

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

### 1.1. Product identifier

|                               |   |
|-------------------------------|---|
| Product form                  | : Substance   |
| Trade name                    | :   |
| Chemical name                 | : N-Cyano-N'.-methyl-N''-[2[[[(5-methyl-1Himidazole- 4-yl)methyl]thio]ethyl]guanidine |
| EC-No.                        | : 257-232-2   |
| CAS-No.                       | : 51481-61-9  |
| REACH registration No         | : &   |
| C&L notification reference no | : 02-2119560299-29-0000   |
| Formula                       | : C10H16N6S   |

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

#### 1.2.1. Relevant identified uses

|                                  |  |
|----------------------------------|--|
| Main use category                | : Industrial use.  |
| Industrial/Professional use spec | : Industrial   |
| Use of the substance/mixture     | : Restricted use as an active ingredient in pharmaceutical industry. |
| Function or use category         | : Pharmaceuticals  |

#### 1.2.2. Uses advised against

No additional information available

### 1.3. Details of the supplier of the safety data sheet

Unión Químico Farmacéutica, S.A  
Mallorca 262  
P.O. Box 3 planta  
08008 Barcelona - SPAIN  
T +34 934 674 810 - F +34 934 880 491  
[uquifareach@uquifa.com](mailto:uquifareach@uquifa.com) - <http://www.uquifa.com>

### 1.4. Emergency telephone number

Emergency number : Tel. +34 938 439 003 +34 938 670 421  
Office hours (monday to friday, 9 am- 17 pm GTM+1)

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

#### Classification according to Regulation (EC) No. 1272/2008 [CLP]

|  |       |
|--|-------|
| Carcinogenicity, Category 2                | H351  |
| Reproductive toxicity, Category 2          | H361f |
| Full text of H statements : see section 16 |       |

#### Adverse physicochemical, human health and environmental effects

No additional information available

### 2.2. Label elements

#### Labelling according to Regulation (EC) No. 1272/2008 [CLP]Extra labelling to displayExtra classification(s) to display

Hazard pictograms (CLP)



GHS08



|                                |   |
|--------------------------------|---|
| Signal word (CLP)              | : Warning   |
| Hazard statements (CLP)        | : H351 - Suspected of causing cancer.<br>H361f - Suspected of damaging fertility.   |
| Precautionary statements (CLP) | : P201 - Obtain special instructions before use.<br>P280 - Wear eye protection, protective gloves, face protection.<br>P308+P313 - IF exposed or concerned: Get medical advice/attention. |

### 2.3. Other hazards

PBT: not yet assessed.

vPvB: not yet assessed.

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

| Name       | Product identifier   | %   |
|------------|--|-----|
| Cimetidine | (CAS-No.) 51481-61-9<br>(EC-No.) 257-232-2<br>(REACH-no) & | 100 |

Full text of H-statements: see section 16

### 3.2. Mixtures

Not applicable.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

|                                       |   |
|---------------------------------------|---|
| First-aid measures general            | : Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.   |
| First-aid measures after inhalation   | : Remove person to fresh air and keep comfortable for breathing. Get medical advice/attention if you feel unwell.                                       |
| First-aid measures after skin contact | : Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower. If skin irritation or rash occurs: Get medical advice/attention. |
| First-aid measures after eye contact  | : Rinse cautiously with water for several minutes. Get medical advice/attention if you feel unwell.   |
| First-aid measures after ingestion    | : Rinse mouth. Do NOT induce vomiting. Get medical advice/attention if you feel unwell.   |

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

|                  |  |
|------------------|--|
| Symptoms/effects | : Not expected to present a significant hazard under anticipated conditions of normal use. |
|------------------|--|

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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

|                                |  |
|--------------------------------|--|
| Suitable extinguishing media   | : Water spray. Sand. Foam. Dry powder. |
| Unsuitable extinguishing media | : Do not use a heavy water stream.     |

### 5.2. Special hazards arising from the substance or mixture

|  |  |
|--|--|
| Fire hazard                                      | : May intensify fire; oxidiser.  |
| Explosion hazard                                 | : Explosion may result if is dispersed and finds an ignition source. Dust may form explosive mixture in air. |
| Hazardous decomposition products in case of fire | : Carbon monoxide. Carbon dioxide. Nitrous gasses. Sulphur dioxide.  |



