西亚试剂® Xiya Reagent 说明书

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化 学 品 安 全 技 术 说 明 书

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MSDS标题

LAMIVUDINE MSDS报告

产品标题

(2R-顺式)-4-氨基-1-(2-羟甲基-1,3-氧硫杂环戊-5-基)-1H-嘧啶-2-酮;(2R-顺式)-4-氨基-1-[2-(羟基甲基)-1,3-噁噻烷-5-基]-2(1H)-嘧啶酮

CAS号

134678-17-4

化学品及企业标识

PRODUCT NAME

LAMIVUDINE

NFPA

Flammability	1
Toxicity	2
Body Contact	0
Reactivity	0
Chronic	0

SCALE: Min/Nil=0 Low=1 Moderate=2 High=3 Extreme=4

PRODUCT USE

Antiviral agent used in the management of AIDS, AIDS- related complex and hepatitis B virus. Normally taken by mouth. Lamivudine is phosphorylated to its active 5' - triphosphate metabolite, lamivudine triphosphate (L- TP) whose principal action is

inhibition of reverse transcriptase via DNA chain termination after incorporation into the nucleoside analogue. L- TP is a weak inhibitor of mammalian polymerases alpha ad beta, and mitochondrial DNA polymerase.

SYNONYMS

C8-H11-N3-O3-S, "2(1H)-pyrimidinone, 4-amino-1-[(2R, 5S)-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl]", "2(1H)-pyrimidinone, 4-amino-1-[(2R, 5S)-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl]", "(2R, cis)-4-amino-1-(2-hydroxymethyl-1, 3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one", "(2R, cis)-4-amino-1-(2-hydroxymethyl-1, 3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one", "2(1H)-pyrimidinone, 4-amino-1-(2-hydroxymethyl)-1, 3-oxathiolan-5-yl)-, (2R-cis)-", "2(1H)-pyrimidinone, 4-amino-1-(2-hydroxymethyl)-1, 3-oxathiolan-5-yl)-, (2R-cis)-", "3'-thia-2', 3'-dideoxycytidine", "3'-thia-2', 3'-dideoxycytidine", (-)-2'-deoxy-3'-thiacytidine, (-)-2'-deoxy-3'-thiacytidine, "(-)-1-[(2R, 5S)]-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl)cytosine]", "(-)-1-[(2R, 5S)]-2-(hydroxymethyl)-1, 3-oxathiolan-5-yl)cytosine]", "(-)enantiomer of a dideoxy analague of cytidine", "(-)-2', 3'-dideoxy, 3'-thiacytidine", "(-)-2', 3'-dideoxy, 3'-thiacytidine", "BCH-189, (-)-", Epivir, GR-109714X, 3TC, "Combivir (lamivudine/ zidovudine combination)", "NRTI/ nucleoside analogue antiviral/ antiretroviral/ HIV-I/hepatitis B (HBV) treatment"

CANADIAN WHMIS SYMBOLS

None

EMERGENCY OVERVIEW

RISK

POTENTIAL HEALTH EFFECTS

ACUTE HEALTH EFFECTS

SWALLOWED

Although ingestion is not thought to produce harmful effects, the material may still be damaging to the health of the individual following ingestion, especially where pre- existing organ (e.g. liver, kidney) damage is evident. Present definitions of harmful or toxic substances are generally based on doses producing mortality (death) rather than those producing morbidity (disease, ill-health). Gastrointestinal tract discomfort may produce nausea and vomiting. In an occupational setting however, ingestion of insignificant quantities is not thought to be cause for concern. Considered an unlikely route of entry in commercial/industrial environments. Lactic acidosis (which produces a number disturbances in tissues and the central nervous system) and severe enlargement of the liver (hepatomegaly), with fatty degeneration (steatosis), including fatal cases, have been reported with the use of antiretroviral nucleoside analogues (NRTIs) alone or in combination. A majority of these cases have been women. Lactic acidosis occurs when cells of the body are unable to convert food into usable energy. As a result, excess

