

Safety Data Sheet (GHS)

according to Regulation (EC) No.1907/2006

Date of issue: 20-MAY-2021

Replaces version of:

GEMCITABINE HCL 5004607 (BASIS)



Section 1: Identification of the substance/preparation and of the company

1.1 Product identifier

Product name GEMCITABINE HCL
Chemical Name GEMCITABINE HYDROCHLORIDE
CAS Number 122111-03-9

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

Usage Pharmaceutical active ingredient

1.3 Details of the supplier of the Safety Data Sheet

Company name Novartis Pharma AG
4002 Basel
Switzerland
Tel: +41 61 324 11 11, email: sds.support@novartis.com

1.4 Emergency telephone number

Emergency phone number CHEMTEL (International) +1 813 676 1670 (365/24/7)

Section 2: Hazards identification

2.1 Classification of the substance or mixture

GHS hazard category

Germ cell mutation: Cat.1B

Reproductive toxicity: Cat.1B

New product without data: Preliminary data

2.2 Label elements

GHS-Label Self assessment according REGULATION (EC) No 1272/2008



Danger

Hazard statements H340: May cause genetic defects.

H360: May damage fertility or the unborn child.

P: Caution: Handle with care - product not fully tested!

Precautionary statements P308/313: IF exposed or concerned: Get medical advice/attention.

2.3 Other hazards

Specific hazards None known

Section 3: Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Type Substance
Chemical Name GEMCITABINE HYDROCHLORIDE
CAS Number 122111-03-9
Content: = 100 %

For TLV values of declared components, see Section 8, Exposure controls / Personal

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Full text of H-Phrases see under Section 16



Section 4: First aid measures

4.1 Description of first aid measures

Inhalation	After inhalation move to fresh air. If shortness of breath occurs, support respiration and consult a physician.
	Bring patient immediately to fresh air. If breathing is heavily give oxygen; if necessary resuscitate artificially. Call physician.
	Consult a physician if irritating symptoms develop and persist.
Skin Contact	Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.
Eye Contact	Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).
Ingestion	Do not induce vomiting. In case of consciousness wash mouth with water and let drink some of water. Seek medical advice. Keep patient at rest. If swallowed, seek medical advice immediately and show this container or label.

Self-protection of the first aider

For personal protection see Section 8

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indication of any immediate medical attention and special treatment needed

Notes to Physician Apply general supportive and symptomatic treatment.

Section 5: Fire fighting measures

5.1. Extinguishing media

Suitable Extinguishing Media Water spray or fog, foam, dry chemical powder, CO₂, dry sand

Unsuitable Extinguishing Media No restrictions

5.2 Special hazards arising from the substance or mixture

5.3. Advice for firefighters

Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suit.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions Avoid contact with skin, eyes and clothing.

6.2 Environmental precautions

Environmental precautions Must not be released into sewers, drains or wells.

6.3 Methods and material for containment and cleaning up

Methods for cleaning Transfer large quantities into a container, rinse the rest with plenty of water.

6.4 Reference to other sections

For personal protection see Section 8, for disposal considerations see Section 13

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Section 7: Handling and storage

7.1. Precautions for safe handling

Storage and Handling Precautions Open handling without suitable personal protective equipment must be avoided. Keep container tightly closed in a dry, cool and well-ventilated place. Ensure efficient exhaust ventilation when using this product

For Industrial Hygiene Measures see Section 8, Exposure controls / Personal protection

7.2 Conditions for safe storage, including any incompatibilities

Technical measures/ Precautions Handle product only in closed system or provide appropriate exhaust ventilation at machinery.

Preventive Precautions (fire/explosion) Take precautionary measures against static discharges. Avoid formation of dust. Keep away from sources of ignition. Observe the usual precautionary measures required for chemicals with dust explosive properties (Observe national regulations).

