

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

DURA EP INJECTION - WINTER A Product name UFI: UDK0-K01D-P00A-DWP7

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

Intended use not available

1.3. Details of the supplier of the safety data sheet

Name **NORDIA SA** 364 Kifisias Av. Full address 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

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

H360F

2.2. Label elements



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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

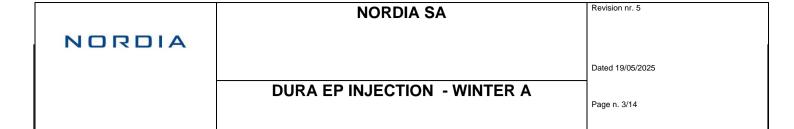
bis-[4-(2,3-epoxipropoxi)phenyl]propane

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



3.2. Mixtures

Contains:

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

bis-[4-(2,3-

epoxipropoxi)phenyl]propane

INDEX 603-073-00-2 75 Eye Irrit. 2 H319, Skin Irrit. 2 H315, Skin Sens. 1 H317, Aquatic Chronic 2

x < 100 H411

EC 216-823-5 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

x < 21

EC 271-846-8 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.

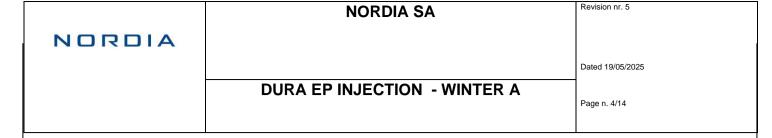
4.2. Most important symptoms and effects, both acute and delayed

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.



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.

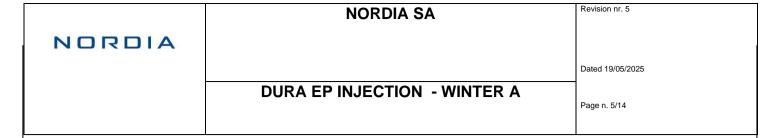
6.3. Methods and material for containment and cleaning up

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

| Predicted no-effect concentra | ation - PNEC | | | | | | | |
|---------------------------------|----------------------|----------------|---------------------|---------------------|-----------------------|-------------------|--------------------|------------------|
| Normal value in fresh water | | | | 0,0072 | mg | 3/ Ι | | |
| Normal value in marine water | r | | | 0,00072 | mg | g/l | | |
| Normal value for fresh water | sediment | | | 307,16 | mg | g/kg/d | | |
| Normal value for marine water | er sediment | | | 30,716 | mg | g/kg/d | | |
| Normal value for the terrestria | al compartment | | | 61,42 | mg | g/kg/d | | |
| Health - Derived no-effe | ct level - DNEL / D | OMEL | | | | | | |
| | Effects on consumers | | | | Effects on workers | | | |
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | 0,05 mg/kg bw/d | Systemic | | Зузіснію | | Зузіснію |
| 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 | | | | | | | | |
| Normal value in fresh water | | | | 0,006 | mg | 1/1 | | |
| Normal value in marine water | - | | | 0,001 | mo | | | |
| | | | | | | · | | |
| Normal value for fresh water | | | | 0,341 | | g/kg/d | | |
| Normal value for marine water | er sediment | | | 0,034 | mg | g/kg/d | | |
| Tromai value foi manne wate | al compartment | | | 0,065 | mg | g/kg/d | | |
| Normal value for the terrestria | | | | | | | | |
| | Effects on consumers | DMEL | | | Effects on workers | | | |
| Normal value for the terrestria | Effects on | Acute systemic | Chronic local | Chronic systemic | | Acute systemic | Chronic local | Chronic systemic |



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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



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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 рΗ not available Kinematic viscosity not available not available Solubility Partition coefficient: n-octanol/water not available Vapour pressure not available 1.20 Density and/or relative density

9.2. Other information

Relative vapour density

Particle characteristics

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.

not available

not applicable

10.2. Chemical stability

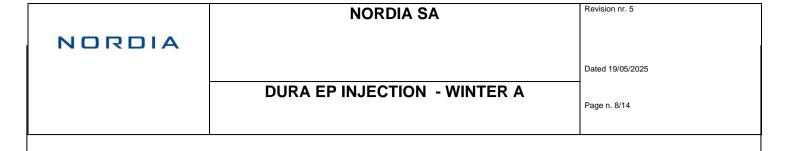
The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

