

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 |

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

Product code : 000000000000609254 000000000000609254

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)

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Hazard pictograms :



Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : **Prevention:**

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 (GHS)

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

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| | | | |
|-----------------------------|---|---|-------------|
| | 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 Acute toxicity esti- mate Acute oral toxicity: 1.000 mg/kg | >= 1 - < 10 |

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 advice 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

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SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances 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 products : Carbon oxides

5.3 Advice for firefighters

Special protective equipment for firefighters : 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).

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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.
- Advice on protection against fire and explosion : 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 substance/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/m ³ | 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 | | | | |

| Components | Basis | Category | Values | Remarks |
|---|-------|----------|----------------------|---------|
| Velagliflozin L-proline monohydrate 1661838-94-3 | BIEL | 3A | 13 µg/m ³ | |
| | BIPC | 1b | | |

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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

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Commission Regulation (EU) 2020/878



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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 warranty 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 |

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| | | | |
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| 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.

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| 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

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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 assay
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.

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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 |
|-----------------------|---|---|

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| 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 development : 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.

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| 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 insufficient 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.

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| 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 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.

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 toxicity) | : NOEC: 250 mg/l Species: fish |
| Toxicity to daphnia and other | : NOEC: 9,6 mg/l |

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aquatic invertebrates (Chronic 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 toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chronic 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

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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 environmental compartments : Koc: 0,2

Velagliflozin L-proline H2O:

Distribution among environmental 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 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.

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 |

12.7 Other adverse effects

Components:

Velagliflozin L-proline H₂O:

Additional ecological information : 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

SAFETY DATA SHEET

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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 |

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 vendor.

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EU) 2019/1021 on persistent organic pollutants (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 dangerous substances. : Not applicable

Water hazard class (Germany) : WGK 2 obviously hazardous to water
Classification according to AwSV, Annex 1 (5.2)

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

SAFETY DATA SHEET

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Commission Regulation (EU) 2020/878



SENVELGO, LIQUI/12ML 1/15MG/ML BE/NL

PR-Case ID: SKU-4017, SKU-4018

| | | | |
|---------|----------------|--------------|---------------------------------|
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| 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 |

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 |

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;

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by
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| 5.0 | 23.08.2023 | 000000046142 | Date of first issue: 28.10.2019 |

SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECL - 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 operators.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Classification of the mixture:

Eye Irrit. 2 H319

Classification procedure:

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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