7.3 Specific end use(s)

See Subsection 1.2

Section 8: Exposure controls / Personal protection

8.1 Control parameters

List type	Value	Unit
Occupational Exposure Limit (OEL)	1	µg/m3

8.2 Exposure controls

Industrial Hygiene	The personal protective measure may be adapted appropriately when working in closed systems or under laboratory conditions.		
	Regular cleaning of equipment, work area and clothing.		
	No open handling without using reliable equipment. One technical barrier between substance and employee resp. environment.		
	Restricted and controlled access for trained personnel only.		
	Designated washing, changing and shower facilities must be available.		
	Internal working procedures available to personnel covering personal hygiene, decontamination /cleaning, consideration of worst case incidents, spills, emergency, alarms, waste disposal and maintenance.		
	Personnel comprehensively instructed, highly trained and experienced. Regular refresher training established including appropriate record keeping.		
	Equipment and protective garments must either be decontaminated or properly contained for disposal before leaving the area.		
	Disposable protective equipment is to be decontaminated before removal (decontamination shower).		
Open Handling	Respiration	: If the Breathing Zone sampling results exceed the established occupational exposure limit (OEL) or the minimum concentration defined by the occupational hazard band, use respiratory protection with sufficient protection factor to ensure exposure is below the exposure limit. Unless the exposure results indicate the requirement for an air supplied device, use HEPA filters for powders or aerosols and cartridge or canister filters for vapors and gases.	
	Filter	: P3 (EN143)	
	Eye	: Yes, by face mask	
	Hand	: Normal length chemical-mechanical-resistant gloves (EN374/EN388) worn over disposable gloves	
	Glove Material	: Nitrile Breakthrough time: 240 min Thickness: 0.4 mm	
	Additional protection	: Disposable dust-proof suit (EN465, type 4) worn over long underwear	

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Disposable boot covers, conductive

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the officially tested permeation time.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Formulation	powder
Odour	no data available
Odour threshold	no data available
pH	not available
Melting point/range	no data available
Boiling Point	no data available
Flash Point	not applicable
Evaporation Rate (Ref: Ether)	not applicable
Combustibility Test	no data available
Explosion Limits	not applicable
Vapour Pressure [hPa]	not applicable
Vapour Density	not applicable
Density	no data available
Solubility (Aqueous Solvents)	no data available
Solubility (Solvents)	no data available
Partition Coefficient	no data available
Autoignition/MIT	no data available
Dynamic Decomposition	no data available
Isoperibolic Decomposition (>8h)	no data available
Viscosity	not applicable
Explosivity/Reactivity	no data available
Test for self-heating	no data available
Fire-promoting properties	no data available

9.2 Other information

Dust Explosion	no data available
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Section 10: Stability and reactivity

10.1 Reactivity

Reaction products with water None known

10.2 Chemical stability

Hydrolysis : no data available

10.3 Possibility of hazardous reactions

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Materials to avoid	strong acids strong bases
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10.4 Conditions to avoid

Conditions to avoid	Stable at normal conditions
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10.5 Incompatible materials

For Incompatible materials see Subsection 7.2 Conditions for safe storage, including any incompatibilities

10.6 Hazardous decomposition products

Hazardous Decomposition Products	None, when used and handled as intended.
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Section 11: Toxicological information

11.1 Information on toxicological effects

Acute Toxicity	LD50: = 236 mg/kg Route: intravenous Species: rat LD50: > 24 mg/kg Route: intravenous Species: dog LD50: > 500 mg/kg Route: oral Species: rat
Irritation, Corrosion	no data available
Sensitisation	no data available
Mutagenicity	Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitroCell: Strains of <i>Salmonella typhimurium</i> and <i>Escherichia coli</i> . Negative (Unscheduled DNA Synthesis) in vitroCell: Liver cells Positive with and without metabolic activation (Mouse Lymphoma Mutagenicity Assay in vitro) in vitroCell: Lymphoma cells L5178Y of the mouse Negative (Sister Chromatid Exchange) in vivo, Species: chinese hamster, Cell: Bone marrow Positive (Chromosome Aberration Study) in vivo, Species: mouse, Cell: Bone marrow Positive (Micronucleus Test) in vivo, Species: mouse, Cell: Bone marrow
Chronic Effects	Moderate toxicity - reversible (Repeated Dose Toxicity (chronic Toxicity)) LOAEL: = 0.06 mg/kg/d Route: intraperitoneal Species: mouse, Organ: Multiple organs Duration: = 6 months Moderate toxicity - reversible (Repeated Dose Toxicity (chronic Toxicity)) LOAEL: = 3 mg/kg/w Route: intravenous Species: dog, Organ: Blood, bone marrow Duration: = 6 months Moderate toxicity - reversible (Repeated Dose Toxicity (chronic Toxicity)) LOAEL: = 0.04 mg/kg/d Route: intravenous Species: dog, Organ: Blood, bone marrow Duration: = 6 months