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



10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

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

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

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture: ATE (Oral) of the mixture: ATE (Dermal) of the mixture:

Glycidyl ether C12-C14 alcohols LD50 (Dermal):

LD50 (Oral):

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

LD50 (Dermal): LD50 (Oral): > 4 mg/kg Rabbit 26800 mg/kg Rat

Not classified (no significant component)

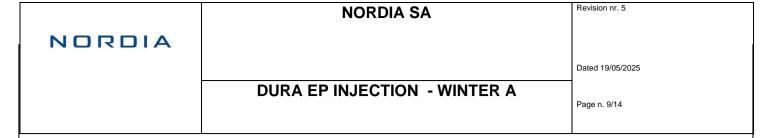
Not classified (no significant component)

Not classified (no significant component)

23000 mg/kg Rabbit 15000 mg/kg Rat

SKIN CORROSION / IRRITATION

Causes skin irritation



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

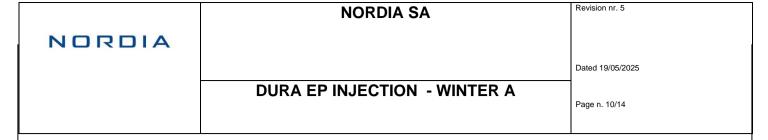
LC50 - for Fish > 0,0018 mg/l/96h Rainbow trout, donaldson

EC50 - for Crustacea 7,2 mg/l/48h Water flea

EC50 - for Algae / Aquatic Plants 844 mg/l/72h

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

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



EC50 - for Crustacea

2,1 mg/l/48h Water flea

Chronic NOEC for Crustacea

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: Ш

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

Special provision: 274, 335, 375, 601

IMDG: EMS: F-A, S-F

IATA: Cargo:

Passengers:

Limited Quantities: 5

Tunnel restriction code: (-)

Limited Quantities: 5

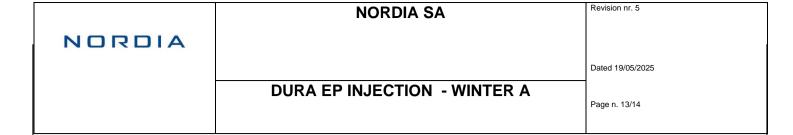
Maximum quantity: 450

instructions: 964 Maximum Packaging

Packaging

quantity: 450 instructions:

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|---|---|------------------------------------|------------------|--|--|--|
| NORDIA | | | | | | |
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| | DURA EP INJEC | ΓΙΟΝ - WINTER A | Page n. 12/14 | | | |
| | | | | | | |
| | Special provision: | L A97, A158, | 964 | | | |
| | | A197, A215 | | | | |
| 14.7. Maritime transport in bulk acco | ording to IMO instruments | | | | | |
| Information not relevant | | | | | | |
| SECTION 15. Regulatory | information | | | | | |
| | ental regulations/legislation specific | for the substance or mixture | | | | |
| Seveso Category - Directive 2012/18/E | | ior the substance of mixture | | | | |
| Restrictions relating to the product or co | | x XVIII to EC Population 1007/2006 | | | | |
| | contained substances pursuant to Anne | X XVII to LC Regulation 1907/2000 | | | | |
| Product Point | 3 | | | | | |
| Contained substance | | | | | | |
| Point | 75 | | | | | |
| Regulation (EU) 2019/1148 - on the ma | arketing and use of explosives precurse | <u>ors</u> | | | | |
| not applicable | | | | | | |
| Substances in Candidate List (Art. 59 I | REACH) | | | | | |
| On the basis of available data, the prod | duct does not contain any SVHC in per | centage | | | | |
| than 0,1%. | | | | | | |
| Substances subject to authorisation (A | nnex XIV REACH) | | | | | |
| None | | | | | | |
| Substances subject to exportation repo | orting pursuant to Regulation (EU) 649/ | <u> 2012:</u> | | | | |
| None | | | | | | |
| Substances subject to the Rotterdam Convention: | | | | | | |
| None | | | | | | |
| Substances subject to the Stockholm (| Convention: | | | | | |
| None | | | | | | |
| Healthcare controls | | | | | | |
| | | | | | | |
| | | | | | | |



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

15.2. Chemical safety assessment

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

SECTION 16. Other information

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

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.

