

SAFETY DATA SHEET

Date of preparation: 15.10.2009

Revision date: 27.09.2015

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

1.1. Product identifier

Cytarabine Injection BP 100 mg/ml, 1 ml, 5 ml, 10 ml and 20 ml.

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

Cytotoxic. For induction of remission in acute myeloid leukaemia in adults and for other acute leukaemias of adults and children.

1.3. Details of the supplier of the safety data sheet

MANUFACTURER:

Accord Healthcare Limited
Sage House 319, Pinner Road,
North Harrow, Middlesex,
HA1 4HF, United Kingdom
phone: +44 (0)208 863 1427
fax: +44 (0)208 863 1426
between: 9 am to 17:30 pm
e-mail: skadaru@accord-healthcare.com

1.4. Emergency telephone number

Emergency telephone number: +442089013370

SECTION 2: Hazards identification



2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP):
Carc. 2, H351

Repr 2, H361d
Skin Sens 1, H317
Eye Irrit. 2, H319
Skin Irrit. 2, H315

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP):

 	<p>Contains Cytarabine (4-Amino-1-β-D-arabinofuranosyl-1H-pyrimidin-2-one).</p> <p>Signal word: Warning</p> <p>Hazard statement(s): H351 - Suspected of causing cancer. H361d - Suspected of damaging the unborn child. H317 - May cause an allergic skin reaction. H319 - Causes serious eye irritation. H315 - Causes skin irritation.</p> <p>Precautionary statement(s): P201 Obtain special instructions before use. P280 Wear protective gloves/protective clothing/eye protection/face protection. P308+P313 IF exposed or concerned: Get medical advice/attention. P302+P352 IF ON SKIN: Wash with plenty of soap and water. P333 + P313 If skin irritation or rash occurs: Get medical advice. P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. P405 Store locked up.</p>
--	--

2.3. Other hazards

This mixture do not meet the criteria for PBT and vPvB.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Cytarabine (4-Amino-1-β-D-arabinofuranosyl-1H-pyrimidin-2-one)	Contains: 10%
CAS number:	147-94-4
EC number:	205-705-9
Index number:	-
Registration number:	Not applicable.
Classification according to Regulation (EC) No 1272/2008 (CLP):	
Carc. 2, H351	
Skin Sens. 1, H317	
Repr. 2, H361d	
Eye Irrit. 2, H319	
Skin Irrit. 2, H315	
STOT SE 3, H335	

The full text of H code(s) is given in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

After inhalation: IF INHALED : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or Doctor/physician.

After contamination of eyes: 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.

After consumption: IF SWALLOWED : Immediately call a POISON CENTER or Doctor/physician. Rinse mouth.

After skin contamination: IF ON SKIN: Wash with plenty of soap and water. Call a POISON CENTER or doctor/physician if you feel unwell. Remove/Take off immediately all contaminated clothing. Wash contaminated clothing before reuse.

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

No data available.

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

Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians' Desk Reference for additional treatment information.

SECTION 5: Firefighting measures

5.1. Extinguishing media

As with any fire, use extinguishing media appropriate for primary cause of fire.
Not recommended extinguishing media: no data available.

5.2. Special hazards arising from the substance or mixture

There is no data about hazardous substances which may occur during fire thermal decomposition of the mixture.

5.3. Advice for firefighters

Firefighters should wear self-contained breathing apparatus to avoid inhalation of smoke. Use caution when approaching fire. Use water to keep containers cool, which are exposed to fire.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Avoid contamination with the product.
Notify the effected individuals of the emergency, to be aware of the issues associated.
Avoid contact of the mixture with skin and eyes.
Remove contaminated clothing and wash before reuse.

6.1.2. For emergency responders

For small releases of this product, wear latex or nitrile gloves and safety glasses.

6.2. Environmental precautions

Avoid entering the product into drains, surface water and groundwater, reservoirs and waterways.

6.3. Methods and material for containment and cleaning up

Put on suitable protective clothing and equipment as specified by site spill procedures. Isolate area around the spill. Absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS.
Refer to section 13 of this MSDS for adequate release measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8).

Cytarabine is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. There is no general agreement that all of the procedures recommended in the guidelines are necessary or appropriate. Consult your site hygienist or safety professional for your site requirements.

Avoid ingestion, inhalation, skin contact, and eye contact. When handling this product, precautions may include the use of a containment cabinet. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this material.

Persons with known hypersensitivity to cytarabine, or who may be immunocompromised. Women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this material.

Industrial hygiene:

Do not eat, drink, smoke or apply cosmetics while handling the product. Wash hands thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for antineoplastic agents. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label, the primary container label, or the product insert.

7.3. Specific end use(s)

No data available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Does not contain materials with occupational exposure limit values at workplace.

