

# Safety Data Sheet for Drug product



Date of issue: 04-NOV-2016

Replaces version of: 15-JUN-2016

ENTRESTO 24/26MG 1X14 FCT - BES 737646 (IT10)

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

**Product name** ENTRESTO 24/26MG 1X14 FCT - BES  
**Generic Name** LCZ696-ABA  
**Pharmacological Action** antihypertensive agent  
**Usage** Drug product (pharmaceutical bulk, primary packed, finished product, pharmaceutical intermediate)  
**Company name** Novartis Pharma AG  
4002 Basel  
Switzerland  
Tel: +41 61 324 11 11, email: sds.support@novartis.com  
**Emergency phone number** CHEMTEL (International) +1 813 676 1670 (365/24/7)

## 2. Hazards identification

For side effects, which could also have impact for people working with this substance, please refer to the Patient Information Leaflet.

## 3. Composition / information on ingredients

For classification of declared components, see section 15, "Regulatory Information"

Chemical Name	Contains:	CAS Number
LCZ696-ABA	> 25 %	936623-90-4

Remaining components are inert ingredients.

For TLV values of declared components, see Section 8, Exposure controls / Personal

## 4. First aid measures

**Eye Contact** Immediately rinse eyes thoroughly with running water as long as possible (approx. 15 min). Take injured quickly to factory medical center or call an ambulance (code word: eye accident).  
**Skin Contact** Remove contaminated clothing. Rinse contaminated skin immediately with plenty of water and soap and seek medical advice.  
**Inhalation** Remove the victim from danger zone, avoid further exposure.  
**Ingestion** If swallowed, seek medical advice immediately and show this container or label.  
**Notes to Physician** General measures to eliminate the substance and to reduce absorption.

## 5. Fire fighting measures

**Suitable Extinguishing Media** Water spray or fog, foam, dry chemical powder, CO2, dry sand  
**Unsuitable Extinguishing Media** No restrictions  
**Dangerous Combustion Products** nitrogen oxides  
**Protective equipment for firefighters** Wear self-contained breathing apparatus and fire protective suite.

## 6. Accidental release measures

**Personal precautions** Avoid contact with skin, eyes and clothing.  
**Environmental precautions** Must not be released into sewers, drains or wells.

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**Methods for cleaning** Transfer large quantities into a container. Clean up the rest with absorbent material and discharge properly.

## 7. Handling and storage

No special handling requirements for normal use of this material.

Store in a dry and cool place and observe special instructions from supplier.

## 8. Exposure controls / Personal protection

### Occupational Exposure Limit (OEL)

no data available

### TLV values of declared components

Contains:

LCZ696-ABA

List type	Value	Unit	
Internal exposure limit	100	µg/m <sup>3</sup>	HHA Database

### Personal protection for open handling

Health care personnel



Safety glasses (EN166) Lab coat Disposable gloves (EN374)

## 9. Physical and chemical properties

**Formulation**

Tablet

**Flash Point**

not applicable

## 10. Stability and reactivity

Under the normal conditions of use, the product is stable.

## 11. Toxicological information

**Acute Toxicity** no data available

**Irritation, Corrosion**

Data of LCZ696-ABA

Eyes (Species: rabbit) irritant

Method: OECD 405 \* 2002 \* Acute Eye Irritation/Corrosion

Result of a related substance.

Data of LCZ696-ABA

Skin (Species: rabbit) non irritant

Method: OECD 404 \* 2002 \* Acute Dermal Irritation/Corrosion

Result of a related substance.

**Sensitisation**

Data of LCZ696-ABA

Skin (Species: mouse) weakly sensitizing

Method: OECD 429 \* 2004 \* Skin sensitisation (LLNA)

Result of a related substance.

**Mutagenicity**

Values of LCZ696-ABA

The product showed negative results in in vitro mutagenicity studies. The product showed negative results in in vivo mutagenicity studies.

