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Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

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

1.1. Product identifier

Product name	DURA EP INJECTION SUMMER A
UFI :	H7K0-J0NM-200C-27H3

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

Intended use	not available
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1.3. Details of the supplier of the safety data sheet

Name	NORDIA SA
Full address	364 Kifisias Av.
District and Country	15233 Chalandri Greece
	Tel. +30 22950 22225
	Fax +30 22950 22120
e-mail address of the competent person responsible for the Safety Data Sheet	info@marmoline.gr

1.4. Emergency telephone number

For urgent inquiries refer to	+30 210 77 93777
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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:

Reproductive toxicity, category 1B	H360F	May damage fertility.
Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.
Skin sensitization, category 1	H317	May cause an allergic skin reaction.
Hazardous to the aquatic environment, chronic toxicity, category 2	H411	Toxic to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms:



Signal words:

Danger

Hazard statements:

- H360F** May damage fertility.
- H319** Causes serious eye irritation.
- H315** Causes skin irritation.
- H317** May cause an allergic skin reaction.
- H411** Toxic to aquatic life with long lasting effects.
Restricted to professional users.

Precautionary statements:

- P201** Obtain special instructions before use.
- P280** Wear protective gloves/ protective clothing / eye protection / face protection.
- P308+P313** IF exposed or concerned: Get medical advice / attention.
- P273** Avoid release to the environment.
- P391** Collect spillage.
- P261** Avoid breathing dust / fume / gas / mist / vapours / spray.

Contains:


Glycidyl ether C12-C14 alcohols
bis-[4-(2,3-epoxipropoxy)phenyl]propane

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

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3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
bis-[4-(2,3-epoxipropoxy)phenyl]propane		
INDEX 603-073-00-2	75	Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Chronic 2 H411
EC 216-823-5	x < 100	
CAS 1675-54-3		
Glycidyl ether C12-C14 alcohols		
INDEX 603-103-00-4	19,5	Repr. 1B H360F, Skin Irrit. 2 H315, Skin Sens. 1 H317
EC 271-846-8	x < 21	
CAS 68609-97-2		

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

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Take off immediately all contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice/attention. Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.

INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.


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

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

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

IF exposed or concerned: Get medical advice / attention.

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Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

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.

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

Block the leakage if there is no hazard.

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 into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. 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

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Glycidyl ether C12-C14 alcohols								
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,0072	mg/l			
Normal value in marine water				0,00072	mg/l			
Normal value for fresh water sediment				307,16	mg/kg/d			
Normal value for marine water sediment				30,716	mg/kg/d			
Normal value for the terrestrial compartment				61,42	mg/kg/d			
Health - Derived no-effect level - DNEL / DMEL								
Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral			0,05 mg/kg bw/d					
Inhalation			0,087 mg/m3				0,49 mg/m3	
Skin			0,089 mg/kg bw/d				0,75 mg/kg bw/d	
bis-[4-(2,3-epoxipropoxi)phenyl]propane								
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,006	mg/l			
Normal value in marine water				0,001	mg/l			
Normal value for fresh water sediment				0,341	mg/kg/d			
Normal value for marine water sediment				0,034	mg/kg/d			
Normal value for the terrestrial compartment				0,065	mg/kg/d			
Health - Derived no-effect level - DNEL / DMEL								
Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral	0,75 mg/kg bw/d		0,75 mg/kg bw/d					

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Inhalation	0,75 mg/m3	0,75 mg/m3	12,3 mg/m3	12,3 mg/m3
Skin	3,6 mg/kg bw/d	3,6 mg/kg bw/d	8,3 mg/kg bw/d	8,3 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

Protect hands with category III work gloves.

The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability time.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

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 ISO 16321).

RESPIRATORY PROTECTION

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. Use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

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	Value	Information
Appearance	not available	
Colour	not available	

Odour	not available
Melting point / freezing point	not available
Initial boiling point	not available
Flammability	not available
Lower explosive limit	not available
Upper explosive limit	not available
Flash point	> 93 °C
Auto-ignition temperature	not available
Decomposition temperature	not available
pH	not available
Kinematic viscosity	not available
Solubility	not available
Partition coefficient: n-octanol/water	not available
Vapour pressure	not available
Density and/or relative density	1,20
Relative vapour density	not available
Particle characteristics	not applicable

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.