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Use with adequate ventilation. Follow standard medical product handling procedures. Wear appropriate chemical resistant gloves, safety goggles and other protective clothing to prevent contact with eyes and skin. Laboratory should be equipped with a safety shower and eye wash station. Avoid prolonged or repeated exposure. Do not breathe dust. Do not get in eyes, on skin or on clothing. Wash thoroughly after handling.

8.2.2. Individual protection measures, such as personal protective equipment

Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

a) Eye / Face protection:

Approved eye protection to safeguard against potential eye contact, irritation or injury is recommended. Depending on conditions of use, a face shield may be necessary.

b) skin protection:

- hand protection:

Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to oncolytic agents. Persons known to be allergic to latex rubber should select a nonlatex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

c) Respiratory protection:

If the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved airpurifying respirator with a HEPA cartridge (P100 or equivalent) is recommended. For large spills, the use of a self-contained breathing apparatus may be required. Personnel who wear respirators should be fit tested and approved for respirator use as required.

d) Thermal hazards:

Not applicable.

8.2.3. Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Appearance :- -The physical state : -Colour:	Clear and colorless sterile isotonic solution
b) Odour:	odourless
c) Odour threshold :	no data available
d) pH:	Between 7.0 and 9.5
e) Melting point/freezing point	no data available
f) Initial boiling point and boiling range	no data available

g) Flash point:	no data available
h) Evaporation rate:	no data available
i) Flammability (solid, gas)	no data available
j) Upper/lower flammability or explosive limits :	no data available
k) Vapour pressure :	no data available
l) Vapour density :	no data available
m) Relative density:	no data available
n) Solubility(ies)	Soluble in water. Slightly soluble in alcohol and chloroform
o) Partition coefficient: n-octanol/water	no data available
p) Auto-ignition temperature	no data available
q) Decomposition temperature:	no data available
r) Viscosity :	no data available
s) Explosive properties:	no data available
t) Oxidising properties :	no data available

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The product is stable when normal handling in accordance with conditions provided by the manufacturer.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The product is stable in conditions provided by the manufacturer.

10.5. Incompatible materials

No data available

10.6. Hazardous decomposition products

Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

No data for the mixture. Toxicological problems should not be expected if the product were used and applied appropriately. The product should be handled with the care usual when dealing with chemicals.

a) acute toxicity:

No data available.

b) irritation:

No data available.

c) corrosivity:

No data available.

d) sensitisation:

No data available.

e) repeated dose toxicity:

No data available.

f) carcinogenicity:

No data available.

g) mutagenicity:

No data available.

h) toxicity for reproduction:

No data available.

SECTION 12: Ecological information

12.1. Toxicity

No data for the mixture. Ecological problems should not be expected if you use and apply the product appropriately. The product should be handled with the care usual when dealing with chemicals.

Ecotoxicity: No data available.

Further ecological data:

Prevent disposal into water, sewage or soil.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

No data available.

12.6. Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product:

Chemical residues, in general, are included into special waste. Disposing of the latter is regulated by appropriate laws and ordinances. We recommend contacting the appropriate authorities, or waste disposal enterprises that will advise you on how to dispose of special waste.

Packing:

Remove in accordance with official regulations. Treat contaminated packages in the same way as the substance itself. If the regulations do not provide otherwise, non-contaminated packages can be treated like household waste or forward them to be utilized

SECTION 14: Transport information

14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****Material Safety Data Sheet was prepared in accordance with:**

Regulation (EC) No 1907/2006 of European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH);

Regulation (EC) No 1272/2008 of the European Parliament and 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.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the product.

SECTION 16: Other information**Full text of abbreviations and acronyms:**

Carc. 2 – Carcinogenicity (category 2)

Skin Sens. 1 - Skin sensitization (category 1)

Repr. 2 - Reproductive toxicity (category 2)
Eye Irrit. 2 – Serious eye irritation (category 2)
Skin Irrit. 2 - Skin irritation (category 2)
STOT SE 3 - Specific target organ toxicity — single exposure (category 3)

Text of H-code(s):

H351 - Suspected of causing cancer.
H361d - Suspected of damaging the unborn child.
H317 - May cause an allergic skin reaction.
H319 - Causes serious eye irritation.
H315 - Causes skin irritation.
H335 - May cause respiratory irritation.

Methods of evaluating information for the purpose of classification: calculation method.

The foregoing information is based on the present state of our knowledge. It characterizes the product with respect to the appropriate safety measures. They do not guarantee the properties of the product.

We do not take responsibility for damage and losses that may result from inappropriate use of the product.

Reason of changes:

Change of mixture classification according to Regulation (EC) No 1272/2008 (CLP).
Changing the MSDS in accordance with Annex II to Commission Regulation (EU) No 453/2010.