**CANDELA - GEMMA** 

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 1/14

Safety Data Sheet

According to Annex II to REACH - Regulation 2020/878 and to Annex II to UK REACH

# SECTION 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name **CANDELA - GEMMA** UFI 7H50-C078-J00R-0A65

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

**Identified Uses** Industrial Professional Consumer

Perfumed candle for environments.

**Uses Advised Against** 

Do not use as a perfume per person.

1.3. Details of the supplier of the safety data sheet

CULTI MILANO S.p.A. Name Full address Via dell'Aprica, 12 District and Country 20158 Milano (MI)

tel. +39 02/49784974 fax +39 02/49789135

e-mail address of the competent person

responsible for the Safety Data Sheet culti@culti.com

1.4. Emergency telephone number

For urgent inquiries refer to (AT): +43 14064343 - (BE): +32 070245245 - (BG): +359 29154233 - (CY): 1401

(DK): +45 82121212 - (ES): +34 915620420 - (HR): +385 12348342

(EE): +372 7943794, 16662 - (FI): +358 800 147111 - (FR): +33 (0) 145425959

(DE): 112 - (EL): +30 2107793777 - (IE): +353 (01) 8092166 - (IS): +354 5432222, 112

(LV): +371 67042473, 112 - (LT): +370 (85) 2362052 - (LU): +352 80025500 (MT): 2545 0000 - (NO): +47 22591300 - (NL): +31 (0) 887558000 - (PL): 112 (PT): +351 800250250 - (CZ): +420 224919293 - (RO): +40 212308000 (SK): +421 254774166 - (SI): 112 - (SE): 112 - (HU):+36 80201199

# **SECTION 2. Hazards identification**

#### 2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Skin sensitization, category 1B H317 May cause an allergic skin reaction.

Hazardous to the aquatic environment, chronic toxicity, Harmful to aquatic life with long lasting effects. H412

category 3

Dated 20/04/2023
First emission
Printed on 20/04/2023
Page n. 2/14

Revision n. 1

## **CANDELA - GEMMA**

#### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms:



Signal words: Warning

Hazard statements:

**H317** May cause an allergic skin reaction.

**H412** Harmful to aquatic life with long lasting effects.

Precautionary statements:

P280 Wear protective gloves. P102 Keep out of reach of children.

P261 Avoid breathing dust / fume / gas / mist / vapours / spray.
P333+P313 If skin irritation or rash occurs: Get medical advice / attention.
P362+P364 Take off contaminated clothing and wash it before reuse.

P101 If medical advice is needed, have product container or label at hand.

**P273** Avoid release to the environment.

Contains: 2-ACETOXY-2,3,8,8-TETRAMETHYLOCTAHYDRONAPHTHALENE

COUMARIN

ACETYL DIISOAMYLENE

LINALOOL

#### 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%. The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

# **SECTION 3. Composition/information on ingredients**

#### 3.2. Mixtures

Contains:

Identification x = Conc. % Classification (EC) 1272/2008 (CLP)

 ${\bf 2\text{-}ACETOXY\text{-}2,} {\bf 3,} {\bf 8,} {\bf 8\text{-}TETRAMETHYLOCTAHYDRONAPHTHALENE}$ 

INDEX -  $0.5 \le x < 2$  Skin Irrit. 2 H315, Skin Sens. 1B H317, Aquatic Chronic 2 H411

EC 915-730-3

CAS -

REACH Reg. 01-2119489989-04

LINALOOL

INDEX 603-235-00-2 0,25 ≤ x < 1 Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1B H317

EC 201-134-4

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 3/14

#### CANDELA - GEMMA

CAS 78-70-6

REACH Reg. 01-2119474016-42

**ACETYL DIISOAMYLENE** 

INDEX - 0,25 ≤ x < 0,5 Skin Sens. 1B H317, Aquatic Chronic 2 H411

EC 946-245-5

CAS -

REACH Reg. 01-2119980043-42

COUMARIN

INDEX - 0,1 ≤ x < 0,25 Acute Tox. 4 H302, Skin Sens. 1B H317

EC 202-086-7 LD50 Oral: 520 mg/kg

CAS 91-64-5

 $\alpha\text{-CEDRENE}$ 

INDEX - 0,025  $\leq$  x < 0,1 Asp. Tox. 1 H304, Skin Irrit. 2 H315, Aquatic Acute 1 H400 M=1, Aquatic

Chronic 1 H410 M=10

EC 207-418-4 CAS 469-61-4 **β-CEDRENE** 

INDEX - 0,025 ≤ x < 0,1 Asp. Tox. 1 H304, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=10

EC 208-898-8 CAS 546-28-1

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## **SECTION 4. First aid measures**

#### 4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

# **SECTION 5. Firefighting measures**

# 5.1. Extinguishing media

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

# **CANDELA - GEMMA**

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 4/14

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

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE Do not breathe combustion products.

