# Lexiscan™ (regadenoson) injection

# Material Safety Data Sheet

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

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| **Product name** | Lexiscan (regadenoson) injection |
| **Supplier of data** | Astellas Pharma US, Inc.<br>Three Parkway North<br>Deerfield, IL 60015-2537<br>(847) 317-8800 |
| **In case of emergency, call** | **(800) 727-7003** |
| **Material name** | CVT-3146 Intravenous Formulation |
| **Chemical formula of active ingredient** | $C_{15}H_{18}N_8O_5$ |
| **CAS number** | 313348-27-5 |
| **Chemical name** | 2-[N-1-(4-N-methylcarboxamidopyrazol)]adenosine |
| **Use** | Pharmaceutical research, manufacturing, and clinical use |

The following MSDS applies to the formulated product only. If handling CVT-3146 in pure form, check the MSDS for the active ingredient and take appropriate precautions.

## 2. COMPOSITION/INFORMATION ON INGREDIENTS

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| **Specific chemical identity** | CVT-3146 (0.008%) |
| **CAS #** | 313348-27-5 |
| **OSHA PEL** | None established |
| **ACGIH TLV** | None established |

Product also contains excipients (methyl boronic acid, sodium bicarbonate, sodium chloride) in water adjusted to pH 6.3-7.7.

## 3. HAZARDS IDENTIFICATION

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| **Emergency overview** | Material intended for pharmaceutical research, manufacturing, and clinical uses only. Dosage form contains CVT-3146, a pharmaceutically active material intended for research and clinical use only. Dosage form contents may pose a health hazard only if exposure occurs to contents, eg, after spill or leak. Overexposure may affect the cardiovascular system and the central nervous system. Symptoms may include increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache. Avoid ingestion, inhalation, skin and eye contact. |
| **Routes of absorption** | Presumed inhalation, ingestion, eye and skin absorption. |
| **Acute effects** | Skin: No data available<br>Eye: No data available<br>Inhalation: If inhaled, may cause effects similar to those described under Target organs.<br>Ingestion: No data available |
| **Target organs/ systemic toxicity** | Patients administered the drug intravenously have shown effects related to the pharmacological effects of the drug on the cardiovascular system with symptoms including increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache. |
| **Reproductive/ developmental toxicity** | No data available |
| **Mutagenicity and carcinogenicity** | CVT-3146 is not considered a mutagen based on standard battery of studies (see Section 11). |
| **Occupational exposure limit** | None established by ACGIH, OSHA, or NIOSH. |
| **Medical conditions aggravated by exposure** | Not known |

## 4. FIRST AID MEASURES

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| **Eye contact** | Exposed eyes should be irrigated thoroughly with copious amounts of lukewarm water for at least 15 minutes. If an irritation develops, contact a supervisor and medical personnel immediately. |
| **Skin contact** | Wash exposed area thoroughly with soap and water for at least 15 minutes. If an irritation develops, contact a supervisor and medical personnel immediately. |
| **Inhalation** | Move victim to fresh air. Monitor for respiratory distress. Contact supervisor and/or medical personnel. |
| **Ingestion** | Never give anything by mouth to an unconscious or convulsing person. Have the conscious and alert person drink one to two glasses of water and contact a supervisor and/or medical personnel immediately. |

*Note to physician: Treatment is symptomatic and supportive.*

## 5. FIRE-FIGHTING MEASURES

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| **Extinguishing media** | Use water spray, appropriate foam, $CO_2$, or dry chemical to extinguish fires. |
| **Special fire-fighting procedures** | Wear full protective clothing to prevent contact with skin and eyes, and positive pressure SCBA. |

## 6. ACCIDENTAL RELEASE MEASURES

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| **In case of spill or release** | **Small spills:** Soak up material with paper towels. **Larger spills:** Use adsorbing material. Scoop into suitable containers for recovery or proper disposal. Ventilate area and wash spill site with soap and water after material pick-up is complete. Dispose of wastes according to recommendations in Section 13. |

## 7. HANDLING AND STORAGE

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| **Special precautions—Storage** | Keep container dry. Keep in a cool, well-ventilated place. Keep container tightly closed. |
| **Label precautionary statement** | Material intended for pharmaceutical research, manufacturing, and clinical uses only. Dosage form contains CVT-3146, a pharmaceutically active material intended for research and clinical use only. Dosage form contents may pose a health hazard only if exposure occurs to contents, eg, after spill or leak. Overexposure may affect the cardiovascular system and the central nervous system. Symptoms may include increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache. Avoid ingestion, inhalation, skin and eye contact. |

## 8. EXPOSURE CONTROL/PERSONAL PROTECTION

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| **Occupational exposure band/handling category** | If this product is spilled, this product should be handled as a potent drug and/or compound with unknown toxicity and potency, based on therapeutic dose and lack of data in some areas. |
| **Protective clothing and equipment** | Use basic laboratory safety protection procedures (safety glasses with side shields and laboratory coat). |
| **Respirator protection** | None needed; under normal handling, no airborne generalization of material is expected. |
| **Skin protection** | Use rubber gloves if skin contact with formulation is possible. Wear lab coat or other protective overgarment if splashing is possible. Base the choice of skin protection on the job activity and potential for skin contact. |
| **Ventilation** | None required during the routine handling of vials. |
| **Comments** | Wash hands, face, and other potentially exposed areas after using this material. |

