ClearKlens® Eco

VH39
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

Product information

ClearKlens ECO is an environmentally friendly, defoamed organic acid based liquid detergent descaler for CIP applications across the pharmaceutical and cosmetic industries.

Key properties

- ClearKlens ECO is highly effective at removing organic and inorganic scale deposits.
- ClearKlens ECO is highly effective to remove many coating across the pharmaceutical industry.
- ClearKlens ECO is highly effective for the manual cleaning of inorganic and organic soil.
- ClearKlens ECO is defoamed and is suitable for use in CIP applications under conditions of high pressure and turbulence.
- ClearKlens ECO is a conductive liquid and is suitable for automatic dosing and control.

Benefits

- Highly effective in removing organic and inorganic scale deposits, thus improving operational efficiency.
- Very low Phosphors and Nitrogen content, which means that it meets most of the customers environmental requirements across all borders.
- Its defoaming properties make it suitable for use under conditions of high pressure and turbulence, improving cleaning performance.
- Suitable for automatic dosing and control by conductivity, ensuring consistent delivery of product.

Use instructions

Typical use concentrations of ClearKlens ECO for equipment surfaces are 1-3% w/w (0.9-2.8% v/v) depending on the application and soil level.
For coatings removal, use a 2% v/v solution.
ClearKlens ECO containing solutions should be thoroughly rinsed after use to remove them from all product contact surfaces.

Technical data

Appearance: Clear, pale yellow liquid

pH (1% solution at 20°C): 2.5

Relative density (20°C): 1.09

Chemical Oxygen Demand (COD): 173 gO2/kg

Nitrogen Content (N): 7

Phosphorous Content (P): 0.2 g/kg

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

Available pack sizes

ClearKlens Eco 20L canister SKU 7519182	
ClearKlens Eco 950L IBC SKU 7522812	

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

Composition

Ingredient(s)	EC number	CAS number	REACH number	Classification	Classification (EC) 1272/2008	Notes	Weight percent
citric acid	201-069-1	77-92-9	01-2119457026-42	Xi; R36	Eye Irrit. 2 (H319)		3-10
sulphamic acid	226-218-8	5329-14-6	01-2119488633-28	Xi; R36/38-52/53	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319) Aquatic Chronic 3 (H412)		3-10
glycolic acid	201-180-5	79-14-1	01-2119485579-17	C; R22-34	Skin Corr. 1B (H314) Acute Tox. 4 (H302)		3-10
sodium cumenesulphonate	248-983-7	28348-53-0	01-2119489411-37	Xi; R36	Eye Irrit. 2 (H319)		1-3
alkyl alcohol alkoxylate	Polymer*	111905-53-4	[4]	Xi; R36/38	Skin Irrit. 2 (H315) Eye Irrit. 2 (H319)		1-3

Water used:
Demineralized

Specifications (as in COA)

Analysis	Methods	UM	Limits (Lower - Upper)
Appearance	PAG N°183 G18 (001)	-	Clear liquid yellow
Free Acidity as %Na2O pH 3.6	DM003	%	(3,0-4,2)
Relative Density at 20°C	DM004	-	(1,080-1,100)
Total acidity as %Na2O pH 8.2	DM003	%	(6,5-8,5)

Procedure for manufacture

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-ionization 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)

Test Method for Quantitative Determination of Product & Active Ingredient Concentrations

Reagents

Reagents:
0.1 N Sodium hydroxide solution Phenolphthalein indicator

Procedure
Add 2-3 drops of the indicator solution to 20 ml of the test solution. Titrate with the caustic to a red end point.

