## Section 1: Identification of the substance/mixture and of the company/undertaking

### 1.1. Product identifier

**Product name:** Siren – The Limey – 3mg/ml Nicotine

**CAS number:** Not applicable. (Mixture)

**EINECS number:** Not applicable.

**Product code:** SITL1003

**Synonyms:** E-LIQUID, E-JUICE, SIREN, THE LIMEY

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

**Identified uses:** For use only in an electronic cigarettes and other vaping devices.

**Users advised against:** Not to be applied to skin, or ingested. Do not mix with other E-liquids.

### 1.3. Details of the supplier of the safety data sheet

**Company name:** Gilla Operations Europe s.r.o.
Kukucinova 8
Nove Zamky, SK
94001

**Tel:** +36 (0) 180 885 60

**Email:** danny.yuranyi@gilla.com (Danny Yuranyi, Managing Director)

### 1.4. Emergency telephone number

**Emergency tel:** +36 (0) 180 885 60 (9:00 – 19:00 CET)
+1 386 254 2865 (9:00 - 19:00 EST)

**If symptomatic:** 999/112

## Section 2: Hazards identification

### 2.1. Classification of the substance or mixture

| Classification according to Regulation (EC) No 1272/2008 (CLP) | SCL and/or M-factor | Classification Procedure |
|---|---|---|
| Oral Tox. 4 | | Classified on the basis of the procedure for mixtures in directive 1272/2008, based on the harmonised classification of the ingredients. Nicotine toxicity is based on the proposed classification, rather than that currently adopted at the time of writing. |

## 2.2. Label elements

**Product identifier:**

**Mixtures:**

**Hazard components for labelling:**

**Hazard pictograms**

| | | |
|---|---|---|
| **Hazard statements:** | H302 | Harmful if swallowed |
| **Precautionary statements:** | P102 | Keep out of reach of children |
| | P103 | Read label before use |
| | P264 | Wash hands thoroughly after handling |
| | P270 | Do not eat, drink or smoke when using this product |
| | P301+312 | IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell |
| | P330 | Rinse mouth |
| | P501 | Dispose of contents/container to domestic recycling waste |

**Supplemental Hazard information:**

**Special Rules for supplemental label elements for certain mixtures:**

**Additional labelling:**

## 2.3. Other hazards

**PBT:** This substance is not identified as a PBT substance.

## Section 3: Composition/information on ingredients

## 3.1 Substances

The product is a mixture.

## 3.2. Mixtures

| **Toxicological data on ingredients:** | | | | |
|---|---|---|---|---|
| L-Nicotine: | $LD^{50}$ 6.5-13mg/kg (>2000 mg/kg) | | | |
| Propylene Glycol: | 1,500mg/kg (causes adverse reactions, no $LD^{50}$ known) | | | |
| Glycerol: | 10,000mg/kg (NOEL level, no $LD^{50}$ known) | | | |
| Flavourings: | Non-toxic at this concentration. | | | |
| **Substance Name** | **CAS No.** | **EC No.** | **Concentration** | **Classification according to Regulation (EC) No 1272/2008 (CLP)** |
| Nicotine | CAS 54-11-5 | | <1.7% | Acute Oral Toxicity category. 4 |
| Propylene glycol | CAS 57-55-6 | | >30% | Not classified |
| Glycerol | CAS 56-81-5 | | >70% | Not classified |
| | | | | |
| | | | | |

## Section 4: First aid measures

### 4.1. Description of first aid measures

**Skin contact:** Wash skin with plenty of soap and water.

**Eye contact:** Rinse immediately with copious amounts of water. If irritation or discomfort persists, seek medical attention.

**Ingestion:** Rinse mouth and contact an Accident and Emergency Department or doctor/physician if you feel unwell. If a child comes into contact with or swallows any of the E-liquid contained in the product, contact your local Accident and Emergency Department immediately.

**Inhalation:** Move affected person from exposure. High vapour concentration unlikely owing to physical properties. Avoid inhalation of mist.

