# CLEARKLENS®

## Technical Dossier
## ClearKlens Plus VH5

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

## Use description

# ClearKlens Plus

Concentrated neutral detergent for manual use

**VH5**

### Description

**ClearKlens Plus** is a concentrated, neutral, high-foaming liquid detergent designed for general-purpose application in the pharmaceutical and cosmetic industries.

### Key properties

- **ClearKlens Plus** contains a concentrated blend of high foaming detergents and emulsifiers. Its balanced neutral formulation is particularly effective against product residues found in the pharmaceutical and cosmetic industries. it can be used on most types of surfaces including plastics and soft metals such as aluminium.
- **ClearKlens Plus** is recommended for manual cleaning of process equipment, floors and walls.

### Benefits

- Powerful
- Highly economical and versatile
- Suitable for manual use
- Suitable for soft or hard water
- Non-perfumed product
- Low level residue detection method available

### Use instructions

Use **ClearKlens Plus** at concentrations between 0.1-1% v/v depending on type and degree of product residue.

**ClearKlens Plus** containing solutions should be thoroughly rinsed after use to remove them from all product contact surfaces.

Pharma™

pharma@diversey.com

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

# ClearKlens Plus

Concentrated neutral detergent for manual use

**Technical data**

| | |
|---|---|
| Appearance | Clear, pale brown liquid |
| Relative Density at 20°C | 1.03 |
| pH (1% solution at 20°C) | 5.9 |
| Chemical Oxygen Demand (COD) | 400 $gO_2/kg$ |
| Nitrogen Content (N) | None |
| Phosphorous Content (P) | None |

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

**Safe handling and storage information**

Store in original closed containers or (where applicable) in approved bulk tanks, away from sunlight and extremes of temperature.

Full guidance on the handling and disposal of this product is provided in a separate Material Safety Data Sheet.

**Product compatibility**

**ClearKlens Plus** is safe for use on materials commonly found in the pharmaceutical and cosmetic industries when applied under the recommended conditions. In the event of uncertainty it is advisable to evaluate individual materials before any prolonged use.

**Test method**

Validated Titration Test method.

HPLC Test Method.

*Packaging available*

| sku | Material |
|---|---|
| 7515165 | DI CLEARKLENS PLUS VH5 100X0.03L - Sterile doses |
| 7513376 | DI CLEARKLENS PLUS VH5 20L |
| 7513374 | DI CLEARKLENS PLUS VH5 2X5L |

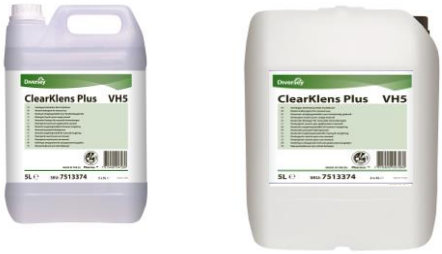
**Certificate of analysis/ available *www.clearklens.com***

pharma@diversey.com

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

# CLEARKLENS
Plus VH5

## Use description

| | |
|---|---|
| **ClearKlens Plus VH5 – 5L & 20L:**<br><br>To be diluted between 0,1% to 1%<br><br>NON STERILE |  <br>*To be diluted |
| **ClearKlens Plus VH5 sterile dose 100x30mL:**<br>*The solution is terminally irradiated. Double bagged with PE/Tyvek for an easy opening.*<br>Each dose to be diluted in a 4 – 10L bucket depending on the results needed.<br>Wet cloth and/or wipe onto surface to ensure complete coverage.<br><br>STERILE |  <br>*To be diluted |

pharma@diversey.com

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

## Compatibility

Applications solutions, when used as directed, will not affect materials normally encountered in the aforementioned industries (suitable for soft metals such as aluminium).

