VILDAGLIPTIN

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878
Issue date: 2/14/2013 Revision date: 11/17/2022 Supersedes version of: 9/21/2020 Version: 5.0

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

1.1. Product identifier

Product form	:	Substance
Trade name	:	VILDAGLIPTIN
Chemical name	:	(2S)-1-{2-[(3-hydroxyadamantan-1-yl)amino]acetyl}pyrrolidine-2-carbonitrile
IUPAC name	:	(2S)-1-{2-[(3-hydroxyadamantan-1-yl)amino]acetyl}pyrrolidine-2-carbonitrile
CAS-No.	:	274901-16-5
Product code	:	79110
Type of product	:	Active Ingredient for Medicinal / Pharmaceutical Use
Formula	:	C17H25N3O2
Synonyms	:	Galvus; / (-)-(2s)-1-(((3-hydroxytricyclo(3.3.1.1(3,7))dec-1-yl)amino)acetyl)pyrrolidine- / 2-carbonitrile
Product group	:	Active Ingredient for Medicinal/Pharmaceutical Use
Other means of identification	:	CANONICAL SMILES:OC12CC3CC(C1)CC(C3)(C2)NCC(=O)N1CCC[C@H]1C#N

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

1.2.1. Relevant identified uses

Main use category	:	API,Medicinal use
Industrial/Professional use spec	:	Active Ingredient for Medicinal / Pharmaceutical Use Industrial For professional use only Laboratory activities
Use of the substance/mixture	:	Vildagliptin belongs to a class of orally active antidiabetic drugs (DPP-IV inhibitors) that have multiple functional benefits beyond simple blood-glucose control. One of these is a protective effect on pancreatic beta cells, which deteriorate in diabetes
Function or use category	:	Pharmaceuticals

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier
MOEHS IBÉRICA, S.L.
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Spain
T +34 93 586 05 20 - F +34 93 699 8350
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Manufacturer
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Manufacturer
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Zenc 12, Pol. Ind Aquiberia
08755 Castellbisbal
Spain
T +34 93 586 05 20 - F + 34 93 699 83 50
hse@moehs.es - www.moehs.es

1.4. Emergency telephone number

Emergency number	:	+34 93 586 05 20 (9:00 - 17:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4	H302

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed.

2.2. Label elements

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

Hazard pictograms (CLP) :

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed.

Precautionary statements (CLP) : P264 - Wash hands, forearms and face thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.
P280 - Wear protective gloves, eye protection, protective clothing, face protection.
P301+P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

2.3. Other hazards

Other hazards which do not result in classification : None under normal conditions.

vPvB: not relevant – no registration required

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type : Mono-constituent

Name	Product identifier	%
VILDAGLIPTIN	CAS-No.: 274901-16-5	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell. If you feel unwell, seek medical advice (show the label where possible).

First-aid measures after inhalation : Allow affected person to breathe fresh air. Allow the victim to rest. If you feel unwell, seek medical advice.

First-aid measures after skin contact : Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists: Get medical advice/attention. Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth. Do NOT induce vomiting. Obtain emergency medical attention. Call a POISON CENTER/doctor if you feel unwell.

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

Symptoms/effects : Not expected to present a significant hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice. Harmful if swallowed.

Symptoms/effects after ingestion : Harmful if swallowed.

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

Never give anything by mouth to an unconscious person.

SECTION 5: Firefighting measures

5.1. Extinguishing media

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

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Precautionary measures fire : Stop leak if safe to do so.
Firefighting instructions : Use water spray or fog for cooling exposed containers. Exercise caution when fighting any chemical fire. Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Evacuate unnecessary personnel.
Measures in case of dust release : Dust formation: dust mask.

6.1.2. For emergency responders

Protective equipment : Equip cleanup crew with proper protection.
Emergency procedures : Ventilate area. Shovel or sweep up and put in a closed container for disposal.

6.2. Environmental precautions

Prevent entry to sewers and public waters. Notify authorities if liquid enters sewers or public waters.

6.3. Methods and material for containment and cleaning up

For containment : Collect spillage.
Methods for cleaning up : On land, sweep or shovel into suitable containers. Minimise generation of dust. Store away from other materials.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

See Section 8. Exposure controls and personal protection.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Keep away from Strong acids, strong bases and oxidation agents, Heat and ignition sources. No smoking.
Precautions for safe handling : Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Provide good ventilation in process area to prevent formation of vapour.
Hygiene measures : Do not eat, drink or smoke when using this product. Wash hands, forearms and face thoroughly after handling.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	:	Store in a well-ventilated place. Keep cool. Keep container closed when not in use. Store in original container.
Incompatible products	:	Strong bases. Strong acids.
Incompatible materials	:	Sources of ignition. Direct sunlight.
Storage area	:	Store in a well-ventilated place.