### 4.2. Most important symptoms and effects, both acute and delayed

**Skin contact:** There may be mild irritation at the site of contact. Small spills or skin exposure are unlikely to have a significant effect on adults, but should be cleaned up as soon as possible.

**Eye contact:** There may be irritation and redness.

**Ingestion:** There may be soreness and redness of the mouth and throat. May be intoxicating with high levels of ingestion.

**Inhalation:** No symptoms.

### 4.3. Indication of any immediate medical attention and special treatment needed

**Immediate / special treatment:** If you suffer persistently from any side effect, or experience significant changes to breathing or heart rate, you should consult your doctor. If you experience significant nausea or changes in heart rate following exposure, seek immediate medical attention. If a child comes into contact with or swallows any of the E-liquid contained in this product, you should contact your local accident and emergency department immediately.

## Section 5: Fire-fighting measures

### 5.1. Extinguishing media

**Extinguishing media:** Water fog. Carbon dioxide. Dry chemical powder.

### 5.2. Special hazards arising from the substance or mixture

**Special hazards:** Not applicable.

### 5.3. Advice for fire-fighters

**Advice for fire-fighters:** Wear self-contained breathing apparatus. Wear protective clothing to prevent contact with skin and eyes.

## Section 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

**Personal precautions:** Isolate the area.

### 6.2 Environmental precautions

**Environmental precautions:** Contain liquid to prevent contamination of soil, surface water or ground water.

### 6.3 Methods and material for containment and cleaning up

**Clean-up procedures:** Small spills: Clean up with absorbent material. Collect material in suitable and properly labelled open containers. Dispose of according to applicable regulations. Large spills: Contain with bund/dike. Pump into suitable and properly labelled containers. Recover if possible, or dispose of according to applicable regulations. Release to groundwater should be avoided.

### 6.4 Reference to other sections

**Reference to other sections:** Refer to section 8 of SDS.

## Section 7: Handling and storage

### 7.1. Precautions for safe handling

**Precautions for safe handling:** Avoid contact with skin and eyes.

### 7.2. Conditions for safe storage, including any incompatibilities

**Storage conditions:** Store in cool place. Keep container tightly closed in a dry and well-ventilated place. Containers which are opened must be carefully resealed and kept upright to prevent leakage. Hygroscopic. Air and light sensitive. Keep out of reach of children and away from pets or animals.

### 7.3. Specific end use(s)

**Specific end use(s):** For use only in electronic cigarettes or other vaping devices.

## Section 8: Exposure controls/personal protection

### 8.1. Control parameters

| Substance Name | CAS No. | EC No. | Occupational exposure limit value | | Monitoring and observation processes | Peak limitation | Source |
|---|---|---|---|---|---|---|---|
| | | | Long term | Short term | | | |
| Nicotine | 54-11-5 | | 0.5 mg/m$^3$ | 1.5 mg/m$^3$ | | | UK. EH40 WEL – Workplace Exposure Limits |
| Glycerol | 56-81-5 | | 10 mg/m$^3$ (mist) | None applicable | | | |
| Propylene glycol | 57-55-6 | | None applicable | None applicable | | | |

### 8.2. Exposure controls

#### 8.2.1 Appropriate engineering controls

**Engineering measures:** Ensure there is sufficient ventilation of the area.

### 8.2.2 Personal protective equipment

#### 8.2.2.1. Eye/face protection

**Suitable eye protection:** Safety glasses.

**Other eye protection measures:**

#### 8.2.2.2. Skin protection

**Hand protection:** Protective gloves.

**Body protection:** Protective clothing.

**Other skin protection measures:**

#### 8.2.2.3. Respiratory protection

Should not be required if ventilation is adequate.

