Diversey™ | Life Sciences

ClearKlens

Cleansinald

VH9/VH9S

Technical Dossier

BPR SUPPORTED

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An introduction to CK Cleansinald

Mode of action

ClearKlens Cleansinald contains a dual biocide system consisting of an alkyl benzakonium chloride and a N-(3-aminopropyl)-N-dodecylpropane-1,3-diamine.

The modes of action of alkyl benzakonium chlorides are well documented and understood namely the capacity to attach themselves onto specific sites on the bacterial cell membrane. Alkyl benzakonium chlorides carry a positive electrical charge in solution and are attracted to the negatively charged portions of the bacterial membrane.
The end result is that alkyl benzakonium chlorides block the uptake of nutrients into the cell and prevent the excretion of waste products which then accumulate within their structure.
In effect, the bacterial cell is both starved and poisoned from the build-up of wastes within its cell.
N-(3-aminopropyl)-N- dodecylpropane-1,3-diamine mode of action is not fully understood but is expected to be that when in a suitably buffered solution a cationic species is formed.
When this cationic species is formed the solution then carries a positive electrical charge and bind to the anionic phosphate groups, the phospholipids in the bacterial cell membrane.

Use description/pack description

ClearKlens Cleansinald is a disinfectant for walls, floors, ceilings and equipment in the pharmaceutical and medical manufacturing industries.

Directions for use:

ClearKlens Cleansinald SC 25mL concentrate: *The solution is 0.2 micron filtered, aseptically filled.* Dilute the content of one 25mL bottle ClearKlens Cleansinald SC with water to 5L (0.5% v/v aqueous solution). This solution can be used for wiping or/and moping. Allow sufficient wet contact time before proceeding (5 minutes minimum for bactericidal effect). STERILE	
ClearKlens Cleansinald RTU* 1L bottle &5L can: *The solution is 0.2 micron filtered, aseptically filled.* Pour the ClearKlens Cleansinald RTU solution into a sterile bucket and then ensure complete coverage of surface while wiping or/and moping. Allow sufficient wet contact time before proceeding (5 minutes minimum for bactericidal effect). ** Ready to use* STERILE	
ClearKlens Cleansinald SS* 900mLTrigger: *The solution is 0.2 micron filtered, aseptically filled.* ClearKlens Cleansinald SS is a ready to use 0.5% v/v aqueous solution. The trigger spray format is a no suck-back device which protects the contents of the bottles from viable and non-viable particle ingress during the in use shelf life of the product. Hold spray approximately 30 to 40 cm from the area to be treated. Spray directly onto the surface to ensure complete coverage. Allow sufficient wet contact time before proceeding (5 minutes minimum for bactericidal effect). Always close the nozzle after use. ** Ready to use* STERILE	

ClearKlens Cleansinald 5L concentrate: To be diluted between 0.1% to 3.5% depending on the microbiological results needed. Typical use concentration is 0.5% v/v (aqueous solution). This solution can be used for wiping or/and moping. Allow sufficient wet contact time before proceeding (5 minutes minimum for bactericidal effect). **NON STERILE**	
ClearKlens Cleansinald RTU* 1L bottle: Pour the ClearKlens Cleansinald RTU solution into a suitable bucket and then ensure complete coverage of surface while wiping or/and moping. Allow sufficient wet contact time before proceeding (5 minutes minimum for bactericidal effect). **NON STERILE** ** Ready to use*	

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 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

Material Compatibility

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

Corrosion stability of Clearklens Cleansinald on plastics

PVC does not show changes on aspect and rigidity when dipped in Clearklens Cleansinald (VH9) concentrate for 7 days at 23°C. It does not show traces of dipping.

PER does not show changes on aspect and rigidity when dipped in Clearklens Cleansinald (VH9) concentrate for 7 days at 40°C. It does not show traces of dipping.

Corrosion stability of Clearklens Cleansinald on stainless steel

ClearKlens Cleansinald (VH9) at concentrations of 0.5% does not show corrosion on stainless steel ASI 304 or ASI 316L when immersed for 15 days at 25°C or 50°C

Corrosion stability of Clearklens Cleansinald on iron

Tests performed with Clearklens Cleansinald (VH9) at a concentration of 0.5% and 2% show that iron is resistant to corrosion and well usable. Tests were conducted with plates immersed for 24 hours at ambient temperature.



Barbara Pospišil

Global Formulation Manager Life Sciences | R&D F+B Europe

2023-04-24

Residues

The product ClearKlens Cleansinald RTU/SS VH9S leaves residues below 10ppm on cleaned surfaces. The same applies for the concentrated product, if used according to use instructions (diluted to 0.5%), provided that water with very low residue on evaporation is used for dilution (the residue of diluted concentrated product heavily depends on quality of water used for dilution).

