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12037904 - INKU-ECO2-440-LM IJS



SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier: 12037904 - INKU-ECO2-440-LM

IJS

Other means of identification:

UFI: W128-S07V-E00U-2Y7J

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

Relevant uses (Industrial user): Printing ink

Uses advised against: All uses not specified in this section or in section 7.3

1.3 Details of the supplier of the safety data sheet:

ROLAND DG EMEA NV BELL-TELEPHONELAAN 2G B-2440 GEEL

BELGIUM

+32 14575911 deu-demand-planning@rolanddg.com

1.4 Emergency telephone number: +34 93 739 9445 (24h/7) Multi-lingual Europe +44 1235 239670 Multilingual

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:

CLP Regulation (EC) No 1272/2008:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319 Skin Irrit. 2: Skin irritation, Category 2, H315

2.2 Label elements:

CLP Regulation (EC) No 1272/2008:

Warning



Hazard statements:

H315 - Causes skin irritation.

H319 - Causes serious eye irritation.

Precautionary statements:

P264: Wash thoroughly after handling.

P280: Wear protective gloves/protective clothing/eye protection/protective footwear.

P302+P352: IF ON SKIN: Wash with plenty of water.

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.

UFI: W128-S07V-E00U-2Y7J

2.3 Other hazards:

Product does not meet PBT/vPvB criteria

Endocrine-disrupting properties: The product does not meet the criteria.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substance:

Not relevant

3.2 Mixture:

Chemical description: Mixture composed of additives, pigments and resins in solvents

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 1/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)

	Identification		Chemical name/Classification		
CAS:		Bis(2-ethoxyethyl) ether ⁽¹⁾ Self-classified		Self-classified	
EC: Index: REACH:	203-963-7 Not relevant 01-2119969946-13- XXXX	Regulation 1272/2008	Skin Irrit. 2: H315 - Warning	(1)	75 - <100 %
CAS:	108-32-7 203-572-1 607-194-00-1 : 01-2119537232-48- XXXX	propylene carbonate ⁽¹)	ATP CLP00	
Index: REACH:		Regulation 1272/2008	Eye Irrit. 2: H319 - Warning	(! >	10 - <25 %

⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

By skin contact:

Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact:

Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

4.2 Most important symptoms and effects, both acute and delayed:

Acute and delayed effects are indicated in sections 2 and 11.

4.3 Indication of any immediate medical attention and special treatment needed:

Not relevant

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Foam extinguisher (AB), Dry Chemical Powder (ABC) Fire Extinguisher, Carbon dioxide extinguisher (BC)

Unsuitable extinguishing media:

Water jet

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and Self Contained Breathing Apparatus. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...)

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 2/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 5: FIREFIGHTING MEASURES (continued)

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Prevent the entrance of product in drains, sewers or watercourses. Absorb the spill using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. Collect the product in appropriate containers and manage it according to current legislation.

Spillages in water or sea:

Small spillages:

Contain spillage using barriers or similar equipment. Use suitable absorbents for collection and treat the waste in accordance with current regulations.

Large spillages:

If possible, contain spillage in open water using barriers or similar equipment. If this is not possible, try to control its spread and collect the product with suitable mechanical means. Always consult experts before using dispersants and make sure you have the necessary approvals if they are to be used. Treat the waste according to current regulations.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights. Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Specific storage requirements

Minimum Temp.: 5 °C Maximum Temp.: 30 °C

B.- General conditions for storage

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 3/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM



SECTION 7: HANDLING AND STORAGE (continued)

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):

There are no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

		Short exposure		Long exposure	
Identification		Systemic	Local	Systemic	Local
Bis(2-ethoxyethyl) ether	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 112-36-7	Dermal	Not relevant	Not relevant	3,43 mg/kg	Not relevant
EC: 203-963-7	Inhalation	Not relevant	Not relevant	50,05 mg/m ³	Not relevant
propylene carbonate	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 108-32-7	Dermal	Not relevant	Not relevant	20 mg/kg	Not relevant
EC: 203-572-1	Inhalation	Not relevant	Not relevant	70,53 mg/m³	20 mg/m³

DNEL (General population):

		Short exposure		Long exposure	
Identification		Systemic	Local	Systemic	Local
(,,	Oral	Not relevant	Not relevant	1,71 mg/kg	Not relevant
	Dermal	Not relevant	Not relevant	1,71 mg/kg	Not relevant
EC: 203-963-7	Inhalation	Not relevant	Not relevant	5,96 mg/m ³	Not relevant
propylene carbonate	Oral	Not relevant	Not relevant	10 mg/kg	Not relevant
CAS: 108-32-7	Dermal	Not relevant	Not relevant	10 mg/kg	Not relevant
EC: 203-572-1	Inhalation	Not relevant	Not relevant	17,4 mg/m³	10 mg/m ³