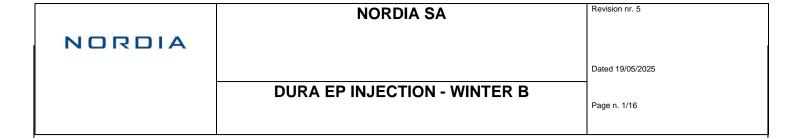
H317 May cause an allergic skin reaction.

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

Revision nr. 5 **NORDIA SA** NORDIA Dated 19/05/2025 **DURA EP INJECTION - WINTER A** Page n. 14/14 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 Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament 9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament 10. Regulation (EÚ) 2015/1221 (VII Atp. CLP) of the European Parliament 11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament 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 **FCHA** 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.



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

DURA EP INJECTION - WINTER B Product name UFI: 2GK0-20QS-Y00U-2889

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

Intended use not available

1.3. Details of the supplier of the safety data sheet

Name **NORDIA SA** 364 Kifisias Av. Full address 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

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

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

Hazard classification and indication:

Skin 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.

Very toxic to aquatic life with long lasting effects. Hazardous to the aquatic environment, chronic toxicity, H410

category 1

2.2. Label elements

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



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Hazard pictograms:







Signal words: Danger

Hazard statements:

H314 Causes severe skin burns and eye damage.

H317 May cause an allergic skin reaction.

H410 Very toxic 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: 4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3-

aminomethyl-3,5,5-trimethylcyclohexylamine

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

DIETHYLENETRIAMINE BENZYL ALCOHOL

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 contains substances with endocrine disrupting properties in concentration 0.1%:

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight 1 540 g/mol)



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SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

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

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3aminomethyl-3,5,5trimethylcyclohexylamine

INDEX - 45 Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1 H317, Aquatic Chronic 3

x < 60 H412

EC 500-101-4
CAS 38294-64-3
BENZYL ALCOHOL

INDEX 603-057-00-5 30 Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Sens. 1B H317

EC 202-859-9 LD50 Oral: 1200 mg/kg

CAS 100-51-6

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight

1 540 g/mol)

INDEX 604-100-00-0 10,5 Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=10

x < 12 FC 500-024-6

CAS 9016-45-9

DIETHYLENETRIAMINE

INDEX 612-058-00-X 4,5 Acute Tox. 4 H302, Acute Tox. 4 H312, Skin Corr. 1B H314, Eye Dam. 1

x < 5 H318, Skin Sens. 1 H317

EC 203-865-4 LD50 Oral: 1140 mg/kg, LD50 Dermal: 1045 mg/kg

CAS 111-40-0

3-AMINOMETHYL-3,5,5-

TRIMETHYLCYCLOHEXYLAMINE

INDEX 612-067-00-9 4 Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Skin Sens. 1A

x < 4,5 H317 EC 220-666-8 Skin :

Skin Sens. 1A H317: 0,001%

CAS 2855-13-2 LD50 Oral: 1030 mg/kg

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

SECTION 4. First aid measures

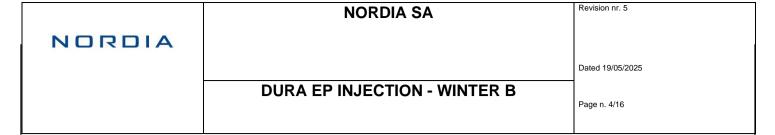
4.1. Description of first aid measures

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. 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

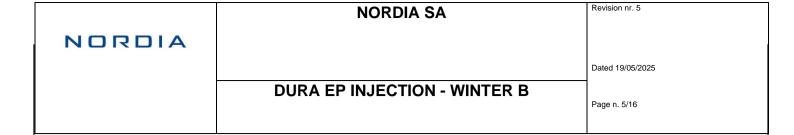
GENERAL INFORMATION

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).

