according to Regulation (EC) No.1907/2008 Date of Issue: 28-AUG-2012 Replaces version of: 28-AUG-2012

Kepiaces version 61: 28-AUG-2012 KALIJEV KLAVULANAT-D-ATB FDA PN100%-P 784214 (SI07)



član skupine Sandoz a Sandoz company

1. Identification of the substance/preparation and of the company

Product name

KALIJEV KLAVULANAT-D-ATB FDA PN100%-P

Usage

Pharmaceutical active ingredient

Company name

Lek Pharmaceuticals d.d.

Verovškova 57 1526 Ljubljana SLOVENIA

Emergency phone

number

+386 1 580 21 11 mail: sds.support@novartis.com

2. Hazards identification

Pictogram, Signal Word Self assessment according REGULATION (EC) No 1272/2008





Danger

Hazard statements

H228: Flammable solid.

H317: May cause an allergic skin reaction.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements

P261: Avoid breathing dust/fume/gas/mist/vapours/spray.

P285: In case of inadequate ventilation wear respiratory protection.

P280: Wear protective gloves/protective clothing/eye protection/face protection. P210: Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P240: Ground/bond container and receiving equipment. P302/352: IF ON SKIN: Wash with plenty of soap and water.

GHS hazard category

Respiratory sensitizer: Cat.1;

Flammable solid: Cat.2; Skin sensitizer: Cat.1B;

Specific hazards

Contact with moisture must be avoided by all means (self-decomposition). Packaging- and

transportation instructions have to be followed.

Classification according EU Directive 67/548/EEC or 1999/45/EC see chapter 15

3. Composition / information on ingredients

Chemical characterisation of the substance / preparation:

Chemical Name

CLAVULANIC ACID POTASSIUM SALT

CAS Number

61177-45-5

EINECS

2626409

Content:

> 98 %

For TLV values of declared components, see chapter 8

Full text of H-Phrases see under chapter 16

4. First aid measures

Inhalation

Remove from danger zone. Obtain immediate medical assistance.

Skin Contact

Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and

seek medical advice.

Eye Contact

Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min).

according to Regulation (EC) No.1907/2006 Date of issue: 28-AUG-2012



član skupine Sandoz a Sandoz company

Replaces version of: 28-AUG-2012

KALIJEV KLAVULANAT-D-ATB FDA PN100%-P 784214 (SI07)

Ingestion

Take injured quickly to factory medical center or call an ambulance (code word: eye accident). If feeling sick, immediately call for a physician or take patient to factory medical centre (if necessary, call for an ambulance). If swallowed, seek medical advice immediately and show this container or label.

5. Fire fighting measures

Suitable Extinguishing Alcohol resistent foam Dry sand carbon dioxide (CO2)

Media

Unsuitable

Water Fire-extinguishing powder N.A.

Extinguishing Media

Protective equipment

Wear self-contained breathing apparatus and fire protective suite.

for firefighters

6. Accidental release measures

Personal precautions

Avoid contact with the skin and the eyes. Avoid breathing hazardous vapors/dusts. Wear

personal protective equipment. Keep away unprotected persons.

Environmental precautions

Suppress gases/vapours/mists with water spray jet. Do not release on the soil or into drains.

Methods for cleaning

Wash away remains with plenty of water. Transfer large quantities into a container, rinse the

rest with plenty of water.

For personal protection see chapter 8; for disposal considerations see chapter 13

7. Handling and storage

Storage and Handling

Keep in a cool place (2-8C°). Keep container tightly closed. Keep dry. Ensure efficient exhaust

Precautions

ventilation when using this product For industrial hygiene measures see chapter 8

Conditions of storage

Protect against humidity, Protect against heat

(fire/explosion)

Preventive Precautions Observe the usual precautionary measures required for chemicals with dust explosive

properties (Observe national regulations).

8. Exposure controls / Personal protection

List type	mg/m3	
Internal exposure limit	0.94	1

Occupational Exposure Controls

Industrial Hygiene

Avoid exposure.

Change contaminated clothes immediately.

Minimize open handling.

Ensure sufficient exhaust ventilation. Wear suitable protective clothing.

Open Handling

Respiration

: Disposable fine dust protection mask (EN149) or reusable halfmask

(EN140)

Eye

: Safety glasses (EN166)

Hand

: Disposable gloves or chemical-resistant gloves, normal length

(EN374/EN388)

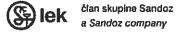
Additional protection : Disposable dust-proof suit (EN465, type 4) worn over long underwear

These values are derived from experiments, literature and information from the glove manufacturer.

They can also be derived from similar materials. In daily work please be aware that the using time depends on several factors and can be shorter than the oficially tested permeation time.