Data of LCZ696-ABA

Negative with and without metabolic activation (AMES-Test (reverse mutation assay)) in vitro

Data of LCZ696-ABA

Negative with and without metabolic activation (Chromosome Aberration Study)

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	in vitroCell: Cultured peripheral human lymphocytes
	Data of LCZ696-ABA
	Negative (Micronucleus Test)
	in vivo, Species: rat, Cell: Bone marrow
<b>Chronic Effects</b>	Data of LCZ696-ABA (Repeated Dose Toxicity) NOAEL: 30 mg/kg/d Route: oral Species: rat Duration: 13 weeks
	Data of LCZ696-ABA (Repeated Dose Toxicity) NOAEL: 30 mg/kg/d Route: oral Species: rat Duration: 26 weeks
	Data of LCZ696-ABA (Repeated Dose Toxicity) NOAEL: 30 mg/kg/d Route: oral Species: cynomolgus monkey (Macaca fascicularis), Organ: Kidneys Duration: 13 weeks
	Data of LCZ696-ABA (Repeated Dose Toxicity) NOAEL: 30 mg/kg/d Route: oral Species: monkey, Organ: Kidneys Duration: 39 weeks
<b>Reproduction Toxicity</b>	Data of LCZ696-ABA Maternal toxicity / embryotoxicity - no teratogenicity (Embryo-Fetal Development) NOAEL: 3 mg/kg/d Route: oral Species: rabbit, Sex: female
	Data of LCZ696-ABA Maternal toxicity (Embryo-Fetal Development) NOAEL: 200 mg/kg/d Route: oral Species: rat, Sex: female
	Data of LCZ696-ABA Paternal toxicity (Fertility and early Embryonic Development) NOAEL: 50 mg/kg/d Route: Dietary Species: rat, Sex: both sexes
	Data of LCZ696-ABA Fertility effects (Fertility and early Embryonic Development) NOEL: 150 mg/kg/d Route: Dietary Species: rat, Sex: both sexes
	Data of LCZ696-ABA Fetotoxicity at maternally non toxic dose (Embryo-Fetal Development) NOAEL: 30 mg/kg/d Route: oral Species: rat, Sex: female

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## 12. Ecological information

<b>Biological Elimination</b>	Data of LCZ696-ABA Degradation: 0 % (Temperature: 23.4 °C DOC)
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	Not readily degradable Initial conc.: 20 mg DOC/l, Duration: 28 days Method: 92/69/EC (L383) C.4-B * Modified OECD screening test
<b>Fish acute toxicity</b>	no data available
<b>Aquatic invertebrate acute toxicity</b>	Data of LCZ696-ABA EC50: > 100 mg/l NOEC: 100 mg/l Species: daphnia magna (water flea) Exp. time: 48 hours Method: 92/69/EEC (L383) C.2 * Acute toxicity for daphnia
<b>Algae Toxicity</b>	Data of LCZ696-ABA ErC50: > 100 mg/l EbC50: > 100 mg/l NOEC: 100 mg/l Species: Green algae - fresh water (Pseudokirchneriella subcapitata) Exp. time: 72 hours Method: 92/69/EC (L383) C.3
<b>Bacterial Respiration Inhibition</b>	Data of LCZ696-ABA EC20: > 300 mg/l EC50: > 300 mg/l EC80: > 300 mg/l Species: activated sludge Exp. time: 3 hours Method: OECD 209 * 1984
<b>Ecotoxicity Summary</b>	Data of LCZ696-ABA No quantifiable data available. Data of LCZ696-ABA Avoid release into soil, rivers or drains.

## 13. Disposal considerations

**Disposal Requirements** Fill into suitable waste receptacles, seal and label them properly. Incineration in an approved, controlled furnace with combustion gas scrubbing and emission gas control. Local regulations should be adhered to.


## 14. Transport information

Regulation	Class	UN No.	PG	Label	LQ
RID/ADR:	Not restricted	0			N.A.
IMDG-Code:	Not restricted	0			
ICAO/IATA-DGR:	Not restricted	0			

ICAO/IATA-DGR: no dangerous good  
Proper shipping name: -

## 15. Regulatory information

Classifications of components:

Chemical Name	Contains:	CAS Number	Picto	Signal Word	Classification
LCZ696-ABA	> 25 %	936623-90-4		W	H319, H317, H361d

Remaining components are inert ingredients.

## 16. Other information

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<b>Changes since the previous version in Section</b>	3. Composition / information on ingredients 15. Regulatory information 16. Other information
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## Abbreviations used

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H361d: Suspected of damaging the unborn child.

<b>Recipient</b>	Henry Delima Delima Associates 1227 Providence Terr McLean, VA USA
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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.
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