

SAFETY DATA SHEET



Jardiance® film-coated tablets (finished dosage product)

Version 1.1 Revision Date: 08/10/2017 SDS Number: 000000031436 Date of last issue: 04/10/2017
Date of first issue: 04/10/2017

SECTION 1. IDENTIFICATION

Product name : Jardiance® film-coated tablets (finished dosage product)
Synonyms : with Active ingredient: Empagliflozin
Jardiance® 10mg; Jardiance® 25mg

Manufacturer or supplier's details

Company name of supplier : Boehringer Ing. Pharma GmbH & Co.KG
Address : Binger Str. 173
Ingelheim am Rhein 07 55216
Telephone : +498007790900
Prepared by : EHS-Services@Boehringer-Ingelheim.com
Emergency telephone number : Int. Emergency Telephone number: +1 703-527-3887
Chemtrec 24-hours

Recommended use of the chemical and restrictions on use

Recommended use : Pharmaceutical
Restrictions on use : Safety Data Sheet only for the professional user.

SECTION 2. HAZARDS IDENTIFICATION

GHS classification in accordance with 29 CFR 1910.1200

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

The pharmacological effect of the medicament has to be considered (see package leaflet).
This drug is not subject to the labelling requirements under the Globally Harmonized System (GHS)

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture
Chemical nature : organic
Substance name : with Active ingredient: Empagliflozin

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
cellulose	9004-34-6	>= 20 - < 30

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SECTION 4. FIRST AID MEASURES

- General advice : In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).
First Aid responders should pay attention to self-protection and use the recommended protective clothing
Remove from exposure, lie down.
Victim to lie down in the recovery position, cover and keep him warm.
- If inhaled : Move to fresh air.
- In case of skin contact : Wash off immediately with plenty of water.
- In case of eye contact : Rinse immediately with plenty of water for at least 15 minutes.
Keep eye wide open while rinsing.
- If swallowed : Rinse mouth.
Drink plenty of water.
- Most important symptoms and effects, both acute and delayed : No information available.
- Notes to physician : Observe the summary of product characteristics of proprietary medicinal products
Symptomatic treatment (decontamination, vital functions).

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Water
Dry chemical
Foam
Carbon dioxide (CO₂)
- Specific hazards during fire-fighting : In case of fire and/or explosion do not breathe fumes.
Can be released in case of fire:
Carbon oxides
Nitrogen oxides (NO_x)
Hydrogen chloride gas
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment : In the event of fire, wear self-contained breathing apparatus.

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for firefighters complete suit protecting against chemicals

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Wear personal protective equipment. Ensure adequate ventilation.
- Environmental precautions : Do not flush into surface water or sanitary sewer system.
- Methods and materials for containment and cleaning up : Pick up and transfer to properly labelled containers.

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : No special protective measures against fire required.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms.
- Conditions for safe storage : No special storage conditions required.
- Materials to avoid : Keep away from food, drink and animal feedingstuffs.
Advice on Segregation

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remark
Empagliflozin 864070-44-0	BIEL	2	100 µg/m ³	
	BIPC	1b		

Abbreviations:
BIEL = Boehringer Ingelheim Exposure Limit (internal value)
BI-STEL = Boehringer Ingelheim Short-Term Exposure Limit (Excursion limit)
BIPC = Boehringer Ingelheim Pregnancy Category
BIPC 1b: No risk of harm to the unborn is to be expected, when the exposure does not exceed the BIEL value. There is evidence in animals and/or humans that this material has the potential to cause harm to the unborn at exposure levels exceeding the BIEL value.

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Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
cellulose	Cellulose microcrystalline	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

Engineering measures : Local exhaust

Personal protective equipment

Respiratory protection : Use NIOSH approved respiratory protection.

Hand protection

- Material : Nitrile rubber
- Break through time : 480 min
- Glove thickness : 0.43 mm
- Directive : Protective gloves against chemicals and micro-organisms
- Protective index : Class 6

Eye protection : Safety glasses with side-shields

Skin and body protection : Laboratory: laboratory coat; factory: disposable Overall.

Protective measures : Handle in accordance with good industrial hygiene and safety practice.
 Do not breathe dust.
 Avoid contact with skin, eyes and clothing.
 Only use protective equipment in accordance with national/international regulations. Follow the national regulations about wearing personal protective equipment and the warranty given by the manufacturer for the safe function.

