

PHARMA GRADE REFINED GLYCERIN-TSE EN 829

Printing: 05/06/2024 Date of compilation: 05/06/2024 Revised: 05/06/2024 Version: 2 (Replaced 1)

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

1.1 Product identifier:	PHARMA GRADE REFINED GLYCERIN-TSE EN 829
Other means of identification:	Not relevant
1.2 Relevant identified uses of the substance or mixture and uses advised against:	Relevant uses: Food industry (as a sweetener, solvent and preservative), pharmaceutical industry, personal care products (as a lubricant, smoothness enhancer and moisture retainer), industrial use, scientific research and development, paint raw materials, antifreeze liquids and softeners.
1.3 Details of the supplier of the safety data sheet:	<p>LEGEND KİMYA SAN. VE TİC. A.Ş. Soğuksu Mah. 308. Sk. Adabel Sit. No:42/61 MURATPAŞA Kırklareli OSB Mh. 15. Sk. N T + 90 288 263 40 07 info@legendkimya.com - www.legendkimya.com</p>
1.4 Emergency telephone number:	114

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture:	<p>CLP Regulation (EC) No 1272/2008: The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.</p>
2.2 Label elements:	<p>CLP Regulation (EC) No 1272/2008: None</p>
2.3 Other hazards:	<p>Product does not meet PBT/vPvB criteria Endocrine-disrupting properties: The product does not meet the criteria.</p>

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS **

3.1 Substance:	Non-applicable								
3.2 Mixture:	<p>Chemical description: Chemical substance</p> <p>Components: In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:</p> <table border="1"> <thead> <tr> <th>Identification</th> <th>Chemical name/Classification</th> <th>Concentration</th> </tr> </thead> <tbody> <tr> <td rowspan="2">CAS: 56-81-5 EC: 200-289-5 Index: Non-applicable REACH:01-2119471987-18-XXXX</td> <td>Glycerol⁽¹⁾</td> <td rowspan="2">99,7 % (GMO Free)</td> </tr> <tr> <td>Regulation 1272/2008</td> <td>Not classified</td> </tr> </tbody> </table>	Identification	Chemical name/Classification	Concentration	CAS: 56-81-5 EC: 200-289-5 Index: Non-applicable REACH:01-2119471987-18-XXXX	Glycerol ⁽¹⁾	99,7 % (GMO Free)	Regulation 1272/2008	Not classified
Identification	Chemical name/Classification	Concentration							
CAS: 56-81-5 EC: 200-289-5 Index: Non-applicable REACH:01-2119471987-18-XXXX	Glycerol ⁽¹⁾	99,7 % (GMO Free)							
	Regulation 1272/2008		Not classified						
<p>⁽¹⁾ Voluntarily-listed substance failing to meet any of the criteria set out in Regulation (EU) No. 2020/878</p> <p>To obtain more information on the hazards of the substances consult sections 11, 12 and 16.</p>									

** Changes with regards to the previous version

SECTION 4: FIRST AID MEASURES

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SECTION 4: FIRST AID MEASURES (continued)**4.1 Description of first aid measures:****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:

In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters,...), seek medical advice with this Safety Data Sheet

By eye contact:

This product does not contain substances classified as hazardous for eye contact. Rinse eyes thoroughly for at least 15 minutes with lukewarm water, ensuring that the person affected does not rub or close their eyes.

By ingestion/aspiration:

In case of consumption, seek immediate medical assistance showing the SDS for the product.

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:**

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems.

Unsuitable extinguishing media:

Non-applicable

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 (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

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 spilled 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.

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SECTION 6: ACCIDENTAL RELEASE MEASURES (continued)

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:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

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.- Technical measures for storage

Minimum Temp.: 5 °C

Maximum Temp.: 25 °C

B.- General conditions for storage

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):

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Glycerol	Oral	Not relevant	Not relevant	Not relevant	Not relevant
CAS: 56-81-5	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
EC: 200-289-5	Inhalation	Not relevant	Not relevant	Not relevant	56 mg/m ³

DNEL (General population):

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SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Glycerol	Oral	Not relevant	Not relevant	229 mg/kg	Not relevant
CAS: 56-81-5	Dermal	Not relevant	Not relevant	Not relevant	Not relevant
EC: 200-289-5	Inhalation	Not relevant	Not relevant	Not relevant	33 mg/m ³

PNEC:

Identification					
Glycerol	STP	1000 mg/L	Fresh water	0,885 mg/L	
CAS: 56-81-5	Soil	0,141 mg/kg	Marine water	0,088 mg/L	
EC: 200-289-5	Intermittent	8,85 mg/L	Sediment (Fresh water)	3,3 mg/kg	
	Oral	Not relevant	Sediment (Marine water)	0,33 mg/kg	

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

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Not relevant

D.- Eye and face protection

Not relevant

E.- Body protection

Not relevant

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Not relevant
Average molecular weight:	Not relevant

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:	Colorless
Colour:	Colorless

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

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES (continued)

Odour: Odourless
Odour threshold: Not relevant *

Volatility:

Boiling point at atmospheric pressure: 290 °C
Vapour pressure at 20 °C: <0.01 hPa
Vapour pressure at 50 °C: Not relevant *
Evaporation rate at 20 °C: Not relevant *

Product description:

Density at 20 °C: 1,26 g/cm³
Relative density at 20 °C: 1,261
Dynamic viscosity at 20 °C: 1,412 mPa.s
Kinematic viscosity at 20 °C: Not relevant *
Kinematic viscosity at 40 °C: Not relevant *
Concentration: Not relevant *
pH: Neutral
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: Water-soluble
Decomposition temperature: Not relevant *
Melting point/freezing point: 18 °C