PNEC:

Identification				
propylene carbonate	STP	7400 mg/L	Fresh water	0,9 mg/L
CAS: 108-32-7	Soil	0,81 mg/kg	Marine water	0,09 mg/L
EC: 203-572-1	Intermittent	9 mg/L	Sediment (Fresh water)	Not relevant
	Oral	Not relevant	Sediment (Marine water)	Not relevant

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

If the working conditions and/or safety measures adopted do not allow keeping the airborne concentration of the product below the exposure limits (if any) or at acceptable levels (if no exposure limits exist), suitable respiratory protection equipment chosen by a qualified professional should be used.

C.- Specific protection for the hands

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 4/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Pictogram	PPE	Labelling	CEN Standard	Remarks
Mandatory hand protection	Chemical protective gloves (Material: Butyl, Breakthrough time: > 480 min, Thickness: 0.7 mm)	CAT III	EN ISO 21420:2020	Replace the gloves at any sign of deterioration.

As the product is a mixture of several substances, the resistance of the glove material can not be calculated in advance with total reliability and has therefore to be checked prior to the application.

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks	l
Mandatory face protection	Panoramic glasses against splash/projections.	CATII	EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.	

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing	CATI		Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes	CATII	EN ISO 20347:2022	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2022 y EN 13832-1:2019

F.- Additional emergency measures

It is advised to implement additional emergency equipments in workplaces that are particularly exposed to the product or in situations where risk assessments highlight the necessity of such equipments.

Emergency measure	Standards	Emergency measure	Standards
^ +	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	**	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011
Emergency shower		Eyewash stations	

Environmental exposure controls:

To comply with environmental protection regulations, it is recommended to prevent any spillage of the product and its container. For more detailed information, please refer to subsection 7.1.D.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20 °C: Liquid

Appearance: Not relevant *

Colour: According to the markings on the package

Odour: Not relevant *
Odour threshold: Not relevant *

Volatility:

Boiling point at atmospheric pressure: 196 °C Vapour pressure at 20 °C: 40 Pa

*Not relevant due to the nature of the product, not providing information property of its hazards.

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 5/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Vapour pressure at 50 °C: 307,19 Pa (0,31 kPa)

Evaporation rate at 20 °C: Not relevant *

Product description:

Density at 20 °C: 956,5 kg/m³ Relative density at 20 °C: 0,956

Dynamic viscosity at 20 °C: Not relevant * Kinematic viscosity at 20 °C: Not relevant * Kinematic viscosity at 40 °C: Not relevant * Concentration: Not relevant * pH: Not relevant * Vapour density at 20 °C: Not relevant * Partition coefficient n-octanol/water 20 °C: Not relevant * Solubility in water at 20 °C: Not relevant * Solubility properties: Not relevant * Decomposition temperature: Not relevant * Melting point/freezing point: Not relevant *

Flammability:

Flash Point: 81 °C

Flammability (solid, gas):

Autoignition temperature:

Lower flammability limit:

Upper flammability limit:

Not relevant *

Not relevant *

Particle characteristics:

Median equivalent diameter: Not relevant *

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:

Oxidising properties:

Not relevant *

Corrosive to metals:

Heat of combustion:

Aerosols-total percentage (by mass) of flammable

Not relevant *

Not relevant *

components:

Other safety characteristics:

Surface tension at 20 °C:

Refraction index:

Not relevant *

Not relevant *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7 from Safety Data Sheet.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 6/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 10: STABILITY AND REACTIVITY (continued)

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Avoid direct impact	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds.

SECTION 11: TOXICOLOGICAL INFORMATION

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

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

- A- Ingestion (acute effect):
 - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for consumption. For more information see section 3
 - Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.
- B- Inhalation (acute effect):
 - Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
 - Corrosivity/Irritability: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- C- Contact with the skin and the eyes (acute effect):
 - Contact with the skin: Produces skin inflammation.
 - Contact with the eyes: Produces eye damage after contact.
- D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):
 - Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.
 - Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
 - Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- E- Sensitizing effects:
 - Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous with sensitising effects. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
- F- Specific target organ toxicity (STOT) single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- G- Specific target organ toxicity (STOT)-repeated exposure:
 - Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.
 - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- CONTINUED ON NEXT PAGE
Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 Page 7/11

(Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 11: TOXICOLOGICAL INFORMATION (continued)

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

Other information:

Not relevant

Specific toxicology information on the substances:

Ic	dentification	Acute toxic	ity	Genus
Bis(2-ethoxyethyl) ether		LD50 oral	4970 mg/kg	Rat
CAS: 112-36-7 EC: 203-963-7		LD50 dermal		
		LC50 inhalation		
propylene carbonate		LD50 oral	29000 mg/kg	Rat
CAS: 108-32-7 EC: 203-572-1		LD50 dermal		
		LC50 inhalation		

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product does not meet the criteria.