### 5.3. Advice for firefighters

|                                |  |
|--------------------------------|--|
| Precautionary measures fire    | : Evacuate area. Fight fire remotely due to the risk of explosion. Stop leak if safe to do so.   |
| Firefighting instructions      | : Eliminate all ignition sources if safe to do so. Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Fight fire with normal precautions from a reasonable distance. |
| Protection during firefighting | : Do not attempt to take action without suitable protective equipment.   |

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

|   |  |
|---|--|
| General measures                          | : Remove ignition sources. Collect spillage.   |
| <b>6.1.1. For non-emergency personnel</b> |  |
| Protective equipment                      | : Concerning personal protective equipment to use, see section 8.  |
| Emergency procedures                      | : Only qualified personnel equipped with suitable protective equipment may intervene.  |
| Measures in case of dust release          | : Avoid dust formation. Avoid dust to spread. Dust production: have neighbourhood close doors and windows.   |
| <b>6.1.2. For emergency responders</b>    |  |
| Protective equipment                      | : Self-contained breathing apparatus. NBC suit.  |
| Emergency procedures                      | : Evacuate unnecessary personnel. Keep away from combustible material. Ventilate area. Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. |

### 6.2. Environmental precautions

Notify authorities if product enters sewers or public waters. Avoid release to the environment.

### 6.3. Methods and material for containment and cleaning up

|                         |  |
|-------------------------|--|
| For containment         | : Collect spillage.  |
| Methods for cleaning up | : Notify authorities if product enters sewers or public waters. On land, sweep or shovel into suitable containers. |
| Other information       | : Dispose of materials or solid residues at an authorized site.  |

### 6.4. Reference to other sections

See Heading 8. Exposure controls/personal protection.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

|                                   |  |
|-----------------------------------|--|
| Additional hazards when processed | : Provide adequate ventilation of the area to prevent the formation of explosive atmospheres.  |
| Precautions for safe handling     | : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Take any precaution to avoid mixing with incompatible materials. |
| Hygiene measures                  | : Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Wash hands, forearms and face thoroughly after handling.           |

### 7.2. Conditions for safe storage, including any incompatibilities

|                               |   |
|-------------------------------|---|
| Technical measures            | : Provide adequate ventilation of the area to prevent the formation of explosive atmospheres. Provide adequate ventilation to minimize dust concentrations. |
| Storage conditions            | : Store in a well-ventilated place. Keep container tightly closed.  |
| Incompatible products         | : Strong acids. Strong bases.   |
| Incompatible materials        | : Heat sources. Sources of ignition. Direct sunlight. Combustible materials.  |
| Heat and ignition sources     | : Keep away from sparks, heat, open flames, hot surfaces. - No smoking.   |
| Prohibitions on mixed storage | : Incompatible products.  |
| Storage area                  | : Store in a dry place. Store in a well-ventilated place.   |
| Special rules on packaging    | : Keep only in original container. Store in a closed container.   |

Packaging materials : Store always product in container of same material as original container.

### 7.3. Specific end use(s)

Restricted use as an active ingredient in pharmaceutical industry.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

No additional information available

### 8.2. Exposure controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station. Provide adequate ventilation of the area to prevent the formation of explosive atmospheres.

#### Hand protection:

Protective gloves made of PVC

#### Eye protection:

Chemical goggles or safety glasses.

#### Respiratory protection:

Mask. P3

#### Personal protective equipment symbol(s):



#### Thermal hazard protection:

Keep away from sparks, heat, open flames, hot surfaces. - No smoking.

#### Environmental exposure controls:

Avoid release to the environment.

#### Consumer exposure controls:

Product should be adapted to be used by general public.