## Section 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

| | |
|---|---|
| **State:** | Liquid. |
| **Colour:** | Light yellow to dark orange. |
| **Odour:** | Key lime. |
| **pH:** | No data is available. Likely to be very mildly alkaline. |
| **Melting point/freezing point:** | No data is available. |
| **Initial boiling point/boiling range:** | No data is available. Azeotropic mixture. |
| **Flash point:** | No data is available. |
| **Evaporation rate:** | No data is available. |
| **Flammability (solid, gas):** | No data is available. |
| **Upper/lower flammability or explosive limits:** | No data is available. |
| **Vapour pressure:** | No data is available. |
| **Vapour density:** | No data is available. |
| **Relative density:** | No data is available. Denser than, but miscible with water. |
| **Solubility(ies):** | No data is available. Components will be water soluble. |
| **Partition coefficient *n-octanol/water*:** | No data is available. |
| **Auto-ignition temperature:** | No data is available. |
| **Decomposition temperature:** | No data is available. |
| **Viscosity:** | No data is available. |
| **Explosive properties** | No data is available. Components are not explosive under normal conditions. |
| **Oxidising properties** | No data is available. Components are not strong oxidising agents under normal conditions. |

### 9.2 Other information

**Other information:** Not applicable.

## Section 10: Stability and reactivity

### 10.1. Reactivity

**Reactivity:** Stable under recommended transport or storage conditions.

### 10.2. Chemical stability

**Chemical stability:** Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

**Hazardous reactions:** Hazardous reactions will not occur under normal transport or storage conditions. Decomposition may occur on exposure to conditions or materials listed below.

### 10.4. Conditions to avoid

**Conditions to avoid:** Direct sunlight. Heat.

### 10.5. Incompatible materials

**Materials to avoid:** Strong oxidising agents. Strong acids.

### 10.6. Hazardous decomposition products

**Hazardous decomposition products:** Not applicable.

## Section 11: Toxicological information

### 11.1. Information on toxicological effects

**Toxicity values:** Toxicity to humans: Acute oral toxicity of mixture ($LD^{50}$ 1666.67mg/kg. This value is calculated using the method given in 3.1.3.6.1 of the CLP regulation.

### 11.1.1. Substances

#### 11.1.1.1. Acute toxicity

| Substance/endpoint | Route and Effect dose/ concentration | Value | Species | Remarks | Source |
|---|---|---|---|---|---|
| **Nicotine 54-11-5** | | | | | |
| Acute oral toxicity | LD50 | 3.3mg/kg bw | Mouse | Considered key study in harmonised classification1 | Lazutka et al (1969) |
| Acute oral toxicity | LD50 | 9.2 mg/kg bw | Dog | | Franke and Thomas, 1932 |
| Acute oral toxicity | ATE | 5mg/kg bw | | Considered as appropriate for calculation of mixtures containing nicotine by ECHA RAC | ECHA RAC report CLH-O-0000001412 |

[1] However the ECHA RAC considered, in its report CLH-O-0000001412-86-68/F, that mouse data was too variable for classification purposes, referencing an apparently unpublished study, Contraft-nicotex-tobacco 2015. This led to a recommendation to classify nicotine as a substance as acute oral toxicity 2, but an ATE of 5mg/kg bw was specified for the classification of mixtures.

| | | | | | |
|---|---|---|---|---|---|
| Acute dermal toxicity | ATE | 50mg/kg bw | Rabbit | Considered justification for maintaining Acute tox 1 in harmonised classification | Not available.2 |
| Acute dermal toxicity | LD50 | 70.4mg/kg bw | Rabbit | Apparently unpublished | Contraft-Nicotex-Tabacco (2015b). Acute dermal toxicity study of test item Nicotine in rabbits |
| Acute dermal toxicity | ATE | 70mg/kg bw | | Value rounded down from study above. | ECHA RAC report CLH-O-0000001412 |
| Inhalation (dusts and mists) | ATE (4 hours) | 0.19 mg/dm3 | Derived from Rat data | Calculated from a 20 min value of 2.3mg/L | ECHA RAC report CLH-O-0000001412 |
| **Propylene Glycol** | | | | | |
| Acute oral toxicity | $LD_{50}$ | 24900 mg/kg bw | mouse | Described as representative data after literature review | Organization for Economic Cooperation and Development; Screening Information Data Set for 1,2-Dihydroxypropane |
| Acute oral toxicity | $LD_{50}$ | 22000mg/kg bw | Rat | Ibid | Ibid |
| Acute dermal toxicity | $LD_{50}$ | 20800mg/kg bw | Rabbit | Ibid | Ibid |
| Acute inhalation toxicity | No LC50 identified NOEL | 1000mg/$m^3$ | Rat | Cited in ibid | Suber, R.L. et al. (1989): Fd. Chem. Toxic. 29: 573-583 |
| **Glycerol** | | | | | |
| Acute oral toxicity | $LD_{50}$ | 23,000mg/kg bw | Mouse | Identified as key study after literature review | Organization for Economic Cooperation and Development; Screening Information Data Set for Glycerol |
| Acute dermal toxicity | $LD_{50}$ | 18,700mg/kg bw | Rabbit | Ibid | Ibid |
| Acute inhalation toxicity | No LC50 identified NOAEC | 165mg/$m^3$ | Rat | Ibid | Ibid |
| | | | | | |
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| | | | | | |
| | | | | | |