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

Regulatory references:

GBR

GRC Ελλάδα Π.Δ. 26/2020 (ΦΕΚ 50/Α` 6.3.2020) Εναρμόνιση της ελληνικής νομοθεσίας προς τις διατάξεις των οδηγιών

2017/2398/ΕΕ, 2019/130/ΕΕ και 2019/983/ΕΕ «για την τροποποίηση της οδηγίας 2004/37/ΕΚ ``σχετικά με την προστασία των εργαζομένων από τους κινδύνους που συνδέονται με την έκθεση σε καρκινογόνους ή

μεταλλαξιγόνους παράγοντες κατά την εργασία``» EH40/2005 Workplace exposure limits (Fourth Edition 2020)

United Kingdom

TLV-ACGIH ACGIH 2023

DIETHYLENETRIAMINE

Threshold Limit Value



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| Туре | Country | TWA/8h | | STEL/15min | | Remarks / Observations | |
|-----------|---------|--------|-----|------------|-----|---------------------------|--|
| | | mg/m3 | ppm | mg/m3 | ppm | | |
| TLV | GRC | 4 | 1 | | | | |
| WEL | GBR | 4,3 | 1 | | | SKIN | |
| TLV-ACGIH | | 4,2 | 1 | | | SKIN | |

4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3-aminomethyl-3,5,5-trimethylcyclohexylamine

| ti inietri y lo y oi o nexy la mine | | | |
|---|-------|---------|--|
| Predicted no-effect concentration - PNEC | | | |
| Normal value in fresh water | 0,011 | mg/l | |
| Normal value in marine water | 0,001 | mg/l | |
| Normal value for fresh water sediment | 4320 | mg/kg/d | |
| Normal value for marine water sediment | 432 | mg/kg/d | |
| Normal value of STP microorganisms | 10 | mg/l | |
| Normal value for the food chain (secondary poisoning) | 1 | mg/kg | |
| Normal value for the terrestrial compartment | 864 | mg/kg/d | |

| Health - Derived no-eff | fect level - DNEL / D Effects on consumers | DMEL | | | Effects on workers | | | |
|-------------------------|--|----------------|---------------|------------------|--------------------|-------------------|---------------|------------------|
| Route of exposure | Acute local | Acute systemic | Chronic local | Chronic systemic | Acute local | Acute systemic | Chronic local | Chronic systemic |
| Oral | | | 0,05 mg/kg/d | | | - | | |
| Inhalation | | | 0,074 mg/m3 | | | | 0,493 mg/m3 | |
| Skin | | | 0,05 mg/kg/d | | | | 0,14 mg/kg/d | |

Legend:

(C) = CEILING; INHAL = Inhalable Fraction; RESP = Respirable Fraction; THORA = Thoracic Fraction.

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.

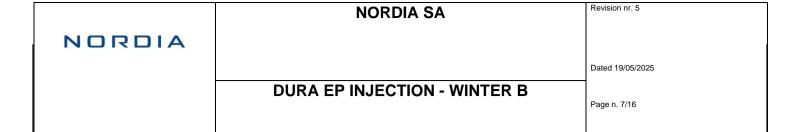
Provide an emergency shower with face and eye wash station.