Other information

Not relevant

SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

12.1 Toxicity:

Acute toxicity:

Identification		Concentration	Species	Genus
propylene carbonate	LC50	5300 mg/L (96 h)	Leuciscus idus	Fish
CAS: 108-32-7	EC50	500 mg/L (48 h)	Daphnia magna	Crustacean
EC: 203-572-1		Not relevant		

12.2 Persistence and degradability:

Substance-specific information:

Identification	Degradability		Biodegradability	
propylene carbonate	BOD5	Not relevant	Concentration	100 mg/L
CAS: 108-32-7	COD	Not relevant	Period	28 days
EC: 203-572-1	BOD5/COD	Not relevant	% Biodegradable	80 %

12.3 Bioaccumulative potential:

Substance-specific information:

Identification		Bioaccumulation potential	
Bis(2-ethoxyethyl) ether CAS: 112-36-7		3	
		0.39	
EC: 203-963-7	Potential	Low	
propylene carbonate	BCF	3	
CAS: 108-32-7	Pow Log	-0.41	
EC: 203-572-1	Potential	Low	

12.4 Mobility in soil:

- CONTINUED ON NEXT PAGE
Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 Page 8/11

(Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 12: ECOLOGICAL INFORMATION (continued)

Identification	Absorption/desorption		Volatility	
Bis(2-ethoxyethyl) ether	Koc	39	Henry	1,013E-2 Pa·m³/mol
CAS: 112-36-7	Conclusion	Very High	Dry soil	Yes
EC: 203-963-7	Surface tension	2,678E-2 N/m (25 °C)	Moist soil	Not relevant

12.5 Results of PBT and vPvB assessment:

Product does not meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

Endocrine-disrupting properties: The product does not meet the criteria.

12.7 Other adverse effects:

Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
08 03 12*	waste ink containing hazardous substances	Hazardous

Type of waste (Regulation (EU) No 1357/2014):

HP4 Irritant — skin irritation and eye damage

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-hazardous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

This product is not regulated for transport (ADR/RID,IMDG,IATA)

SECTION 15: REGULATORY INFORMATION

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

- Article 95, REGULATION (EU) No 528/2012: Not relevant
- Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Not relevant
- Regulation (EU) 2019/1021 on persistent organic pollutants: Not relevant
- Regulation (EU) No 2024/590, about substances that deplete the ozone layer: Not relevant
- REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Not relevant

Seveso III:

Not relevant

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Shall not be used in:

- —ornamental articles intended to produce light or colour effects by means of different phases, for example in ornamental lamps and ashtrays,
- -tricks and jokes,
- —games for one or more participants, or any article intended to be used as such, even with ornamental aspects.

Contains Octamethylcyclotetrasiloxane, Decamethylcyclopentasiloxane, Dodecamethylcyclohexasiloxane. 1. Shall not be placed

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 9/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

12037904 - INKU-ECO2-440-LM IJS



SECTION 15: REGULATORY INFORMATION (continued)