**11.1.1.2. Skin corrosion/irritation**

**Practical experience/human evidence:**

**Animal data:**

**Other information:**

**Assessment/Classification:**

[2] Referenced in CLH report- Proposal for Harmonised Classification and Labelling Based on Regulation (EC) No 1272/2008 (CLP Regulation), Annex VI, Part 2 Substance Name: nicotine (ISO); 3-[(2S)-1-methylpyrrolidin-2-l]pyridine. However ECHA RAC supports this value, citing another apparently unpublished Contraft-nicotex-tobacco study.

### 11.1.1.3. Eye damage/irritation

**Assessment / Classification:** No data is available on the mixture. However, based on the ingredients, the mixture can be expected to be irritating to the eye with reversible effect, but not to an extent that justifies classification.

### 11.1.1.4. Sensitisation to the respiratory tract/skin

#### 11.1.1.4.1. Sensitisation to the respiratory tract

**Assessment / Classification:** Insufficient data is available to classify.

#### 11.1.1.4.2. Skin sensitisation

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Practical experience/human evidence:** | | | | | | | |
| **Animal data:** | **Substance** | **Effect dose/-concentration** | **Value** | **Species** | **Method** | **Result/ Evaluation** | **Remark** |
| | | | | | | | |
| **Other information:** | | | | | | | |
| **Assessment/Classification:** | Insufficient data is available to classify. | | | | | | |

### 11.1.1.5. CMR effects (carcinogenicity, mutagenicity, and reprotoxicity)

**Overall assessment on CMR properties:** No components of this mixture exhibit CMR properties.

### 11.1.1.6. Specific target organ toxicity (single exposure)

#### 11.1.1.6.1. STOT SE 1 and 2

**Practical experience/human evidence:**

| **Substance 1** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Animal data:** | **Effect dose/-concentration** | **Value** | **Exposure duration** | **Species** | **Method** | **Specific effects** | **Organs affected** | **Remark** |
| **Oral specific target organ toxicity (single exposure)** | | | | | | | | |
| **Dermal specific target organ toxicity (single exposure)** | | | | | | | | |
| **Inhalative specific target organ toxicity (single exposure)** | | | | | | | | |

**Other information:**

**Assessment/Classification:**

### 11.1.1.6.2. STOT SE 3

#### 11.1.1.6.2.1. Irritation to respiratory tract

**Practical experience/human evidence:**

**Other information:**

**Assessment/Classification:**

#### 11.1.1.6.2.2. Narcotic effects

**Practical experience/human evidence:**

**Other information:**

**Assessment/Classification:**

### 11.1.1.7. Specific target organ toxicity (repeated exposure)

#### 11.1.1.7.1. STOT RE 1 and 2

**Practical experience/human evidence:**

| Substance 1 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Animal data:** | **Effect dose/-concentration** | **Value** | **Exposure duration** | **Species** | **Method** | **Specific effects** | **Organs affected** | **Remark** |
| **Oral specific target organ toxicity (single exposure)** | | | | | | | | |
| **Dermal specific target organ toxicity (single exposure)** | | | | | | | | |
| **Inhalative specific target organ toxicity (single exposure)** | | | | | | | | |