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

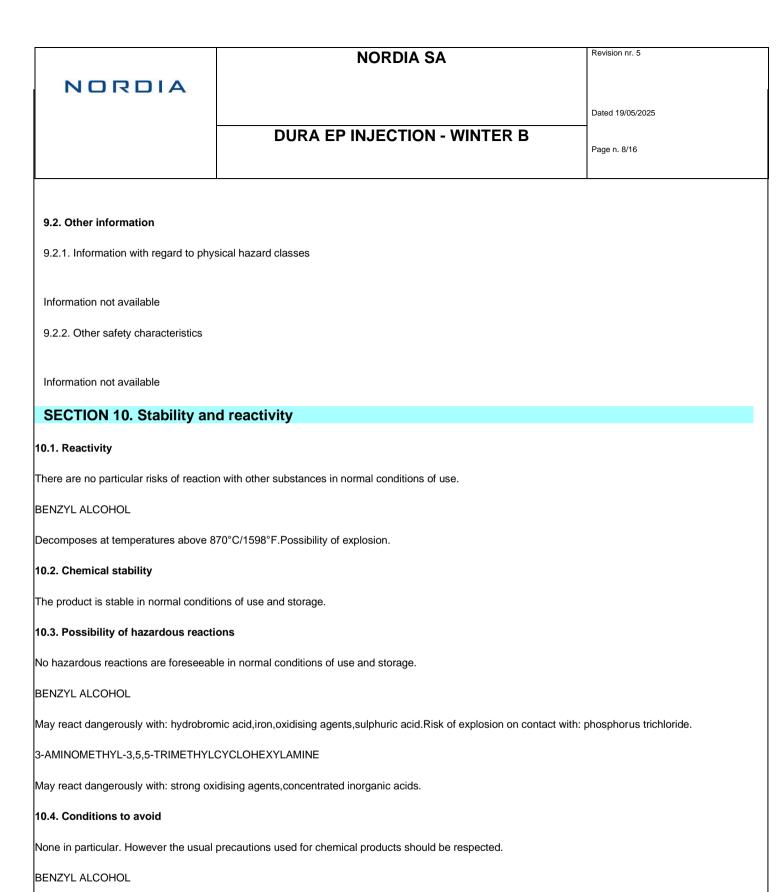
The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

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

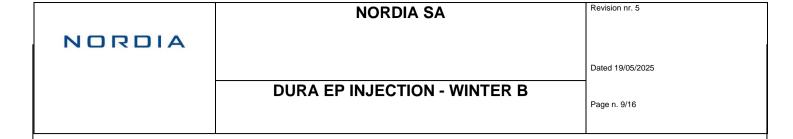
| Properties Appearance | Value not available | Information |
|--|------------------------|-------------|
| Colour | not available | |
| Odour | not available | |
| Melting point / freezing point | not available | |
| Initial boiling point | not available | |
| Flammability | not available | |
| Lower explosive limit | not available | |
| Upper explosive limit | not available | |
| Flash point | > 93 °C | |
| Auto-ignition temperature | not available | |
| Decomposition temperature | not available | |
| рН | 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 | |



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

Avoid contact with: strong acids, strong oxidants.

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE



10.5. Incompatible materials

BENZYL ALCOHOL

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: >2000 mg/kg
ATE (Dermal) of the mixture: >2000 mg/kg

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight

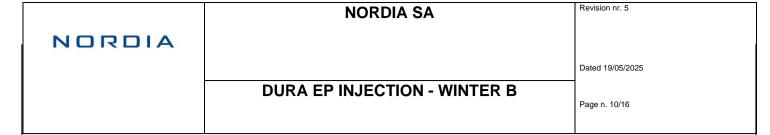
1 540 g/mol)

LD50 (Dermal): 1780 mg/kg Rabbit LD50 (Oral): 1310 mg/kg Rat

BENZYL ALCOHOL

 $\begin{array}{lll} \mbox{LD50 (Dermal):} & 2000 \mbox{ mg/kg Rabbit} \\ \mbox{LD50 (Oral):} & 1200 \mbox{ mg/kg} \\ \mbox{LC50 (Inhalation vapours):} & > 4,1 \mbox{ mg/l/4h Rat} \\ \end{array}$

DIETHYLENETRIAMINE



 LD50 (Dermal):
 1045 mg/kg Rabbit

 LD50 (Oral):
 1140 mg/kg Rat

 LC50 (Inhalation vapours):
 1,8 mg/l/4h Rat

3-AMINOMETHYL-3,5,5-TRIMETHYLCYCLOHEXYLAMINE

LD50 (Oral):

1030 mg/kg

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

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

11.2. Information on other hazards

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

SECTION 12. Ecological information

This product is dangerous for the environment and highly toxic for aquatic organisms. In the long term, it has negative effects on the aquatic environment. **12.1. Toxicity**



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4,4'-Isopropylidenediphenol, oligomeric reaction products with 1-chloro-2,3-epoxypropane, reaction products with 3-aminomethyl-3,5,5-trimethylcyclohexylamine

