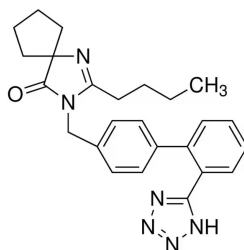


### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Product form : Substance  
Trade name : IRBESARTAN  
CAS-No. : 138402-11-6  
Product code : 4205E  
Type of product : Heterocyclic organic compound  
Formula : C<sub>25</sub>H<sub>28</sub>N<sub>6</sub>O  
Chemical structure :



Synonyms : 2-butyl-3-[[2'-(2H-tetrazol-5-yl)[1,1'-biphenyl]-4-yl]methyl]-1,3-diazaspiro[4.4]non-1-en-4-one

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : Pharmaceuticals  
Manufacture of substances

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

LOBA CHEMIE PVT.LTD.  
107 Wode House Road, Jehangir Villa, Colaba  
400005 Mumbai  
INDIA  
T +91 22 6663 6663, F +91 22 6663 6699  
[info@lobachemie.com](mailto:info@lobachemie.com), [www.lobachemie.com](http://www.lobachemie.com)

#### 1.4. Emergency telephone number

Emergency number : + 91 22 6663 6663 (9:00am - 6:00 pm)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

##### Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

##### Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

#### 2.2. Label elements

##### Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

#### 2.3. Other hazards

No additional information available

# IRBESARTAN

## Safety Data Sheet

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### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
IRBESARTAN	CAS-No.: 138402-11-6	100

#### 3.2. Mixtures

Not applicable

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : If you feel unwell, seek medical advice.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
First-aid measures after skin contact : Wash skin with plenty of water.  
First-aid measures after eye contact : Rinse eyes with water as a precaution.  
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

#### 4.2. Most important symptoms and effects, both acute and delayed

Symptoms/effects after inhalation : Dust of the product, if present, may cause respiratory irritation after an excessive inhalation exposure. Although no appropriate human or animal health effects data are known to exist, this material is expected to be an inhalation hazard.  
Symptoms/effects after skin contact : None under normal conditions. Dust may cause irritation in skin folds or by contact in combination with tight clothing.  
Symptoms/effects after eye contact : None under normal conditions. Dust from this product may cause eye irritation.  
Symptoms/effects after ingestion : None under normal conditions.

#### 4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.  
Unsuitable extinguishing media : Do not use a heavy water stream.

#### 5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.  
Explosion hazard : No direct explosion hazard.  
Hazardous decomposition products in case of fire : Toxic fumes may be released.

#### 5.3. Advice for firefighters

Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.  
Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

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### SECTION 6: Accidental release measures

#### 6.1. Personal precautions, protective equipment and emergency procedures

General measures : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage.

##### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.  
Emergency procedures : Ventilate spillage area.

##### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".  
Emergency procedures : Evacuate unnecessary personnel.

#### 6.2. Environmental precautions

Avoid release to the environment.

#### 6.3. Methods and material for containment and cleaning up

For containment : Using a clean shovel, put the material in a dry container and cover without compressing it.  
Methods for cleaning up : Mechanically recover the product.  
Other information : Dispose of materials or solid residues at an authorized site.

#### 6.4. Reference to other sections

For further information refer to section 13.

### SECTION 7: Handling and storage

#### 7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.  
Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.  
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

#### 7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.  
Storage conditions : Keep cool. Protect from sunlight.  
Storage temperature : 2 – 8 °C  
Packaging materials : Store always product in container of same material as original container.

##### Switzerland

Storage class (LK) : NG - Non-hazardous

#### 7.3. Specific end use(s)

No additional information available

### SECTION 8: Exposure controls/personal protection

#### 8.1. Control parameters

##### 8.1.1 National occupational exposure and biological limit values

No additional information available

##### 8.1.2. Recommended monitoring procedures

No additional information available

##### 8.1.3. Air contaminants formed

No additional information available

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### 8.1.4. DNEL and PNEC

No additional information available

### 8.1.5. Control banding

No additional information available

## 8.2. Exposure controls

### 8.2.1. Appropriate engineering controls

#### Appropriate engineering controls:

Ensure good ventilation of the work station.

