

## Safety Data Sheet

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

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

#### 1.1. Product identifier

Product name	1,2-dimethyl-1,4,5,6-tetrahydropyrimidine
EC number	224-262-2
CAS number	4271-96-9
Registration Number	01-2120052211-75-0002

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

Intended use	Intermediate for the preparation of active pharmaceutical ingredients
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#### 1.3. Details of the supplier of the safety data sheet

Name	Cosma S.p.A.		
Full address	Via Colleoni 15/17		
District and Country	24040 Ciserano		(BG)
	Italia		
	Tel.	+39 035883055	
	Fax	+39 0354820501	
e-mail address of the competent person responsible for the Safety Data Sheet	info@cosma.it		

#### 1.4. Emergency telephone number

For urgent inquiries refer to	<p>Centro Antiveleni di Milano Ospedale Niguarda Ca' Granda Piazza Ospedale Maggiore 3 20162 Milano +39 02 6610 1029</p> <p>Centro Antiveleni di Pavia Centro Nazionale di Informazione Tossicologica, IRCCS Fondazione Maugeri Via Salvatore Maugeri, 10 27100 Pavia +39 03 822 4444</p>
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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:

Acute toxicity, category 4	H302	Harmful if swallowed.
Skin corrosion, category 1B	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.

#### 2.2. Label elements

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

##### Hazard pictograms:



Signal words: **Danger**

**SECTION 2. Hazards identification** ... / >>**Hazard statements:**

H302 Harmful if swallowed.  
H314 Causes severe skin burns and eye damage.

**Precautionary statements:**

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 hands thoroughly after handling.  
P260 Do not breathe mist / vapours / spray.

Contains: 1,2-dimethyl-1,4,5,6-tetrahydropyrimidine

Nr. EC: 224-262-2

**2.3. Other hazards**

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

The substance does not have endocrine disrupting properties.

**SECTION 3. Composition/information on ingredients****3.1. Substances****Contains:**

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
1,2-dimethyl-1,4,5,6-tetrahydropyrimidine		
CAS 4271-96-9	100	Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318
EC 224-262-2		LD50 Oral: 1334 mg/kg
INDEX		
REACH Reg. 01-2120052211-75-0002		

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

As regards the concentration of the substance, see note in Sect. 16

**SECTION 4. First aid measures****4.1. Description of first aid measures**

**EYES:** Remove contact lenses, if present. Wash immediately with plenty of water for at least 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

**SKIN:** Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

**INGESTION:** Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

**INHALATION:** Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

Adverse effects can be: sleepiness, dizziness, dry mouth, nose or throat and skin rash.

It may cause an allergic reaction if swallowed or in contact with the skin.

**Acute symptoms:**

- Ingestion: burning, abdominal pain, burns
- Inhalation: can be irritating
- Skin contact: causes severe burns
- Contact with eyes: causes serious eye damage

**SECTION 4. First aid measures** ... / >>**4.3. Indication of any immediate medical attention and special treatment needed**

Refer to the chemical risk assessment

**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.

It is essential to perform the grounding of the equipment in contact with the substance in order to dissipate the potential of static electricity.

**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.



## SECTION 7. Handling and storage ... / &gt;&gt;

## 7.3. Specific end use(s)

Information not available

## SECTION 8. Exposure controls/personal protection

## 8.1. Control parameters

Information not available

## 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 (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

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 166).

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**

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, 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). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

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. The protection provided by masks is in any case limited.

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.

## SECTION 9. Physical and chemical properties

## 9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	blue-green	
Odour	amino	
Melting point / freezing point	Not available	
Initial boiling point	176 °C	
Flammability	Not available	
Lower explosive limit	Not available	
Upper explosive limit	Not available	
Flash point	73 °C	
Auto-ignition temperature	Not available	
pH	12	Remark: more than 12 Concentration: 50 %
Kinematic viscosity	Not available	
Solubility	soluble in water	Remark: soluble in organic solvents Temperature: 20 °C Remark: Pred. QSAR
Partition coefficient: n-octanol/water	1,15	
Vapour pressure	4 hPa	
Density and/or relative density	955-970 g/dm3	
Relative vapour density	Not available	

**SECTION 9. Physical and chemical properties** ... / >>

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.

