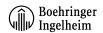
according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID:

SKU-4017, SKU-4018

Synonyms : Velagliflozin 15mg/ml Oral Solution

with active ingredient: Velagliflozin L-Proline H2O

1.2 Relevant identified uses of the substance or mixture and uses advised against

Use of the Sub-

stance/Mixture

: Veterinary product

Recommended restrictions

on use

For professional and industrial installation and use only., For

veterinary use only, Refer to the product insert for complete

instructions on usage

1.3 Details of the supplier of the safety data sheet

Company : Boehringer Ing. Pharma GmbH & Co.KG

Binger Straße 173 55216 Ingelheim

Germany

Telephone : +498007790900

E-mail address of person responsible for the SDS

: EHS-Services@Boehringer-Ingelheim.com

1.4 Emergency telephone number

Int. Emergency Telephone number: +1 703-527-3887 German Emergency Telephone number: +49800 1817059

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

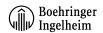
Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 H319: Causes serious eye irritation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

Version Revision Date: SDS Number: Date of last issue: 15.12.2022 5.0 23.08.2023 000000046142 Date of first issue: 28.10.2019

Hazard pictograms

Signal word Warning

Hazard statements H319 Causes serious eye irritation.

Prevention: Precautionary statements

> P264 Wash skin thoroughly after handling. P280 Wear eye protection/ face protection.

Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and

easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

This drug is not subject to the labelling requirements under the Globally Harmonized System

The pharmacological effect of the medicament has to be considered (see package leaflet).

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Chemical nature Mixture

Components			
Chemical name	CAS-No.	Classification	Concentration
	EC-No.		(% w/w)
	Index-No.		
	Registration number		
ethanol	64-17-5	Flam. Liq. 2; H225	>= 1 - < 10
	200-578-6	Eye Irrit. 2; H319	

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

	603-002-00-5 01-2119457610-43- xxxx	specific concentration limit Eye Irrit. 2 >= 50 %	
Velagliflozin L-proline H2O	1661838-94-3	Acute Tox. 4; H302	>= 1 - < 10
		Acute toxicity esti- mate	
		Acute oral toxicity: 1.000 mg/kg	

For explanation of abbreviations see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical ad-

vice immediately (show the label where possible).

(show the package insert where possible).

First Aid responders should pay attention to self-protection

and use the recommended protective clothing

Remove from exposure, lie down.

Take off immediately all contaminated clothing.

Victim to lie down in the recovery position, cover and keep him

warm.

If inhaled : Move to fresh air.

In case of skin contact : Wash off immediately with plenty of water.

In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.

Keep eye wide open while rinsing.

If swallowed : Rinse mouth.

Drink plenty of water.

4.2 Most important symptoms and effects, both acute and delayed

Risks : Causes serious eye irritation.

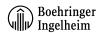
4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

Observe the summary of product characteristics of proprietary

medicinal products

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

Version Revision Date: SDS Number: Date of last issue: 15.12.2022 23.08.2023 000000046142 Date of first issue: 28.10.2019 5.0

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local cir-

cumstances and the surrounding environment.

Water

Dry chemical Foam

Carbon dioxide (CO2)

Unsuitable extinguishing

media

None known.

5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-

fighting

: In case of fire and/or explosion do not breathe fumes.

Hazardous combustion prod- : Carbon oxides

ucts

5.3 Advice for firefighters

for firefighters

Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

Complete suit protecting against chemicals

Further information Collect contaminated fire extinguishing water separately. This

must not be discharged into drains.

Fire residues and contaminated fire extinguishing water must

be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Wear personal protective equipment.

Ensure adequate ventilation.

High risk of slipping due to leakage/spillage of product.

6.2 Environmental precautions

Environmental precautions Do not flush into surface water or sanitary sewer system.

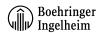
6.3 Methods and material for containment and cleaning up

Methods for cleaning up Pick up and transfer to properly labelled containers.

