

Sitagliptin, 100 µg/ml in Acetonitril

Version number: GHS 1.0

Date of compilation: 2021-12-08

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

1.1 Product identifier

Trade name	Sitagliptin, 100 µg/ml in Acetonitril
Registration number (REACH)	not relevant (mixture)
CAS number	486460-32-6
Article number	A0279223

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

Relevant identified uses	General use
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1.3 Details of the supplier of the safety data sheet

Chemos GmbH & Co. KG
Sonnenring 7
84032 Altdorf
Germany

Telephone: +49 871-966346-0
Telefax: +49 871-966346-13
e-mail: chemos@chemos.de
Website: <http://www.chemos.de/>

e-mail (competent person) chemos@chemos.de

1.4 Emergency telephone number

Emergency information service +49 89 1 92 40

Poison centre				
Country	Name	Postal code/ city	Telephone	Telefax
United Kingdom	National Poison Information Centre Medical Toxicology Unit	SE14 5ER Lon- don	+44 171 635 91 91	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and cat- egory	Hazard state- ment
2.6	flammable liquid	2	Flam. Liq. 2	H225
3.1O	acute toxicity (oral)	4	Acute Tox. 4	H302
3.1D	acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

The product is combustible and can be ignited by potential ignition sources.

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2.2 Label elements

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

- Signal word danger

- Pictograms

GHS02, GHS06



- Hazard statements

H225 Highly flammable liquid and vapour.

H302+H332 Harmful if swallowed or if inhaled.

H311 Toxic in contact with skin.

H319 Causes serious eye irritation.

- Precautionary statements

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

P233 Keep container tightly closed.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/....

P312 Call a POISON CENTRE/doctor if you feel unwell.

P361+P364 Take off immediately all contaminated clothing and wash it before reuse.

P370+P378 In case of fire: Use sand, carbon dioxide or powder extinguisher to extinguish.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling acetonitrile

2.3 Other hazards

of no significance

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

Identifiers

CAS No

486460-32-6

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
acetonitrile	CAS No 75-05-8 EC No 200-835-2 Index No 608-001-00-3	≥ 90	Flam. Liq. 2 / H225 Acute Tox. 4 / H302 Acute Tox. 3 / H311 Acute Tox. 4 / H332 Eye Irrit. 2 / H319	

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
acetonitrile	-	-	469 mg/kg 300 mg/kg 11 mg/l/4h	oral dermal inhalation: vapour

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For full text of abbreviations: see SECTION 16.

SECTION 4: First aid measures**4.1 Description of first aid measures**

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures**5.1 Extinguishing media**

Suitable extinguishing media

Water spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

In case of insufficient ventilation and/or in use, may form flammable/explosive vapour-air mixture. Solvent vapours are heavier than air and may spread along floors. Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures.

Hazardous combustion products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Avoidance of ignition sources. Keep away from sources of ignition - No smoking. Take precautionary measures against static discharge. Use only in well-ventilated areas. Due to danger of explosion, prevent leakage of vapours into cellars, flues and ditches. Ground/bond container and receiving equipment. Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools.

- Specific notes/details

Places which are not ventilated, e.g. unventilated below ground level areas such as trenches, conduits and shafts, are particularly prone to the presence of flammable substances or mixtures. Vapours are heavier than air, spread along floors and form explosive mixtures with air. Vapours may form explosive mixtures with air.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Keep container tightly closed and in a well-ventilated place. Use local and general ventilation. Keep cool. Protect from sunlight.

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- Flammability hazards

Keep away from sources of ignition - No smoking. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Take precautionary measures against static discharge. Protect from sunlight.

- Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation. Ground/bond container and receiving equipment.

- Packaging compatibilities

Only packagings which are approved (e.g. acc. to ADR) may be used.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)											
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Ceiling-C [ppm]	Ceiling-C [mg/m³]	Notation	Source
EU	acetonitrile	75-05-8	IOELV	40	70						2006/15/EC
GB	acetonitrile	75-05-8	WEL	40	68	60	102				EH40/2005

Notation

Ceiling-C
STEL

ceiling value is a limit value above which exposure should not occur
short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours
time-weighted average (unless otherwise specified)

Relevant DNELs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
acetonitrile	75-05-8	DNEL	68 mg/m³	human, inhalatory	worker (industry)	chronic - systemic effects
acetonitrile	75-05-8	DNEL	68 mg/m³	human, inhalatory	worker (industry)	acute - systemic effects
acetonitrile	75-05-8	DNEL	68 mg/m³	human, inhalatory	worker (industry)	chronic - local effects
acetonitrile	75-05-8	DNEL	68 mg/m³	human, inhalatory	worker (industry)	acute - local effects
acetonitrile	75-05-8	DNEL	32.2 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