#### Other information:

Do not eat, drink or smoke during use.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|  |   |
|--|---|
| Physical state                             | : Solid   |
| Appearance                                 | : Solid.  |
| Molecular mass                             | : 55,3392 g/mol   |
| Colour                                     | : Pale.   |
| Odour                                      | : Characteristic.   |
| Odour threshold                            | : Not determined. Reason: No additional information available |
| pH   | : 9 – 10,5  |
| pH solution                                | : Not determined. Reason: No additional information available |
| Relative evaporation rate (butylacetate=1) | : Not determined. Reason: No additional information available |
| Relative evaporation rate (ether=1)        | : Not determined. Reason: No additional information available |
| Melting point                              | : 139 – 144 °C  |
| Freezing point                             | : Not determined. Reason: No additional information available |



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment  
Regulation (EU) 2015/830

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|   |  |
|---|--|
| Boiling point                                 | : 488 °C at 760 mmHg   |
| Flash point                                   | : Not determined. Reason: No additional information available  |
| Critical temperature                          | : Not determined. Reason: No additional information available  |
| Auto-ignition temperature                     | : Not determined. Reason: No additional information available  |
| Decomposition temperature                     | : Not determined. Reason: No additional information available  |
| Flammability (solid, gas)                     | : Not determined. Reason: No available data  |
| Vapour pressure                               | : 0,000000001 mm Hg (25°C) #   |
| Vapour pressure at 50 °C                      | : Not determined. Reason: No additional information available  |
| Critical pressure                             | : Not determined. Reason: No additional information available  |
| Relative vapour density at 20 °C              | : Not determined. Reason: No additional information available  |
| Relative density                              | : Not determined. Reason: No additional information available  |
| Relative density of saturated gas/air mixture | : Not determined. Reason: No additional information available  |
| Density                                       | : 1,27 kg/m <sup>3</sup>   |
| Relative gas density                          | : Not determined. Reason: No additional information available  |
| Solubility                                    | : Alcohol. Dichloromethane.<br>Water.: ≥ 1 mg/l  |
| Log Pow                                       | : 0,879  |
| Log Kow                                       | : Not determined. Reason: No additional information available  |
| Viscosity, kinematic                          | : No data available.   |
| Viscosity, dynamic                            | : Not determined. Reason: No additional information available  |
| Explosive properties                          | : Explosion may result if is dispersed and finds an ignition source. Not classified as explosive according to EC criteria, but may present risks in the event of a fire. |
| Oxidising properties                          | : May cause fire or explosion; strong oxidiser.  |
| Explosive limits                              | : Not determined. Reason: No additional information available  |

### 9.2. Other information

|                                      |   |
|--------------------------------------|---|
| Class                                | St1   |
| Kst                                  | :181 bar m/s  |
| Maximum pressure                     | :7,2 bar  |
| Minimum Ignition Temperature (cloud) | :490 °C   |
| Minimum Ignition Temperature (layer) | :> 400 °C   |
| Explosive limits                     | Not determined. Reason: No additional information available   |
| Specific conductivity                | : Not determined. Reason: No additional information available |
| SADT                                 | : Not determined. Reason: No additional information available |
| Softening point                      | : Not determined. Reason: No additional information available |
| Sublimation point                    | : Not determined. Reason: No additional information available |
| Saturation concentration             | : Not determined. Reason: No additional information available |
| Miscibility                          | : Not determined. Reason: No additional information available |
| VOC content                          | : Not determined. Reason: No additional information available |
| Fat solubility                       | : Not determined. Reason: No additional information available |
| Bulk density                         | : Not determined. Reason: No additional information available |
| Refractive index                     | : Not determined. Reason: No additional information available |

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

May intensify fire; oxidiser.



### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Direct sunlight. Avoid dust formation.

### 10.5. Incompatible materials

Strong acids. Oxidizing agent. Strong bases. Combustible materials.

### 10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrous gasses. Sulphur oxides.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

|                             |   |
|-----------------------------|---|
| Acute toxicity (oral)       | : Not classified (No reference available) |
| Acute toxicity (dermal)     | : Not classified (No reference available) |
| Acute toxicity (inhalation) | : Not classified (No reference available) |

#### (51481-61-9)

|                                   |   |
|-----------------------------------|---|
| LD50 oral rat                     | 5000 mg/kg  |
| Skin corrosion/irritation         | : Not classified (No reference available)<br>pH: 9 – 10,5 |
| Serious eye damage/irritation     | : Not classified (No reference available)<br>pH: 9 – 10,5 |
| Respiratory or skin sensitisation | : Not classified (No reference available)                 |
| Germ cell mutagenicity            | : Not classified (No reference available)                 |
| Carcinogenicity                   | : Suspected of causing cancer.                            |