## 5.3. Advice for firefighters

#### GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

#### **SECTION 6. Accidental release measures**

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

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

#### 6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

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

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

#### 6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

# **SECTION 7. Handling and storage**

#### 7.1. Precautions for safe handling

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

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

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

#### 7.3. Specific end use(s)

Information not available

# **CANDELA - GEMMA**

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 5/14

# **SECTION 8. Exposure controls/personal protection**

# 8.1. Control parameters

Predicted no-effect concentra	MOIT - FINEC							
Normal value in fresh water				0,2	mg	/I		
Normal value in marine water				0,02	mg	/I	·	
Normal value for fresh water	sediment			2,22	mg/kg/d			
Normal value for marine water	r sediment			0,222	mg/kg/d			
Normal value for marine water	r, intermittent release			2	mg/l			
Normal value of STP microor	ganisms			10	mg/l			
Normal value for the food cha	in (secondary poison	ng)		7,8	mg/kg			
Normal value for the terrestria	al compartment			0,327	mg/kg/d			
Health - Derived no-effe	ct level - DNEL / D Effects on consumers	MEL			Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic	Acute local	Acute	Chronic local	Chronic
Oral		<del>.</del>		systemic 2,49 mg/kg	<u>.</u>	systemic	<u>.</u>	systemic
Inhalation	<u> </u>	<del></del>		bw/d 4,33 mg/m3	-			24,58 mg/m3
Skin	1,5 mg/cm2		1,5 mg/cm2	1,25 mg/kg	3 mg/cm2	<del>.</del>	3 mg/cm2	3,5 mg/kg
Skill	1,5 mg/cm2		1,5 mg/cmz	bw/d	3 mg/cmz		3 mg/cmz	bw/d
COUMARIN								
Predicted no-effect concentra	tion - PNEC							
Normal value in fresh water				19	µg/l			
Normal value in marine water				1,9	μg/	<b>/</b> I	,	
Normal value for fresh water sediment				0,15	mg/kg/d			
Normal value for marine water sediment				0,015	mg	/kg/d		
Normal value for marine water, intermittent release				14,2	μg/	1		
Normal value of STP microorganisms				6,4	mg	/I	·	
Normal value for the food chain (secondary poisoning)				30,7	mg/kg			
Normal value for the terrestrial compartment				0,018	mg/kg/d			
Health - Derived no-effect level - DNEL / DMEL  Effects on  consumers					Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic	Acute local	Acute	Chronic local	Chronic
Oral	<del>.</del>	<del></del>		systemic 0,39 mg/kg		systemic	<del>.</del>	systemic
Inhalation				bw/d 1,69 mg/m3				6,78 mg/m3
Skin				0,39 mg/kg				0,79 mg/kg
				bw/d				bw/d
2-ACETOXY-2,3,8,8-TET Predicted no-effect concentra		HYDRONAPHTH	IALENE					
Normal value in fresh water				4,4	µg/	/1		
Normal value in marine water				0,44	μg/	/1		
Normal value for fresh water sediment				3,73	mg	/kg/d		
Normal value for marine water sediment			0,75		/kg/d	*		

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 6/14

## **CANDELA - GEMMA**

Normal value of STP microorganisms			10	mg	g/l			
Normal value for the food chain (secondary poisoning)				26,7	mg/kg			
Normal value for the terrestrial compartment				2,7	mg/kg/d			
Health - Derived no-effe	ct level - DNEL / [	OMEL						
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral	•		•	3 mg/kg bw/d	•		•	
Inhalation				9 mg/m3				30 mg/m3
Skin			380 μg/cm2	17,2 mg/kg bw/d			648 µg/cm2	28,7 mg/kg bw/d
ACETYL DIISOAMYLEN	E							
Predicted no-effect concentra	tion - PNEC							
Normal value in fresh water				9,6	μg	/I		
Normal value in marine water				0,96	μg	/I		
Normal value for fresh water	sediment			1,24	mç	g/kg/d		
Normal value for marine water sediment				0,124	mg/kg/d			
Normal value of STP microorganisms				22	mg/l			
Normal value for the terrestrial compartment			0,243	mg/kg/d				
Health - Derived no-effe	ct level - DNEL / D	OMEL						
	Effects on consumers				Effects on workers			
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral	-			1 mg/kg bw/d		,		
Inhalation				1,8 mg/m3				6 mg/m3
Skin			2100 µg/cm2	1 mg/kg bw/d			3600 μg/cm2	1,7 mg/kg bw/d

