ClearKlens® Ultra

Technical Dossier
VH4

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

Product description

ClearKlens Ultra is a general-purpose liquid detergent designed for manual cleaning applications in the Pharmaceutical and Cosmetic industries.

Key properties

- ClearKlens Ultra is a mildly alkaline product containing an optimized blend of sequestrants, wetting agents and emulsifiers. Its powerful formulation is particularly effective for the removal of residues typically found in the Pharmaceutical and Cosmetic industries.
- ClearKlens Ultra is designed for the manual cleaning of equipment, walls and floors.

Benefits

- Powerful cleaner, effective against a wide range of product residues.
- Versatile and economical
- Use in soft or hard water
- Non-perfumed product
- Free rinsing
- Moderate low foam
- Low level residue detection method

Use instructions

Use ClearKlens Ultra at concentrations between 0.5-5% v/v dependent on the type and degree of product residue.

Technical data

Appearance: Clear, colourless liquid
pH (1% solution at 20°C): 11.5
Relative density (20°C): 1.07

Chemical Oxygen Demand (COD): 220 gO2/kg
Nitrogen Content (N): 2.6 g/kg

Phosphorous Content (P): None

Available pack sizes:

ClearKlens Ultra VH4 20L can *SKU* 7517147	
ClearKlens Ultra VH4 950L IBC *SKU* 100830638	

Certificate of analysis (COA) available on *www.clearklens.com*

Compatibility

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



Barbara Pospišil
Lab Manager and Global Formulation Manager Life Sciences | R&D F&B Europe
2018-02-28

Composition (Extract from SDS)

SECTION 3: Composition/information on ingredients

Ingredient(s)	EC number	CAS number	REACH number	Classification	Notes	Weight percent
(2-methoxymethylethoxy)propanol	252-104-2	34590-94-8	01-2119450011-60	Not classified as hazardous		3-10
alkyl alcohol ethoxylate	Polymer*	69011-36-5	[4]	Acute Tox. 4 (H302) Eye Dam. 1 (H318)		1-3
sodium hydroxide	215-185-5	1310-73-2	01-2119457892-27	Skin Corr. 1A (H314) Met. Corr. 1 (H290)		1-3
sodium cumenesulphonate	239-854-6	15763-76-5	01-2119489411-37	Eye Irrit. 2A (H319)		1-3

Water used:
Demineralized

Specifications (as will appear on COA)

Analysis	Methods	UM	Limits (Lower - Upper)
Appearance	PAG N°183 G18 (001)	-	Clear liquid
Free Alkalinity as %Na2O pH 8.2	DM002	%	(1,0-2,0)
pH (for neat solution)	DM001	-	(12,5-14,0)
pH (sol. in water 1%)	DM001	-	(10,9-12,1)
Relative Density at 20°C	DM004	-	(1,050-1,090)
Total Alkalinity as %Na2O pH 3.6	DM002	%	(2,0-3,0)

Procedure for manufacture

Diversey Italy Production S.r.L.
SS235 Crema Lodi
26010 Bagnolo Cremasco
Italy

Intake of raw material

↓

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

↓

Cleaning & Sanitisation of manufacture equipment

↓

Treatment of Water
(Softened&De-ionisation and uv radiation)

↓

BOM issued to production

↓

Addition controlled by weight
(Weighing equipment calibrated)

↓

Testing of manufactured Intermediate Product
(pH, specific gravity, activity)

↓

Packaging of Intermediate product
(First off testing and generation of CoA)

↓

Release & Stock shipped to storage location

Test Method for Quantitative Determination of Product & Active Ingredient Concentrations

Reagents: 100mL of the dilute **– ClearKlens Ultra –** caustic detergent solution.

0.1 M (or 0.1 normal) hydrochloric acid (HCl(aq)).

Phenolphthalein indicator solution.

Procedure: Take a sample, and measure 100mL of the sample **ClearKlens Ultra** solution, using a measuring cylinder. Pour the 100mL sample into a transparent conical flask.
Add 2- 3 drops of phenolphthalein indicator solution, the sampled **ClearKlens Ultra** solution will turn red / pink in colour.