#### (51481-61-9)

|                        |   |
|------------------------|---|
| IARC group             | 3 - Not classifiable                      |
| Reproductive toxicity  | : Suspected of damaging fertility.        |
| STOT-single exposure   | : Not classified (No reference available) |
| STOT-repeated exposure | : Not classified (No reference available) |
| Aspiration hazard      | : Not classified (No reference available) |

## SECTION 12: Ecological information

### 12.1. Toxicity

|   |   |
|---|---|
| Ecology - general   | : Not established.                        |
| Ecology - water   | : Not established.                        |
| Hazardous to the aquatic environment, short-term (acute)  | : Not classified (No reference available) |
| Hazardous to the aquatic environment, long-term (chronic) | : Not classified (No reference available) |

#### (51481-61-9)

|                    |           |
|--------------------|-----------|
| LC50 fish 1        | 1000 mg/l |
| EC50 Daphnia 1     | 760 mg/l  |
| EC50 72h algae (1) | 105 mg/l  |



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## 12.2. Persistence and degradability

(51481-61-9)

Persistence and degradability Not established.

## 12.3. Bioaccumulative potential

(51481-61-9)

Log Pow 0,879  
Log Kow Not determined. Reason: No additional information available  
Bioaccumulative potential Not established.

## 12.4. Mobility in soil

(51481-61-9)

Ecology - soil Not established.

## 12.5. Results of PBT and vPvB assessment

(51481-61-9)

PBT: not yet assessed.

vPvB: not yet assessed.

## 12.6. Other adverse effects

Additional information : Avoid release to the environment.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.  
Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.  
Sewage disposal recommendations : Prevent from entering sewers, basements and workpits, or any place where its accumulation can be dangerous. Disposal must be done according to official regulations.  
Product/Packaging disposal recommendations : Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation. Avoid release to the environment. Do not pierce or burn, even after use.  
Additional information : Follow the instructions on handling and technical measures of paragraph 7. Avoid release to the environment. Dispose in a safe manner in accordance with local/national regulations.  
Ecology - waste materials : Avoid release to the environment.  
European List of Waste (LoW) code : 16 03 05\* - organic wastes containing dangerous substances  
HP Code : HP7 - "Carcinogenic:" waste which induces cancer or increases its incidence  
HP10 - "Toxic for reproduction:" waste which has adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring.

## SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

### 14.1. UN number

UN-No. (ADR) : UN ----- TO BE COMPLETED/CALCULATED -----  
UN-No. (IMDG) : Not regulated  
UN-No. (IATA) : Not regulated

### 14.2. UN proper shipping name

Proper Shipping Name (ADR) : Not applicable.



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment  
Regulation (EU) 2015/830

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|                                      |   |
|--------------------------------------|---|
| Proper Shipping Name (IMDG)          | : Not regulated                             |
| Proper Shipping Name (IATA)          | : Not regulated                             |
| Transport document description (ADR) | : UN ----- TO BE COMPLETED/CALCULATED ----- |

**14.3. Transport hazard class(es)****ADR**

|                                  |                   |
|----------------------------------|-------------------|
| Transport hazard class(es) (ADR) | : Not applicable. |
|----------------------------------|-------------------|

**IMDG**

|                                   |                 |
|-----------------------------------|-----------------|
| Transport hazard class(es) (IMDG) | : Not regulated |
|-----------------------------------|-----------------|

**IATA**

|                                   |                 |
|-----------------------------------|-----------------|
| Transport hazard class(es) (IATA) | : Not regulated |
|-----------------------------------|-----------------|

**14.4. Packing group**

|                      |                   |
|----------------------|-------------------|
| Packing group (ADR)  | : Not applicable. |
| Packing group (IMDG) | : Not regulated   |
| Packing group (IATA) | : Not regulated   |

**14.5. Environmental hazards**

|                               |  |
|-------------------------------|--|
| Dangerous for the environment | : No                                     |
| Marine pollutant              | : No                                     |
| Other information             | : No supplementary information available |