## 9. PHYSICAL AND CHEMICAL PROPERTIES

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| **Physical state** | Liquid |
| **Color** | Clear |
| **Odor** | None |
| **Boiling point** | Approx. 100°C |
| **Melting point** | Not applicable/liquid |
| **Percent volatility** | None |

## 9. PHYSICAL AND CHEMICAL PROPERTIES (continued)

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| **Specific gravity** | Approx. 1. |
| **Molecular weight** | 390.35 (CVT-3146) |
| **Solubility** | Already in water |
| **Vapor pressure (mm/Hg)** | Not available |
| **Vapor density (Air=1)** | Not available |
| **Evaporation rate (Butyl acetate=1)** | Not available |
| **pH** | 6.3-7.7 |

## 10. STABILITY AND REACTIVITY

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| **Stability** | Stable |
| **Incompatibility** | N/A |

## 11. TOXICOLOGICAL INFORMATION OF CVT-3146

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| **Acute toxicity** | Single IV doses of up to 1.5 mg/kg in rats and 2.4 mg/kg in dogs did not cause lethality. Minimal cardiomyopathy (myocyte necrosis and inflammation) was observed in rats following single dose intravenous administration of Lexiscan at doses >0.08 mg/kg. Mean arterial pressure was decreased by 30 to 50% for up to 90 minutes at doses >0.2 mg/kg. Intravenous administration, of single doses up to 2400 µg/kg in dogs, caused pharmacological effects including decreased blood pressure and T-wave inversion. |
| **Repeated dose studies** | Decreased weight gain, and increased serum creatine kinase, alanine aminotransferase, aspartate aminotransferase, lactate dehydrogenase and chloride were observed in rats treated intravenously with Lexiscan at 0.2 mg/kg. Repeated dose studies have shown similar pharmacological effects studies of the drug as in acute studies. |
| **Carcinogenicity** | No studies conducted. |
| **Genotoxicity** | Negative in several short-term screening tests for genetic damage (Ames bacterial cell test for point mutations, mouse micronucleus test for chromosomal aberrations, and Chinese hamster ovary test for chromosomal aberrations). |
| **Teratogenicity/ Reproductive toxicity** | Fertility studies were not performed.<br>Pregnant rabbits treated with Lexiscan exhibited tachypnea, soft, liquid or scant feces, localized alopecia, and reduction in body weight and feed consumption at 0.3 and 0.5 mg/kg/day. Fetal toxicity included decreased number, reduced body weight, and variations and malformations; increased fetal resorptions occurred at 0.5 mg/kg. The no effect dose level (NOEL) for fetal toxicity is 0.1 mg/kg. The NOEL was not identified for maternal toxicity.<br>Decreased motor activity, difficulty breathing, increased limb extension, excess salivation, and decreased body weight and feed consumption were noted in treated pregnant rats at >0.5 mg/kg. Deaths occurred in the >0.8 mg/kg/day group. Decreased fetal body weights and ossification delays in fore- and hindlimb phalanges and metatarsals were observed at doses ≥0.5 mg/kg. The NOEL for maternal and fetal toxicity is 0.1 mg/kg/day. |
| **Local irritation** | Intravenous administration of Lexiscan to rabbits resulted in perivascular hemorrhage, vein vasculitis, inflammation, thrombosis and necrosis. Perivascular administration resulted in hemorrhage, inflammation, pustule formation, and epidermal hyperplasia. Subcutaneous administration resulted in hemorrhage, acute inflammation, and necrosis. |

## 12. ECOLOGICAL INFORMATION

No evaluation performed.

## 13. DISPOSAL CONSIDERATIONS

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| **Disposal** | All wastes containing the material should be properly contained and labeled and stored separately from other facility discharges. Dispose of any waste residues according to prescribed federal, state, or local guidelines, eg, appropriately permitted chemical waste incinerator. Rinsewaters resulting from spill cleanups should be discharged in an environmentally safe manner, eg, appropriately licensed waste disposal facilities. Disposal methods should be used which, in addition to preventing environmental contamination, also prevent human exposure to the waste residues. |
| **CERCLA** | No reportable quantity. |

## 14. TRANSPORTATION INFORMATION

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| **DOT shipping name** | Not regulated |
| **DOT hazard class/division** | Not applicable |
| **DOT #** | Not applicable |
| **Packaging authorization** | Not applicable |
| **Non-bulk packaging** | Not applicable |
| **Quantity limits** | No limit |
| **DOT packaging group** | Not applicable |
| **DOT labels** | Not applicable |
| **Vessel stowage** | Not applicable |

## 15. REGULATORY INFORMATION

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| **US TSCA** | Active pharmaceutical ingredients are exempt under TSCA. |
| **EPA** | This product does not contain any components regulated under TPQ, RQ, S313, RCRA, or TSCA 12B. |
| **SARA** | Not applicable under SARA Title III. |
| **EU risk and safety phrases** | None applicable |

## 16. OTHER INFORMATION

Bulk containers of CVT-3146 IV formulation should have affixed the following warning label (in addition to the material identity label):

Material intended for pharmaceutical research, manufacturing, and clinical uses only. Dosage form contains CVT-3146, a pharmaceutically active material intended for research and clinical use only. Dosage form contents may pose a health hazard only if exposure occurs to contents, eg, after spill or leak. Overexposure may affect the cardiovascular system and the central nervous system. Symptoms may include increased heart rate, palpitations, flushing, nausea, hyperventilation, and headache. Avoid ingestion, inhalation, skin and eye contact. Read and understand the Material Safety Data Sheet for additional information before handling material.

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