

Safety Data Sheet (GHS)

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)



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).

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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 Media Alcohol resistant foam Dry sand carbon dioxide (CO2)

Unsuitable Extinguishing Media Water Fire-extinguishing powder N.A.

Protective equipment for firefighters Wear self-contained breathing apparatus and fire protective suite.

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 Precautions Keep in a cool place (2-8°C). Keep container tightly closed. Keep dry. Ensure efficient exhaust ventilation when using this product

For industrial hygiene measures see chapter 8

Conditions of storage Protect against humidity, Protect against heat

Preventive Precautions (fire/explosion) 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 /

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 officially tested permeation time.

9. Physical and chemical properties

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Appearance

Formulation	powder
Physical state	solid
Colour	white to faint yellow
Odour	faint

Safety relevant basic data

Melting point/range	115 °C (decomposing)
Boiling Point	unknown
Bulk Density	200 - 400 kg/m ³
Solubility (Aqueous Solvents)	Water: highly soluble (Temperature: 20 °C)
Solubility (Solvents)	not available
pH	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 ignition (Temperature: 20 °C) Method: Combustibility test SANDOZ
Dust Explosion	Positive
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 Products	Carbon dioxide 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.
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Environmental Toxicity

Fish acute toxicity unknown

Aquatic invertebrate acute toxicity unknown

Algae Toxicity unknown

Bacterial Respiration Inhibition unknown

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	

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:



F 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 chapter 2. Hazards identification

Abbreviations used

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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.