## Composition (extract from SDS)

**SECTION 3: Composition/information on ingredients**

**3.2 Mixtures**

| Ingredient(s) | EC number | CAS number | REACH number | Classification | Notes | Weight percent |
|---|---|---|---|---|---|---|
| sodium alkylbenzenesulphonate | 290-656-6 | 90194-45-9 | [1] | Acute Tox. 4 (H302)<br>Skin Irrit. 2 (H315)<br>Eye Dam. 1 (H318) | | 10-20 |
| sodium alkylethersulphate | Polymer* | 68585-34-2 | 01-2119488639-16 | Skin Irrit. 2 (H315)<br>Eye Dam. 1 (H318)<br>Aquatic Chronic 3 (H412) | | 3-10 |
| bronopol (INN) | 200-143-0 | 52-51-7 | No data available | Acute Tox. 4 (H302)<br>Acute Tox. 4 (H312)<br>STOT SE 3 (H335) | | 0.01-0.1 |
| | | | | Skin Irrit. 2 (H315)<br>Eye Dam. 1 (H318)<br>Aquatic Acute 1 (H400)<br>Aquatic Chronic 2 (H411) | | |

**Water used:**
De-ionized

## Specifications (as will appear on COA)

| Analysis | Methods | UM | Limits (Lower - Upper) |
|---|---|---|---|
| Anionic content | DM021 | % | (15,50-16,50) |
| Appearance | PAG N°183 G18 (001) | - | Clear colourless to yellow liquid |
| Odour | PAG N°186 G46 (001) | - | as standard |
| pH (for neat solution) | DM001 | - | (5,0-6,0) |
| pH (sol. in water 1%) | DM001 | - | (5,4-6,4) |
| Relative Density at 20°C | DM004 | - | (1,010-1,050) |
| Viscosity (MV2 21/s v.4) | DM006 | mPa s | (250-350) |
| Total viable count | DM019 | CFU/mL | <300 |

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

# Manufacturing process – Non Sterile 5L & 20L

**Diversey Bagnolo Factory**
**ss235 Crema Lodi**
**26010 Bagnolo Cremasco**
**Italy**
ISO cGMP 22716

Intake of raw material

↓

Testing & Positive release
(Identity testing & Certificates of Analysis)

↓

Cleaning & sanitisation of manufacture equipment

↓

Treatment of Water
( De-ionisation and uv radiation)

↓

BOM issued to production

↓

Addition controlled by weight
(Weighing equipment calibrated)

↓

Testing of manufactured bulk
(Appearance, specific gravity, alkalinity)

↓

Stock approved for distribution
(Diversey)

pharma@diversey.com

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

# STAGE 2 – Only for ClearKlens Plus 30mL sterile dose

## Manufacturing process

**Entegris Cleaning Process**
**395 Rue Louis Lépine**
**34 000 Montpellier – France**

Testing of manufactured solution
(Physical appearance, odor, compliance of COA from Bagnolo compared to specs)

↓

CLEANING OF PACKAGING

Cleaning of bottles, caps
according to the specification level

↓

PRODUCTION

Solution filled into packaging (ISO 6 room)

↓

Goods sent to gamma radiation (25-40KGy)
(Certificate of Irradiation)

## STAGE 2 – Only for ClearKlens Plus 30mL sterile dose

## Release

**Entegris Cleaning Process**
**395 Rue Louis Lépine**
**34 000 Montpellier – France**

Testing of manufactured solution
(Microbiological Testing – Sterility test by Medical Lab)

↓

Generation/Checking of Certificates
(Analysis, Irradiation & Microbiological Sterility)

↓

Stock approved for distribution
(Entegris)

↓

Certificates loaded onto website
(www.clearklens.com by Diversey 3PA European Quality Manager)

↓

Stock shipped to Diversey

# Test Method for Quantitative Determination of Product & Active Ingredient Concentrations

## Determination of total EDTA

**Reagents:-**

100mL of the dilute – **CLEARKLENS PLUS –** detergent solution.
0.004molar Hyamine 1622.
Chloroform $CHCl_3$(l) technical or analytical grades.
2.5 molar sulphuric acid ($H_2SO_4$(aq)).

Dimidium bromide indicator (cationic dye).
Disulphine blue V (erioglaucine or alphazurine) indicator (anionic dye).

*Preparation of Mixed Indicator Solution:- Dissolve 0.5g dimidium bromide in 20- 30mL hot 10% v/v aqueous ethanol.*

*Dissolve 0.25g disulphine blue V in 20- 30mL hot 10% v/v aqueous ethanol.*

*Transfer both solutions to a 250mL graduated volumetric flask and make- up to 250mL with 10% v/v aqueous ethanol and mix.*
*"Otherwise buy ready made".*

**Procedure:-**

Mix 200mL of water and 20mL of the *mixed indicator solution* in a 500mL volumetric flask. Add 20mL of 2.5M sulphuric acid, mix thoroughly and make-up with water to 500mL. Store the resulting *acid indicator* solution in an amber bottle to prevent direct sunlight penetration.