Specification

ClearKlens Cleansinald RTU 5L & 1L (Ready to use)

Appearance	Clear colorless liquid
Specific gravity (20°C) g/cm3	0.99-1.01
pH (20°C)	9.0-11.4

- Water used: Water for Injection (USP)

Additional parameters

Content of active cationic substance (%)	0.070-0.090
COD level	3 g O2/kg
Nitrogen content (N)	0 g/kg

ClearKlens Cleansinald SS 900mL (Ready to use)

Appearance	Clear colorless liquid
Specific gravity (20°C) g/cm3	0.99-1.01
pH (20°C)	9.0-11.4

- Water used: Water for Injection (USP)

Additional parameters

COD level	3 g O2/kg
Nitrogen content (N)	0 g/kg

ClearKlens Cleansinald SC 25mL & 5L (Concentrate)

Appearance	Clear light yellow liquid
Specific gravity (20°C) g/cm3	1.04-1.06
pH neat (20°C)	12-13
Content of active cationic substance (%)	14.25-15.75
pH (1% solution at 20°C)	10.5-11.5

Additional parameters

COD level	563 g O2/kg
Nitrogen content (N)	14 g/kg

Shelf life

- ClearKlens Cleansinald SS & RTU have a shelf life of 18 months.
    - ClearKlens Cleansinald SS has a proven shelf life of 5.5 months after the first use.
- ClearKlens Cleansinald SC has a shelf life of 2 years.
- ClearKlens Cleansinald has a shelf life of 2 years.

Microbiological efficacy Summary*

ClearKlens Cleansinald SC VH9 & ClearKlens Cleansinald VH9 (Concentrate)

BACTERICIDAL ACTIVITY						
TEST METHOD	TYPE OF ORGANISM	ORGANISMS	SOIL CONDITIONS	TEMPERATURE	CONC./ CONTACT TIME	LOG REDUCTION REQUIRED TO PASS
EN 1276	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	clean	20°C	*0.25%, 5 min*	≥5 log
			dirty		*0.5%, 5 min*	
EN 13727	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	dirty		*1.0%, 5 min*	≥5 log
EN 13697	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	clean		*0.5%, 5 min (40°C : 0.5%, 5 min)*	≥4 log
			dirty		*0.5%, 5 min*	

YEASTICIDAL ACTIVITY						
TEST METHOD	TYPE OF ORGANISM	ORGANISMS	SOIL CONDITIONS	TEMPERATURE	CONC./ CONTACT TIME	LOG REDUCTION REQUIRED TO PASS
EN 1650	Yeast	Candida albicans	clean	20°C	*0.25%, 15 min*	≥4 log
			dirty		*0.5%, 15 min*	
EN 13624	Yeast	Candida albicans	dirty		*0.5% 15 min*	≥4 log
EN 13697	Yeast	Candida albicans	clean		*0.5%, 15 min (40°C : 0.1%, 15 min)*	≥3 log
			dirty		*0.5%, 15 min*	

Issue Date Test Reports: Oct 2018

** Due to biocidal registration timelines, in particular countries, the authorization of this product may not contain all listed efficacy claims*

VIRUCIDAL ACTIVITY						
TEST METHOD	**TYPE OF ORGANISM**	**ORGANISMS**	**SOIL CONDITIONS**	**TEMP.**	**CONC./ CONTACT TIME**	**LOG REDUCTION REQUIRED TO PASS**
EN 14476	Virus	Murine Norovirus	clean	20°C	*conc. 2%, 30 min*	≥4 log
			dirty		*conc. 3%, 30 min*	
EN 14476	Virus	Adenovirus Type 5	clean		*conc. 1.5%, 30 min*	≥4 log
			dirty		*conc. 2%, 30 min*	
EN 14476	Virus	Poliovirus Type 1	clean		*conc. 3.5%, 60 min*	≥4 log
			dirty		*conc. 4.5%, 60 min*	

Issue Date Test Reports: Nov 2019 and March 2020

** Due to biocidal registration timelines, in particular countries, the authorization of this product may not contain all listed efficacy claims*

ClearKlens Cleansinald SS/RTU (Ready to use) & SC (Conc. at 0.5%)

BACTERICIDAL ACTIVITY						
TEST METHOD	TYPE OF ORGANISM	ORGANISMS	SOIL CONDITIONS	TEMPERATURE	CONTACT TIME	LOG REDUCTION REQUIRED TO PASS
EN 1276	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	dirty	20°C	*5 min*	≥5 log
EN 13697	Bacteria	Staphylococcus aureus; Enterococcus hirae; Escherichia coli; Pseudomonas aeruginosa	dirty/ clean	20°C	*5 min*	≥4 log