9. Physical and chemical properties

according to Regulation (EC) No.1907/2006 Date of issue: 28-AUG-2012 Replaces version of: 28-AUG-2012



KALIJEV KLAVULANAT-D-ATB FDA PN100%-P 784214 (SI07)

Appearance

Formulation

powder

Physical state

solid

Colour

white to faint yellow

Odour

Safety relevant basic data

Melting point/range

115 °C (decomposing)

Boiling Point

unknown

Bulk Density

200 - 400 kg/m3

Solubility (Aqueous

Water: highly soluble (Temperature: 20 °C)

Solvents)

Solubility (Solvents)

not available

pН

5.5 - 7.5 (Concentration: 10 g/l, Temperature: 20 °C)

pKa

not available

Safety Tests

Combustibility Test

Standard conditions: 5 = complete burn after local igntion (Temperature: 20 °C)

Method: Combustibility test SANDOZ

Dust Explosion

Flammable Gases over

Temperature: 360 °C (Gas volume: approx. 65 l/kg)

Explosivity/Reactivity

Deflagration: Positive (Temperature: 25 °C)

Method: SANDOZ deflagration test

10. Stability and reactivity

Materials to avoid

oxidants

Dangerous Combustion Carbon dioxide

Products

carbon monoxide nitrogen oxides

11. Toxicological information

Acute Toxicity

LD50 oral: 7936 mg/kg

Species: rat

LD50 oral: 4500 mg/kg

Species: mouse

Irritation, Corrosion

Skin (Species: rabbit) non irritant

Method: 92/69/EC (L383) B.4 * Acute toxicity (skin irritation)

Sensitisation

Skin (Species: guinea pig) sensitizing

Method: OECD 406 * 1981 * Guinea pig maximisation test

Respiratory system (Species: human) sensitizing

value from experience

Skin (Species: human) sensitizing

value from experience

Additional advice

Animal studies showed no reproductive toxicity potential relevant to man.

Mutagenicity

Negative (AMES-Test (reverse mutation assay))

Cell: Strains of salmonella typhimurium.

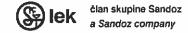
12. Ecological information

Ecotoxicity Summary

No quantifiable data available.

Easily biodegradable.

according to Regulation (EC) No.1907/2006 Date of Issue: 28-AUG-2012 Replaces version of: 28-AUG-2012



KALIJEV KLAVULANAT-D-ATB FDA PN100%-P 784214 (SI07)

Environmental Toxicity

Fish acute toxicity

unknown

Aquatic invertebrate

unknown

acute toxicity

Algae Toxicity

unknown

Bacterial Respiration

unknown

Inhibition

Persistence and degradability Biological Elimination unknown

13. Disposal considerations

Disposal Requirements May be incinerated if local official regulations are observed.

After the product has been diluted it may be discharged in an effluent treatment plant.

Container Disposal

Empty containers can be disposed or re-used after cleaning, when in compliance with the

environmental regulations (Duty of Care).

14. Transport information

Regulation	Class	UN No.	PG	Label	LQ	
RID/ADR:	4.1 / F1	1325	III	4.1	5 kg	
IMDG-Code:	4.1	1325	III	4.1	5 kg	
ICAO/IATA-DGR:	4.1	1325	III	4.1	ū	

ICAO/IATA-DGR:

classified

Proper shipping name: Flammable solid, organic, n.o.s. (Potassium clavulanate)

Transport only in the original packaging. When packing up together enable air circulation between the units for cooling. No more than 4 packages may be in direct contact (be careful when using shrink wrap).

15. Regulatory information

EC Label

assessment: Labelling according to EC Directives:





highly flammable

Xn

harmful

Risk Phrases

R11: Highly flammable.

R44: Risk of explosion if heated under confinement.

R42/43: May cause sensitization by inhalation and skin contact.

Safety Phrases

S22: Do not breathe dust.

S24/25: Avoid contact with skin and eyes.

S3: Keep in a cool place (2-8C°).

S36: Wear suitable protective clothing.

Chemical Safety Assessment not required.

16. Other information

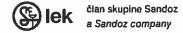
Changes since the previous version in Hazards identification

chapter Abbreviations used

according to Regulation (EC) No.1907/2006

Date of issue: 28-AUG-2012

Replaces version of: 28-AUG-2012



KALIJEV KLAVULANAT-D-ATB FDA PN100%-P 784214 (Si07)

Recipient

Product should be stored, handled and used in accordance with good industrial hygiene practices and in conformity with legal regulations. The information contained herein is based on the present state of our knowledge and is intended to describe our products from the point of view of safety requirements. It should therefore not be construed as guaranteeing specific properties.