

**Synjardy® tablets**

Version            Revision Date:            MSDS Number:            Date of last issue: 06/03/2015  
2.0                09/09/2015                000000031956            Date of first issue: 06/03/2015

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**SECTION 1. IDENTIFICATION**

Product name                                : Synjardy® tablets

Synonyms                                     : Synjardy® tablets 5mg/500mg, 5mg/850mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/850mg and 12.5mg/1000mg, Jardiance Duo® tablets 5 mg/500mg, 5 mg/850mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/850mg and 12.5mg/1000mg, Jardiamet® tablets 5mg/500mg, 5mg/850mg, 5mg/1000mg, 12.5mg/500mg, 12.5mg/850mg and 12.5mg/1000mg  
Active ingredient: Empagliflozin and Metformin hydrochloride

Product code                                : 000000031956

**Manufacturer or supplier's details**

Company name of supplier                : Boehringer-Ingelheim Pharmaceuticals, Incorporated

Address                                        : 900 Ridgebury Road  
Ridgefield, Connecticut  
06877-0368

Telephone                                     :

Telefax                                        :

Emergency telephone number            : +1-800-424-9300 CHEMTREC Emergency Phone Number  
CHEMTREC – 24 Hours

Routine Contact Number                 : (203) 778-7759

**Recommended use of the chemical and restrictions on use**

Recommended use                            : Mixture for production of finished medicinal products.

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

Prepared by                                   : Corp. Div. EHS & Sustainability / Global EHS Services  
[EHS-service@boehringer-ingelheim.com](mailto:EHS-service@boehringer-ingelheim.com)

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**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

Acute toxicity (Oral)                      : Category 4

**GHS Label element (Hazard Communication Standard (HCS) 29 CFR 1910.1200)**

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Hazard pictograms	:	
Signal word	:	Warning
Hazard statements	:	H302 Harmful if swallowed.
Precautionary statements	:	<p><b>Prevention:</b> P264 Wash skin thoroughly after handling. P270 Do not eat, drink or smoke when using this product.</p> <p><b>Response:</b> P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER or doctor/ physician if you feel unwell. Rinse mouth.</p> <p><b>Disposal:</b> P501 Dispose of contents/ container to an approved waste disposal plant.</p>
<b>Other hazards</b>		None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
Metformin hydrochloride	1115-70-4	85

**SECTION 4. FIRST AID MEASURES**

General advice	:	<p>Remove from exposure, lie down. Take off immediately all contaminated clothing. Victim to lie down in the recovery position, cover and keep him warm. First Aid responders should pay attention to self-protection and use the recommended protective clothing</p>
If inhaled	:	<p>Move to fresh air. Call a physician immediately.</p>
In case of skin contact	:	<p>Wash off immediately with plenty of water. If symptoms persist, call a physician.</p>
In case of eye contact	:	<p>Rinse immediately with plenty of water for at least 15 minutes. Keep eye wide open while rinsing. Call a physician immediately.</p>

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If swallowed	:	Rinse mouth. Drink plenty of water. Call a physician immediately.
Most important symptoms and effects, both acute and delayed	:	Harmful if swallowed.
Notes to physician	:	Observe the summary of product characteristics of proprietary medicinal products Symptomatic treatment (decontamination, vital functions).

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**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 (CO <sub>2</sub> )
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 <sub>x</sub> ) 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 for firefighters	:	Self-contained breathing apparatus (EN 133) complete suit protecting against chemicals

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	:	Wear personal protective equipment. Keep people away from and upwind of spill/leak. Ensure adequate ventilation.
Environmental precautions	:	Do not flush into surface water or sanitary sewer system.
Methods and materials for containment and cleaning up	:	Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Clean-up methods - large spillage Dampen, pick up mechanically and dispose of. Clean-up methods - small spillage Use approved industrial vacuum cleaner for removal. Keep in suitable, closed containers for disposal. Never return spills in original containers for re-use.

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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Keep away from heat and sources of ignition. Avoid dust formation.
- Advice on safe handling : Provide sufficient air exchange and/or exhaust in work rooms. Minimize dust generation and accumulation. Breathing must be protected when large quantities are de-canted without local exhaust ventilation. Keep container closed when not in use.
- Conditions for safe storage : Keep tightly closed in a dry and cool place. Protect from heat and direct sunlight. Jointless smooth floor
- 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	Factor	Catergory	Values	Remark
N,N-Dimethyl-imidodicarbonimidic-diamid Hydrochloride 1115-70-4	ECL		1	1,300 µg/m3	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					
Factor = Ceiling limit/Exceeding factor					

Components	Basis	Factor	Catergory	Values	Remark
(2S,3R,4R,5S,6R)-2-(4-Chloro-3-{4-[(S)-(tetrahydro-furan-3-yl)oxy]-benzyl}-phenyl)-6-hydroxymethyl-tetrahydro-pyran-3,4,5-triol 864070-44-0	ECL		2	100 µg/m3	
	BIPC		1b		
ECL (BIPI Exposure Control Limit)					
Factor = Ceiling limit/Exceeding factor					

**Engineering measures** : Local exhaust

**Personal protective equipment**

Respiratory protection : No personal respiratory protective equipment normally required.