Avoid exposure to: heat.

**10.5. Incompatible materials**

Incompatible with: strong acids, oxidising agents.

**10.6. Hazardous decomposition products**

When heated to decomposition releases: carbon oxides, nitric oxide.

**SECTION 11. Toxicological information****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

1,2-dimethyl-1,4,5,6-tetrahydropyrimidine

LD50 (Oral):

1334 mg/kg Pred. in-silico EPA

Acute toxicity, category 4. Harmful if swallowed.

SKIN CORROSION / IRRITATION

Corrosive for the skin

SERIOUS EYE DAMAGE / IRRITATION

**SECTION 11. Toxicological information** ... / >>

Causes serious eye damage

**RESPIRATORY OR SKIN SENSITISATION**

Does not meet the classification criteria for this hazard class

**Respiratory sensitization**

Information not available

**Skin sensitization**

Information not available

**GERM CELL MUTAGENICITY**

Does not meet the classification criteria for this hazard class

Ames test: Negative (Pred QSAR ACDTox / Leadscope)

**CARCINOGENICITY**

Does not meet the classification criteria for this hazard class

**REPRODUCTIVE TOXICITY**

Does not meet the classification criteria for this hazard class

**Adverse effects on sexual function and fertility**

Information not available

**Adverse effects on development of the offspring**

Information not available

**Effects on or via lactation**

Information not available

**STOT - SINGLE EXPOSURE**

Does not meet the classification criteria for this hazard class

**Target organs**

Information not available

**Route of exposure**

Information not available

**STOT - REPEATED EXPOSURE**

Does not meet the classification criteria for this hazard class

**Target organs**

Information not available

**Route of exposure**

Information not available

**ASPIRATION HAZARD**

Does not meet the classification criteria for this hazard class

**SECTION 11. Toxicological information** ... / >>**11.2. Information on other hazards**

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

**SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

**12.1. Toxicity**

1,2-dimethyl-1,4,5,6-tetrahydropyrimidine  
EC50 - for Crustacea

169,71 mg/l/48h Daphnia pred. in-silico QSAR

**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**

The substance does not have persistence, bioaccumulation and toxicity (PBT) properties and is not very persistent and very bioaccumulative. (vPvB).

**12.6. Endocrine disrupting properties**

Based on the available data, the substance is not 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.

**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: 3267

**14.2. UN proper shipping name**

ADR / RID: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.  
IMDG: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.  
IATA: CORROSIVE LIQUID, BASIC, ORGANIC, N.O.S.

**Cosma S.p.A.****1,2-dimethyl-1,4,5,6-tetrahydropyrimidine**Revision nr.1  
Dated 01/07/2022  
First compilation  
Printed on 01/07/2022  
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EN

**SECTION 14. Transport information** ... / >>**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: II

**14.5. Environmental hazards**

ADR / RID: NO

IMDG: NO

IATA: NO

**14.6. Special precautions for user**ADR / RID: HIN - Kemler: 80  
Special provision: 274

IMDG: EMS: F-A, S-B

IATA: Cargo:

Pass.:

Special provision:

Limited Quantities: 1 L

Limited Quantities: 1 L

Maximum quantity: 30 L

Maximum quantity: 1 L

A3, A803

Tunnel restriction code: (E)

Packaging instructions: 855

Packaging instructions: 851

**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

Product  
Point 3Regulation (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  $\geq$  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

Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks



**SECTION 15. Regulatory information** ... / >>

related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

**15.2. Chemical safety assessment**

Has not been performed / is not yet available a chemical safety assessment for the substance.

**SECTION 16. Other information**

For the actual assay of the substance, refer to the Certificate of Analysis or to company specifications

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
H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.

**LEGEND:**

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

**GENERAL BIBLIOGRAPHY**

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

**SECTION 16. Other information** ... / >>

- 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)

- 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.