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Reproduction Toxicity Male fertility decreased (Fertility and early Embryonic Development)

LOAEL: = 0.5 mg/kg/d

Route: intraperitoneal

Species: mouse, Sex: male

Effect on embryo-fetal development (Fertility and early Embryonic Development)

LOAEL: = 0.25 mg/kg/d

Route: intravenous

Species: mouse, Sex: female

Teratogenicity was found (Embryo-Fetal Development)

NOAEL: = 0.005 mg/kg/d

Route: intravenous

Species: rabbit, Sex: female

Peri-Postnatal developmental effects (Peri- and Postnatal Development)

LOAEL: = 1.5 mg/kg/d

Route: intravenous

Species: mouse

Section 12: Ecological information

12.1 Toxicity

Fish acute toxicity no data available

Aquatic invertebrate acute toxicity no data available

Algae Toxicity no data available

Bacterial Respiration Inhibition no data available

12.2 Persistence and degradability

Biological Elimination no data available

12.3 Bioaccumulative potential

Partition Coefficient no data available

Biological accumulation no data available

12.4 Mobility in soil

Soil and Sludge Sorption/Desorption no data available

12.5 Results of PBT and vPvB assessment

PBT assessment no data available

12.6 Other adverse effects

Other adverse effects no data available

12.7 Additional information

no data available

Section 13: Disposal considerations

13.1. Waste treatment methods

Disposal Requirements Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control.

Container Disposal For disposal local regulation is binding.

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Section 14: Transport information

Regulation	RID/ADR:	IMDG-Code:	ICAO/IATA-DGR:
14.1 UN Number	3249	3249	3249
14.2 UN Proper Shipping Name	Medicine, solid, toxic, n.o.s.	Medicine, solid, toxic, n.o.s.	Medicine, solid, toxic, n.o.s.
14.3 Transport Hazard Class(es)	6.1 / T2	6.1	6.1
Transport Label(s)			
14.4 Packing Group	III	III	III
14.5 Environmental Hazard			
Additional Information	Special Provision(s): 221,601 Limited Quantities: 5 kg Excepted Quantities: max. quantity per: inner packaging 30g/30ml - outer packaging 1kg/1L ADR Tank Tankcode: SGAH,L4BH Tunnel Code: E Hazard Identification Number (Orange Panel Number): 60	Special Provision(s): 221 223 Limited Quantities: 5 kg EMS number: F-A,S-A	Passenger/Cargo aircraft info.: 670 100 kg Passenger/Cargo aircraft LQ info.: Y645 10 kg Cargo aircraft only: 677 200 kg

14.6 Special Precaution for User

Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

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

not applicable

Temperature
Conditions for
Transport

Section 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

List type	Comment
Swiss Chemical Ordinance (ChemO)	Anhang 5 - Gruppe 1 Anhang 5 - Gruppe 2

Emergency Regulations List type: Emergency Regulations (CH)
Lower: 20 kg (2021-MAY-20)
Highly active substance
List type: Seveso III - Health Hazard
Lower: 5 t (2017-AUG-23)
Upper: 20 t
Default value, evaluation not possible (ACUTE TOXIC Category 1, all exposure routes)
List type: Seveso III - No threshold required (2021-MAY-20)
Self Classification (Not a reportable chemical according to Seveso III directive)

15.2 Chemical Safety Assessment

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Chemical Safety Assessment not required.



Section 16: Other information

Abbreviations used

Recipient HDS Chile Wilson González
NVTS
SCM

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.