**14.6. Special precautions for user****Overland transport****Transport by sea**

Not regulated

**Air transport**

Not regulated

**14.7. Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

**SECTION 15: Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

| Reference code | Applicable on | Entry title or description   |
|----------------|---------------|--|
| 28.            |               | Substances which are classified as carcinogen category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 1 or Appendix 2, respectively.            |
| 30.            |               | Substances which are classified as reproductive toxicant category 1A or 1B in Part 3 of Annex VI to Regulation (EC) No 1272/2008 and are listed in Appendix 5 or Appendix 6, respectively. |

is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

|             |   |
|-------------|---|
| VOC content | : Not determined. Reason: No additional information available |
|-------------|---|





according to Regulation (EC) No. 1907/2006 (REACH) with its amendment  
Regulation (EU) 2015/830

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**15.1.2. National regulations**

Not listed on the United States TSCA (Toxic Substances Control Act) inventory

Listed on the Canadian DSL (Domestic Substances List)

**Bulgaria**

Bulgarian National Regulations

: Environmental Protection Act.  
Health and Safety at Work Act.  
Law of protection from the harmful impact of the chemical substances and mixtures.  
Ordinance No 13 on protection of workers from the risks related to exposure to chemical agents at work.  
Ordinance No. 6 on the terms and conditions for granting permission for work of persons under 18 years of age.  
Ordinance No. RD-07-4 on improvement of the working conditions of pregnant workers and workers have recently given birth or nursing mothers.  
Ordinance No.3 on the minimum requirements for the workers' safety and health protection in using personal protection means at the workplace.  
Ordinance on the conditions and manner for storage of hazardous chemical substances and mixtures.  
Waste management law.

**Croatia**

Croatian National Regulations

: Chemicals Act, Regulation on classification, labelling and packaging of chemicals, Regulations on dangerous substances.  
Waste Act, Waste types regulations, Packaging Waste Regulation, Dangerous.  
Waste Regulation.

**Czech Republic**

Czech National Regulations

: Government Regulation no. 9/2013 Coll, amending Regulation no. 361/2007 Coll, governing the conditions of Health Protection at Work, as amended.  
Act no. 185/2001 Coll, on waste and amendment of some other acts, as amended.  
Act no. 20/1966 Coll, on Public Health Care.  
Act no. 350/2011 Coll. on chemical substances and mixtures and amendment of some other acts (Chemical Act).  
Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.  
Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).

**Germany**

Regulatory reference

: Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV)

Storage class (LGK)

: LGK 13 - Non-combustible solids

Employment restrictions

: Employment prohibitions for the protection of young people at work according to § 22 section 1(6) JArbSchG have to be observed.  
Employment prohibitions or restrictions on the protection of young people at work according to § 22 JArbSchG in the case of formation of hazardous substances have to be observed.  
Employment prohibitions and restrictions according to § 11 and § 12 MuSchG have to be observed.

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV

: Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

TA Luft

: 5.2.5 Organic Substances



according to Regulation (EC) No. 1907/2006 (REACH) with its amendment  
Regulation (EU) 2015/830

