# usp

# SAFETY DATA SHEET

# 1. Identification

Product identifier Dacarbazine

Other means of identification

Catalog number 1162308 CAS number 4342-03-4

**Chemical name** 5-(3,3-Dimethyltriaz-1-enyl)-1H-imidazole-4-carboxamide

**Recommended use** For analytical laboratory use only.

**Recommended restrictions** Not for use as a drug. Not for administration to humans or animals.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

**Company name**U. S. Pharmacopeia **Address**12601 Twinbrook Parkway

Rockville MD 20852-1790

United States

**Telephone** Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

# 2. Hazard(s) identification

Physical hazards Not classified.

**Health hazards** Skin corrosion/irritation Category 2

Serious eye damage/eye irritation Category 2A
Germ cell mutagenicity Category 1B
Carcinogenicity Category 2
Reproductive toxicity Category 1

Specific target organ toxicity, repeated Category 1 (bone marrow)

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Danger

Hazard statement Causes skin irritation. Causes serious eye irritation. May cause genetic defects. Suspected of

causing cancer. May damage fertility or the unborn child. Causes damage to organs (bone

marrow) through prolonged or repeated exposure.

Precautionary statement

**Prevention** Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after

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

Material name: Dacarbazine USP SDS US

If on skin: Wash with plenty of water, If skin irritation occurs; Get medical advice/attention, Take Response

off contaminated clothing and wash before reuse. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention. If exposed or concerned: Get medical

advice/attention.

Storage Store locked up.

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

Hazard(s) not otherwise classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

# 3. Composition/information on ingredients

#### **Substance**

Chemical name	Common name and synonyms	CAS number	%
Dacarbazine		4342-03-4	100

## 4. First-aid measures

If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. Inhalation

Call a physician if symptoms develop or persist.

Remove contaminated clothing. Wash with plenty of soap and water. Get medical attention if Skin contact

irritation develops and persists. Wash contaminated clothing before reuse.

Eye contact Rinse with water. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical

attention if irritation develops and persists.

Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately. Ingestion

**Most important** 

Bone marrow depression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects. symptoms/effects, acute and

delaved

Indication of immediate

medical attention and special treatment needed

Provide general supportive measures and treat symptomatically.

**General information** 

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

### 5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

the chemical

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters Wear suitable protective equipment.

Fire fighting

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Specific methods Use standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

## 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal

protection, see section 8 of the SDS.

Methods and materials for containment and cleaning up Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination. For waste disposal, see section 13 of the SDS.

**Environmental precautions** Avoid discharge into drains, water courses or onto the ground.

Material name: Dacarbazine USP SDS US

## 7. Handling and storage

Precautions for safe handling

As a general rule, when handling USP materials, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage. including any incompatibilities Store in tight container. This material should be handled and stored per label instructions to ensure product integrity.

## 8. Exposure controls/personal protection

#### Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

#### **Exposure limit values**

**Industrial Use** 

Material	Туре	Value
Dacarbazine (CAS	TWA	0.9 micrograms/m3
4342-03-4)		

**Biological limit values** 

No biological exposure limits noted for the ingredient(s).

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.

#### Individual protection measures, such as personal protective equipment

Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Eye/face protection

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When **Hand protection** 

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Train employees in proper gowning and degowning practices. Wear disposable lab coat. Other

> disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head Respiratory protection

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Wear appropriate thermal protective clothing, when necessary. Thermal hazards

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS

are recommendations for laboratory use of USP materials.

# 9. Physical and chemical properties

Appearance descriptions are general information and not specific to any USP lot. **Appearance** 

Physical state Solid. **Form** Powder.

Off-white. White. Color

Odorless. Odor **Odor threshold** Not available. Not available. Melting point/freezing point 401 °F (205 °C) Initial boiling point and boiling Not available.

range

Not available. Flash point Not available. **Evaporation rate** Flammability (solid, gas) Not available.

Material name: Dacarbazine USP SDS US Upper/lower flammability or explosive limits

Flammability limit - lower Not available.

(%)

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

**Vapor pressure** < 0.0000001 kPa (77 °F (25 °C))

Vapor densityNot available.Relative densityNot available.

Solubility(ies)

Solubility (water) Slightly soluble.

**Solubility (other)** Methylene chloride: Slightly soluble.

0.24

Ethanol: Slightly soluble.

Partition coefficient

(n-octanol/water)

-0.24

Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical familyImidazole.Molecular formulaC6-H10-N6-OMolecular weight182.18

# 10. Stability and reactivity

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

Chemical stability Stable at normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents.

Hazardous decomposition

products

Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. NOx.

### 11. Toxicological information

Information on likely routes of exposure

**Inhalation** Knowledge about health hazard is incomplete.

**Skin contact** Causes skin irritation.

**Eye contact** Causes serious eye irritation.

**Ingestion** Knowledge about health hazard is incomplete.

Symptoms related to the physical, chemical and toxicological characteristics

Alkylating antineoplastics: Gastrointestinal disturbances. Hair loss. Central nervous system

depression. Loss of appetite. Mouth sores.