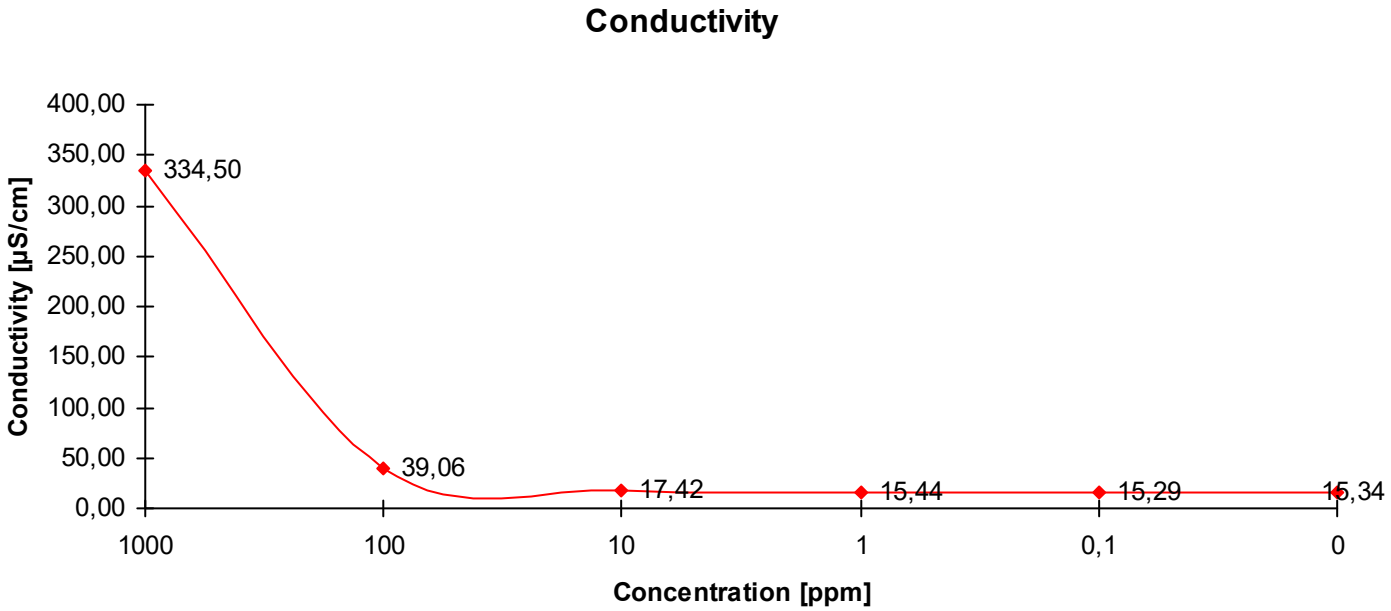
Calculation

% w/w ClearKlens ECO = titre (ml) x 0.2
% v/v ClearKlens ECO = titre (ml) x 0.18

HPLC method available on request

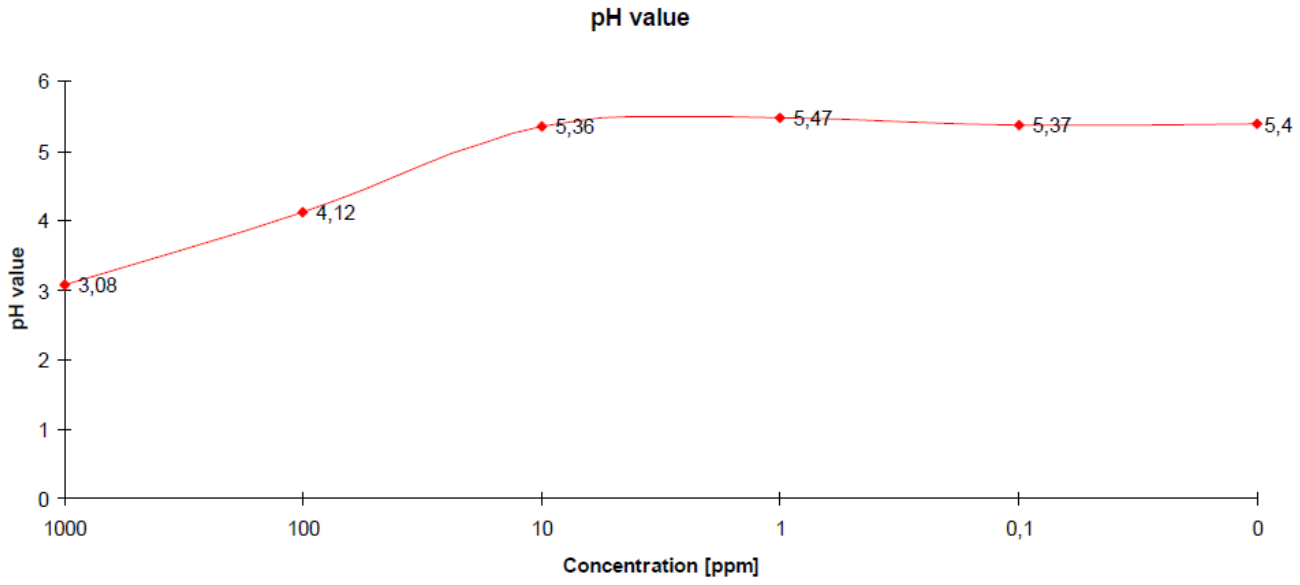
Rinsability – Conductivity curve

Concentration (ppm)	1000	100	10	1	0,1	0,01
Conductivity (µS/cm)	334,50	39,06	17,42	15,44	15,29	15,34



Rinsability – pH curve

Concentration (ppm)	1000	100	10	1	0,1	0,01
pH	3,08	4,12	5,36	5,47	5,37	5,4



Shelf life

ClearKlens Eco (VH39) has a shelf life of 540 days.

ATE

The calculated Acute Toxicity Equivalent - Oral value (LD 50) of **ClearKlens Eco (VH39) is**:

>2000 mg/kg

TOC

A sample of ClearKlens ECO VH39 was measured according to Ph.Eur.2.2.44 6th ed. 2008

The following value has been determined:
Total organic carbon (TOC): **55.6 g / L**

With a Specific gravity of 1.09 this corresponds to
Total organic carbon (TOC): **5.1 % (w/w)**

May 16th 2013

AOX, GMO or TSE declaration

Our product ClearKlens Eco (VH39) does not contain AOX, GMO or TSE.



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

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 ECO VH39 is as Food process cleaner. It is an extremely acidic liquid with a pH smaller than 2.

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: Skin corrosion, Category 1B

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 10 (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
Sulfamic acid	1.06	REACH Derived No Effect Level (DNEL) Oral Consumer	