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|   |  |
|---|--|
| National Rules and Recommendations  | <p>: TRGS 560: Air recirculation in activities involving carcinogenic, mutagenic and fertility hazardous dusts</p> <p>TRGS 905: List of mutagenic, carcinogenic or teratogenic substances</p> <p>Observe prohibitions in accordance with chemicals Prohibition Ordinance</p> <p>Note information and record-keeping obligations for the supply to third parties in accordance with the Chemicals Prohibition Ordinance</p> <p>Note permission and notification requirements in accordance with the Chemicals Prohibition Ordinance</p> <p>TRGS 400: Risk Assessment for Activities involving Hazardous Substances</p> <p>TRGS 500: Protective measures</p> <p>TRGS 555: Working instruction and information for workers</p> <p>TRGS 910: Risk-related concept of measures for activities involving carcinogenic hazardous substances</p> |
| <b>Hungary</b>  |  |
| Hungarian National Regulations  | <p>: 26/2000 (IX.30) Provision of the Ministry of Health on the occupational safety measures against carcinogenic substances and the prevention of health impairments caused by them.</p> <p>25/2000. (IX.30.) Joint Provision of the Ministry of Health and Social and Family Affairs on the Occupational Safety in Chemistry.</p> <p>Act CLXXXV of 2012 on waste.</p> <p>Act XXV. of 2000 on the Safety in Chemistry, 44/2000. (XII. 27.) Provision of the Ministry of Health on detailed rules of procedures and activities related to hazardous substances and preparations.</p>   |
| <b>Netherlands</b>  |  |
| SZW-lijst van kankerverwekkende stoffen   | : The substance is not listed  |
| SZW-lijst van mutagene stoffen  | : The substance is not listed  |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding   | : The substance is not listed  |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid | : The substance is not listed  |
| NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling   | : The substance is not listed  |
| <b>Denmark</b>  |  |
| Danish National Regulations   | <p>: Young people below the age of 18 years are not allowed to use the product</p> <p>Pregnant/breastfeeding women working with the product must not be in direct contact with the product.</p> <p>The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal</p>   |
| <b>Norway</b>   |  |
| Norwegian National Regulations  | <p>: The user needs to be instructed on how to execute such work, on the dangers surrounding such a product and on the necessary safety instructions.</p> <p>This training must be provided by a qualified staff.</p>  |

**Slovenia**

Slovenian National Regulations

: Decree on waste management.  
Decree on packaging and packaging waste handling.  
Chemicals Act (ZKem).  
Rules on the classification, packaging and labelling of dangerous preparations.  
Rules on the classification, packaging and labelling of dangerous substances.  
Rules on the protection of workers from the risks related to exposure to chemical substances at work.  
Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.  
Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

**Switzerland**

Swiss National Regulations

: Article 13 Order on the protection of maternity (RS 822.111.52):  
Pregnant women and breastfeeding mothers cannot come into contact with this product (this substance/this preparation) when working except where it has been established, on the basis of a risk analysis performed in accordance with Art. 63 OLT 1 (RS 822.111), that there is no concrete threat to the health of the mother or baby or that said threat can be excluded thanks to the suitable protection measures taken.  
Article 4, subparagraph 4 Order on the protection of young workers (OLT 5, RS 822.115) and Article 1, letter f Order of the DEFR on dangerous works for young workers (822.115.2):  
Young workers undergoing initial professional training cannot work with this product (this substance/this preparation) except where envisaged in the order of professional training to achieve the training purposes and if the training plan conditions and applicable age limits are respected. Young workers who do not undergo initial professional training cannot work with this product (this substance/this preparation). Workers of either sex aged under 18 years old are considered as young.  
Observe the Chemical Risk Reduction Ordinance (SR 814.81).

Ordinance on Air Pollution Control (OAPC)

: Annex 1, number 4

**15.2. Chemical safety assessment**

No chemical safety assessment has been carried out

**SECTION 16: Other information****Indication of changes:**

| Section | Changed item   | Change   | Comments |
|---------|--|----------|----------|
|         | Supersedes   | Modified |          |
|         | Revision date  | Modified |          |
|         | Reason for no classification   | Added    |          |
|         | Reason for no classification   | Added    |          |
|         | Refractive index   | Added    |          |
| 1.1     | Formula  | Modified |          |
| 1.1     | Name   | Modified |          |
| 2.1     | Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD] | Modified |          |
| 2.2     | Precautionary statements (CLP)   | Modified |          |
| 4.1     | First-aid measures general   | Modified |          |