Relevant PNECs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
acetonitrile	75-05-8	PNEC	10 mg/l	aquatic organisms	freshwater	short-term (single instance)
acetonitrile	75-05-8	PNEC	1 mg/l	aquatic organisms	marine water	short-term (single instance)

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Relevant PNECs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
acetonitrile	75-05-8	PNEC	32 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
acetonitrile	75-05-8	PNEC	7.53 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
acetonitrile	75-05-8	PNEC	2.41 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	not determined
Odour	characteristic
Melting point/freezing point	-45.7 °C
Boiling point or initial boiling point and boiling range	81.6 °C at 1,013 hPa
Flammability	flammable liquid in accordance with GHS criteria
Lower and upper explosion limit	not determined

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Flash point	12.8 °C
Auto-ignition temperature	524 °C (auto-ignition temperature (liquids and gases))
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	94.51 hPa at 20 °C
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Density and/or relative density

Density	not determined
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	there is no additional information
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Other safety characteristics

Solvent content	100 %
Solid content	0.001 %
Temperature class (EU, acc. to ATEX)	T1 (maximum permissible surface temperature on the equipment: 450°C)

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials". The mixture contains reactive substance(s). Risk of ignition.

If heated:

Risk of ignition

10.2 Chemical stability

See below "Conditions to avoid".

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10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

Hints to prevent fire or explosion

Use explosion-proof electrical/ventilating/lighting/equipment. Use only non-sparking tools. Take precautionary measures against static discharge.

10.5 Incompatible materials

Oxidisers

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful if swallowed. Toxic in contact with skin. Harmful if inhaled.

- Acute toxicity estimate (ATE)

Oral	469 mg/kg
Dermal	300 mg/kg
Inhalation: vapour	11 mg/l/4h

Acute toxicity estimate (ATE) of components of the mixture			
Name of substance	CAS No	Exposure route	ATE
acetonitrile	75-05-8	oral	469 mg/kg
acetonitrile	75-05-8	dermal	300 mg/kg
acetonitrile	75-05-8	inhalation: vapour	11 mg/l/4h

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

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Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information**12.1 Toxicity**

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Information on this property is not available.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Waste treatment-relevant information

Solvent reclamation/regeneration.

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used. Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.

Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

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SECTION 14: Transport information

14.1 UN number or ID number

ADR/RID/ADN	UN 1648
IMDG-Code	UN 1648
ICAO-TI	UN 1648

14.2 UN proper shipping name

ADR/RID/ADN	ACETONITRILE
IMDG-Code	ACETONITRILE
ICAO-TI	Acetonitrile

14.3 Transport hazard class(es)

ADR/RID/ADN	3
IMDG-Code	3
ICAO-TI	3

14.4 Packing group

ADR/RID/ADN	II
IMDG-Code	II
ICAO-TI	II

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Classification code	F1
Danger label(s)	3



Excepted quantities (EQ)	E2
Limited quantities (LQ)	1 L
Transport category (TC)	2
Tunnel restriction code (TRC)	D/E
Hazard identification No	33
Emergency Action Code	2YE

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International Maritime Dangerous Goods Code (IMDG) - Additional information

Marine pollutant -

Danger label(s) 3



Excepted quantities (EQ) E2

Limited quantities (LQ) 1 L

EmS F-E, S-D

Stowage category B

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Danger label(s) 3



Excepted quantities (EQ) E2

Limited quantities (LQ) 1 L

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Deco-Paint Directive

VOC content	100 %
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Industrial Emissions Directive (IED)

VOC content	100 %
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15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
2006/15/EC	Commission Directive establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC
Acute Tox.	Acute toxicity
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ADR/RID/ADN	Agreements concerning the International Carriage of Dangerous Goods by Road/Rail/Inland Waterways (ADR/RID/ADN)
ATE	Acute Toxicity Estimate

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Abbr.	Descriptions of used abbreviations
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
Eye Dam.	Seriously damaging to the eye
Eye Irrit.	Irritant to the eye
Flam. Liq.	Flammable liquid
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
IOELV	Indicative occupational exposure limit value
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

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Abbr.	Descriptions of used abbreviations
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H225	Highly flammable liquid and vapour.
H302	Harmful if swallowed.
H311	Toxic in contact with skin.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.