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Respirator must be worn if exposed to dust.  
half mask (EN 140)  
particle filter P2

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	: Always wear eye protection when the potential for inadvertent eye contact with the product cannot be excluded. Safety glasses with side-shields
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Skin and body protection	: Laboratory: laboratory coat; factory: disposable Overall.
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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.
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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	: Decomposes before melting.
Boiling point/boiling range	: Not applicable
Flash point	: Not applicable
Evaporation rate	: Not applicable
Flammability (solid, gas)	: No data available

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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 : partly soluble  
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

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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

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#### SECTION 11. TOXICOLOGICAL INFORMATION

##### Acute toxicity

Harmful if swallowed.

##### Product:

Acute oral toxicity : Acute toxicity estimate: 1,176 mg/kg  
Method: Calculation method

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**Components:****Metformin hydrochloride:**

Acute oral toxicity : LD50 (Mouse): = 1,450 mg/kg

LD50 (Rat): = 1,000 mg/kg

Acute inhalation toxicity : Remarks: No data available

Acute dermal toxicity : Remarks: No data available

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Metformin hydrochloride:**

Species: Rabbit

Assessment: No skin irritation

Result: Mild skin irritation

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Metformin hydrochloride:**

Species: Rabbit

Result: Causes mild skin and eye irritation

Assessment: No eye irritation

**Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

**Components:****Metformin hydrochloride:**

Remarks: No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Metformin hydrochloride:**

Genotoxicity in vitro : Test Type: Ames-test  
Species: Salmonella typhimurium  
Result: negative

: Test Type: Chromosomal aberration test  
Result: negative

: Test Type: Chromosomal aberration test  
Species: Human lymphocytes  
Result: negative

Genotoxicity in vivo : Test Type: Micronucleus test

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Species: Mouse  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Metformin hydrochloride:**

Remarks: Did not show carcinogenic effects in animal experiments.

**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**

No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**Components:****Metformin hydrochloride:**

No data available

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**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****Metformin hydrochloride:**

Toxicity to fish : Remarks: No data available

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): = 64 mg/l  
Exposure time: 48 h

Toxicity to algae : EC50 (Desmodesmus subspicatus): > 320 mg/l  
EC50 (Lemna minor (duckweed)): = 110 mg/l



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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)      :    Remarks: No data available

Toxicity to bacteria      :    Remarks: No data available

**Persistence and degradability**

No data available

**Bioaccumulative potential****Components:****Metformin hydrochloride:**

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

**Mobility in soil**

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).

Additional ecological information      :    No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

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

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

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**SECTION 14. TRANSPORT INFORMATION****International Regulation****IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

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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**

**TSCA list** : Not relevant

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

**SARA 311/312 Hazards** : Acute Health Hazard

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**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 12 (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 Intermediate or Final VOC's (40 CFR 60.489).

**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

**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Metformin hydrochloride	1115-70-4	70 - 90 %
Empagliflozin	864070-44-0	1 - 5 %

**New Jersey Right To Know**

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
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Metformin hydrochloride	1115-70-4	70 - 90 %
Empagliflozin	864070-44-0	1 - 5 %

**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.

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

REACH : Not in compliance with the inventory

: Metformin hydrochloride

: Empagliflozin

: Non-hazardous galenic excipients

CH INV : Not in compliance with the inventory

: Metformin hydrochloride

: Empagliflozin

: Non-hazardous galenic excipients

TSCA : Not On TSCA Inventory

: Metformin hydrochloride

: Empagliflozin

: Non-hazardous galenic excipients

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

: Metformin hydrochloride

: Empagliflozin

: Non-hazardous galenic excipients

CEPA : Not in compliance with the inventory

: Metformin hydrochloride

: Empagliflozin

: Non-hazardous galenic excipients

AICS : Not in compliance with the inventory

: Metformin hydrochloride

: Empagliflozin

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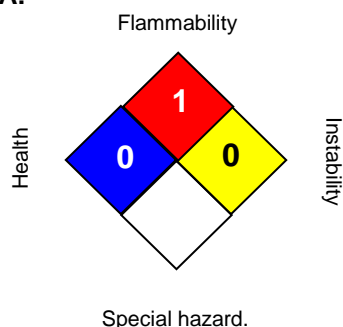
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	: Non-hazardous galenic excipients
NZIoC	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients
ENCS	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients
ISHL	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients
KECI	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients
PICCS	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients
IECSC	: Not in compliance with the inventory
	: Metformin hydrochloride
	: Empagliflozin
	: Non-hazardous galenic excipients

#### Inventories

AICS (Australia), DSL (Canada), IECSC (China), REACH (European Union), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

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**SECTION 16. OTHER INFORMATION****Further information****NFPA:****HMIS III:**

<b>HEALTH</b>	<b>0</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

0 = not significant, 1 =Slight,  
 2 = Moderate, 3 = High  
 4 = Extreme, \* = Chronic

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.

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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.