YEASTICIDAL ACTIVITY						
TEST METHOD	TYPE OF ORGANISM	ORGANISMS	SOIL CONDITIONS	TEMPERATURE	CONTACT TIME	LOG REDUCTION REQUIRED TO PASS
EN 1650	Yeast	Candida albicans	dirty	20°C	*15 min*	≥4 log
EN 13697	Yeast	Candida albicans			*15 min*	≥3 log

Issue Date Test Reports: Oct 2018

** Due to biocidal registration timelines, in particular countries, the authorization of this product may not contain all listed efficacy claims*

ATE

The calculated value for the acute oral toxicity of the rat with consideration of lethal doses for the individual raw materials, **ClearKlens Cleansinald SS/RTU VH9S** is:

ATE – Oral: >5000 mg/kg

The calculated value for the acute toxicity of the rat with consideration of lethal doses for the individual raw materials, **ClearKlens Cleansinald SC VH9 & ClearKlens Cleansinald VH9** is:

ATE – Oral: 2000 mg/kg

ATE – Inhalatory, mists: >5 mg/L

TOC

ClearKlens Cleansinald SS/RTU (*Ready to use)

Total Organic Carbon (TOC) value:
0.03%

ClearKlens Cleansinald SC (*Concentrate)
ClearKlens Cleansinald (*Concentrate)

Total Organic Carbon (TOC) value:
6.08%

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

SDM (Servei de Desenvolupament del Medicament)

AOX, GMO, BSE or TSE declaration

Our product ClearKlens Cleansinald SC/SS/RTU does not contain AOX, GMO, BSE or TSE.



Barbara Pospišil

Global Formulation Manager Life Sciences | R&D F+B Europe

2023-04-24

PDE – Permissible Daily Exposure assessment

ClearKlens Cleansinald SC VH9

(As in MS1005592 - Revision: 2023-04-14)

Overall permissible daily exposure for ClearKlens Cleansinald SC VH9
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:

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

i	components in mixture
$\%_i$	component concentration (% w/w)
ADE_i	component ADE (mg/kg BW/day)
PDE_{mix}	mixture PDE (mg/kg BW/day)

EMA/CHMP/ CVMP/ SWP/169430/2012

Assuming such additivity, the permissible daily exposure of the undiluted mixture by the general public is then estimated to be 0.2 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 0.009 mg/kg BW/day based on Alkyl propylene diamine.
The derivation of limits will need to take account of the dose to be administered, which will be influenced by the body weight of the species to be treated.

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.

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

ClearKlens Cleansinald VH9 (non-sterile conc.)

(As in MSDS5572 - Revision: 2023-04-14)

Overall permissible daily exposure for Clearklens Cleansinald VH9

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:

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

i	components in mixture
$\%_i$	component concentration (% w/w)
ADE_i	component ADE (mg/kg BW/day)
PDE_{mix}	mixture PDE (mg/kg BW/day)

EMA/CHMP/ CVMP/ SWP/169430/2012

Assuming such additivity, the permissible daily exposure of the undiluted mixture by the general public is then estimated to be 0.2 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 0.009 mg/kg BW/day based on Alkyl propylene diamine.
The derivation of limits will need to take account of the dose to be administered, which will be influenced by the body weight of the species to be treated.

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.

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ClearKlens Cleansinald RTU VH9S sterile & non-sterile

(As in MSDS5635 - Revision: 2023-04-19)

Overall permissible daily exposure for Clearklens Cleansinald RTU VH9S

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:

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

i	components in mixture
$\%_i$	component concentration (% w/w)
ADE_i	component ADE (mg/kg BW/day)
PDE_{mix}	mixture PDE (mg/kg BW/day)

EMA/CHMP/ CVMP/ SWP/169430/2012

Assuming such additivity, the permissible daily exposure of the undiluted mixture by the general public is then estimated to be 42 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 0.018 mg/kg BW/day based on trisodium nitrilotriacetate.
The derivation of limits will need to take account of the dose to be administered, which will be influenced by the body weight of the species to be treated.

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.

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ClearKlens Cleansinald SS VH9S

(As in MS1002691 - Revision: 2023-04-19)

Overall permissible daily exposure for ClearKlens Cleansinald SS VH9S

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:

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

i	components in mixture
$\%_i$	component concentration (% w/w)
ADE_i	component ADE (mg/kg BW/day)
PDE_{mix}	mixture PDE (mg/kg BW/day)

EMA/CHMP/ CVMP/ SWP/169430/2012

Assuming such additivity, the permissible daily exposure of the undiluted mixture by the general public is then estimated to be 42 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 0.018 mg/kg BW/day based on trisodium nitrilotriacetate.
The derivation of limits will need to take account of the dose to be administered, which will be influenced by the body weight of the species to be treated.

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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.

For more information, visit www.diversey.com

or follow us on social media.

Disclaimer

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