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

Catalogue Number	CS-O-11998
Product Name	Ixabepilone
CAS No.	219989-84-1
Category	API
Synonyms	(1S;3S;7S;10R;11S;12S;16R)-7;11-dihydroxy-8;8;10;12;16-pentamethyl-3-((E)-1-(2-methylthiazol-4-yl)prop-1-en-2-yl)-17-oxa-4-aztadecane-5;9-dione
Brand	Clearsynth Labs Ltd.
Identified uses	Laboratory Chemicals
Uses advised against	Not available
Company	Clearsynth Labs Ltd. Mumbai, India
Emergency Phone #	+91-22-245045900
REACH No.	Not available

SECTION 2: Hazards identification

Disclaimer: This is sample MSDS. Please email **sales@clearsynth.com** for more details.

2.1 Classification of the substance or mixture-Regulation (EC) No 1272/2008:

Not available

2.2 Label Elements

Signal Word: Warning

Hazard Statement(s)

Code	Statement
H300	Not available
H301	Not available
H317	May cause an allergic skin reaction.

H341	Not available
H360	Not available
H361	Not available
H372	Not available
H400	Not available
H410	Not available

Precautionary Statement(s)

Code	Statement
P203	Not available
P260	Not available
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P270	Not available
P272	Not available
P273	Not available
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P316	Not available
P302+P352	IF ON SKIN: Wash with plenty of water and soap.
P318	Not available
P319	Get medical help if you feel unwell.
P321	Specific treatment (see … on this label).
P330	Not available
P333+P317	Not available
P362+P364	Take off contaminated clothing and wash it before reuse.
P391	Not available
P405	Store locked up.
P501	Dispose of contents/container in accordance with local/regional/national/international regulatio

SECTION 3: Composition / information on ingredients

3.1 Substance

Component : Ixabepilone
CAS Number : 219989-84-1
Molecular Formula : C27H42N2O5S
Molecular Weight : 506.7
Parent Chemical : Ixabepilone
Synonyms : (1S;3S;7S;10R;11S;12S;16R)-7;11-dihydroxy-8;8;10;12;16-pentamethyl-3-((E)-1-(2-methylthiazol-4-yl)prop-1-en-2-yl)-17-oxa-4-aztadecane-5;9-dione
Concentration : Not available

SECTION 4: First aid measures

Not available

SECTION 5: Firefighting measures

Not available

SECTION 6: Accidental release measures

Not available

SECTION-7: Handling and storage

Not available

SECTION 8: Exposure controls / personal protection

Not available

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Test	Result
Appearance	No data available
IR spectrum	No data available
pH	No data available
Solubility	No data available

Property	Value
a) Physical State	No data available
b) Color	No data available
c) Odor	No data available
d) pH	No data available
e) Vapour Pressure	No data available
f) Viscosity	No data available
g) Initial Boiling Point and boiling range	No data available
h) Melting Point / Freezing Point	No data available
i) Auto Ignition Temperature	No data available
j) Flash Point	No data available
k) Explosion Limit, Lower	No data available
l) Explosion Limit, Upper	No data available
m) Decomposition Temperature	No data available
n) Loss on Drying	No data available
o) Relative Density	No data available
p) Solubility (in DMSO)	No data available
q) Oxidizing Properties	No data available

SECTION 10: Stability and reactivity

Not available

SECTION 11: Toxicological information

11.1 Information on toxicological effects
- Acute toxicity: In preregistration controlled trials, serum aminotransferase elevations and other liver test abnormalities were rarely mentioned. A high proportion of patients treated had mild-to-moderate serum enzyme elevations at the time of starting ixabepilone, probably because of hepatic metastases and the use of other antineoplastic agents. During ixabepilone therapy, worsening of serum enzyme elevations occurred in up to 15% of patients, but ALT elevations above 5 times the upper limit of normal were rare, and there were no reports of severe hepatic adverse events or discontinuations because of enzyme elevations or clinically apparent liver disease. Nevertheless, jaundice and acute liver failure as well as elevations in serum ALT, AST, alkaline phosphatase, and bilirubin are mentioned as occurring in clinical trials in the product label. Since the approval and more widescale use of ixabepilone, there have been no publications or descriptions of the clinical features of hepatotoxicity with jaundice