**Other information:**

**Assessment/Classification:**

### 11.1.2. Mixtures

| | |
|---|---|
| **(a) Acute toxicity:** | Oral tox 3. (derived from toxicity values of ingredients. No data is available for the mixture itself) |
| **(b) Irritation** | Not classified. |
| **(c) Corrosivity** | Not classified. |
| **(d) Sensitisation** | Not classified, insufficient data for classification. |
| **(e) Repeated dose toxicity** | No evidence for repeated dose toxicity exists, unless the acute toxicity of nicotine is reached. |
| **(f) Carcinogenicity** | Not carcinogenic. |
| **(g) Mutagenicity** | Not mutagenic. |
| **(h) reprotoxicity** | Not classified, although concerns exist for nicotine. |

**Other information:**

## Section 12: Ecological information

### 12.1. Toxicity

#### 12.1.1. Aquatic toxicity

| Substance | Effect dose/ concentration | Value | Duration | Species | Remarks | Source |
|---|---|---|---|---|---|---|
| **Nicotine** | LC50 (static) | 4mg/L | 9h hr | Rainbow trout (fry) | Non-OECD method | Acute toxicities to larval rainbow trout of representative compounds detected in Great Lakes fish. Bull Environ Contam Toxicol. 1991 Feb;46(2):173-8. |
| | EC50 (static) | 5.7mg/L | 24 hr | Daphnia magna | Method uncertain | Reach registration dossier for Nicotine |
| | EC50 (static) | 37mg/L | 72 hr | Desmodesmus subspicatus | OECD 201 | Reach registration dossier for Nicotine |
| **Propylene glycol** | LC50 (static) | 51,600mg/L | 96 hr | Rainbow Trout | OECD 203 | Organization for Economic Cooperation and Development; Screening Information Data Set for 1,2-Dihydroxypropane |
| | LC50 (static) | 43,500mg/L | 48 hr | Daphnia magna | OECD 202 | Ibid |
| | Chronic NOEC | 13,020mg/L | Not specified | Daphnia magna | EPA Reproduction; Other | Ibid |
| | EC50 | 19,000mg/L | 96 hr | Selenastrum capricornutum | OECD 201 | Ibid |
| | EC50 | 18,100mg/L | 14 day | Selenastrum capricornutum | OECD 201 | Ibid |
| **Glycerol** | LC50 (static) | >50,000mg/L | 96 hr | Rainbow trout | Uncertain methodology | Organization for Economic Cooperation and Development; Screening Information Data Set for Glycerol |
| | LC50 | 184,000mg/L | 96 hr | Generic for fish | QSAR estimate | Ibid |
| | LC50 (static) | >10,000mg/L | 24 hr | Daphnia magna | Non-OECD method | Ibid |
| | No EC50 determined<br>EC0 >10,000mg/L | >10,000mg/L | 8 days | Microcystis aeruginosa | Non-OECD method | Ibid |
| **Flavourings** | As the flavouring are approved for food use, and are present in limited amounts, they are not expected to contribute significantly to ecotoxicty. | | | | | |