Absorb with liquid-binding material (sand, diatomite, acid

binders, universal binders).

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

Version Revision Date: SDS Number: Date of last issue: 15.12.2022 5.0 23.08.2023 000000046142 Date of first issue: 28.10.2019

6.4 Reference to other sections

For personal protection see section 8., For disposal considerations see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.

fire and explosion

Advice on protection against : No special protective measures against fire required.

Hygiene measures General industrial hygiene practice. Wash hands and face

before breaks and immediately after handling the product.

Keep working clothes separately.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

Refer to the product insert for instructions on storage.

Advice on common storage Keep away from food, drink and animal feedingstuffs.

Observe joint storage prohibition.

Storage class (TRGS 510) : 10

7.3 Specific end use(s)

Specific use(s) Consult the technical guidelines for the use of this sub-

stance/mixture.

SECTION 8: Exposure controls/personal protection

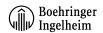
8.1 Control parameters

Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
ethanol	64-17-5	AGW	200 ppm 380 mg/m3	DE TRGS 900
	Peak-limit: excursion factor (category): 4;(II)			
	Further information: When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child			

•

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Abbreviations:

BIEL = Boehringer Ingelheim Exposure Limit (internal value)

BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)

BIPC = Boehringer Ingelheim Pregnancy Category

BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
ethanol	Workers	Dermal	Long-term systemic effects	343 mg/kg
	Workers	Inhalation	Long-term systemic effects	950 mg/m3

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006:

Substance name	Environmental Compartment	Value
ethanol	Fresh water	0,96 mg/l
	Marine water	0,79 mg/l
	Soil	0,63 mg/kg
	Fresh water sediment	3,6 mg/kg
	Sewage treatment plant	580 mg/l
	Intermittent use/release	2,75 mg/l
	Marine sediment	2,9 mg/l

8.2 Exposure controls

Engineering measures

Local exhaust

Emergency sprinkling nozzle

Personal protective equipment

Eye/face protection : Safety glasses with side-shields

(Not necessary when using full face mask)

Hand protection

Material : Nitrile rubber Glove thickness : 0,43 mm Protective index : Class 6

Remarks : The break through time depends amongst other things on the

material, the thickness and the type of glove and therefore

has to be measured for each case.

Skin and body protection : Laboratory: laboratory coat; Factory: disposable Overall.

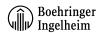
Respiratory protection : Breathing apparatus needed only when aerosol or mist is

formed.

Half protecting mask with filter:

ABEK-P2-filter

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Protective measures : Handle in accordance with good industrial hygiene and safety

practice.

Avoid contact with skin, eyes and clothing.

Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warran-

ty given by the manufacturer for the safe function.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state : liquid

Colour : clear, colourless to yellowish

Odour : No data available

Melting point/range : Not applicable

Boiling point/boiling range : No data available

Upper explosion limit / Upper

flammability limit

No data available

Lower explosion limit / Lower

flammability limit

No data available

Flash point : 47 °C

Auto-ignition temperature : No data available

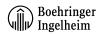
Decomposition temperature : No data available

pH : 7

Viscosity

Viscosity, dynamic : No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : No data available

Partition coefficient: n-

octanol/water

No data available

Vapour pressure : No data available

Relative density : No data available

Density : No data available

Bulk density : Not applicable

Relative vapour density : No data available

Particle characteristics

Particle size : Not applicable

9.2 Other information

Explosives : Not tested

Oxidizing properties : No data available

Flammability (liquids) : Does not sustain combustion.

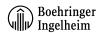
Self-ignition : No data available

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

10.2 Chemical stability

No decomposition if stored and applied as directed.

10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified due to lack of data.