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:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

Glycidyl ether C12-C14 alcohols	
LD50 (Dermal):	> 4 mg/kg Rabbit
LD50 (Oral):	26800 mg/kg Rat

bis-[4-(2,3-epoxipropoxi)phenyl]propane	
LD50 (Dermal):	23000 mg/kg Rabbit
LD50 (Oral):	15000 mg/kg Rat

SKIN CORROSION / IRRITATION

Causes skin irritation

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SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

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

May damage fertility

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 is toxic for aquatic organisms. In the long term, it has negative effects on the aquatic environment.

12.1. Toxicity

Glycidyl ether C12-C14 alcohols

LC50 - for Fish

> 0,0018 mg/l/96h Rainbow trout, donaldson

EC50 - for Crustacea

7,2 mg/l/48h Water flea


EC50 - for Algae / Aquatic Plants

844 mg/l/72h

bis-[4-(2,3-epoxipropoxy)phenyl]propane

LC50 - for Fish

1,3 mg/l/96h

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EC50 - for Crustacea
Chronic NOEC for Crustacea

2,1 mg/l/48h Water flea
0,3 mg/l Water flea, 21 days

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

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.
Waste transportation may be subject to ADR restrictions.
The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA:

UN 3082


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ADR / RID:	In accordance with Special Provision 375, this product, when is packed in receptacles of a capacity 5Kg or 5L, is not submitted to ADR provisions.		
IMDG:	In accordance with Section 2.10.2.7 of IMDG Code, this product, when is packed in receptacles of a capacity 5Kg or 5L, is not submitted to IMDG Code provisions.		
IATA:	In accordance with SP A197, this product, when is packed in receptacles of a capacity 5Kg or 5L, is not submitted to IATA dangerous goods regulations.		

14.2. UN proper shipping name

ADR / RID:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)		
IMDG:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)		
IATA:	ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (bis-[4-(2,3-epoxipropoxi)phenyl]propane)		


14.3. Transport hazard class(es)

ADR / RID:	Class: 9	Label: 9	
IMDG:	Class: 9	Label: 9	
IATA:	Class: 9	Label: 9	

14.4. Packing group

ADR / RID, IMDG, IATA:	III
------------------------	-----

14.5. Environmental hazards

ADR / RID:	Environmentally Hazardous	
IMDG:	Marine Pollutant	
IATA:	Environmentally Hazardous	

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 90	Limited Quantities: 5 lt	Tunnel restriction code: (-)
	Special provision: 274, 335, 375, 601		
IMDG:	EMS: F-A, S-F	Limited Quantities: 5 lt	
IATA:	Cargo:	Maximum quantity: 450 L	Packaging instructions: 964
	Passengers:	Maximum quantity: 450	Packaging instructions:

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Special provision:

L
A97, A158,
A197, A215

964

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: E2

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

Product

Point3

Contained substance

Point75

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)

None

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

None


Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

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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:

Repr. 1B	Reproductive toxicity, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
Skin Sens. 1	Skin sensitization, category 1
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H360F	May damage fertility.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H411	Toxic 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
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- 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

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- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- 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 (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 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)
 23. Delegated Regulation (UE) 2023/707
 24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
 25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
 26. Delegated Regulation (UE) 2024/197 (XXI 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.

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Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

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

1.1. Product identifier

Product name	DURA EP INJECTION SUMMER - B
UFI :	T9K0-20C0-C00U-RK35

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

Intended use	not available
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1.3. Details of the supplier of the safety data sheet

Name	NORDIA SA
Full address	364 Kifisias Av.
District and Country	15233 Chalandri Greece
	Tel. +30 22950 22225
	Fax +30 22950 22120
e-mail address of the competent person responsible for the Safety Data Sheet	info@marmoline.gr

1.4. Emergency telephone number

For urgent inquiries refer to	+30 210 77 93777
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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:

Reproductive toxicity, category 2	H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
Acute toxicity, category 4	H302	Harmful if swallowed.
Specific target organ toxicity - repeated exposure, category 1	H372	Causes damage to organs through prolonged or repeated exposure.
Skin corrosion, category 1B	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.
Skin sensitization, category 1A	H317	May cause an allergic skin reaction.
Hazardous to the aquatic environment, chronic toxicity, category 3	H412	Harmful to aquatic life with long lasting effects.

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2.2. Label elements

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

Hazard pictograms:



Signal words: Danger

Hazard statements:


H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H302	Harmful if swallowed.
H372	Causes damage to organs through prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.

Precautionary statements:

P260	Do not breathe dust / fume / gas / mist / vapours / spray.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P310	Immediately call a POISON CENTER / doctor / . . .
P264	Wash . . . thoroughly after handling.