Take 100mL of **CLEARKLENS PLUS** sample solution and dilute to 250mL with water. Pipette 20mL of this solution into a stoppered 100mL-measuring cylinder; and to this add 10mL of *acid indicator* & add 15mL of chloroform. Shake the measuring cylinder thoroughly.
The chloroform and aqueous phases separate into 2 immiscible phases, the chloroform layer gives a red- pink colour as dimidium bromide combines with the anionic surfactant.
Into a burette pour 0.004M Hyamine 1622, record the level of the liquid in the graduated column as $\mathbf{T_1}$.

Add the 0.004M sodium Hyamine 1622 to the 2 immiscible phases in the open ended measuring cylinder. Shake the container well after each incremental addition.

Continue adding, the Hyamine 1622, until the pink dye in the chloroform layer passes into the aqueous water phase and gives a pale grey/blue colour. The Hyamine cation displaces the dimidium bromide dye.

A deep blue colour shows an excess of Hyamine is complexed with disulphine blue V, this dissolves in chloroform and the end- point is passed.

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

Record the final level reading – $\mathbf{T_2}$ of Hyamine 1622 left in the burette.
The titre added $\mathbf{T_3 = T_2 - T_1}$.

**Calculation:-** The concentration **% w/w anionic surfactant** is given by the formula:-

***Anionic surfactant % w/w = ($(T_3$ x 1.74)/ volume of sample)***

The disinfectant product concentrations can be expressed as percentage weight / weight **CLEARKLENS PLUS** and is given by the formula:-

***Conc'. of CLEARKLENS PLUS % w/w = ($(T_3$ x 10.36)/ vol. of sample)***

Alternatively, detergent product concentration can also be expressed as percentage volume / volume **CLEARKLENS PLUS** given by the formula:-

***Conc'. of CLEARKLENS PLUS % v/v = ($(T_3$ x 10.06)/ vol. of sample)***

**Target Conc's:-** For general detergency **CLEARKLENS PLUS** can be used successfully within the following concentration range.

***0.04% - 0.17% w/w anionic surfactant*** or alternatively expressed as:-

***0.25% – 1.00% v/v CLEARKLENS PLUS.***

***0.26% - 1.03% w/w CLEARKLENS PLUS.***

**Validation:-** 0.5% and 1.0% v/v solutions of **CLEARKLENS PLUS** were prepared accurately in mains water. Concentrations were checked using the above method. Tests were completed in triplicate and then reported as an average.

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

# CLEARKLENS
Plus VH5

| Batch Sample no. | | Prepared % Conc'. | Measured % v/v Conc'. |
|---|---|---|---|
| Batch no. 11386956 | | 0.50% v/v | 0.5231% v/v ***CLEARKLENS PLUS*** |
| Batch no. 11386956 | | 0.50% v/v | 0.4929% v/v ***CLEARKLENS PLUS*** |
| Batch no. 11386956 | | 0.50% v/v | 0.5030% v/v ***CLEARKLENS PLUS*** |
| **Average** | | **0.50% v/v** | **0.506% v/v *CLEARKLENS PLUS*** |

| Batch Sample no. | | Prepared % Conc'. | Measured % v/v Conc'. |
|---|---|---|---|
| Batch no. 11386956 | | 1.00% v/v | 1.0060% v/v ***CLEARKLENS PLUS*** |
| Batch no. 11386956 | | 1.00% v/v | 1.0060% v/v ***CLEARKLENS PLUS*** |
| Batch no. 11386956 | | 1.00% v/v | 1.0060% v/v ***CLEARKLENS PLUS*** |
| **Average** | | **1.00% v/v** | **1.006% v/v *CLEARKLENS PLUS*** |

pharma@diversey.com

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

## Shelf life

ClearKlens Plus VH5 has a shelf life of 740 days.

## LD 50

The calculation for the acute oral toxicity of the rat with consideration of lethal doses for the individual raw materials, **ClearKlens PLUS VH5** has a LD50 value of:

- **>2000 mg/kg**

## TOC

A sample of ClearKlens Plus VH5 was measured according to EN1484 : 1997.
The following value has been determined:
Total organic carbon (TOC): 8.8 g / L
With a Specific gravity of 1.03 this corresponds to

Total organic carbon (TOC): **0.85 % (w/w)**

February 15th 2013

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

# AOX, GMO, BSE or TSE declaration

Our product ClearKlens PLUS VH5 does not contain AOX, GMO, BSE or TSE.