LC50 - for Fish 70,7 mg/l/96h

EC50 - for Crustacea 11,1 mg/l/48h Daphnia

12.2. Persistence and degradability

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight

1 540 g/mol)

Solubility in water > 10000 mg/l

Rapidly degradable BENZYL ALCOHOL Rapidly degradable DIETHYLENETRIAMINE

Solubility in water 1000 - 10000 mg/l

Rapidly degradable 3-AMINOMETHYL-3.5.5-

TRIMETHYLCYCLOHEXYLAMINE

Solubility in water 1000 - 10000 mg/l

NOT rapidly degradable

12.3. Bioaccumulative potential

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight

1 540 g/mol)

Partition coefficient: n-octanol/water 3,7

BENZYL ALCOHOL

Partition coefficient: n-octanol/water 1,1

DIETHYLENETRIAMINE

Partition coefficient: n-octanol/water -5,58

12.4. Mobility in soil

DIETHYLENETRIAMINE

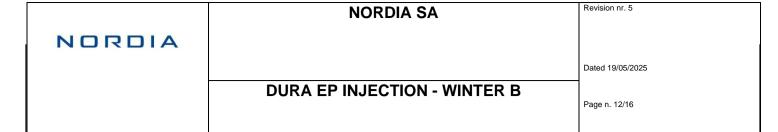
Partition coefficient: soil/water 3,4

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 contains the following endocrine disruptors in concentrations of 0.1% or greater by weight that may have



endocrine disrupting effects on the environment and on animal species causing adverse effects on the exposed organisms or on their progeny: NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight 1540 g/mol)

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 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

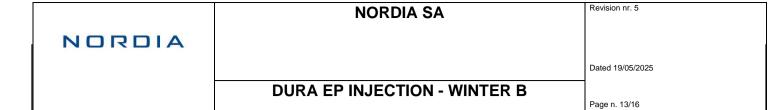
IMDG: Class: 8 Label: 8

IATA: Class: 8 Label: 8



14.4. Packing group

ADR / RID, IMDG, IATA:



14.5. Environmental hazards

ADR / RID:

IMDG: not marine pollutant

IATA: NO

14.6. Special precautions for user

ADR / RID: HIN - Kemler: 80 Limited Tunnel Quantities: 5 restriction

code: (E)

Special provision: -

Special provision:

Cargo:

IMDG: EMS: F-A, S-B Limited Quantities: 5

IATA:

Packaging Maximum quantity: 60 L instructions:

856

Passengers: Maximum Packaging quantity: 5 L instructions:

852 A803

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: E1

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

<u>Product</u>

Point 3

Contained substance

Point 75

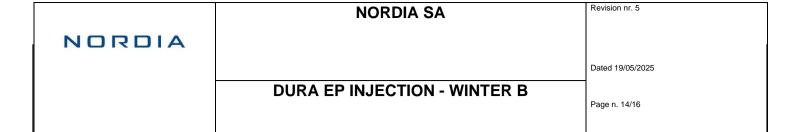
Point 46-46a NONYLPHENOL, BRANCHED AND

LINEAR, ETHOXYLATED (with average molecular weight

1 540 g/mol)

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

not applicable



Substances in Candidate List (Art. 59 REACH)

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight 1 540 g/mol)

Substances subject to authorisation (Annex XIV REACH)

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight 1 540 g/mol)

Sunset Date: 4/1/2021

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

NONYLPHENOL, BRANCHED AND LINEAR, ETHOXYLATED (with average molecular weight 1 540 g/mol) - (NONYLPHENOL ETHOXYLATES)

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

Healthcare controls

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

15.2. Chemical safety assessment

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

SECTION 16. Other information

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

Acute Tox. 4 Acute toxicity, category 4

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 Acute 1 Hazardous to the aquatic environment, acute toxicity, category 1

Aquatic Chronic 1 Hazardous to the aquatic environment, chronic toxicity, category 1



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Aquatic Chronic 3 Hazardous to the aquatic environment, chronic toxicity, category 3

H302 Harmful if swallowed. H312 Harmful in contact with skin.

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.

H400 Very toxic to aquatic life.

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

EGEND:

- 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
- 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)
- 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

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