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|     |   |          |
|-----|---|----------|
| 4.1 | First-aid measures after skin contact         | Modified |
| 5.2 | Explosion hazard                              | Modified |
| 5.2 | Fire hazard                                   | Modified |
| 6.1 | Measures in case of dust release              | Modified |
| 6.1 | Protective equipment                          | Modified |
| 6.1 | Emergency procedures                          | Modified |
| 6.1 | Protective equipment                          | Modified |
| 7.2 | Heat and ignition sources                     | Modified |
| 7.2 | Prohibitions on mixed storage                 | Modified |
| 7.2 | Packaging materials                           | Added    |
| 8.2 | Other information                             | Modified |
| 8.2 | Thermal hazard protection                     | Added    |
| 8.2 | Consumer exposure controls                    | Modified |
| 8.2 | Respiratory protection                        | Modified |
| 8.2 | Hand protection                               | Modified |
| 8.2 | Eye protection                                | Modified |
| 9.1 | Explosive limits (vol %)                      | Added    |
| 9.1 | Odour   | Added    |
| 9.1 | Oxidising properties                          | Added    |
| 9.1 | Viscosity, kinematic                          | Added    |
| 9.1 | Viscosity, dynamic                            | Added    |
| 9.1 | Flammability (solid, gas)                     | Added    |
| 9.1 | Log Kow                                       | Added    |
| 9.1 | Vapour pressure at 50 °C                      | Added    |
| 9.1 | Freezing point                                | Added    |
| 9.1 | Relative vapour density at 20 °C              | Added    |
| 9.1 | Relative gas density                          | Added    |
| 9.1 | Relative density of saturated gas/air mixture | Added    |
| 9.1 | Relative density                              | Added    |
| 9.1 | Relative evaporation rate (ether=1)           | Added    |
| 9.1 | Relative evaporation rate (butylacetate=1)    | Added    |
| 9.1 | pH solution                                   | Added    |
| 9.1 | Odour threshold (ppm)                         | Added    |
| 9.1 | Flash point                                   | Added    |
| 9.1 | Decomposition temperature                     | Added    |
| 9.1 | Critical temperature                          | Added    |
| 9.1 | Critical pressure                             | Added    |
| 9.1 | Auto-ignition temperature                     | Added    |
| 9.1 | Explosive properties                          | Modified |
| 9.2 | Bulk density                                  | Added    |



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|      |                                   |          |
|------|-----------------------------------|----------|
| 9.2  | VOC content                       | Added    |
| 9.2  | Sublimation point                 | Added    |
| 9.2  | Specific conductivity             | Added    |
| 9.2  | Fat solubility                    | Added    |
| 9.2  | Softening point                   | Added    |
| 9.2  | Saturation concentration          | Added    |
| 9.2  | SADT                              | Added    |
| 9.2  | Miscibility                       | Added    |
| 11.1 | Reason for no classification      | Added    |
| 11.1 | Reason for no classification      | Added    |
| 11.1 | Reason for no classification      | Added    |
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| 11.1 | Reason for no classification      | Added    |
| 11.1 | IARC group                        | Added    |
| 12.3 | Log Kow                           | Added    |
| 13.1 | Sewage disposal recommendations   | Added    |
| 13.1 | European List of Waste (LoW) code | Added    |
| 14.1 | UN-No. (ADR)                      | Added    |
| 14.1 | UN-No. (IMDG)                     | Added    |
| 14.1 | UN-No. (IATA)                     | Added    |
| 15.1 | VOC content                       | Added    |
| 15.1 | Regulatory reference              | Added    |
| 15.2 | Chemical safety assessment        | Modified |
| 16   | Notes                             | Added    |
| 16   | Training advice                   | Added    |
| 16   | Abbreviations and acronyms        | Modified |

## Abbreviations and acronyms:

|      |   |
|------|---|
| #    | Estimated or calculated values.   |
| &    | Exempt under REACH for Active Ingredients, <1000 kg, natural substances...          |
| *    | Transmission of information in the supply chain.                                    |
| ADR  | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| CLP  | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008         |
| IATA | International Air Transport Association   |
| IMDG | International Maritime Dangerous Goods  |
| Lit  | Bibliography  |
| vPvB | Very Persistent and Very Bioaccumulative  |



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## Cimetidine

|                 |   |
|-----------------|---|
| PBT             | Persistent Bioaccumulative Toxic  |
| REACH           | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006   |
| SDS             | Safety Data Sheet   |
| Data sources    | : REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. |
| Training advice | : Training staff on good practice.  |
| Notes           | : THIS DOCUMENT HAS BEEN AUTOMATICALLY APPROVED, SO IT IS NOT SIGNED.   |

### Full text of H- and EUH-statements:

|         |                                   |
|---------|-----------------------------------|
| Carc. 2 | Carcinogenicity, Category 2       |
| Repr. 2 | Reproductive toxicity, Category 2 |
| H351    | Suspected of causing cancer       |
| H361f   | Suspected of damaging fertility.  |

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