**Barbara Pospišil**
Lab Manager | R&D F&B Europe

2018-04-20

# 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 Plus VH5 is as Hard surface cleaner. It is an acidic liquid with a pH around 5.

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: 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 2.4 (mg/kg BW/day).** This value is equivalent to the Permitted Daily Exposure (PDE) as described above.

The following components contribute to this endpoint:

| Ingredient(s) | Acceptable daily exposure (mg/kg BW/day) | Chronic oral toxicity reference | Comment |
|---|---|---|---|
| ionic mixture: benzenesulphonic acid, mono-C10-13-alkyl derivs., sodium salts | 0.425 | Acceptable Daily Exposure (ADE) Oral Consumer | REACH registration dossier, DNEL for salt with CAS# 68411-30-3. |
| Sodium alkylethersulphate (2-3 EO) | 15 | Acceptable Daily Exposure (ADE) Oral Consumer | ECHA REACH Dossier, CAS 68891-38-3 |
| Trisodium citrate | 4000 | Acceptable Daily Exposure (ADE) Oral Consumer | read across to citric acid, REACH registration dossier: A fairly limited report of an unspecified study without guideline or GLP compliance, |



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

| | | | |
|---|---|---|---|
| | | | identified 10-day NOAEL and LOAEL values in the rat of 4 and 8 g/kg bw/day respectively. The 10-day LD50 was given as 5.66 (+/- 0.44) g/kg bw |
| Preservative (bronopol) | 0.001135 | JECFA Acceptable Daily Intake (ADI) | |

## 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.

**The chronic toxicity equivalent for exposure by inhalation of the undiluted product to the general public is estimated to be 14 (mg/m$^3$).**

The following components are relevant for assessing the calculated acute oral LD50 of the mixture:

| Ingredient(s) | Acceptable daily exposure (mg/m$^3$) | Chronic inhalation toxicity reference | Comment |
|---|---|---|---|
| ionic mixture: benzenesulphonic acid, mono-C10-13-alkyl derivs., sodium salts | 1.5 | Acceptable Daily Exposure (ADE) Inhalation Consumer | REACH registration dossier, DNEL for salt with CAS# 68411-30-3. |
| Preservative (bronopol) | 3 | Occupational exposure limit | |

This product is not intended to be sprayed.

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.

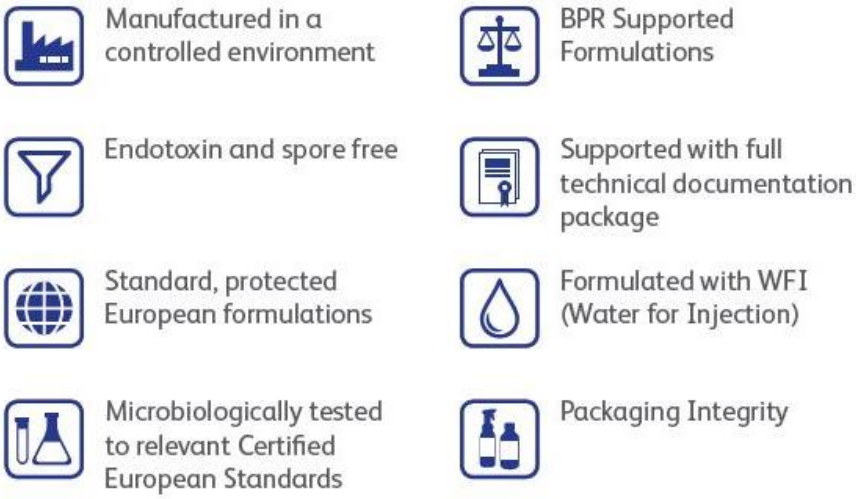
**- - - - - End of Statement - - - - - -**

## ClearKlens range:

### ClearKlens Hygiene Solutions – Sterile

The ClearKlens sterile range is an advanced range developed to serve the specific needs of the sterile processing industry. Manufactured in a controlled environment the range is presented in packaging validated to maintain the sterility of the product until point of use in the clean room.

- Standard formulations, aiding standardised international operating procedures
- Manufactured to GMP standards with full batch traceability
- Testing against relevant microbiological standards
- Supported by full technical documentation including: Certificates of Analysis, Irradiation and Sterility where appropriate




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