

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

- **Product identifier**
- **Trade name:** 5-(3,3-Dimethyl-1-triazenyl)imidazole-4-carboxamide; "Dacarbazine"
- **Article number:** 89730025
- **CAS Number:**  
4342-03-4
- **EC number:**  
224-396-1
- **Relevant identified uses of the substance or mixture and uses advised against**
- **Application of the substance / the preparation** Active pharmaceutical ingredients
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**  
Heraeus Precious Metals GmbH & Co. KG  
Chemicals Division - Pharmaceutical Ingredients  
Heraeusstr. 12-14, D-63450 Hanau  
Germany/ Deutschland
- **Further information obtainable from:**  
Herr Dr. Friedrich Wissmann  
Phone: +49 6181 35-4303  
mobile: +49 151 12543294  
Fax: +49 6181 35-4302  
E-Mail: [friedrich.wissmann@heraeus.de](mailto:friedrich.wissmann@heraeus.de)
- **Emergency telephone number:** Tel: +49 151 12543294

## 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**
  - Muta. 1B H340 May cause genetic defects.
  - Carc. 1A H350 May cause cancer.
  - Repr. 2 H361d Suspected of damaging the unborn child.
  - Acute Tox. 4 H302 Harmful if swallowed.
  - Acute Tox. 4 H312 Harmful in contact with skin.
  - Acute Tox. 4 H332 Harmful if inhaled.
  - Skin Irrit. 2 H315 Causes skin irritation.
  - Eye Irrit. 2 H319 Causes serious eye irritation.
  - STOT SE 3 H335 May cause respiratory irritation.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC**
  - T; Toxic
  - R45-46: May cause cancer. May cause heritable genetic damage.
  - Xn; Harmful
  - R20/21/22-63: Harmful by inhalation, in contact with skin and if swallowed. Possible risk of harm to the unborn child.
  - Xi; Irritant
  - R36/37/38: Irritating to eyes, respiratory system and skin.
- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The substance is classified and labelled according to the CLP regulation.

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· **Hazard pictograms**



GHS07 GHS08

· **Signal word** *Danger*

· **Hazard statements**

*Harmful if swallowed.*

*Harmful in contact with skin.*

*Harmful if inhaled.*

*Causes skin irritation.*

*Causes serious eye irritation.*

*May cause genetic defects.*

*May cause cancer.*

*Suspected of damaging the unborn child.*

*May cause respiratory irritation.*

*Restricted to professional users.*

· **Precautionary statements**

*Obtain special instructions before use.*

*Wear protective gloves/protective clothing/eye protection/face protection.*

*Do not get in eyes, on skin, or on clothing.*

*Do no eat, drink or smoke when using this product.*

*Dispose of contents/container in accordance with local/regional/national/international regulations.*

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** *Not applicable.*

· **vPvB:** *Not applicable.*

### 3 Composition/information on ingredients

· **Chemical characterization: Substances**

· **CAS No. Description**

4342-03-4 Dacarbazine

· **Identification number(s)**

· **EC number:** 224-396-1

### 4 First aid measures

· **Description of first aid measures**

· **General information:** *In case of accident or if you feel unwell, seek medical advice immediately.*

· **After inhalation:** *Supply fresh air and to be sure call for a doctor.*

· **After skin contact:**

*Immediately wash with water and soap and rinse thoroughly.*

*Immediately remove all soiled and contaminated clothing*

· **After eye contact:** *Rinse opened eye for several minutes under running water. Then consult a doctor.*

· **After swallowing:**

*Rinse mouth with water.*

*Call for a doctor immediately.*

· **Information for doctor:**

· **Most important symptoms and effects, both acute and delayed** *No further relevant information available.*

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· **Indication of any immediate medical attention and special treatment needed** Cytostatic drug

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## 5 Firefighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
*CO<sub>2</sub>, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.*
- **For safety reasons unsuitable extinguishing agents:** *Water with full jet*
- **Special hazards arising from the substance or mixture**  
*Formation of toxic gases is possible during heating or in case of fire.*  
*Carbon monoxide (CO)*  
*Nitrogen oxides (NO<sub>x</sub>)*
- **Advice for firefighters**
- **Protective equipment:**  
*Wear self-contained respiratory protective device.*  
*Wear fully protective suit.*

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
*Wear protective equipment. Keep unprotected persons away.*  
*Avoid formation of dust.*  
*Use respiratory protective device against the effects of fumes/dust/aerosol.*  
*Avoid contact with substance.*
- **Environmental precautions:**  
*Do not allow to enter sewers/ surface or ground water.*  
*Do not allow to penetrate the ground/soil.*
- **Methods and material for containment and cleaning up:**  
*Dispose contaminated material as waste according to item 13.*
- **Reference to other sections**  
*See Section 7 for information on safe handling.*  
*See Section 8 for information on personal protection equipment.*  
*See Section 13 for disposal information.*

## 7 Handling and storage

- **Handling:**
- **Precautions for safe handling**  
*Wear protective equipment. Keep unprotected persons away.*  
*Work only in fume cupboard.*  
*Open and handle receptacle with care.*  
*Prevent formation of dust.*  
*Store under lock and key and with access restricted to technical experts or their assistants only.*
- **Information about fire - and explosion protection:** *see chapter 5*
- **Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
*Store in a cool location.*  
*Store in dry conditions.*
- **Information about storage in one common storage facility:**  
*Store away from flammable substances.*

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- Store away from foodstuffs.
- **Further information about storage conditions:**
  - Keep container tightly sealed.
  - Protect from exposure to the light.
  - **Recommended storage temperature:** < 5 °C
  - **Specific end use(s)** No further relevant information available.

