ingo-man Touchless Spender

Passend für Artikel 09239

pure11-Nr.: 09240, Hersteller: Distributor pure11

AUTOKLAVIERBAR

Zusammenfassung

- Neue pure11-Artikelnummer (ab 01.07.2023): 1109240
- Zur Verwendung mit ClearKlens IPA70% 7522373
- "Touchless"-Funktion, funktioniert ohne Berührung
- Autoklavierbare, austauschbare Pumpe
- Dosierung von 1,5 ml reduzierbar auf 0,5 ml
- Batteriebetrieben
- "BACTERIOSTATIC" Gehäuse aus eloxiertem Aluminium
- Automatische Dosierung
- Mit Sicherheits-Hebel
- Diverses Zubehör erhältlich

Empfohlene Reinraumklassen

ISO	3	4	5	6	7	8	9
GMP			A/B		C	D	

Produktvarianten

pure11-Nr.: 09240

VE: 1 Stück

Quelle: https://www.pure11.de/ingo-man-touchless-spender

pure11 GmbH
Bavariafilmplatz 7 | D-82031 Grünwald
Geschäftsführer: Gitte Hansen, Julian Kropp
AG München HRB 171307

T +49 89 5589434 0
F +49 89 5589434 77
www.pure11.de
info@pure11.de

Diversey

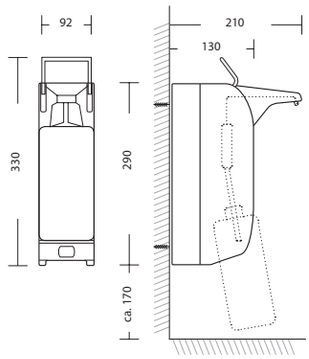
ClearKlens

Touchless dispenser for ClearKlens® IPA

You want a flexible dispenser solution, that combines the highest functionality, reliablity and longevity?

You need a dispenser that merges proven quality with the hygienic advantages of a touchless system?

Do you expect a useful accessory program that can be individually adapted to different requirements and applications?



Then the IMP Touchless is your dispenser system of choice

- Pump technology proven in continuous use
- Selection of materials according to hygienic viewpoints
- Touchless operation optimizes hand hygiene
- Simple pump removal from the front
- Battery level indicator
- Suitable for Sterile ClearKlens® IPA bottles
- Lockable cover available as an accessory

Body

- High hygienic standard through anodized aluminum surfaces
- Stress resistant construction optimized for continuous use
- Exchangeable face shield for individual product labelling

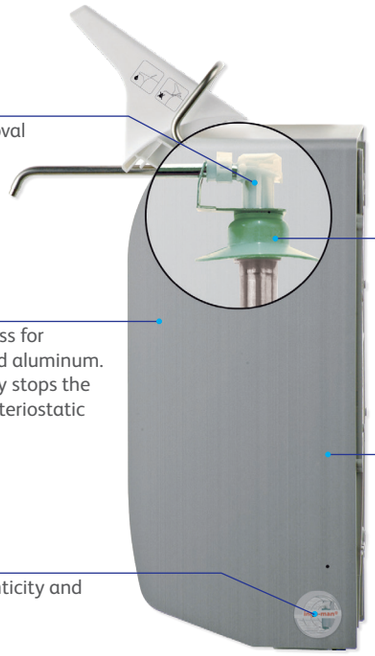
Pump and dosage

- IMP Touchless stainless steel pump, angled stainless steel suction tube, autoclavable
- Dosage amount: approx. 1.5 ml/push, reducible to approx. 0.5 ml/push

Filling

- Designed to be used with ClearKlens IPA (70% IPA, 30% WFI)

Touchless dispenser for ClearKlens IPA



Autoclavable pumps
Easy exchange through front removal

Flexible sealing cap
Ensures secure hold of the bottle within the dispenser.