Product:

Acute oral toxicity : Acute toxicity estimate: > 2.000 mg/kg

Method: Calculation method

Components:

ethanol:

Acute oral toxicity : LD50 (Rat): 10.470 mg/kg

Method: OECD Test Guideline 401

Acute inhalation toxicity : LC50 (Rat): 116,9 mg/l

Exposure time: 4 h
Test atmosphere: vapour

Method: OECD Test Guideline 403

Velagliflozin L-proline H2O:

Acute oral toxicity : ALD (Mouse, male and female): 1.000 - 2.000 mg/kg

Assessment: The component/mixture is moderately toxic after

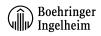
single ingestion.

ALD (Rat, male and female): > 2.000 mg/kg

Acute toxicity estimate: 1.000 mg/kg

Acute inhalation toxicity : Remarks: No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Product:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Components:

ethanol:

Species : Rabbit Exposure time : 24 h

Method : OECD Test Guideline 404

Result : No skin irritation

Velagliflozin L-proline H2O:

Species : Rabbit

Method : OECD Test Guideline 404

Result : No skin irritation

Test substance : An aqueous solution was tested.

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : Not corrosive

Species : in vitro assav

Method : OECD Test Guideline 492

Result : Eye irritation

Components:

ethanol:

Species : Rabbit

Method : OECD Test Guideline 405

Result : Irritation to eyes, reversing within 21 days

Velagliflozin L-proline H2O:

Species : Bovine cornea

Method : OECD Test Guideline 437

Result : Not corrosive

Test substance : An aqueous solution was tested.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Respiratory or skin sensitisation

Skin sensitisation

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components:

ethanol:

Test Type : Maximisation Test

Species : Guinea pig

Method : OECD Test Guideline 406

Result : negative

The value is given in analogy to the following substances: methanol

Velagliflozin L-proline H2O:

Method : DEREK

Result : No alert for skin sensitization

The value is given in analogy to the following substances: Velagliflozin

Germ cell mutagenicity

Not classified due to lack of data.

Components:

ethanol:

Genotoxicity in vitro : Test Type: Ames test

Test system: Salmonella typhimurium

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 471

Result: negative

Test Type: In vitro mammalian cell gene mutation test

Test system: mouse lymphoma cells

Metabolic activation: with and without metabolic activation

Method: OECD Test Guideline 476

Result: negative

Genotoxicity in vivo : Test Type: dominant lethal test

Species: Mouse Application Route: Oral

Method: OECD Test Guideline 478

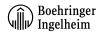
Result: Positive results were obtained in some in vivo tests.

Velagliflozin L-proline H2O:

Genotoxicity in vitro : Test Type: Ames test

Test system: S. typhimurium and E. coli

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Concentration: 33,3 - 5000 µg/plate

Metabolic activation: with and without metabolic activation

Result: negative

Remarks: In vitro tests did not show mutagenic effects

Test Type: Mouse lymphoma assay Test system: mouse lymphoma cells

Concentration: 1 - 350 µg/mL

Metabolic activation: with and without metabolic activation

Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

Species: Rat

Application Route: Oral

Dose: 500, 1000, 2000 mg/kg/day

Result: negative

Carcinogenicity

Not classified due to lack of data.

Components:

Velagliflozin L-proline H2O:

Remarks : No data available

Reproductive toxicity

Not classified due to lack of data.

Components:

Velagliflozin L-proline H2O:

Effects on fertility : Test Type: Fertility

Species: Rat

Application Route: Oral Dose: 40, 100, 400 mg/kg/day

Fertility: NOAEL: 100 mg/kg body weight

Symptoms: Effects on fertility

Remarks: Not classified due to data which are conclusive

although insufficient for classification.

Effects on foetal develop-

ment

Test Type: Embryo-foetal development

Species: Rat

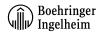
Application Route: Oral Dose: 40, 100, 400 mg/kg/day

General Toxicity Maternal: NOAEL: 100 mg/kg bw/day Embryo-foetal toxicity: NOAEL: 100 mg/kg bw/day

STOT - single exposure

Not classified due to lack of data.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Components:

Velagliflozin L-proline H2O:

Remarks : No data available

STOT - repeated exposure

Not classified due to lack of data.