7.3. Specific end use(s)

Active Ingredient for Medicinal/Pharmaceutical Use.

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

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

Control banding : MOEHS occupational exposure band: 2 (0.1 - 1 mg/m3)

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:
Avoid all unnecessary exposure. Gloves. Safety glasses. Dust/aerosol mask with filter type P3.

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

Hand protection:
Wear protective gloves.

Hand protection		
Type	**Material**	**Standard**
Disposable gloves	Natural rubber, Latex, Butyl rubber, Polyvinylchloride (PVC), Polyvinylalcohol (PVA), Vinyl	EN ISO 374

Other skin protection Materials for protective clothing		
Condition	**Material**	**Standard**
Good resistance:	Tyvek®, Polyethylene, Synthetic material	EN 1149-1, EN ISO 13982-1, EN 13034

8.2.2.3. Respiratory protection

Respiratory protection:
Wear appropriate mask

Respiratory protection			
Device	**Filter type**	**Condition**	**Standard**
Dust mask, Powered mask, Supplied-Air Respirator (SAR)	Type P3	High dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:
Avoid release to the environment.

Other information:
Do not eat, drink or smoke during use.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	:	Solid
Colour	:	white to slightly yellow.
Appearance	:	Dust.
Molecular mass	:	303.4 g/mol
Odour	:	characteristic.
Odour threshold	:	Not available
Melting point	:	148 – 150 °C [SciFinder]
Freezing point	:	Not available
Boiling point	:	531.3 °C [± 50 °C (760 mmHg) Predicted SciFinder, accessed July 2018]
Flammability	:	May form combustible dust concentrations in air
Explosive limits	:	Not applicable
Lower explosion limit	:	Not applicable
Upper explosion limit	:	Not applicable
Flash point	:	275.1 °C
Auto-ignition temperature	:	Not applicable
Decomposition temperature	:	Not available
pH	:	Not available
pH solution	:	Not available
Viscosity, kinematic	:	Not applicable
Solubility	:	Water: 3 g/l [Predicted; Unbuffered water pH=10.26; 25 °C; SciFinder]
Partition coefficient n-octanol/water (Log Kow)	:	Not available
Partition coefficient n-octanol/water (Log Pow)	:	0.056 [OECD Guideline 107; FASS.es, 2020]
Vapour pressure	:	Not available
Vapour pressure at 50°C	:	Not available
Density	:	1.27 g/cm³ [± 0.1 g/cm3 (20°C, 760 Torr); predicted by Scifinder]
Relative density	:	Not available
Relative vapour density at 20°C	:	Not applicable
Particle size	:	Not available
Particle size distribution	:	Not available

Particle shape	:	Not available
Particle aspect ratio	:	Not available
Particle aggregation state	:	Not available
Particle agglomeration state	:	Not available
Particle specific surface area	:	Not available
Particle dustiness	:	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

Additional information : Layer Minimum flammability Temperature : > 400 ºC.
Dust Cloud minimum Flammability Temperature : 360 ºC.
Minimum ignition energy : 5-6 mJ.
Explosion Class : St2.
Explosivity Pmax : 7,5 bar·g.
Explosion Severity Factor Kmax (bar.m/s) : 207

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

Not established.

10.4. Conditions to avoid

Direct sunlight. Extremely high or low temperatures.

10.5. Incompatible materials

Strong acids. Strong bases.

10.6. Hazardous decomposition products

fume. Carbon monoxide. Nitrogen oxides. Carbon dioxide.