Information on toxicological effects

**Acute toxicity** 

irritation

Product Species Test Results

Dacarbazine (CAS 4342-03-4)

Oral

LD50 Rat 2147 mg/kg

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye Causes serious eye irritation.

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## Respiratory or skin sensitization

Respiratory sensitization Knowledge about health hazard is incomplete. Knowledge about health hazard is incomplete. Skin sensitization

Germ cell mutagenicity

May cause genetic defects.

Alkylating antineoplastic agents have been shown to increase genotoxic effects in both

occupational and therapeutic exposures.

Mutagenicity

Dominant lethal test Result: Positive. Species: Rodent

Mouse heritable translocation assav

Result: Positive.

Carcinogenicity

Suspected of causing cancer.

Secondary malignancies are potential delayed effects of alkylating antineoplastic agents. Risk seems to increase with long-term use. There is no clear indication whether the effect is related to

their mutagenic potential or immunosuppressive action.

Carcinogenicity

Result: Intraperitoneal injection caused uterine tumors in females, lymphoma and blood-vessel tumors (hemangioma in

the spleen) in males, and lung tumors in both sexes.

Species: Mouse Carcinogenicity

Result: Tumors occured as soon as 18 weeks after dietary

exposure began: In males and females, mammary

adenocarcinomas and thymic and splenic lymphosarcomas were induced; cerebral ependymomas and pulmonary alveolar

carcinomas were also induced in female rats.

Species: Rat Carcinogenicity

Result: Tumors were induced by prenatal exposure, predominantly cancer of the peripheral nerves (malignant

neurinoma). Species: Rat

IARC Monographs. Overall Evaluation of Carcinogenicity

Dacarbazine (CAS 4342-03-4)

2B Possibly carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

### **US. National Toxicology Program (NTP) Report on Carcinogens**

Dacarbazine (CAS 4342-03-4)

Reasonably Anticipated to be a Human Carcinogen.

Reproductive toxicity

May damage fertility or the unborn child.

Alkylating antineoplastic agents have been associated with severe birth defects when administered to mothers during pregnancy. Adverse fertility effects have been observed during therapy treatment in males and females. The effects appear to be dose related and length of therapy and

may be irreversible.

# Reproductivity

10 mg/kg/day Reproductivity: pregnant rabbits Result: Produced abortions and increased major

malformations.

30 mg/kg/day Reproductivity: pregnant rats, administered by

intraperitoneal injection throughout organogenesis Result: Increased resorptions, decreased litter sizes, and

increased skeletal anomalies; increased major malformations

at maternal dose levels of 50 and 70 mg/kg/day.

400 mg/kg Reproductivity: pregnant rats, administered in a

single dose on day 11 or 12 of gestation

Result: Increased incidence of congenital anomalies.

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

Causes damage to organs (bone marrow) through prolonged or repeated exposure.

repeated exposure **Aspiration hazard** 

Based on available data, the classification criteria are not met.

**Chronic effects** 

Causes damage to organs through prolonged or repeated exposure.

Material name: Dacarbazine USP SDS US Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

**Ecotoxicity**The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this substance.

Bioaccumulative potential

Octanol/water partition coefficient log Kow

0.24 -0.24

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

**Disposal instructions**Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

**Local disposal regulations** Dispose in accordance with all applicable regulations.

**Hazardous waste code**The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Contaminated packaging Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

## 14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to

Annex II of MARPOL 73/78 and

the IBC Code

General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

Not applicable.

15. Regulatory information

US federal regulations This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication

Standard, 29 CFR 1910.1200.

**Toxic Substances Control Act (TSCA)** 

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

**CERCLA Hazardous Substance List (40 CFR 302.4)** 

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous Yes

chemical

Material name: Dacarbazine USP SDS US

Classified hazard

Skin corrosion or irritation

categories Serious eye damage or eye irritation

Germ cell mutagenicity Carcinogenicity Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

#### SARA 313 (TRI reporting)

Not regulated.

#### Other federal regulations

### Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

#### Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

Not regulated.

(SDWA)

# **US state regulations**

## **California Proposition 65**



WARNING: This product can expose you to Dacarbazine, which is known to the State of California to cause

cancer and birth defects or other reproductive harm. For more information go

to www.P65Warnings.ca.gov.

#### California Proposition 65 - CRT: Listed date/Carcinogenic substance

Dacarbazine (CAS 4342-03-4) Listed: January 1, 1988

### California Proposition 65 - CRT: Listed date/Developmental toxin

Inventory name

Dacarbazine (CAS 4342-03-4) Listed: January 29, 1999

# International Inventories

Australia

Taiwan

Country(s) or region

Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Australian Inventory of Chemical Substances (AICS)

\*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

Taiwan Chemical Substance Inventory (TCSI)

Toxic Substances Control Act (TSCA) Inventory

## 16. Other information, including date of preparation or last revision

 Issue date
 02-28-2008

 Revision date
 11-16-2021

Version # 03

United States & Puerto Rico

Material name: Dacarbazine usp sps us

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On inventory (yes/no)\*

Yes

Yes

No

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

#### **Disclaimer**

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