

SAFETY DATA SHEET

Jentaduetto® Tablets

Version 2.1 Revision Date: 06/09/2016 SDS Number: 000000028685 Date of last issue: 06/08/2016
Date of first issue: 05/28/2015

SECTION 1. IDENTIFICATION

Product name : Jentaduetto® Tablets

Synonyms : Jentaduetto® Tablets 2.5/500 mg, 2.5/850 mg, and 2.5/1000 mg,
Jentaduetto® extended-release tablets 2.5/750 mg, 2.5/1000 mg, and 5/1000 mg

Active ingredients: Linagliptin <1 % and Metformin hydrochloride >=25%,

Manufacturer or supplier's details

Company name of supplier : Boehringer Ingelheim Pharmaceuticals, Incorporated

Address : 900 Ridgebury Road
Ridgefield CT 06877-0368

Telephone : (203) 778-7759

Prepared by : EHS-Services@Boehringer-Ingelheim.com

Emergency telephone number : 1-800-424-9300 Chemtrec 24-hours DE

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

Acute toxicity (Oral) : Category 4

GHS label elements

Hazard pictograms : 

Signal word : Warning

Hazard statements : H302 Harmful if swallowed.

Precautionary statements : **Prevention:**

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P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.

Response:

P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

The pharmacological effect of the medicament has to be considered (e.g. see package leaflet).

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Substance name : Jentaduetto® Tablets 2.5/500 mg, 2.5/850 mg, and 2.5/1000 mg, Jentaduetto® extended-release tablets 2.5/750 mg, 2.5/1000 mg, and 5/100

Hazardous components

Chemical name	CAS-No.	Concentration (% w/w)
Metformin hydrochloride	1115-70-4	>= 25
Linagliptin	668270-12-0	< 1

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.
Take off immediately all contaminated clothing.
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.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Components with workplace control parameters

Components	Basis	Category	Values	Remark
Metformin hydrochloride 1115-70-4	ECL	1	1,300 µg/m ³ 4,000 µg/m ³ (BI-STEL 15 min, 4x)	
	BIPC	1b		
Abbreviations: ECL (BIPI Exposure Control Limit)				

Components	Basis	Category	Values	Remark
Linagliptin 668270-12-0	ECL	3A	30 µg/m ³ 240 µg/m ³ (BI-STEL 15 min, 4x)	
	BIPC	1b	60 µg/m ³ (BI-STEL 60 min, 4x)	
Abbreviations: ECL (BIPI Exposure Control Limit)				

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.

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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.

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 : No data available

Boiling point/boiling range : Not applicable

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : 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 : No data available

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Explosive properties : No data available
Oxidizing properties : No data available

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

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

Linagliptin:

Acute oral toxicity : Acute toxicity estimate (Rat): > 2,000 mg/kg
Method: OECD Test Guideline 423
Acute toxicity estimate (Mouse): > 1,000 mg/kg
Acute inhalation toxicity : Remarks: No data available
Acute dermal toxicity : Remarks: No data available

Skin corrosion/irritation

Components:

Metformin hydrochloride:

Species: Rabbit
Assessment: No skin irritation

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Linagliptin:

Effects on fertility : Test Type: Fertility/early embryonic development
Species: Rat
Application Route: Oral
Dose: 10, 30, 240 milligram per kilogram
General Toxicity - Parent: NOAEL: 30 mg/kg body weight
Early Embryonic Development: 240 mg/kg body weight

Test Type: Pre-/postnatal development
Species: Rat
Application Route: Oral
Dose: 10, 30, 300 milligram per kilogram
General Toxicity - Parent: NOAEL: 30 mg/kg body weight

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Oral
Dose: 10, 30, 240 milligram per kilogram
General Toxicity Maternal: NOAEL: 4 mg/kg body weight
Embryo-foetal toxicity: NOAEL: 25 mg/kg body weight

STOT - single exposure

Components:

Metformin hydrochloride:
Remarks: No data available

Linagliptin:
Remarks: No data available

STOT - repeated exposure

Components:

Metformin hydrochloride:
Remarks: No data available

Linagliptin:
Remarks: No data available

Repeated dose toxicity

Components:

Linagliptin:
Species: Rat
NOAEL: 30 mg/kg
Application Route: Oral
Exposure time: 26 weeks

Species: Monkey

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NOAEL: 10 mg/kg
Application Route: Oral
Exposure time: 52 weeks

Aspiration toxicity

Components:

Metformin hydrochloride:

No data available

Linagliptin:

No data available

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

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

Linagliptin:

Toxicity to fish : Remarks: No data available

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

Toxicity to algae : EC50 (Algae): = 16 mg/l
End point: Biomass
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

EC50 (Algae): = 49 mg/l

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- End point: Growth rate
Exposure time: 72 h
GLP: yes
- NOEC (Algae): = 4.1 mg/l
End point: Biomass
Exposure time: 72 h
- NOEC (Algae): = 4.1 mg/l
End point: Growth rate
Exposure time: 72 h
- Toxicity to fish (Chronic toxicity) : NOEC (Brachydanio rerio (zebrafish)): > 12 mg/l
Exposure time: 30 d
Test Type: semi-static test
Method: Fish, Early-Life Stage Toxicity Test
- Lowest Observed Effect Concentration (Brachydanio rerio (zebrafish)): > 12 mg/l
Exposure time: 30 d
Test Type: semi-static test
Method: Fish, Early-Life Stage Toxicity Test
- Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia (water flea)): = 3.2 mg/l
Exposure time: 21 d
Test Type: semi-static test
Method: OECD Test Guideline 211
- Lowest Observed Effect Concentration (Daphnia (water flea)): = 10 mg/l
Exposure time: 21 d
Test Type: semi-static test
Method: OECD Test Guideline 211
- NOEC (Chironomus riparius (harlequin fly)): = 125 mg/l
Exposure time: 28 d
- Toxicity to bacteria : EC50 (activated sludge, industrial): = 792 mg/l
Method: OECD 209
GLP:
- Toxicity to terrestrial organisms : NOEC (flies): = 125 mg/kg

Persistence and degradability

Components:

Metformin hydrochloride:

Biodegradability : Remarks: No data available

Linagliptin:

Biodegradability : Result: Not readily biodegradable.
Biodegradation: 0 %

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Exposure time: 28 d
Method: OECD Test Guideline 301A

Bioaccumulative potential

Components:

Metformin hydrochloride:

Bioaccumulation : Remarks: No data available

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

Linagliptin:

Bioaccumulation : Bioconcentration factor (BCF): 31
Remarks: No bioaccumulation is to be expected (log P(o/w)<1).

Partition coefficient: n-octanol/water : log Pow: 0.4

Mobility in soil

Components:

Metformin hydrochloride:

Distribution among environmental compartments : Remarks: No data available

Linagliptin:

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:

Metformin hydrochloride:

Additional ecological information : No data available

Linagliptin:

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.
-

SECTION 14. TRANSPORT INFORMATION

International Regulation

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

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 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 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

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	90 - 100 %

New Jersey Right To Know

Non-hazardous galenic excipients	Not Assigned	90 - 100 %
Metformin hydrochloride	1115-70-4	90 - 100 %

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

REACH	Not in compliance with the inventory Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
CH INV	Not in compliance with the inventory Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
TSCA	Not On TSCA Inventory Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
CEPA	Not in compliance with the inventory Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
AICS	Not in compliance with the inventory Metformin hydrochloride Non-hazardous galenic excipients Linagliptin
NZIoC	Not in compliance with the inventory Metformin hydrochloride

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

TSCA list

Not relevant

Not relevant

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

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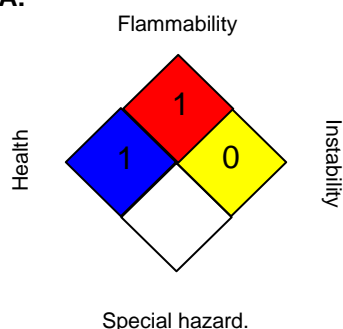
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Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (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

Further information

NFPA:



HMIS III:

HEALTH	1
FLAMMABILITY	1
PHYSICAL HAZARD	0

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.

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