SECTION 11: Toxicological information

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

Acute toxicity (oral)	:	Harmful if swallowed.
Acute toxicity (dermal)	:	Not classified
Acute toxicity (inhalation)	:	Not classified

VILDAGLIPTIN (274901-16-5)	
LD50 oral rat	300 – 2000 mg/kg [Predicted]
LD50, intravenous, rat	[Only English] For the IV route, the maximum non-lethal dose (MNLD) was 100 mg/kg (males) and 500 mg/kg (females) in mice, and 200 mg/kg in rats. In mice, severe clinical signs were observed at 500 mg/kg/IV and consisted of ataxia, tremors, laboured respiration, decreased locomotor activity and convulsions. (Australian Public Assesment Report for Vildagliptin)

Skin corrosion/irritation	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met

Serious eye damage/irritation	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met
Respiratory or skin sensitisation	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met
Germ cell mutagenicity	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met :[Only English] An appropriate ser of genotoxicity studies was submitted, including bacterial reverse mutation assays in Salmonella typhimurium, an in vitro mutation assay in mammalian cells, an in vitro chromosome aberration assay in human lymphocytes, an in vivo assay of DNA damage, and in vivo chromosome aberration assays in mice and rats. Vildagliptin was negative in the remaining in vitro an in vivo studies, Vildagliptin is unlihely to be genotoxic in humans at the proposed dose.
Carcinogenicity	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met :[Only English] Carcinogenicity studies of 2 years duration were conducted in mice and rats by the oral route. Mammary tumours. An increase in mammary adenocarcinoma was observed in female mice. In the absence of genotoxicicty and in the absence of a positivesignal in rats, the mammary adenocarcinomas are considered the product of mouse-specific hormanal changes occurring at high relative exposures that are not clinically relevant. Haemangiosarcoma. The incidence was only increased at large exposure margins, predominantly in male mice, and with flat dose-response. Therefore, in the absence of a genotoxicity signal or the occurrence of tumours at key sites of pharmacological action (for example the pancreas), Vildagliptin is not considered to pose a carcinogenic risk to humans at clinically relevant doses.
Reproductive toxicity	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met :[Only English] An acceptable set of well-designed reproductive toxicity studies was submitted. Vildagliptin exhibited minimal effects on reproductive parameters even at relatively high animal:human systemic exposure ratios. Vildagliptin and/or its metabolites were shown to cross the placenta in rats. There was no evidence of teratogenicity in rats or rabbits at exposure ratios up to 117 and 39, respectively.
STOT-single exposure	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met
STOT-repeated exposure	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met
Aspiration hazard	:	Not classified
Additional information	:	Based on available data, the classification criteria are not met

11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties	:	The substance is not included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

11.2.2. Other information

Potential adverse human health effects and symptoms	:	Harmful if swallowed.

SECTION 12: Ecological information

12.1. Toxicity

Hazardous to the aquatic environment, short–term (acute)	:	Not classified
Hazardous to the aquatic environment, long–term (chronic)	:	Not classified

VILDAGLIPTIN (274901-16-5)	
EC50 - Crustacea [1]	> 100 mg/l [Experimental study (FASS.es, 2020)]

VILDAGLIPTIN (274901-16-5)	
EC50 72h - Algae [1]	> 100 mg/l [Selenastrum capricornutum; Experimental study (FASS.es, 2020)]
NOEC chronic fish	10 mg/l [NOEC 30 days; Pimephales promelas, Fathead minnow; Experimental study (FASS.es, 2020)]
NOEC chronic crustacea	5.6 mg/l [NOEC 21 days; Experimental study (FASS.es, 2020)]
NOEC chronic algae	100 mg/l [NOEC 21 days; Experimental study (FASS.es, 2020)]

12.2. Persistence and degradability

VILDAGLIPTIN (274901-16-5)	
Persistence and degradability	Not established.

12.3. Bioaccumulative potential

VILDAGLIPTIN (274901-16-5)	
Partition coefficient n-octanol/water (Log Pow)	0.056 [OECD Guideline 107; FASS.es, 2020]
Bioaccumulative potential	Not established.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

VILDAGLIPTIN (274901-16-5)
vPvB: not relevant – no registration required

12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture has no endocrine disrupting properties.

12.7. Other adverse effects

Additional information : Avoid release to the environment.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.

Ecology - waste materials : Avoid release to the environment.

SECTION 14: Transport information

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

14.1. UN number or ID number

UN-No. (ADR) : Not regulated
UN-No. (IMDG) : Not regulated
UN-No. (IATA) : Not regulated
UN-No. (ADN) : Not regulated
UN-No. (RID) : Not regulated

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

Dangerous for the environment	:	No
Marine pollutant	:	No
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

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)

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

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 of 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

Denmark

Danish National Regulations	:	Young people below the age of 18 years are not allowed to use the product

Switzerland

Storage class (LK)	:	LK 11/13 - Solids

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Data sources	:	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
Other information	:	None.

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

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.