Components:

Velagliflozin L-proline H2O:

Remarks : Not classified due to data which are conclusive although insuf-

ficient for classification.

Repeated dose toxicity

Components:

ethanol:

Species : Rat

NOAEL : 1,730 mg/kg LOAEL : 3.200 mg/kg

Application Route : Oral

Method : OECD Test Guideline 408

Species : Rat NOAEL : > 20 mg/l

Application Route : inhalation (dust/mist/fume)

Exposure time : 20 d

Velagliflozin L-proline H2O:

Species : Rat
NOAEL : 100 mg/kg
Application Route : Oral
Exposure time : 28 days

Dose : 30,100,300 mg/kg

Symptoms : Gastrointestinal disturbance

Species : Mouse Application Route : Oral Exposure time : 14 days

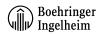
Dose : 100, 300, 500 mg/kg

Symptoms : Liver effects, Gastrointestinal disturbance

Aspiration toxicity

Not classified due to lack of data.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Components:

Velagliflozin L-proline H2O:

No data available

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

SECTION 12: Ecological information

12.1 Toxicity

Components:

ethanol:

Toxicity to fish : LC50 (Onchorhynchus mykiss): 11.200 mg/l

Exposure time: 24 h

LC50 (Pimephales promelas (fathead minnow)): 15.300 mg/l

Exposure time: 96 h

Toxicity to daphnia and other :

aquatic invertebrates

EC50 (Ceriodaphnia dubia (water flea)): 5.012 mg/l

Exposure time: 48 h Test Type: static test

EC50 (Marine invertebrates): 857 mg/l

Exposure time: 48 h

Toxicity to algae/aquatic

plants

ErC50 (Chlorella vulgaris): 275 mg/l

Exposure time: 72 h Test Type: static test

Method: OECD Test Guideline 201

Toxicity to microorganisms : IC50 (activated sludge): > 1.000 mg/l

Exposure time: 3 h Test Type: static test

Method: Activated Sludge, Respiration Inhibition Test

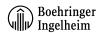
Toxicity to fish (Chronic tox-

icity)

NOEC: 250 mg/l Species: fish

Toxicity to daphnia and other : NOEC: 9,6 mg/l

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

aquatic invertebrates (Chron-

ic toxicity)

Exposure time: 10 d

Species: Freshwater invertebrates

NOEC: 79 mg/l Exposure time: 10 d

Velagliflozin L-proline H2O:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other :

aquatic invertebrates

Remarks: No data available

Toxicity to algae/aquatic

plants

Remarks: No data available

Toxicity to microorganisms

Remarks: No data available

Toxicity to fish (Chronic tox-

icity)

Remarks: No data available

Toxicity to daphnia and other : aquatic invertebrates (Chron-

ic toxicity)

Remarks: No data available

Ecotoxicology Assessment

Acute aquatic toxicity : Toxic effects cannot be excluded

Chronic aquatic toxicity : Toxic effects cannot be excluded

12.2 Persistence and degradability

Components:

ethanol:

Biodegradability : Result: Readily biodegradable.

Biodegradation: > 60 % Exposure time: 10 d

Method: OECD Test Guideline 301B

Test Type: aerobic

Result: Readily biodegradable.

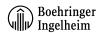
Biodegradation: 95 % Exposure time: 15 d

Method: OECD Test Guideline 301E

Velagliflozin L-proline H2O:

Biodegradability : Result: No data available

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

12.3 Bioaccumulative potential

Components:

ethanol:

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log

P(o/w)<1).

Partition coefficient: n-

octanol/water

log Pow: -0,35

Velagliflozin L-proline H2O:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-

octanol/water

: Remarks: No data available

12.4 Mobility in soil

Components:

ethanol:

Distribution among environ-

mental compartments

Koc: 0,2

Velagliflozin L-proline H2O:

Distribution among environ-

mental compartments

Remarks: No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered

to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of

0.1% or higher.