High hygienic standard
The body of the ingo-man Touchless for ClearKlens IPA is made of anodized aluminum. This high-grade material effectively stops the growth of bacteria through its bacteriostatic properties

Energy supply
Use with batteries or connect to the electric grid. Long battery life (up to 2 years) is possible through low energy consumption.

Quality Guarantee
The hologram confirms the authenticity and quality of an Original product

Technical data		Article code
IMP Touchless for ClearKlens® IPA	Anodized aluminum, silver	4400420
ClearKlens IPA RTU	1L sterile bottle	7522373

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

Accessories	Part description
	ingo-man® plus locking plate IMP Touchless including lock and key for 1000 ml IMP Touchless dispenser anodized aluminum, matte silver, with window
	ingo-man® plus catch tray IMP Touchless hangs over the dispenser body, with removable plastic tray for touchless dispenser IMP Touchless, 1000 ml
	ingo-man® plus table stand IMP Touchless hangs over the dispenser body, with removable plastic tray for touchless dispenser IMP Touchless, 1000 ml

pharma@diversey.com
www.clearklens.com

ClearKlens® IPA

Technical Dossier

Diversey Europe Operations BV, Maarssenbroeksedijk 2, 3542 DN Utrecht, The Netherlands
Tel. +31 (0)30 247 6427, www.diversey.com, pharma@diversey.com

ClearKlens IPA

Use description

ClearKlens IPA is ideal for the routine disinfection of all surfaces in pharmaceutical & cosmetics facilities, such as cleanroom work surfaces, process equipment, isolators and biosafety cabinets, etc. It is also recommended for decontamination of materials before entering the cleanroom, 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)* Hold spray approximately 30 - 40 cm from area to be treated. Spray directly onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. Bottle has 81mm diameter (fits most of the bottle holders) Spray head: Spray/JET/Off NON STERILE SKU 100981042 – Grey label	
ClearKlens IPA 12x500mLTrigger: *The solution is a 0.2 micron filtered.* *(70% IPA/ 30% deionized water)* Hold spray approximately 30 - 40 cm from area to be treated. Spray directly onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. Spray head: Spray /Off NON STERILE SKU 100865611 – Grey label	
ClearKlens IPA 2x5L can: *The solution is 0.2 micron filtered.* *(70% IPA/ 30% deionized USP)* Dispense directly into bucket. Wet cloth with alcohol and wipe onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. NON STERILE SKU 100981043 – Grey label	
ClearKlens IPA 12x1LBottle with flip cap, bagged: *The solution is a 0.2 micron filtered.* *(70% IPA/ 30% deionized water)* Hold spray approximately 30 - 40 cm from area to be treated. Spray directly onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. Bottle has 81mm diameter (fits most of the bottle holders) Spray head: Spray/JET/Off NON STERILE SKU 101102300 – Grey label	*No picture available yet*

ClearKlens IPA swipe: (cleaning wipe) *ClearKlens IPA Swipes are manufactured from a white non-woven non-linting thermally bonded Polypropylene/Viscose 23gsm substrate.* ClearKlens IPA Swipe is a ready to use cleaning wipe for the Pharmaceutical and Cosmetic industry used for cleaning surfaces, utensils and gloves. NON STERILE SKU 12x 200wipes: 100868204	
ClearKlens IPA RTU 4x5L or 10x1L can: *The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* Dispense directly into bucket. Wet cloth with alcohol and wipe onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. STERILE SKU 10x1L: 7522373 – Green label SKU 4x5L: 100865612– Green label	
ClearKlens IPA RTU 10x1L can (glove disinfection): *The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* To be used with the dedicated touchless dispenser STERILE SKU 7522373 – Green label Touchless dispensor for IPA: 4400420 (previous was 1219011)	
ClearKlens IPA SS 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. Shelf life after opening : **5,5months** Hold spray approximately 30 - 40 cm from area to be treated. Spray directly onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. STERILE SKU: 7513400 – Green label	

ClearKlens IPA Airless spray 12x 250ml: *The solution is a 0.2 micron filtered, sterile filled preparation. Double bagged.* *(70% IPA/ 30% WFI USP)* Hold spray approximately 30 - 40 cm from area to be treated. Spray directly onto surface to ensure complete coverage. Allow sufficient wet contact time before proceeding. Ergonomic design, reducing risk of repetitive strain injury. STERILE SKU 100899521 – Green label	

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

ClearKlens Trigger Sterile

Our sterile trigger spray "Bag in Bottle" technology maintains sterility for 6 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.