acid accumulates in the body and vital organs such as the liver and pancreas may be damaged. Elevated serum levels of lactic acid (hyperlactataemia) are common in individuals undergoing NRTI therapy; generally the condition is mild and reversible and is likely to result, in greater part, from hepatic rather than muscle dysfunction (though this remains conjectural). Clinical symptoms include abnormal fatigue, tachycardia (rapid heart beat), abdominal pain, weight loss, peripheral neuropathy (surface nerve damage) and more specifically exercised induced dyspnea (shortness of breath) despite effective antitretroviral treatment. Functional respiratory tests show a metabolic deviation towards anaerobiosis. Ultrastructural mitochondrial abnormalities have been seen in several patients undergoing NRTI therapies. There was a marked decrease in complex IV activity in muscle biopsies consistent with mitochondrial dysfunction. Sometimes fatal pancreatitis (a pain in the stomach area progressing to the back), paraesthesias (burning, pricking, tingling sensations) and peripheral neuropathies (burning or numbing of the hands and feet) have been reported in mono- or combination therapies. Hypersensitivity reactions (anaphylaxis), some severe and life-threatening, may occur. Hypersensitivity might produce fever, skin rash, urticaria, fatigue, gastrointestinal symptoms such as nausea, vomiting diarrhoea, abdominal pain and respiratory symptoms such as sore throat, shortness of breath and cough. Haemic and lymphatic dyscrasias (including anaemia, lymphadenopathy and splenomegaly) are seen in some settings whilst musculoskeletal symptoms, such as weakness and rhabdomyolysis, are seen on occasion. NRTIs may also be important in inducing subcutaneous fat wasting (lipoatrophy/lipodystropy) when used in combination therapies with protease inhibitors. Patients receiving highly active antiretroviral therapy (HAART), generally a combination of reverse transcriptase and protease inhibitors, frequently develop lipodystrophy with elevated levels of serum cortisol, lowered levels of serum DHEA (dehydroepiandrosterone) and increased levels of atherogenic lipids (important in the pathogenesis of arteriosclerosis). In one study researchers have also identified lipid abnormalities associated with coronary heart disease, along with alterations in glucose and insulin metabolism amongst patients undergoing HAART. There have been reports of increased bleeding, including spontaneous skin haematomas and haemarthrosis in haemophiliacs given protease inhibitors. Antiretroviral nucleoside analogues may act as reverse transcriptase inhibitors (NRTIs) or introduce themselves into viral DNA/RNA; in either case DNA chain elongation is disturbed during cell division.

EYE

Although the material is not thought to be an irritant, direct contact with the eye may produce transient discomfort characterized by tearing or conjunctival redness (as with windburn).

SKIN

The material is not thought to produce adverse health effects or skin irritation following contact (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable gloves be used in an occupational setting.

INHALED

The material is not thought to produce adverse health effects or irritation of the respiratory tract (as classified using animal models). Nevertheless, good hygiene practice requires that exposure be kept to a minimum and that suitable control measures be used in an occupational setting. Persons with impaired respiratory function, airway diseases and conditions such as emphysema or chronic bronchitis, may incur further disability if excessive concentrations of particulate are inhaled.

CHRONIC HEALTH EFFECTS

Principal routes of exposure are usually by skin contact/absorption and inhalation of generated dust. Long-term carcinogenicity studies in mice and rats showed no evidence for carcinogenic potential at exposures up to 10 times (mice) and 578 times (rats) those observed in humans at the recommended therapeutic dose for HIV infection. Lamivudine was not active in a microbial mutagenicity screen or an in vitro cell transformation assay but showed weak in vitro mutagenic activity in a cytogenetic assay using cultured human lymphocytes and in the mouse lymphoma assay. However, lamivudine showed no evidence of in vivo genotoxic activity in the rat at oral doses of up to 2000 mg/kg producing plasma levels of 35-45 times those in humans receiving the recommended dose for HIV treatment. In a study of reproductive performance in rats doses of 4000 mg/kg/day (plasma levels of 47-70 times those in humans), there was no evidence of impaired fertility and no effect on survival, growth and the development to weaning offspring. No evidence of teratogenicity was seen in rats and rabbits receiving oral doses of 4000 mg/kg/day and 1000 mg/kg/day (producing up to about 35 times the plasma level of humans receiving HIV therapy), Evidence of early embryolethality was seen in the rabbit at exposure levels similar to those produced in humans, but there was no indication of this effect in rats receiving up to 35 times that in humans. The drug is transferred to the foetus through the placenta in rats and rabbits.