## 8 Exposure controls/personal protection

- **Additional information about design of technical facilities:**
  - No further data; see item 7.
  - Waste air is to be released into the atmosphere only via suitable separators.
- **Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
  - Work only in fume cupboard.
  - Keep away from foodstuffs, beverages and feed.
  - Immediately remove all soiled and contaminated clothing
  - Wash hands before breaks and at the end of work.
  - Store protective clothing separately.
  - Avoid contact with the eyes and skin.
  - Do not inhale dust / smoke / mist.
- **Respiratory protection:**
  - If dust or aerosol is present use respiratory protection filter P3 (push on filter EN 143 or screwed filter EN 149).
- **Protection of hands:**
  - Impervious gloves
  - Long cuffed gloves
- **Penetration time of glove material**
  - The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.
- **For the permanent contact gloves made of the following materials are suitable:** Natural rubber, NR
- **Eye protection:**



Tightly sealed goggles

- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Solid
<b>Colour:</b>	Yellow
	Green

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· <b>Odour:</b>	Odourless
· <b>Change in condition</b> Melting point/Melting range: 212-215°C Boiling point/Boiling range: Undetermined.	
· <b>Flash point:</b>	Not applicable.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Vapour pressure:</b>	Undetermined.
· <b>Density:</b> Bulk density at 20°C:	650 kg/m <sup>3</sup>
· <b>Solubility in / Miscibility with water:</b>	Slightly soluble.
· <b>Other information</b>	No further relevant information available.

## 10 Stability and reactivity

- **Reactivity**
- **Chemical stability**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used according to specifications.  
Explosive thermal decomposition.  
T > 250 °C
- **Possibility of hazardous reactions** No dangerous reactions known.
- **Conditions to avoid** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** Nitrogen oxides (NOx)

## 11 Toxicological information

- **Information on toxicological effects**
- **Acute toxicity:**

· **LD/LC50 values relevant for classification:**

4342-03-4 Dacarbazine

Oral	LD50	2032 mg/kg (mouse)
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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Additional toxicological information:**  
Carcinogenic.  
The product can cause deformations.  
The product can cause inheritable damage.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**  
Muta. 1B, Carc. 1A, Repr. 2

GB

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## 12 Ecological information

- **Toxicity**
- **Acquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behaviour in environmental systems:**
- **Bioaccumulative potential** No further relevant information available.
- **Mobility in soil** No further relevant information available.
- **Ecotoxicological effects:**
- **Remark:** No data available.
- **Additional ecological information:**
- **General notes:** Avoid transfer into the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No further relevant information available.

## 13 Disposal considerations


- **Waste treatment methods**
- **Recommendation**  
After prior treatment product has to be disposed of in an incinerator for hazardous waste adhering to the regulations pertaining to the disposal of particularly hazardous waste.

· **European waste catalogue**

18 01 08	cytotoxic and cytostatic medicines
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- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |   |   |
|---|---|
| · <b>UN-Number</b>  | 2811  |
| · <b>ADR, IMDG, IATA</b>  |   |
| · <b>UN proper shipping name</b>  | 2811 TOXIC SOLID, ORGANIC, N.O.S. (Dacarbazine) |
| · <b>ADR</b>  | TOXIC SOLID, ORGANIC, N.O.S. (Dacarbazine)      |
| · <b>IMDG, IATA</b>   |   |
| · <b>Transport hazard class(es)</b>   |   |
| · <b>ADR</b>  |   |
|  |   |
| · <b>Class</b>  | 6.1 Toxic substances.                           |
| · <b>Label</b>  | 6.1   |

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· **IMDG, IATA**

· **Class** 6.1 Toxic substances.  
 · **Label** 6.1

· **Packing group**  
 · **ADR, IMDG, IATA** III

· **Special precautions for user** Warning: Toxic substances.  
 · **Danger code (Kemler):** 60  
 · **EMS Number:** F-A,S-A

· **Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

· **Transport/Additional information:**· **ADR**

· **Tunnel restriction code** E

· **UN "Model Regulation":** UN2811, TOXIC SOLID, ORGANIC, N.O.S., 6.1, III

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **National regulations:**
- **Information about limitation of use:**  
 Employment restrictions concerning juveniles must be observed.  
 Employment restrictions concerning pregnant and lactating women must be observed.

**16 Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Department issuing MSDS: HH-US**· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

CAS: Chemical Abstracts Service (division of the American Chemical Society)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

- **\* Data compared to the previous version altered.**