VND = hazard identified but no DNEL/PNEC available; NEA = no exposure expected; NPI = no hazard identified; LOW = low hazard; MED = medium hazard; HIGH = high hazard.

## 8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

## HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

## SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

# EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

## RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

# **CANDELA - GEMMA**

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 7/14

ENVIRONMENTAL EXPOSURE CONTROLS
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

# **SECTION 9. Physical and chemical properties**

# 9.1. Information on basic physical and chemical properties

Properties Appearance	<b>Value</b> wax	Information
Colour	white	
Odour	characteristic	
Melting point / freezing point	not available	Reason for missing data:not relevant for the characterization of the product
Initial boiling point	not available	Reason for missing data:not relevant for the characterization of the product
Flammability	not flammable	
Lower explosive limit Upper explosive limit Flash point Auto-ignition temperature Decomposition temperature pH Kinematic viscosity Solubility	not applicable not applicable not applicable not applicable not available not available not applicable insoluble in water	Reason for missing data:The substance/mixture is a solid Reason for missing data:not relevant for the characterization of the product Reason for missing data:substance/mixture is non-soluble (in water) Reason for missing data:The substance/mixture is a solid
Partition coefficient: n-octanol/water Vapour pressure	not applicable not available	Reason for missing data:substance/mixture is non-soluble (in water) Reason for missing data:not relevant for the characterization of the product
Density and/or relative density	not available	Reason for missing data:not relevant for the characterization of the product
Relative vapour density Particle characteristics	not applicable not available	Reason for missing data:The substance/mixture is a solid Reason for missing data:not relevant for the characterization of the product

### 9.2. Other information

9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Information not available

# **SECTION 10. Stability and reactivity**

## 10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 8/14

## **CANDELA - GEMMA**

#### 10.2. Chemical stability

The product is stable in normal conditions of use and storage.

#### 10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

#### 10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

#### 10.5. Incompatible materials

Information not available

#### 10.6. Hazardous decomposition products

Information not available

# **SECTION 11. Toxicological information**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

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

Metabolism, toxicokinetics, mechanism of action and other information Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

## ACUTE TOXICITY

ATE (Inhalation) of the mixture:

ATE (Oral) of the mixture:

Not classified (no significant component)

Not classified (no significant component)

Not classified (no significant component)

LINALOOL

LD50 (Dermal): 5610 mg/kg OECD 402 LD50 (Oral): 2790 mg/kg OECD 401

LC50 (Inhalation vapours): > 3.2 mg/l/1h

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 9/14

## **CANDELA - GEMMA**

COUMARIN

520 ma/ka OECD 401 LD50 (Oral):

2-ACETOXY-2,3,8,8-TETRAMETHYLOCTAHYDRONAPHTHALENE

> 5000 mg/kg OECD 402 LD50 (Dermal): > 5000 mg/kg OECD 401 LD50 (Oral):

ACETYL DIISOAMYLENE

> 5000 mg/kg OECD 402 LD50 (Dermal): 2350 mg/kg OECD 401 LD50 (Oral):

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY
Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

# **SECTION 12. Ecological information**

This product is dangerous for the environment and the aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

LINALOOL

LC50 - for Fish 27,8 mg/l/96h OECD 203

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 10/14

# **CANDELA - GEMMA**

EC50 - for Crustacea 59 mg/l/48h OECD 202

EC50 - for Algae / Aquatic Plants 156,7 mg/l/72h EC10 for Algae / Aquatic Plants 54,3 mg/l/4d