Contains: 2-piperazin-1-ylethylamine
3,6-diazaoctanethylenediamin, triethylenetetramine
3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE
BENZYL ALCOHOL

2.3. Other hazards

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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)
3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE		
INDEX 612-067-00-9	26,5	Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1A H317
EC 220-666-8	x < 51,5	Skin Sens. 1A H317: 0,001%
CAS 2855-13-2		LD50 Oral: 1030 mg/kg
2-piperazin-1-ylethylamine		
INDEX 612-105-00-4	20	Repr. 2 H361fd, Acute Tox. 3 H311, Acute Tox. 4 H302, STOT RE 1 H372,
EC 205-411-0	x < 30	Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1 H317, Aquatic Chronic 3 H412
CAS 140-31-8		ATE Oral: 500 mg/kg, LD50 Dermal: 866 mg/kg
REACH Reg. 01-2119471486-30		
BENZYL ALCOHOL		
INDEX 603-057-00-5	10	Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Sens. 1B H317
EC 202-859-9	x < 20	LD50 Oral: 1200 mg/kg
CAS 100-51-6		
3,6-diazaoctanethylenediamin, triethylenetetramine		
INDEX 612-059-00-5	5	Acute Tox. 4 H302, Acute Tox. 4 H312, Skin Corr. 1B H314, Eye Dam. 1
EC 292-588-2	x < 12	H318, Skin Sens. 1 H317, Aquatic Chronic 3 H412
CAS 90640-67-8		LD50 Oral: 1716 mg/kg, LD50 Dermal: 1465 mg/kg
REACH Reg. 01-2119487919-13		

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

In case of doubt or in the presence of symptoms contact a doctor and show him this document.
 In case of more severe symptoms, ask for immediate medical aid.
 EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.
 SKIN: Take off immediately all contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical

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advice/attention. Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Rinse your mouth with running water. Do not give anything by mouth to an unconscious person. Get medical advice/attention.

INHALATION: Remove victim to fresh air, away from the accident scene. In the event of respiratory symptoms (coughing, wheezing, breathing difficulty, asthma) keep the victim in a comfortable position for breathing. If necessary administer oxygen. If the subject stops breathing, administer artificial respiration. Get medical advice/attention.

Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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

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

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

Immediately call a POISON CENTER / doctor / . . .

Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

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.

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).

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SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Block the leakage if there is no hazard.

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 into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. 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

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

2-piperazin-1-ylethylamine

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,058	mg/l
Normal value in marine water	0,0058	mg/l
Normal value for fresh water sediment	215	mg/kg
Normal value for marine water sediment	21,5	mg/kg/d
Normal value of STP microorganisms	250	mg/l

Health - Derived no-effect level - DNEL / DMEL								
Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Inhalation					10,6 mg/m3		10,6 mg/m3	

3,6-diazaoctanethylenediamin, triethylenetetramine								
Predicted no-effect concentration - PNEC								
Normal value in fresh water				0,19	mg/l			
Normal value in marine water				0,038	mg/l			
Normal value for fresh water sediment				95,5	mg/kg			
Normal value for marine water sediment				19,2	mg/kg			
Normal value for the terrestrial compartment				19,1	mg/kg			

Health - Derived no-effect level - DNEL / DMEL								
	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	20 mg/kg bw/d		0,41 mg/kg/d					
Inhalation	1600 mg/m3				5380 mg/m3			
Skin	0,43 mg/cm2		0,25 mg/kg bw/d		0,028 mg/cm2		0,57 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.

Exposure levels must be kept as low as possible to avoid significant build-up in the organism. Manage personal protective equipment so as to guarantee maximum protection (e.g. reduction in replacement times).

HAND PROTECTION


Protect hands with category III work gloves.
The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, permeability time.
The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category III 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 ISO 16321).

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In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

RESPIRATORY PROTECTION

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. Use a mask with a type A filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387).

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

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	Value	Information
Appearance	not available	
Colour	not available	
Odour	not available	
Melting point / freezing point	not available	
Initial boiling point	not available	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	> 93 °C	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	not available	
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information

9.2.1. Information with regard to physical hazard classes

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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.

BENZYL ALCOHOL

Decomposes at temperatures above 870°C/1598°F. Possibility of explosion.

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.

BENZYL ALCOHOL

May react dangerously with: hydrobromic acid, iron, oxidising agents, sulphuric acid. Risk of explosion on contact with: phosphorus trichloride.