12.6 Endocrine disrupting properties

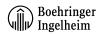
Product:

Assessment : The substance/mixture does not contain components consid-

ered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at

levels of 0.1% or higher.

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

12.7 Other adverse effects

Components:

Velagliflozin L-proline H2O:

Additional ecological infor-

mation

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Packs that cannot be cleaned should be disposed of in the

same manner as the contents.

Uncontaminated packaging can be recycled.

SECTION 14: Transport information

14.1 UN number or ID number

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

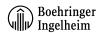
14.4 Packing group

ADR : Not regulated as a dangerous good

RID : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

Version Revision Date: SDS Number: Date of last issue: 15.12.2022 23.08.2023 000000046142 Date of first issue: 28.10.2019 5.0

IATA (Cargo) Not regulated as a dangerous good IATA (Passenger) Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Not applicable

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII)

Conditions of restriction for the following entries should be considered: Number on list 75, 3

If you intend to use this product as tattoo ink, please contact your ven-

dor.

REACH - Candidate List of Substances of Very High

Concern for Authorisation (Article 59).

Not applicable

Regulation (EC) No 1005/2009 on substances that de-

plete the ozone layer

Not applicable

Regulation (EU) 2019/1021 on persistent organic pollu-

tants (recast)

Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import

of dangerous chemicals

Not applicable

REACH - List of substances subject to authorisation

(Annex XIV)

Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving

Not applicable

Water hazard class (Germa:

dangerous substances.

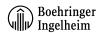
ny)

WGK 2 obviously hazardous to water

Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1: Total dust:

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

Not applicable

5.2.2: Inorganic substances in powdered form:

Not applicable

5.2.4: Inorganic substances in gaseous form:

Not applicable

5.2.5: Organic Substances:

Class 1: 0,4 % Citric acid, monohydrate 5.2.7.1.1: Carcinogenic substance:

Not applicable

5.2.7.1.1: Quartz fine dust PM4:

Not applicable

5.2.7.1.1: Formaldehyde:

Not applicable 5.2.7.1.1: fibres: Not applicable

5.2.7.1.2: Germ cell mutagens:

Not applicable

5.2.7.1.3: Substances toxic to reproduction:

Not applicable

5.2.7.2: Poorly degradable, easily enrichable and highly toxic

organic substances: Not applicable

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial

emissions (integrated pollution prevention and control)

Not applicable

The components of this product are reported in the following inventories:

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not

on the Canadian DSL nor NDSL.

Velagliflozin L-proline H2O

ENCS : Not in compliance with the inventory

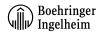
ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

 Version
 Revision Date:
 SDS Number:
 Date of last issue: 15.12.2022

 5.0
 23.08.2023
 000000046142
 Date of first issue: 28.10.2019

NZIoC : Not in compliance with the inventory

TECI: Not in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of H-Statements

H225 : Highly flammable liquid and vapour.

H302 : Harmful if swallowed.

H319 : Causes serious eye irritation.

Full text of other abbreviations

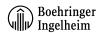
Acute Tox. : Acute toxicity
Eye Irrit. : Eye irritation
Flam. Liq. : Flammable liquids

DE TRGS 900 : Germany. TRGS 900 - Occupational exposure limit values.

DE TRGS 900 / AGW : Time Weighted Average

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA -European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet;

according to Regulation (EC) No. 1907/2006, as amended by Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL PR-Case ID: SKU-4017, SKU-4018

Version Revision Date: SDS Number: Date of last issue: 15.12.2022 5.0 23.08.2023 000000046142 Date of first issue: 28.10.2019

SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI -Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

Training advice Provide adequate information, instruction and training for op-

erators.

Sources of key data used to

compile the Safety Data

The specifications are based on own tests and/or literature

data.

Classification of the mixture:

Classification procedure:

Eye Irrit. 2 H319 Based on product data or assessment

Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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