

# MATERIAL SAFETY DATA SHEET

Version No: MSDS/Aci-AUS/DP-001

Effective Date: 1<sup>st</sup> July 2020

## ACICLOVIR INJECTION, 25 mg/mL, 10 mL, 20 mL and 40 mL

### SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

**Product Name:** Aciclovir Injection, 25 mg/mL, 10 mL, 20 mL and 40 mL

<b>Intended Use:</b>	Pharmaceutical product used as antiviral
<b>Details of the Supplier of the Safety Data Sheet</b>	
<b>Manufacturer:</b> Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	<b>Sponsor:</b> Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia

### SECTION 2 – COMPOSITION, INFORMATION ON INGREDIENTS

#### Hazardous:

Active Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Acyclovir Sodium	69657-51-8	Not listed	Mut. Cat.3;R68 Repr. Cat.3;R62 Repr. Cat.3;R63	2.5

Inactive Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	**
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**
Water for injection	7732-18-5	231-791-2	Not Listed	*

**Additional Information:** \* Proprietary \*\* to adjust pH  
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

**For the full text of the R phrases mentioned in this Section, see Section 16**

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## SECTION 3 - HAZARDS IDENTIFICATION

**Appearance** : Clear, colorless to pale yellow solution.  
**Signal Word** : WARNING  
**Statement of Hazard** : Suspected of damaging fertility or the unborn child.  
Suspected of causing genetic defects.

### Additional Hazard Information

**Short Term** : Not acutely toxic (based on animal data).  
**Long Term** : Repeat-dose studies in animals have shown a potential to cause adverse effects on testes, the developing fetus

**Known Clinical Effects** : The most common adverse effects reported with clinical use were diarrhea, nausea, rash, and vomiting. Kidney dysfunction has been seen during clinical use.

**EU Indication of danger** : Toxic to Reproduction: Category 3  
Mutagenic: Category 3

**EU Hazard Symbols** :



**EU Risk Phrases** : R62 - Possible risk of impaired fertility.  
R63 - Possible risk of harm to the unborn child.  
R68 - Possible risk of irreversible effects.

**Australian Hazard Classification (NOHSC) Note** : Hazardous Substance. Non-Dangerous Goods.  
: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

## SECTION 4 - FIRST AID MEASURES

**Eye Contact:** Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

**Skin Contact:** Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention

**Ingestion:** Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

**Inhalation:** Remove to fresh air and keep patient at rest. Seek medical attention immediately.

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**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 3 – Hazards Identification and/or Section 11 - Toxicological Information

## SECTION 5 - FIRE FIGHTING MEASURES

**Extinguishing Media:** Use carbon dioxide, dry chemical, or water spray.

**Hazardous Combustion Products:** Formation of toxic gases is possible during heating or fire.

**Fire Fighting Procedures:** During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

**Fire / Explosion Hazards:** Not applicable

## SECTION 6 - ACCIDENTAL RELEASE MEASURES

**Health and Safety Precautions:** Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

**Measures for Cleaning / Collecting:** Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

**Measures for Environmental Protections:** Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

**Additional Consideration for Large Spills:** Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

## SECTION 7 - HANDLING AND STORAGE

**General Handling:** Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the

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atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

**Storage Conditions:** Store as directed by product packaging.

## SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

### Hydrochloric Acid:

<b>ACGIH Ceiling Threshold Limit</b>	: 2 ppm
<b>Australia PEAK</b>	: 5 ppm 7.5 mg/m <sup>3</sup>
<b>Austria OEL - MAKs</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Belgium OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Bulgaria OEL - TWA</b>	: 5 ppm 8.0 mg/m <sup>3</sup>
<b>Cyprus OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Czech Republic OEL - TWA</b>	: 8 mg/m <sup>3</sup>
<b>Estonia OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Germany - TRGS 900 - TWAs</b>	: 2 ppm 3 mg/m <sup>3</sup>
<b>Germany (DFG) - MAK</b>	: 2 ppm 3.0 mg/m <sup>3</sup>
<b>Greece OEL - TWA</b>	: 5 ppm 7 mg/m <sup>3</sup>
<b>Hungary OEL - TWA</b>	: 8 mg/m <sup>3</sup>
<b>Ireland OEL - TWAs</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Italy OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Japan - OELs - Ceilings</b>	: 2 ppm 3.0 mg/m <sup>3</sup>
<b>Latvia OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Lithuania OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Luxembourg OEL - TWA</b>	: 5 ppm 8 mg/m <sup>3</sup>
<b>Malta OEL - TWA</b>	: 5 ppm