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:

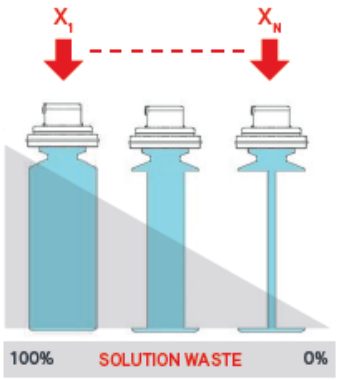
- Totally flat when emptied : x5 less volume
- Plastic based components: x3 less weight

	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

Airless versus aerosol:

ALCOHOL RESIDUE COMPARISON

Spray airless 250 ml
Average residues < 5 ml
(20 pouches tested)

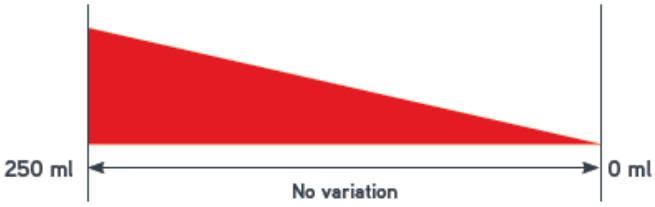


Aerosol can 300 ml
Average residues = 12 ml
(20 cans tested)

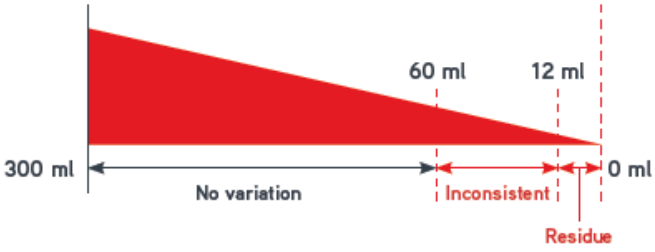
An under pressure aerosol doesn't allow full extraction of the solution.

SPRAY PATTERN COMPARISON

Spray airless



Aerosol can



Compatibility

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

Residues

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

Composition

Composition:

70% volume/volume IPA (+/- 1%)
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.

Microbiological efficiency Summary

BACTERICIDAL ACTIVITY

NORM	LABORATORY	INTERFERING SUBSTANCES	TEMPERATURE	CONTACT TIME	MICROORGANISMS TESTED	PASS
EN 1276	HygCen Germany GmbH, Germany 23/02/16	0.3 g/l bovine albumin (clean conditions)	20°C	5 min	*Escherichia coli* *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus*	50% 50% 50% 50%
EN 13697	HygCen Germany GmbH, Germany 23/02/16	0.3 g/l bovine albumin (clean conditions)	20°C	5 min	*Escherichia coli* *Enterococcus hirae* *Pseudomonas aeruginosa* *Staphylococcus aureus*	100% 100% 100% 100%

YEASTICIDAL ACTIVITY

NORM	LABORATORY	INTERFERING SUBSTANCES	TEMPERATURE	CONTACT TIME	MICROORGANISMS TESTED	PASS
EN 1650	HygCen Germany GmbH, Germany 23/02/16	0.3g/l bovine albumine (clean conditions)	20°C	15 min	*Candida albicans*	50%
EN 13697	HygCen Germany GmbH, Germany 23/02/16	0.3 g/l bovine albumin (clean conditions)	20°C	15 min	*Candida albicans*	100%

VIRUCIDAL ACTIVITY

NORM	LABORATORY	INTERFERING SUBSTANCES	TEMPERATURE	CONTACT TIME	MICROORGANISMS TESTED	PASS
EN 14476	Dr. Brill + Partner GmbH, Bremen, Germany 22/12/15	0.3 g/l bovine albumin (clean conditions)	20°C	30 sec	*Modified vaccinia virus Ankara /MVA*	100%

Shelf life

ClearKlens IPA has a shelf life of 24 months.