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

May react dangerously with: strong oxidising agents, concentrated inorganic acids.

10.4. Conditions to avoid

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

BENZYL ALCOHOL


Avoid exposure to: air, sources of heat, naked flames.

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

Avoid contact with: strong acids, strong oxidants.

10.5. Incompatible materials

BENZYL ALCOHOL

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Incompatible with: sulphuric acid, oxidising substances, aluminium.

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:	Not classified (no significant component)
ATE (Oral) of the mixture:	813,88 mg/kg
ATE (Dermal) of the mixture:	>2000 mg/kg
BENZYL ALCOHOL	
LD50 (Dermal):	2000 mg/kg Rabbit
LD50 (Oral):	1200 mg/kg
LC50 (Inhalation vapours):	> 4,1 mg/l/4h Rat
3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE	
LD50 (Oral):	1030 mg/kg
2-piperazin-1-ylethylamine	
LD50 (Dermal):	866 mg/kg Rabbit
LD50 (Oral):	2140 mg/kg Rat
ATE (Oral):	500 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)
3,6-diazaoctanethylenediamin, triethylenetetramine	
LD50 (Dermal):	1465 mg/kg Rabbit

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LD50 (Oral): 1716 mg/kg Rat

SKIN CORROSION / IRRITATION

Corrosive for the skin

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

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

Suspected of damaging fertility - Suspected of damaging the unborn child

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Causes damage to organs

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 has negative effects on the aquatic environment.

12.1. Toxicity

2-piperazin-1-ylethylamine

LC50 - for Fish 2190 mg/l/96h

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EC50 - for Crustacea	58 mg/l/48h Daphnia
EC50 - for Algae / Aquatic Plants	1000 mg/l/72h
3,6-diazaoctanethylenediamin, triethylenetetramine	
LC50 - for Fish	330 mg/l/96h
EC50 - for Crustacea	31,1 mg/l/48h Daphnia
EC50 - for Algae / Aquatic Plants	20 mg/l/72h

12.2. Persistence and degradability

BENZYL ALCOHOL	
Rapidly degradable	
3-AMINOMETHYL-3,5,5- TRIMETHYLCYCLOHEXYLAMINE	
Solubility in water	1000 - 10000 mg/l
NOT rapidly degradable	

12.3. Bioaccumulative potential

BENZYL ALCOHOL	
Partition coefficient: n-octanol/water	1,1

12.4. Mobility in soil

Information not available

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.

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Waste transportation may be subject to ADR restrictions.
The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA:UN 2289

14.2. UN proper shipping name

ADR / RID:

ISOPHORONEDIAMINE SOLUTION

IMDG:

ISOPHORONEDIAMINE SOLUTION

IATA:

ISOPHORONEDIAMINE SOLUTION

14.3. Transport hazard class(es)

ADR / RID:

Class: 8

Label: 8

IMDG:

Class: 8

Label: 8

IATA:

Class: 8

Label: 8



14.4. Packing group

ADR / RID, IMDG, IATA:III

14.5. Environmental hazards

ADR / RID:

NO

IMDG:

not marine pollutant

IATA:

NO

14.6. Special precautions for user

ADR / RID:

HIN - Kemler: 80

Limited Quantities: 5 It

Tunnel restriction code: (E)

Special provision: -

IMDG:

EMS: F-A, S-B

Limited Quantities: 5 It

IATA:

Cargo:

Maximum quantity: 60 L

Packaging instructions:

Passengers:	Maximum quantity: 5 L	856 Packaging instructions:
Special provision:	A803	852

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	3

<u>Contained substance</u>	
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)

None

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


None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

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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:

Repr. 2	Reproductive toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
Skin Corr. 1B	Skin corrosion, category 1B
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Sens. 1	Skin sensitization, category 1
Skin Sens. 1A	Skin sensitization, category 1A
Skin Sens. 1B	Skin sensitization, category 1B
Aquatic Chronic 3	Hazardous to the aquatic environment, chronic toxicity, category 3
H361fd	Suspected of damaging fertility. Suspected of damaging the unborn child.
H311	Toxic in contact with skin.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H372	Causes damage to organs through prolonged or repeated exposure.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H317	May cause an allergic skin reaction.
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


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- 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
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- 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
- vPvM: Very persistent and very mobile
- 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 (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
 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)
 23. Delegated Regulation (UE) 2023/707
 24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)
 25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
 26. Delegated Regulation (UE) 2024/197 (XXI 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:

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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.