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	8 mg/m <sup>3</sup>
<b>Netherlands OEL - TWA</b>	: 8 mg/m <sup>3</sup>
<b>Poland OEL - TWA</b>	: 5 mg/m <sup>3</sup>
<b>Portugal OEL - TWA</b>	: 5 ppm
	8 mg/m <sup>3</sup>
<b>Romania OEL - TWA</b>	: 5 ppm
	8 mg/m <sup>3</sup>
<b>Slovakia OEL - TWA</b>	: 5 ppm
	8.0 mg/m <sup>3</sup>
<b>Slovenia OEL - TWA</b>	: 5 ppm
	8 mg/m <sup>3</sup>
<b>Spain OEL - TWA</b>	: 5 ppm
	7.6 mg/m <sup>3</sup>
<b>Switzerland OEL -TWAs</b>	: 2 ppm
	3.0 mg/m <sup>3</sup>
<b>Vietnam OEL - TWAs</b>	: 5 mg/m <sup>3</sup>

## **Sodium hydroxide:**

<b>ACGIH Ceiling Threshold Limit</b>	: 2 mg/m <sup>3</sup>
<b>Australia PEAK</b>	: 2 mg/m <sup>3</sup>
<b>Austria OEL – MAKs</b>	: 2 mg/m <sup>3</sup>
<b>Bulgaria OEL – TWA</b>	: 2.0 mg/m <sup>3</sup>
<b>Czech Republic OEL – TWA</b>	: 1 mg/m <sup>3</sup>
<b>Estonia OEL – TWA</b>	: 1 mg/m <sup>3</sup>
<b>France OEL – TWA</b>	: 2 mg/m <sup>3</sup>
<b>Greece OEL – TWA</b>	: 2 mg/m <sup>3</sup>
<b>Hungary OEL – TWA</b>	: 2 mg/m <sup>3</sup>
<b>Japan - OELs – Ceilings</b>	: 2 mg/m <sup>3</sup>
<b>Latvia OEL – TWA</b>	: 0.5 mg/m <sup>3</sup>
<b>OSHA - Final PELs - TWAs</b>	: 2 mg/m <sup>3</sup>
<b>Poland OEL – TWA</b>	: 0.5 mg/m <sup>3</sup>
<b>Slovakia OEL – TWA</b>	: 2 mg/m <sup>3</sup>
<b>Slovenia OEL – TWA</b>	: 2 mg/m <sup>3</sup>
<b>Sweden OEL - TWAs</b>	: 1 mg/m <sup>3</sup>

**Engineering Controls:** Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes.

**Environmental Exposure Controls:** Refer to specific Member State legislation for requirements under Community environmental legislation.

**Personal Protective Equipment:** Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

**Hands:** Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

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**Eyes:** Wear safety glasses or goggles if eye contact is possible.

**Skin:** Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

**Respiratory protection:** Whenever excessive air contamination (dust, mist, vapor) is generated, respiratory protection, with appropriate protection factors, should be used to minimize exposure.

## SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

**Physical State:** Solution  
**Color:** Clear, colorless to pale yellow  
**Molecular Formula:** Mixture  
**Molecular Weight:** Mixture

## SECTION 10 - STABILITY AND REACTIVITY

**Chemical Stability:** Stable under normal conditions of use.  
**Conditions to Avoid:** None known.  
**Incompatible Materials:** As a precautionary measure, keep away from strong oxidizers

## SECTION 11 - TOXICOLOGY INFORMATION

**General Information:** The information included in this section describes the potential hazards of the individual ingredients.

### Acute Toxicity:

#### **Acyclovir Sodium:**

Species	Route	End Point	Dose
Rat	Oral	LD 50	> 20 g/kg
Rat	Para-periosteal	LD 50	750 mg/kg
Rat	Intraperitoneal	LD 50	860 mg/kg
Mouse	Oral	LD 50	> 10 g/kg
Mouse	Intravenous	LD 50	400 mg/kg

#### **Sodium hydroxide:**

Species	Route	End Point	Dose
Mouse	IP	LD50	40 mg/kg

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**Acute Toxicity Comments:** A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

## **Irritation / Sensitization:**

### **Hydrochloric Acid:**

Study Type	Severity
Skin Irritation	Severe
Eye Irritation	Severe

### **Sodium hydroxide:**

Study Type	Species	Severity
Eye Irritation	Rabbit	Severe
Skin Irritation	Rabbit	Severe

## **Repeated Dose Toxicity:**

### **Acyclovir Sodium:**

Duration	Species	Route	Dose	End Point	Target Organ
1 Month(s)	Rat	Intraperitoneal	320 mg/kg/day	LOAEL	Male reproductive system
1 Month(s)	Dog	Intravenous	100-200 mg/kg/day	LOAEL	Male reproductive system
1 Month(s)	Dog	Intravenous	50 mg/kg/day	NOAEL	Male reproductive system
6 Month(s)	Rat	Intraperitoneal	80 mg/kg/day	LOAEL	Male reproductive system
1 Year (s)	Dog	Intravenous	60 mg/kg/day	NOAEL	Male reproductive system