Hygiene measures : General industrial hygiene practice.
 Wash hands and face before breaks and immediately after handling the product.
 Keep working clothes separately.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid
Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	No data available
Melting point/range	:	Not applicable
Boiling point/boiling range	:	Not applicable
Flash point	:	Not applicable
Evaporation rate	:	Not applicable
Flammability (solid, gas)	:	No data available
Self-ignition	:	No data available
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	Not applicable
Relative vapour density	:	Not applicable
Relative density	:	No data available
Bulk density	:	No data available
Solubility(ies) Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity Viscosity, dynamic	:	Not applicable
Explosive properties	:	Not tested
Oxidizing properties	:	No data available

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SECTION 10. STABILITY AND REACTIVITY

Reactivity : No dangerous reaction known under conditions of normal use.

Chemical stability : No decomposition if stored and applied as directed.

Possibility of hazardous reactions : No dangerous reaction known under conditions of normal use.

Conditions to avoid : Extremes of temperature and direct sunlight.

Incompatible materials : No data available

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION

Acute toxicity

Not classified based on available information.

Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg
Method: Calculation method

Components:

cellulose:

Acute oral toxicity : LD50 (Rat): > 5,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : LD50 (Rabbit): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

cellulose:

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

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Components:

cellulose:

Effects on fertility : Remarks: No data available

Effects on foetal development : Remarks: No data available

STOT - single exposure

Not classified based on available information.

Components:

cellulose:

Remarks: No data available

STOT - repeated exposure

Not classified based on available information.

Components:

cellulose:

Remarks: No data available

Aspiration toxicity

Not classified based on available information.

Components:

cellulose:

No data available

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

Components:

cellulose:

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : Remarks: No data available

Toxicity to algae : Remarks: No data available

Toxicity to fish (Chronic toxicity) : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates (Chron-

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ic toxicity)

Toxicity to microorganisms : Remarks: No data available

Persistence and degradability

Components:

cellulose:

Biodegradability : Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Bioaccumulative potential

Components:

cellulose:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

Components:

cellulose:

Distribution among environmental compartments : Remarks: No data available

Other adverse effects

Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Components:

cellulose:

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Dispose of in accordance with local regulations.

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Contaminated packaging : Packs that cannot be cleaned should be disposed of in the same manner as the contents.
Uncontaminated packaging can be recycled.

SECTION 14. TRANSPORT INFORMATION

International Regulations

IATA-DGR

Not regulated as a dangerous good

IMDG-Code

Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

SARA 313 : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Clean Air Act

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

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Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations
Massachusetts Right To Know

Lactose Monohydrate

D-Glucose, 4-O-
.beta.-D-
galactopyranosyl-,
monohydrate
Cellulose microcrys-
talline

cellulose

Pennsylvania Right To Know

Lactose Monohydrate

D-Glucose, 4-O-
.beta.-D-
galactopyranosyl-,
monohydrate
Cellulose microcrys-
talline
864070-44-0
Not Assigned

cellulose

Empagliflozin

Non-hazardous galenic excipients, solid

California Prop. 65

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

California Permissible Exposure Limits for Chemical Contaminants

cellulose

Cellulose microcrys-
talline

The components of this product are reported in the following inventories:

REACH : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Empagliflozin

Non-hazardous galenic excipients, solid

AICS : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

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PICCS : Not in compliance with the inventory
IECSC : Not in compliance with the inventory
TCSI : Not in compliance with the inventory
TSCA : Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION

Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

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Version
1.1

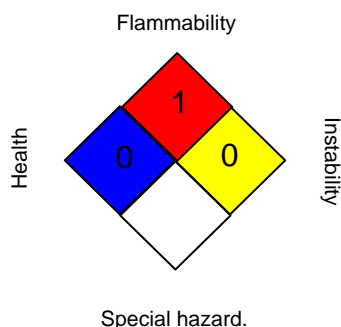
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Further information

NFPA:



HMIS® IV:

HEALTH	/	0
FLAMMABILITY		1
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Vertical lines in the left hand margin indicate an amendment from the previous version. Refer to NFPA 654, Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate Solids, for safe handling.

Sources of key data used to compile the Safety Data Sheet : The specifications are based on own tests and/or literature data.

Revision Date : 08/10/2017

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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