LD 50

The calculation for the acute oral toxicity of the rat with consideration of lethal doses for the individual raw materials, **ClearKlens IPA VH01** has a LD50 value of:

7799 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.

Health based exposure limits for use in risk identification

Introduction

The European Medicines Agency published a guideline on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities. The guideline is solely intended to assess the acceptability of pharmaceutically active contaminants which should be managed according to the risk posed which in turn are related to levels that can be considered safe for all populations.
Cleaning products used in manufacturing facilities are not subject to this guideline. Nevertheless, it is prudent to use the same principles for cleaning products so it can be used in an overall hygiene structure.

The intended use of ClearKlens IPA VH1 is as Surface disinfectant. It is a neutral liquid with a pH around 7.

The hazard profile of a mixture may be determined by interpreting the hazard profile of the indvidual ingredients in relation to the concentration used in the mixture and information available for the mixture. Criteria for this interpretation have been described as part the Globally Harmonized System f the United Nations (GHS). Applying these criteria, the classification for health effects for this product is: Specific target organ toxicity (single exposure), Category 3 , Serious eye irritation, Category 2

Chronic ingestion hazard assessment

The procedure for determination of health based exposure limits for residual active pharmaceutical substances is based on the method for establishing the so-called Permitted Daily Exposure (PDE) as described in Appendix 3 of ICH Q3C (R4) "Impurities: Guideline for Residual Solvents" and Appendix 3 of VICH GL 18 on "residual solvents in new veterinary medicinal products, active substances and excipients (Revision)". The PDE represents a substance-specific dose that is unlikely to cause an adverse effect if an individual is exposed at or below this dose every day for a lifetime.
Determination of a PDE involves (i) hazard identification by reviewing all relevant data, (ii) identification of "critical effects", (iii) determination of the no-observed-adverse-effect level (NOAEL) of the findings that are considered to be critical effects, and (iv) use of several adjustment factors to account for various uncertainties.

Reference data for components are preferably based on reviewed and published data such as the ADI (Acceptable Daily Intake) for food additives or DNEL (REACH Derived No Effect Levels for chronic exposure to the general population). In the absence thereof, an internally derived acceptable daily exposure may also be used.

The chronic oral toxicity equivalent for oral ingestion of the undiluted product by the general public is estimated to be 40 (mg/kg BW/day). This value is equivalent to the Permitted Daily Exposure (PDE) as described above.

This product contains 1 component that contributes to this edpoint:

Ingredient(s)	Acceptable daily exposure (mg/kg BW/day)	Chronic oral toxicity reference	Comment
Isopropyl alcohol	26	REACH Derived No Effect Level (DNEL) Oral Consumer	DNEL General Population - Hazard via oral route, long term exposure. Reach Dossier CAS 67-63-0

Chronic inhalation hazard summary

In analogy to the PDE derivation as decribed above, a similar assessment can be made for exposure by inhalation. Reference data for components are preferably based on reviewed and published data such as the OEL (Occupational exposure limits) for the worker environment or DNEL (REACH Derived No Effect Levels for chronic inhalation exposure to the general population). In the absence thereof, an internally derived acceptable daily exposure may also be used.

MS1002418

The chronic toxicity equivalent for exposure by inhalation of the undiluted product to the general public is estimated to be 140 (mg/m³).

This product contains 1 component that contributes to this edpoint:

Ingredient(s)	Acceptable daily exposure (mg/m³)	Chronic inhalation toxicity reference	Comment
Isopropyl alcohol	89	REACH Derived No Effect Level (DNEL) Inhalation Consumer	

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 - - - - - -

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 and spores. 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 LD50 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.