**Assessment/Classification:** No data is available on the mixture as a whole.

## 12.2. Persistence and degradability

### 12.2.1. Biodegradation

| Substance | Data source | Key comments |
|---|---|---|
| **Nicotine** | REACH dossier for Nicotine | The test item nicotine was tested using a concentration of at least 20 mg organic carbon/L (corresponding to 27.0 mg nicotine/L) in test medium following OECD 301B and EU-Method C.4-C.<br>Aniline was chosen as positive control.<br>Activated sludge was used as inoculum (concentration in the test 25.0 mg dry matter/L). The test was left running for 28 days.<br>All validity criteria were met. Degradation of the positive control was 71% after seven days.<br>The following data were determined for the test item nicotine:<br>10-day-window: day 3 – 13<br>degradation at the end of 10-day-window: 72%<br>degradation at the end of the test: 71%<br>pass level following guideline: 60% at the end of 10-day-window<br>Therefore, when applying the 10-day-window, nicotine is readily biodegradable following OECD 301B/EU C.4-C. |
| **Propylene glycol** | Organization for Economic Cooperation and Development; Screening Information Data Set for1,2-Dihydroxypropane | Because of its low vapor pressure, propylene glycol is not expected to volatilize. As a consequence, photodegradation is a relatively unimportant means of removing propylene glycol from the environment, although reaction with hydroxyl radicals in air has been estimated to be rapid (Atkinson et al., 1985). Removal of propylene glycol from aquatic and terrestrial environment occurs by biodegradation. It is readily biodegradable by unadapted sludge under aerobic conditions (79% in 20 days; Price et al., 1974), while breakdown in acclimated systems is rapid (84-99% in 20-24 hr; Martino et al., 1990). It is also removed by soil microcosms under aerobic (Klecka et al., 1993) and anaerobic (Klier et al., 1997) conditions.<br>No tests of bioaccumulation were reported in fish, however a BCF of 1.40 was calculated using a log $K_{ow}$ of -0.78 and the method of Bysshe (1982). |
| **Glycerol** | Organization for Economic Cooperation and Development; Screening Information Data Set for Glycerol | A number of biodegradation assays have been carried out with glycerol. In a Closed Bottle test (performed according to OECD 301) 92% biodegradation was reported after 30 days. More than 60% biodegradation measured as ThOD was reached within the 10-day window (Henkel 2001).<br>Glycerol is considered to be readily biodegradable. In addition, the relationship between BOD5, COD and ThOD was determined. The standard dilution method for a period of 5 days (BOD5) and the standard potassium dichromate method (COD) were used for the determinations. Both tests were performed according to APHA and ASTM guidelines, respectively. BOD5 was 82% of ThOD and 86% of COD. It can be concluded that glycerol has the potential to be rapidly biodegraded in a wastewater treatment plant (Bridie 1979). The BOD5/COD ratio is 0.86 and the fact that it is >0.5 further supports the ready biodegradability of glycerol.<br>Several other studies using adapted activated sludge or effluent from a sewage treatment plant demonstrates rapid biodegradation of glycerol (Matsui 1975, Matsui 1988, Pitter 1976, and Belly 1976). Under anaerobic conditions, using microorganisms adapted to acetate, glycerol was biodegradable (Chou 1978).<br>Conclusion<br>Glycerol is considered to be readily biodegradable in the aquatic environment. Pre-adapted micro-organisms can degrade glycerol rapidly under both aerobic and anaerobic conditions.<br>Based on Log $K_{ow}$ -1.76, glycerol will have a low bioaccumulation potential and is not expected to bioaccumulate. |
| The use of flavourings that are approved for food use would mitigate any concerns that they might be environmentally persistent or bio accumulative. | | |

## 12.3. Bioaccumulative potential

Based on the current uses of the ingredients, solubility in water and metabolic pathways, no ingredients are expected to have bio accumulative potential.

## 12.4. Mobility in soil

The components are all highly miscible with water and will remain in the water phase.

### 12.5. Results of PBT and vPvB assessment

The substances in this mixture do not meet the PBT/vPvB criteria of REACH, annex XIII.

### 12.6. Other adverse effects

Nicotine is suspected of being particularly toxic to bees. Propylene glycol is moderately toxic to felines.

## Section 13: Disposal considerations

### 13.1 Waste treatment methods

**Disposal operations:** Deposit into or on to land. (e.g. landfill, etc.)

**Disposal of packaging:** Dispose of as normal industrial waste.

**NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.

## Section 14: Transport information

14.1 UN No.- 3144

14.2 UN proper shipping name - Nicotine preparation, liquid, N.O.S

14.3 Transport hazard class - 6.1

Hazard label

14.3 Packing group III

## Section 15: Regulatory information

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

**SHE regulations/legislation:** Not applicable.

### 15.2. Chemical Safety Assessment

**Chemical safety assessment:** A chemical safety assessment has not been carried out for the substance or the mixture by the supplier.

## Section 16: Other information

### 16.1 Other information

**Other information:** This safety data sheet is prepared in accordance with Regulation (EC) No 1907/2006 (REACH).

**Legal disclaimer:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product. It is the responsibility of the user to comply with the laws and regulations applicable to this material.