COUMARIN

 LC50 - for Fish
 37,62 mg/l/96h

 EC50 - for Crustacea
 82,39 mg/l/48h

 EC50 - for Algae / Aquatic Plants
 37,88 mg/l/72h

2-ACETOXY-2,3,8,8-TETRAMETHYLOCTAHYDRONAPHTHALENE

 LC50 - for Fish
 1,3 mg/l/96h OECD 203

 EC50 - for Crustacea
 1,38 mg/l/48h OECD 202

 EC50 - for Algae / Aquatic Plants
 2,6 mg/l/72h OECD 201

 EC10 for Crustacea
 0,044 mg/l/21d OECD 211

 EC10 for Algae / Aquatic Plants
 2,6 mg/l/72h OECD 201

 Chronic NOEC for Fish
 0,16 mg/l OECD 210

ACETYL DIISOAMYLENE

 LC50 - for Fish
 4,8 mg/l/96h OECD 203

 EC50 - for Crustacea
 6,1 mg/l/48h OECD 202

 EC50 - for Algae / Aquatic Plants
 21 mg/l/72h OECD 201

 EC10 for Algae / Aquatic Plants
 12 mg/l/72h OECD 201

## 12.2. Persistence and degradability

LINALOOL

Rapidly degradable 64% / 28d OECD 301

COUMARIN Rapidly degradable 90% / 28d OECD 301 F

2-ACETOXY-2,3,8,8-TETRAMETHYLOCTAHYDRONAPHTHALENE Rapidly degradable 96,3% / 28d OECD 301 F

ACETYL DIISOAMYLENE NOT rapidly degradable 0% / 28d, OECD 301D

### 12.3. Bioaccumulative potential

Information not available

## 12.4. Mobility in soil

Information not available

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 11/14

## **CANDELA - GEMMA**

#### 12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0.1%.

#### 12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

#### 12.7. Other adverse effects

Information not available

## **SECTION 13. Disposal considerations**

#### 13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

# **SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

#### 14.1. UN number or ID number

not applicable

# 14.2. UN proper shipping name

not applicable

### 14.3. Transport hazard class(es)

not applicable

# 14.4. Packing group

not applicable

## 14.5. Environmental hazards

not applicable

## 14.6. Special precautions for user

not applicable

Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 12/14

Revision n. 1

## **CANDELA - GEMMA**

#### 14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

## **SECTION 15. Regulatory information**

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

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006

<u>Product</u>

Point 40

Contained substance

Point 75

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

Substances subject to the Rotterdam Convention:

Substances subject to the Stockholm Convention:

None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

### 15.2. Chemical safety assessment

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

## **SECTION 16. Other information**

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Acute Tox. 4 Acute toxicity, category 4 Asp. Tox. 1 Aspiration hazard, category 1 Eye Irrit. 2 Eye irritation, category 2 Skin Irrit. 2 Skin irritation, category 2

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 13/14

## CANDELA - GEMMA

Skin Sens. 1B Skin sensitization, category 1B

**Aquatic Acute 1** Hazardous to the aquatic environment, acute toxicity, category 1 Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1 **Aquatic Chronic 2** Hazardous to the aquatic environment, chronic toxicity, category 2 **Aquatic Chronic 3** Hazardous to the aquatic environment, chronic toxicity, category 3

H302 Harmful if swallowed.

H304 May be fatal if swallowed and enters airways.

H319 Causes serious eye irritation.

H315 Causes skin irritation.

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects. H411 Toxic to aquatic life with long lasting effects. H412 Harmful to aquatic life with long lasting effects.

#### LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

#### GENERAL BIBLIOGRAPHY

- 1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
- 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
- 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
- 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
- 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament 7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
- 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
- 10. Regulation (EÚ) 2015/1221 (VII Atp. CLP) of the European Parliament
- 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

Revision n. 1 Dated 20/04/2023 First emission Printed on 20/04/2023 Page n. 14/14

## **CANDELA - GEMMA**

- 12. Regulation (EU) 2016/1179 (IX Atp. CLP)
- 13. Regulation (EU) 2017/776 (X Atp. CLP) 14. Regulation (EU) 2018/669 (XI Atp. CLP)
- 15. Regulation (EU) 2019/521 (XII Atp. CLP)
- 16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
- 17. Regulation (EU) 2019/1148
- 18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
- 19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
- 20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP) 21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
- 22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
- The Merck Index. 10th Edition
   Handling Chemical Safety
- INRS Fiche Toxicologique (toxicological sheet)
- Patty Industrial Hygiene and Toxicology
- N.I. Sax Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals Ministry of Health and ISS (Istituto Superiore di Sanità) Italy

#### Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.