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

1.1. Product identifier

Product name: Siren – The Muse – 3mg/ml Nicotine

CAS number: Not applicable. (Mixture)

EINECS number: Not applicable.

Product code: SITM1003

Synonyms: E-LIQUID, E-JUICE, SIREN, THE MUSE

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:	Grapefruit.
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

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 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. Aniline was chosen as positive control. Activated sludge was used as inoculum (concentration in the test 25.0 mg dry matter/L). The test was left running for 28 days. All validity criteria were met. Degradation of the positive control was 71% after seven days. The following data were determined for the test item nicotine: 10-day-window: day 3 – 13 degradation at the end of 10-day-window: 72% degradation at the end of the test: 71% pass level following guideline: 60% at the end of 10-day-window 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. 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). 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. 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). Conclusion 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. 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.