Flammability:

Flash Point: 199 °C
Flammability (solid, gas): Not relevant *
Autoignition temperature: Not relevant *
Lower flammability limit: 2,6 % Volume
Upper flammability limit: 11,3 % Volume

Particle characteristics:

Median equivalent diameter: Non-applicable

9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties: Not relevant *
Oxidising properties: Not relevant *
Corrosive to metals: Not relevant *
Heat of combustion: 15,41 kJ/g
Aerosols-total percentage (by mass) of flammable components: Not relevant *

Other safety characteristics:

Surface tension at 20 °C: Not relevant *
Refraction index: Not relevant *

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

SECTION 10: STABILITY AND REACTIVITY

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SECTION 10: STABILITY AND REACTIVITY (continued)

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.

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	Not applicable	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: 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.

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: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for skin contact. For more information see section 3.
- Contact with the eyes: 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.

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.
IARC: Not relevant
- 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:

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SECTION 11: TOXICOLOGICAL INFORMATION ** (continued)

- 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.

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:

Identification	Acute toxicity		Genus
	Glycerol	LD50 oral	
CAS: 56-81-5	LD50 dermal	>2000 mg/kg	Guinean pig
EC: 200-289-5	LC50 inhalation	>5,85 mg/L (6 h)	Rat

Acute Toxicity Estimate (ATE mix):

ATE mix		Ingredient(s) of unknown toxicity
Oral	>2000 mg/kg (Calculation method)	Non-applicable
Dermal	>2000 mg/kg (Calculation method)	Non-applicable
Inhalation	>20 mg/L (4 h) (Calculation method)	Non-applicable

11.2 Information on other hazards:**Endocrine disrupting properties**

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

Other information

Not relevant

** Changes with regards to the previous version

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:

Not available

12.2 Persistence and degradability:**Substance-specific information:**

Identification	Degradability		Biodegradability	
	Glycerol	BOD5	Not relevant	Concentration
CAS: 56-81-5	COD	Not relevant	14 days	cellPeriodoTesteoContenido
EC: 200-289-5	BOD5/COD	Not relevant	% Biodegradable	63 %

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SECTION 12: ECOLOGICAL INFORMATION ** (continued)

12.3 Bioaccumulative potential:

Substance-specific information:

Identification	Bioaccumulation potential	
Glycerol	BCF	3
CAS: 56-81-5	Pow Log	-1.76
EC: 200-289-5	Potential	Low

12.4 Mobility in soil:

Identification	Absorption/desorption		Volatility	
Glycerol	Koc	Not relevant	Henry	Not relevant
CAS: 56-81-5	Conclusion	Not relevant	Dry soil	Not relevant
EC: 200-289-5	Surface tension	6,516E-2 N/m (25 °C)	Moist soil	Not relevant

Water-soluble

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

** Changes with regards to the previous version

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Non-hazardous

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

Not relevant

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

Transport of dangerous goods by land:

With regard to ADR 2023 and RID 2023:

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SECTION 14: TRANSPORT INFORMATION (continued)

- 14.1 **UN number or ID number:** Not relevant
- 14.2 **UN proper shipping name:** Not relevant
- 14.3 **Transport hazard class(es):** Not relevant
- Labels: Not relevant
- 14.4 **Packing group:** Not relevant
- 14.5 **Environmental hazards:** No
- 14.6 **Special precautions for user**
- Special regulations: Not relevant
- Tunnel restriction code: Not relevant
- Physico-Chemical properties: see section 9
- Limited quantities: Not relevant
- 14.7 **Maritime transport in bulk according to IMO instruments:** Not relevant

Transport of dangerous goods by sea:

With regard to IMDG 41-22:

- 14.1 **UN number or ID number:** Not relevant
- 14.2 **UN proper shipping name:** Not relevant
- 14.3 **Transport hazard class(es):** Not relevant
- Labels: Not relevant
- 14.4 **Packing group:** Not relevant
- 14.5 **Marine pollutant:** No
- 14.6 **Special precautions for user**
- Special regulations: Not relevant
- EmS Codes:
- Physico-Chemical properties: see section 9
- Limited quantities: Not relevant
- Segregation group: Not relevant
- 14.7 **Maritime transport in bulk according to IMO instruments:** Not relevant

Transport of dangerous goods by air:

With regard to IATA/ICAO 2024:

- 14.1 **UN number or ID number:** Not relevant
- 14.2 **UN proper shipping name:** Not relevant
- 14.3 **Transport hazard class(es):** Not relevant
- Labels: Not relevant
- 14.4 **Packing group:** Not relevant
- 14.5 **Environmental hazards:** No
- 14.6 **Special precautions for user**
- Physico-Chemical properties: see section 9
- 14.7 **Maritime transport in bulk according to IMO instruments:** Not relevant

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) No 649/2012, in relation to the import and export of hazardous chemical products: Not relevant
- Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: 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):

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SECTION 15: REGULATORY INFORMATION (continued)

Not relevant

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.:

COMPOSITION/INFORMATION ON INGREDIENTS (SECTION 3, SECTION 11, SECTION 12):

- New declared substances
Glycerol (56-81-5)

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:

Not relevant

Classification procedure:

Not relevant

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

Other information:

Safety Data Sheet author's:

Name İrem BEKTAŞ KART

Certificate number KDU-A-0-0295

Certificate valid until 07/05/2029

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