Hydroxyacetic acid	0.75	REACH Derived No Effect Level (DNEL) Oral Consumer	
Sodium cumenesulphonate	3.8	REACH Derived No Effect Level (DNEL) Oral Consumer	
Alcohols,	25	Acceptable Daily	The ADE is based on the REACH DNEL of a related

MS1000594

C13-15-branched and linear, butoxylated (unspecifed BO) ethoxylated (unspecified EO)		Exposure (ADE) Oral Consumer	non-ionic surfactant.
Phosphonic acid	6.5	REACH Derived No Effect Level (DNEL) Oral Consumer	

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 7.2 (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
citric acid	1	Occupational exposure limit	
Sulfamic acid	1.85	REACH Derived No Effect Level (DNEL) Inhalation Consumer	
Hydroxyacetic acid	2.6	REACH Derived No Effect Level (DNEL) Inhalation Consumer	
Sodium cumenesulphonate	3.8	REACH Derived No Effect Level (DNEL) Inhalation Worker	
Alcohols, C13-15-branched and linear, butoxylated (unspecifed BO) ethoxylated (unspecified EO)	87	Acceptable Daily Exposure (ADE) Inhalation Consumer	No Occupational Exposure Limits have been established for this surfactant, but chronic inhalation data are available for a related non-ionic surfactant. Derived No-Effect Level (DNEL) for local effects via inhalation exposure for the general population has been determined to be 87 mg/m³ as part of the REACH submission of this related surfactant. This is based on a chronic rat inhalation study with a NOAEC of 435 mg/m³.
Phosphonic acid	2	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

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.