Into a burette pour 0.1M HCl, record the level of the liquid in the graduated column as T_1.
Add the 0.1M HCl to the **ClearKlens Ultra** solution, continuously swirling the contents of the flask. Continue adding carefully, the hydrochloric acid, until all traces of the pink colour disappear to a colourless solution.
Record the volume of hydrochloric acid added to the sample solution :– T_2.

The titre added $T_a = T_2 - T_1$.

Calculation: The detergent product concentrations can be expressed as percentage volume / volume **ClearKlens Ultra** and is given by the formula:

$$[\text{ ClearKlens Ultra}]\ \%\ v/v = T_a \times 0.143$$

Alternatively, detergent product concentration can also be expressed as percentage weight / weight **ClearKlens Ultra** and is given by the formula:-

$$[\text{ ClearKlens Ultra}]\ \%\ w/w = T_a \times 0.154$$

The concentration of active ingredient, expressed in terms of **% w/w NaOH** (causticity) is given by the formula:-

$$\%\ w/w\ NaOH = T_a \times 0.002$$

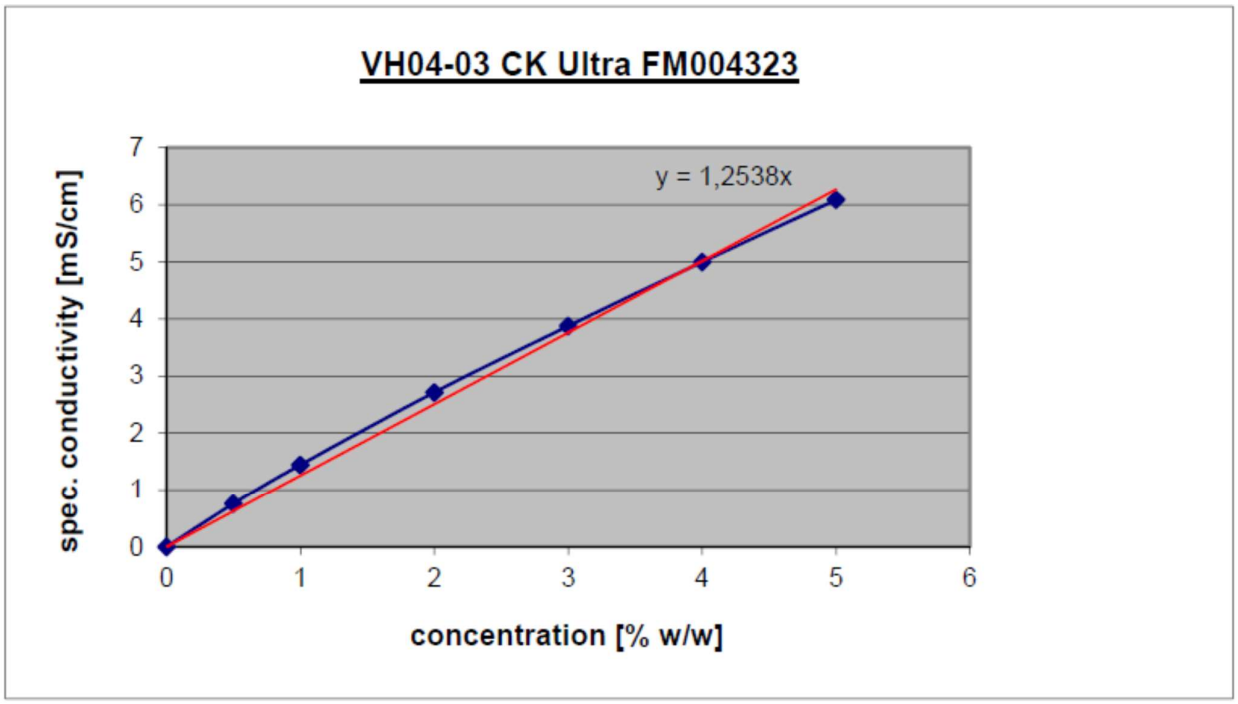
Target Conc's: For general manual external cleaning operations, **ClearKlens Ultra** can be used successfully within the following concentration ranges, depending on type and degree of soiling, the temperature and contact time at which the cleaning regime takes place.