associated with its use. Thus, clinically apparent liver injury probably occurs in a small proportion of patients receiving ixabepilone, but its relationship with the drug is unclear. Likelihood score: E* (unproven but suspected rare cause of clinically apparent liver injury). /HUMAN EXPOSURE STUDIES/ Forty-four patients were treated with a median (range) of three (1-14) cycles of ixabepilone. The vibration perception threshold (VPT) (5-min duration) and nerve conduction test (NCT, 10-min duration) were carried out in the office, before ixabepilone dosing, and every two cycles thereafter. Neuropathy (grade 1 and grades 2-3) was observed in 17 (38.6%) and 11 (25%) patients, respectively. The mean increase in VPT as a function of grade 0-1 versus grades 2-3 neuropathy was 0.235 +/- 0.03 versus 0.869 +/- 0.09 (P = 0.049) vibration units. The F-wave frequency and distal motor latency, as assessed using the NCT, did not correlate with clinical neurotoxicity. The change in VPT is observed early and likely reflects early vibration perception change. Mean change in VPT correlates with the severity of clinical neuropathy. ...
- Skin corrosion/irritation: No data available.
- Serious eye damage/eye irritation: No data available.
- Respiratory or skin sensitization: No data available.
- Germ cell mutagenicity: /GENOTOXICITY/ Ixabepilone ... was not clastogenic in an in vitro cytogenetic assay using primary human lymphocytes.
- Carcinogenicity: No data available.
- Reproductive toxicity: /LABORATORY ANIMALS: Acute Exposure/ In rats, single intravenous doses of ixabepilone from 60 to 180 mg/sq m (mean AUC values =8156 ng*hr/mL) were associated with mortality occurring between 5 and 14 days after dosing, and toxicity was principally manifested in the gastrointestinal, hematopoietic (bone-marrow), lymphatic, peripheral-nervous, and male-reproductive systems. /LABORATORY ANIMALS: Developmental or Reproductive Toxicity/ Ixabepilone was studied for effects on embryo-fetal development in pregnant rats and rabbits given IV doses of 0.02, 0.08, and 0.3 mg/kg/day and 0.01, 0.03, 0.11 and 0.3 mg/kg/day, respectively. There were no teratogenic effects. In rats, an increase in resorptions and post-implantation loss and a decrease in the number of live fetuses and fetal weight was observed at the maternally toxic dose of 0.3 mg/kg/day (approximately one-tenth the human clinical exposure based on AUC). Abnormalities included a reduced ossification of caudal vertebrae, sternebrae, and metacarpals. In rabbits, ixabepilone caused maternal toxicity (death) and embryo-fetal toxicity (resorptions) at 0.3 mg/kg/day (approximately one-tenth the human clinical dose based on body surface area). No fetuses were available at this dose for evaluation.
- STOT-single exposure: No data available.
- STOT-repeated exposure: No data available.
- Aspiration hazard: No data available.

Likely routes of exposure
- No data available.

Symptoms related to the physical, chemical and toxicological characteristics
- /CASE REPORTS/ ... The major toxicities associated with ixabepilone are myelosuppression, sensory neuropathy and neutropenia. Other minor side-effects include asthenia/fatigue, stomatitis, anorexia, alopecia, skin reaction, hypersensitivity reactions and a fluid-retention syndrome. Although ixabepilone is functionally correlated to taxanes, no previous evidence exists regarding Ix-related nail disorders. A case of a 59-year-old woman treated with Ix at 40 mg/sq m day 1 q 21 days who, after 8 cycles of therapy, developed onycholysis and subungual hemorrhagic bullas in the fingernails /is reported/..

SECTION 12: Ecological information

Not available

SECTION 13: Disposal considerations

Not available

SECTION 14: Transport information

Not available

SECTION 15: Regulatory information

Not available

SECTION 16: Other information

Not available

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