### 8.2.2. Personal protection equipment

#### Personal protective equipment:

Wear recommended personal protective equipment.

#### Personal protective equipment symbol(s):



#### 8.2.2.1. Eye and face protection

##### Eye protection:

Chemical goggles or safety glasses

#### 8.2.2.2. Skin protection

##### Skin and body protection:

Wear a mask

##### Hand protection:

Protective gloves

#### 8.2.2.3. Respiratory protection

##### Respiratory protection:

Wear appropriate mask

#### 8.2.2.4. Thermal hazards

No additional information available

### 8.2.3. Environmental exposure controls

#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White to almost white.
Appearance	: Crystalline powder.
Molecular mass	: 428.53 g/mol
Odour	: characteristic.
Odour threshold	: Not available
Melting point	: 180 – 184 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable

# IRBESARTAN

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Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Water: Insoluble in water
Partition coefficient n-octanol/water (Log Kow)	: Not available
Partition coefficient n-octanol/water (Log Pow)	: 3.993
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

No additional information available

#### 9.2.2. Other safety characteristics

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Not classified
Serious eye damage/irritation	: Not classified
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
STOT-repeated exposure	: Not classified

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Aspiration hazard : Not classified

### IRBESARTAN (138402-11-6)

Viscosity, kinematic	Not applicable
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### 11.2. Information on other hazards

No additional information available

## SECTION 12: Ecological information

### 12.1. Toxicity

Ecology - general	: The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
Hazardous to the aquatic environment, short-term (acute)	: Not classified
Hazardous to the aquatic environment, long-term (chronic)	: Not classified

### 12.2. Persistence and degradability

#### IRBESARTAN (138402-11-6)

Persistence and degradability	Rapidly degradable
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### 12.3. Bioaccumulative potential

#### IRBESARTAN (138402-11-6)

Partition coefficient n-octanol/water (Log Pow)	3.993
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### 12.4. Mobility in soil

No additional information available

### 12.5. Results of PBT and vPvB assessment

No additional information available

### 12.6. Endocrine disrupting properties

No additional information available

### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional waste regulation	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Product/Packaging disposal recommendations	: Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations.
Additional information	: Do not re-use empty containers.

## SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

# IRBESARTAN

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### 14.1. UN number or ID number

Not regulated for transport

### 14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (ADN)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

### 14.3. Transport hazard class(es)

#### ADR

Transport hazard class(es) (ADR) : Not regulated

#### IMDG

Transport hazard class(es) (IMDG) : Not regulated

#### IATA

Transport hazard class(es) (IATA) : Not regulated

#### ADN

Transport hazard class(es) (ADN) : Not regulated

#### RID

Transport hazard class(es) (RID) : Not regulated

### 14.4. Packing group

Packing group (ADR)	: Not regulated
Packing group (IMDG)	: Not regulated
Packing group (IATA)	: Not regulated
Packing group (ADN)	: Not regulated
Packing group (RID)	: Not regulated

### 14.5. Environmental hazards

Other information : No supplementary information available

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

# IRBESARTAN

## Safety Data Sheet

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### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

##### 15.1.1. EU-Regulations

###### REACH Annex XVII (Restriction List)

Not listed on REACH Annex XVII

###### REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

###### REACH Candidate List (SVHC)

Not listed on the REACH Candidate List

###### PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

###### POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

###### Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 1005/2009)

###### Dual-Use Regulation (428/2009)

Not listed on the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

###### Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

###### Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

##### 15.1.2. National regulations

###### Germany

- Employment restrictions : Observe restrictions according Act on the Protection of Working Mothers (MuSchG).  
Observe restrictions according Act on the Protection of Young People in Employment (JArbSchG).
- Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).
- Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

###### Netherlands

- SZW-lijst van kankerverwekkende stoffen : The substance is not listed
- SZW-lijst van mutagene stoffen : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed
- SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

#### Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road



# IRBESARTAN

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Abbreviations and acronyms:	
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.