0.50% - 5.00% v/v ClearKlens Ultra.

0.54% - 5.38% w/w ClearKlens Ultra or alternatively expressed as:

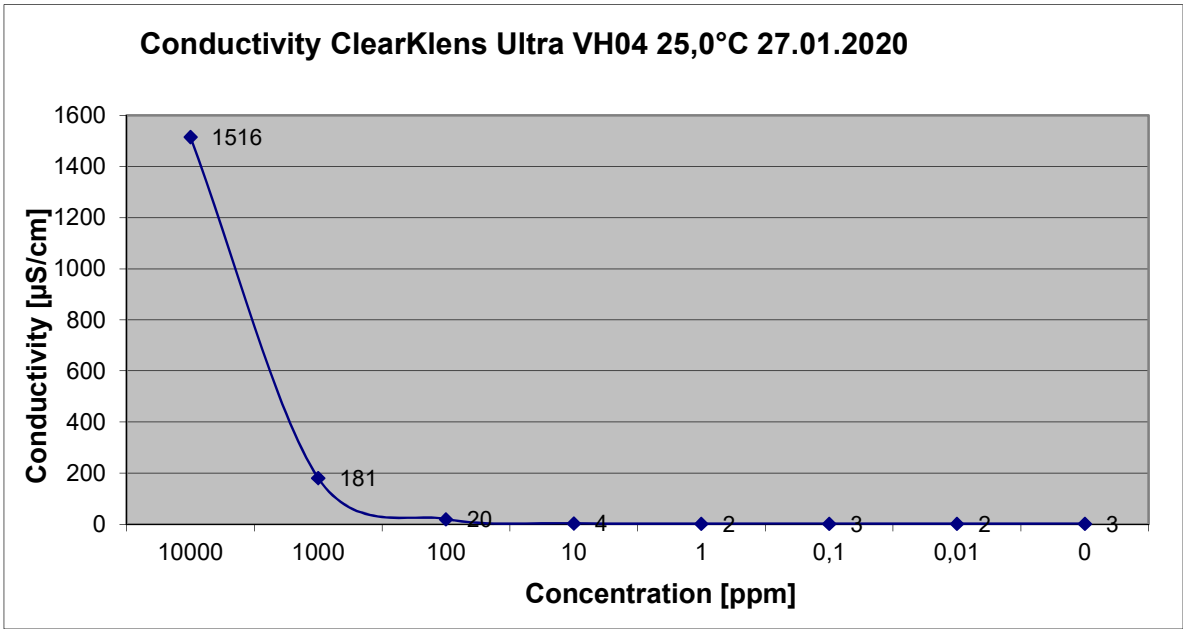
0.01% - 0.06% w/w NaOH

Conductivities: The corresponding specific conductivity (normalized at 25°C.) is pre- set to fall typically within the range of ***0.3 – 3.3 mS/cm.***