on the market (a) as a substance on its own; (b) as a constituent of other substances; or (c) in mixtures; in a concentration equal to or greater than 0,1 % by weight of the respective substance after 6 June 2026. 2. Shall not be used as a solvent for the dry cleaning of textiles, leather and fur after 6 June 2026. 3. By way of derogation: (a) for D4 and D5 in wash-off cosmetic products, paragraph 1, point (c), shall apply after 31 January 2020. For the purposes of this point, "wash-off cosmetic products" means cosmetic products as defined in Article 2(1), point (a), of Regulation (EC) No 1223/2009 of the European Parliament and of the Council (*) that, under normal conditions of use, are washed off with water after application; (b) for all cosmetic products other than the ones mentioned in paragraph 3(a), paragraph 1 shall apply after 6 June 2027; (c) for devices as defined in Article 1(4) of Regulation (EU) 2017/745 of the European Parliament and of the Council (**) and in Article 1(2) of Regulation (EU) 2017/746 of the European Parliament and the Council (***), paragraph 1 shall apply after 6 June 2031; (d) for medicinal products, as defined in Article 1, point 2, of Directive 2001/83/EC, and for veterinary medicinal products, as defined in Article 4(1) of Regulation (EU) 2019/6 (****), paragraph 1 shall apply after 6 June 2031; (e) for D5 as a solvent in the dry cleaning of textiles, leather and fur, paragraphs 1 and 2 shall apply after 6 June 2034. 4. By way of derogation, paragraph 1 shall not apply to the: (a) placing on the market of D4, D5 and D6 for the following industrial uses: — as a monomer in the production of silicone polymer, — as an intermediate in the production of other silicon substances, — as a monomer in polymerisation, — in the formulation or (re)packing of mixtures, — in the production of articles, — in non-metal surface treatment; (b) placing on the market of D5 and D6 for use as devices, as defined in Article 1(4) of Regulation (EU) 2017/745, for the treatment and care of scars and wounds, the prevention of wounds and the care of stoma; (c) placing on the market of D5 for professional use in the cleaning or restoration of art and antiques; (d) placing on the market of D4, D5 and D6 for use as laboratory reagent in research and development activities carried out under controlled conditions. 5. By way of derogation, paragraph 1, point (b), shall not apply to the placing on the market of D4, D5 and D6: — as a constituent of a silicone polymer on its own, — as a constituent of a silicone polymer in a mixture derogated under paragraph 6. 6. By way of derogation, paragraph 1, point (c), shall not apply to the placing on the market of mixtures that contain D4, D5 or D6 as residues from silicone polymers, under the following conditions: (a) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in adhesion, sealing, gluing and casting; (b) D4 in a concentration equal to or less than 0,5 % by weight, or D5 or D6 in a concentration equal to or less than 0,3 % by weight of either substance in the mixture for use as protective coatings (including marine coatings); (c) D4, D5 or D6 in a concentration equal to or less than 0,2 % by weight of the respective substance in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745 and in Article 1(2) of Regulation (EU) 2017/746, other than the devices referred to in paragraph 6(d); (d) D5 in a concentration equal to or less than 0,3 % by weight in the mixture or D6 in a concentration equal to or less than 1 % by weight in the mixture, for use as devices as defined in Article 1(4) of Regulation (EU) 2017/745, for dental impression; (e) D4 in a concentration equal to or less than 0,2 % by weight in the mixture, or D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture for use as silicone insoles for horses, or as horseshoes; (f) D4, D5 or D6 in a concentration equal to or less than 0,5 % by weight of the respective substance in the mixture, for use as adhesion promoters; (g) D4, D5 or D6 in a concentration equal to or less than 1 % by weight of the respective substance in the mixture, for use in 3D-printing; (h) D5 in a concentration equal to or less than 1 % by weight in the mixture or D6 in a concentration equal to or less than 3 % by weight in the mixture, for rapid prototyping and mould making, or high performance uses stabilised by quartz filler; (i) D5 or D6 in a concentration equal to or less than 1 % by weight of either substance in the mixture, for use in pad printing, or manufacturing of printing pads; (j) D6 in a concentration equal to or less than 1 % by weight of the mixture, for professional use in the cleaning or restoration of art and antiques. 7. By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for use, or to the use, of D5 as a solvent in strictly controlled closed dry cleaning systems for textile, leather and fur, where the cleaning solvent is recycled or incinerated.

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Modifications related to the previous Safety Data Sheet which concerns the ways of managing risks.: COMMISSION REGULATION (EU) 2020/878

Texts of the legislative phrases mentioned in section 2:

H315: Causes skin irritation.

H319: Causes serious eye irritation.

- CONTINUED ON NEXT PAGE -

Printing: 10/12/2024 Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 10/11** (Replaced 5)

This SDS is an English translation of COMMISSION REGULATION (EU) 2020/878, without any country-specific legislation

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SECTION 16: OTHER INFORMATION (continued)

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Skin Irrit. 2: H315 - Causes skin irritation.

Classification procedure:

Skin Irrit. 2: Calculation method Eye Irrit. 2: Calculation method **Advice related to training:**

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

http://echa.europa.eu http://eur-lex.europa.eu

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand

BCF: Bioconcentration factor LD50: Lethal Dose 50 LC50: Lethal Concentration 50 EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product, it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.

- END OF SAFETY DATA SHEET -

Date of compilation: 28/06/2013 Revised: 03/12/2024 Version: 6 **Page 11/11**

Printing: 10/12/2024 (Replaced 5)