## **Reproduction & Development Toxicity:**

### **Acyclovir Sodium:**

Duration	Species	Route	Dose	End Point	Effect (s)
Fertility & Embryonic Development	Rat	Subcutaneous	50 mg/kg/day	LOAEL	Fertility, Fetotoxicity,
Reproductive & Fertility	Rat	Subcutaneous	25 mg/kg/day	NOAEL	Fertility
Embryo / Fetal Development	Mouse	Oral	450 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rabbit	Intravenous	50 mg/kg/day	NOAEL	Not Teratogenic
Embryo / Fetal Development	Rat	Subcutaneous	50 mg/kg/day	NOAEL	Not Teratogenic

## **Genetic Toxicity:**

### **Acyclovir Sodium:**

Study Type	Cell Type/Organism	Result
<i>In Vitro</i> Mammalian Cell Mutagenicity	Mouse Lymphoma	Positive
<i>In Vivo</i> Chromosome Aberration	Rat	Positive
<i>In Vivo</i> Chromosome Aberration	Hamster	Positive
<i>In Vitro</i> Cell Transformation Assay		Equivocal
Dominant Lethal Assay	Mouse	Negative

## **Carcinogenicity:**

### **Acyclovir Sodium:**

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Duration	Species	Route	Dose	End Point	Effect (s)
2 Year(s)	Mouse	Oral	450 mg/kg/day	NOAEL	Not carcinogenic
2 Year(s)	Rat	Oral	450 mg/kg/day	NOAEL	Not carcinogenic

**Carcinogen Status:** None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA. See below.

**Acyclovir Sodium IARC:** Group 3 (Not Classifiable)

**Hydrochloric Acid IARC:** Group 3 (Not Classifiable)

## SECTION 12 - ENVIRONMENTAL IMPACT INFORMATION

**Environmental Overview:** Environmental properties have not been investigated. Releases to the environment should be avoided.

## SECTION 13 - DISPOSAL INFORMATION

**Waste Treatment Methods:** Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

## SECTION 14 - TRANSPORTATION INFORMATION

**The following refers to all modes of transportation unless specified below.**

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

## SECTION 15 - REGULATORY INFORMATION

**EU Symbol** : Xn  
**EU Indication of danger** : Toxic to reproduction, Category 3  
: Mutagenic: Category 3  
**EU Risk Phrases** : R62 - Possible risk of impaired fertility.  
R63- Possible risk of harm to the unborn child.  
R68 - Possible risk of irreversible effects.



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**EU Risk Phrases** : S22 - Do not breathe dust  
S53 - Avoid exposure - obtain special instructions before use.  
S36/37 - Wear suitable protective clothing and gloves.

**OSHA Label** : WARNING  
Suspected of damaging fertility or the unborn child.  
Suspected of causing genetic defects.

## Canada - WHMIS: Classifications

**WHMIS hazard class** : Class D, Division 2, Subdivision A



## **Water for Injection:**

**Inventory - United States TSCA - Sect. 8(b)** : Present  
**Australia (AICS)** : Present  
**REACH - Annex IV - Exemptions from the obligations of Register** : Present  
**EU EINECS/ELINCS List** : 231-791-2

## **Hydrochloric Acid:**

**CERCLA/SARA 313 Emission reporting** : 1.0 %  
**CERCLA/SARA Hazardous Substances and their Reportable Quantities:** 2270 kg  
**CERCLA/SARA - Section 302 Extremely Hazardous TPQs** : 500 lb  
**CERCLA/SARA - Section 302 Extremely Hazardous Substances EPCRA RQs** : 5000 lb  
**California Proposition 65** : Not Listed  
**Inventory - United States TSCA - Sect. 8(b)** : Present  
**Australia (AICS)** : Present  
**Standard for the Uniform Scheduling for Drugs and Poisons** : Schedule 5  
Schedule 6  
**EU EINECS/ELINCS List** : 231-595-7

## **Sodium hydroxide:**

**CERCLA/SARA Hazardous Substances and their Reportable Quantities** : 1000 lb  
454 kg  
**Inventory - United States TSCA - Sect. 8(b)** : Present  
**Australia (AICS)** : Present  
**Standard for the Uniform Scheduling for Drugs and Poisons** : Schedule 5  
Schedule 6  
**EU EINECS/ELINCS List** : 215-185-5

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## SECTION 16 - OTHER DATA

### **Text of R phrases mentioned in Section 3**

R62 - Possible risk of impaired fertility.

R63 - Possible risk of harm to the unborn child.

R68 - Possible risks of irreversible effects

**Data Sources:** Publicly available toxicity information. Safety data sheets for individual ingredients.

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