integrity

The ClearKlens sterile range is manufactured in sterile conditions to ensure the integrity of the product. Our packaging has been rigorously tested to ensure the integrity of the product is not compromised before or during use.

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ClearKlens IPA

For more information, visit www.diversey.com
or follow us on social media.

Disclaimer

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