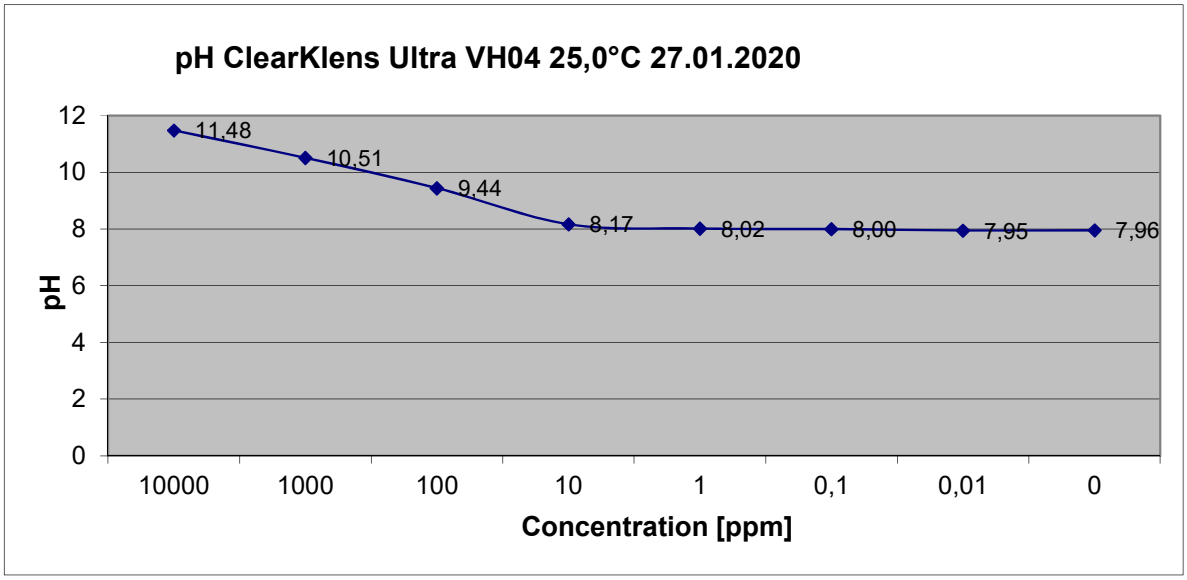
Rinsability – Conductivity curve

ClearKlens Ultra VH04	Average conductivity
[ppm]	[µS/cm]
10000	1516
1000	181
100	20
10	4
1	2
0,1	3
0,01	2
0	3



Rinsability – pH curve

ClearKlens Ultra VH04	Average pH
10000	11,48
1000	10,51
100	9,44
10	8,17
1	8,02
0,1	8,00
0,01	7,95
0	7,96



Shelf life

ClearKlens Ultra VH4 has a shelf life of 360 days.

ATE

The relevant calculated Acute Toxicity Equivalent - Oral value of **ClearKlens Ultra VH4** is:

>5000 mg/kg

TOC

Total Organic Carbon (TOC) value:
1.35%

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 Ultra VH4 does not contain AOX, GMO, BSE or TSE.



Barbara Pospišil
Lab Manager and Global Formulation Manager Life Sciences | R&D F&B Europe

2018-04-20

Clearklens Ultra VH4

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 Ultra VH4 is as Floor cleaner. Hard surface cleaner. It is an alkaline liquid with a pH around 13.4.

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 damage, Category 1, Skin 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 8.1 (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
Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate	1.5	REACH Derived No Effect Level (DNEL) Oral Consumer	
Dipropylene glycol methyl ether	1.67	REACH Derived No Effect Level (DNEL) Oral Consumer	
isotridecanol, ethoxylated (8EO)	0.5	Acceptable Daily Exposure (ADE) Oral Consumer	ADI, Read across to CAS # 111905-53-4. HERA Report (50 mg/kg NOAEL/SF)

MSDS7316

Sodium cumenesulphonate	3.8	REACH Derived No Effect Level (DNEL) Oral Consumer	
Sodium alkylethersulphate (2-3 EO)	15	Acceptable Daily Exposure (ADE) Oral Consumer	ECHA REACH Dossier, CAS 68891-38-3

This product is classified as corrive to skin, local effects are likely to be the critical toxicological hazard.

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 24 (mg/m³).

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

Ingredient(s)	Acceptable daily exposure (mg/m³)	Chronic inhalation toxicity reference	Comment
Tetrasodium N,N-bis(carboxylatomethyl)-L-glutamate	1.8	REACH Derived No Effect Level (DNEL) Inhalation Consumer	
Dipropylene glycol methyl ether	37.2	REACH Derived No Effect Level (DNEL) Inhalation Consumer	
isotridecanol, ethoxylated (8EO)	87	Acceptable Daily Exposure (ADE) Inhalation Consumer	
Sodium hydroxide	4	Occupational exposure limit	
Sodium cumenesulphonate	3.8	REACH Derived No Effect Level (DNEL) Inhalation Worker	

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:

