# **Safety Data Sheet**

according to Regulation (EC) No. 1907/2006 (REACH)

## **Nicotinamide**

Version number: 5.0 Revision: 2020-05-27 Replaces version of: 2019-06-14 (4) First version: 2016-10-27

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

#### 1.1 Product identifier

Trade name <u>Nicotinamide</u>

**Registration number (REACH)** 01-2119968268-22-0001

**EC number** 202-713-4

**CAS number** 98-92-0

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

**Relevant identified uses**Cosmetic raw material

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

SUMMIT PHARMACEUTICALS EUROPE LTD. Telephone: +49-2114570 510 Schwannstraße 10 Telefax: +49-2114570 518

D-40476 Düsseldorf e-mail: SPE-Germany@sumitomocorp.com

#### **Additional information**

Manufacturer		
Country	Name	
India	Jubilant Life Sciences Ltd.	

#### 1.4 Emergency telephone number

As above or nearest toxicological information centre.

## **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

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

Classification					
Section	Hazard class	Category	Hazard class and category	Hazard state- ment	
3.3	serious eye damage/eye irritation	2	Eye Irrit. 2	H319	

For full text of abbreviations: see SECTION 16

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#### 2.2 Label elements

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

Signal word warning

**Pictograms** 

GHS07



#### **Hazard statements**

**H319** Causes serious eye irritation.

#### **Precautionary statements**

**P264** Wash thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact

lenses, if present and easy to do. Continue rinsing.

**P337+P313** If eye irritation persists: Get medical advice/attention.

**P405** Store locked up.

**P501** Dispose of contents/container in accordance with local/regional/national/interna-

tional regulations.

#### 2.3 Other hazards

There is no additional information.

#### Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Name of substance nicotinamide

**Identifiers** 

CAS No 98-92-0

EC No 202-713-4

**Purity** >99%

Molecular formula C6H6N2O

Molar mass 122.1 g/<sub>mol</sub>

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#### **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures

#### **General notes**

Take off immediately all contaminated clothing.

In all cases of doubt, or when symptoms persist, seek medical advice.

#### **Following inhalation**

Provide fresh air.

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

#### Following skin contact

Rinse skin with water/shower.

#### Following eye contact

Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

#### **Following ingestion**

Rinse mouth. Do not induce vomiting.

Get medical advice/attention if you feel unwell.

#### Notes for the doctor

None.

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

These information are not available.

## 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, foam, alcohol resistant foam, fire extinguishing powder

#### Unsuitable extinguishing media

none

## 5.2 Special hazards arising from the substance or mixture

Hazardous decomposition products: Section 10.

Deposited combustible dust has considerable explosion potential.

#### **Hazardous combustion products**

nitrogen oxides (NOx), carbon monoxide (CO), carbon dioxide (CO2)

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## 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.

#### Special protective equipment for firefighters

wear self-contained breathing apparatus

#### **SECTION 6: Accidental release measures**

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

#### For non-emergency personnel

Remove persons to safety.

Ventilate affected area.

Wearing of suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing.

#### 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

Take up mechanically.

#### Advice on how to clean up a spill

Take up mechanically.

Collect spillage.

#### 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.

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## **SECTION 7: Handling and storage**

## 7.1 Precautions for safe handling

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

Use local and general ventilation.

Keep away from sources of ignition - No smoking.

#### Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room.

#### Measures to protect the environment

Avoid release to the environment.

#### Advice on general occupational hygiene

Do not eat, drink and smoke in work areas.

Wash hands after use.

Preventive skin protection (barrier creams/ointments) is recommended.

Remove contaminated clothing and protective equipment before entering eating areas.

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

#### **Explosive atmospheres**

Removal of dust deposits.

#### Flammability hazards

None.

## Incompatible substances or mixtures

Incompatible materials: see section 10.

#### Protect against external exposure, such as

heat, humidity

#### **Consideration of other advice**

Keep away from food, drink and animal feedingstuffs.

#### **Ventilation requirements**

Provision of sufficient ventilation.

## **Packaging compatibilities**

Keep only in original container.

#### 7.3 Specific end use(s)

No information available.

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## **SECTION 8: Exposure controls/personal protection**

## 8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)									
Coun- try	Name of agent	CAS No	Identi- fier	TWA [ppm]	TWA [mg/m³]	STEL [ppm]	STEL [mg/m³]	Nota- tion	Source
GB	dust		WEL		10			i	EH40/2005
GB	dust		WEL		4			r	EH40/2005

#### Notation

i inhalable fractionr respirable fraction

STEL 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)

#### **Human health values**

Relevant DNE	Relevant DNELs and other threshold levels					
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time		
DNEL	43.75 mg/m <sup>3</sup>	human, inhalatory	worker (industry)	chronic - systemic effects		
DNEL	12.5 mg/kg bw/ day	human, dermal	worker (industry)	chronic - systemic effects		
DNEL	21.88 mg/m³	human, inhalatory	consumer (private house- holds)	chronic - systemic effects		
DNEL	12.5 mg/kg bw/ day	human, dermal	consumer (private house- holds)	chronic - systemic effects		
DNEL	12.5 mg/kg bw/ day	human, oral	consumer (private house- holds)	chronic - systemic effects		

## **Environmental values**

Relevant PNECs and other threshold levels			
Endpoint	Threshold level	Environmental compartment	
PNEC	1 <sup>mg</sup> / <sub>l</sub>	freshwater	
PNEC	0.1 <sup>mg</sup> / <sub>l</sub>	marine water	
PNEC	423.5 <sup>mg</sup> / <sub>l</sub>	sewage treatment plant (STP)	
PNEC	1.109 <sup>mg</sup> / <sub>kg</sub>	freshwater sediment	

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#### **Relevant PNECs and other threshold levels**

Endpoint	Threshold level	Environmental compartment
PNEC	0.111 <sup>mg</sup> / <sub>kg</sub>	marine sediment
PNEC	0.33 <sup>mg</sup> / <sub>kg</sub>	soil

#### 8.2 Exposure controls

#### **Appropriate engineering controls**

General ventilation.

## Individual protection measures (personal protective equipment)

#### **Eye/face protection**

Wear eye/face protection.

Use safety goggle with side protection.

#### **Hand protection**

## **Protective gloves**

Material	Material thickness	Breakthrough times of the glove material
plastic and rubber	≥ 0,35 mm	>480 minutes (permeation: level 6)
NBR: acrylonitrile-butadiene rubber	≥ 0,35 mm	>480 minutes (permeation: level 6)
IIR: isobutene-isoprene (butyl) rubber	≥ 0,5 mm	>480 minutes (permeation: level 6)
FKM: fluoro-elastomer	≥ 0,4 mm	>480 minutes (permeation: level 6)

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.

#### **Respiratory protection**

In case of inadequate ventilation wear respiratory protection.

Particulate filter device (EN 143).

## **Environmental exposure controls**

Use appropriate container to avoid environmental contamination.

Keep away from drains, surface and ground water.

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## **SECTION 9: Physical and chemical properties**

## 9.1 Information on basic physical and chemical properties

#### **Appearance**

Physical state Solid

Form Solid matter

Colour White

Odour Odourless

Odour threshold These information are not available

Other safety parameters

pH (value) 6 - 7.5 (water: 50  $\frac{9}{1}$ )

Melting point/freezing point 128 – 131 °C

Initial boiling point and boiling range 150 – 160 °C

Flash point 182 °C

Evaporation rate These information are not available

Flammability (solid, gas)

This material is combustible, but will not ignite

readily

Explosion limits of dust clouds Not determined

Vapour pressure 0 Pa at 25 °C

(ECHA, OECD Guideline 104)

Density  $1.4 \, \mathrm{g/_{cm^3}}$  at 25 °C

(ECHA, OECD Guideline 109)

Vapour density These information are not available

Relative density These information are not available

Solubility(ies)

Water solubility 500 g/I

**Partition coefficient** 

n-octanol/water (log KOW) -0.38 (21 °C)

(ECHA, OECD Guideline 117)

Auto-ignition temperature 480 °C

Decomposition temperature These information are not available

Viscosity

Kinematic viscosity Not relevant

(Solid matter)

Dynamic viscosity Not relevant

(Solid matter)

Explosive properties Not explosive

Oxidising properties Shall not be classified as oxidising

9.2 Other information

Dissociation constant (pKa) 3,35

(ECHA, OECD Guideline 112)

Temperature class (EU, acc. to ATEX) T1

## **SECTION 10: Stability and reactivity**

## 10.1 Reactivity

This material is not reactive under normal ambient conditions.

## 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

#### 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.

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

## 10.5 Incompatible materials

acids, bases, 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 toxicological effects

If not otherwise specified the classification is based on:

Animal studies; Evidence from any other toxicity tests; Expert judgement (weight of evidence determination).

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

### **Acute toxicity**

Shall not be classified as acutely toxic (oral).

Shall not be classified as acutely toxic (dermal).

#### Inhalation.

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	>2,500 <sup>mg</sup> / <sub>kg</sub>	rat	OECD Guideline 423	ECHA
dermal	LD50	>2,000 <sup>mg</sup> / <sub>kg</sub>	rabbit	OECD Guideline 402	ECHA

#### Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

(ECHA, EU method B.4, OECD Guideline 404)

#### Serious eye damage/eye irritation

Causes serious eye irritation.

(ECHA, OECD Guideline 405, EU method B.5)

#### Respiratory or skin sensitisation

#### Skin sensitisation

Shall not be classified as a skin sensitiser.

(ECHA, OECD Guideline 406)

#### **Respiratory sensitisation**

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

(ECHA, EU method B.10, EU method B.12, OECD Guideline 471, OECD Guideline 473, OECD Guideline 474, EU method B.13/14)

#### Carcinogenicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### Reproductive toxicity

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

## Specific target organ toxicity - single exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

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## Specific target organ toxicity - repeated exposure

Classification could not be established because:

Data are lacking, inconclusive, or conclusive but not sufficient for classification.

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

## **SECTION 12: Ecological information**

## 12.1 Toxicity

## Aquatic toxicity (acute)

Based on available data, the classification criteria are not met.

Endpoint	Value	Species	Method	Source	Exposure time
LC50	>1,000 <sup>mg</sup> / <sub>l</sub>	guppy (Poecilia retic- ulata)	OECD Guideline 203	ECHA	96 h
EC50	>1,000 mg/ <sub>l</sub>	daphnia magna	OECD Guideline 202	ЕСНА	24 h

### **Aquatic toxicity (chronic)**

Based on available data, the classification criteria are not met.

Endpoint	Value	Species	Method	Source	Exposure time
NOEC	560 <sup>mg</sup> / <sub>l</sub>	algae (Scenedesmus subspicatus)	OECD Guideline 201	ECHA	72 h
NOEC	4,235 <sup>mg</sup> / <sub>l</sub>	activated sludge (Pseudomonas putida)	OECD Guideline 209	ЕСНА	18 h

## 12.2 Persistence and degradability

Process of degradability				
Process	Degradation rate	Time	Method	Source
DOC removal	96 %	14 d	OECD Guideline 301 E	ECHA

#### **Biodegradation**

The substance is readily biodegradable.

#### **Persistence**

No data available.

## 12.3 Bioaccumulative potential

n-octanol/water (log KOW)

-0.38 (21 °C)

(ECHA)

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## 12.4 Mobility in soil

No data available.

#### 12.5 Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

#### 12.6 Other adverse effects

Data are not available.

#### **Remarks**

Wassergefährdungsklasse, WGK (water hazard class): 1

## **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods

This material and its container must be disposed of as hazardous waste.

#### Sewage disposal-relevant information

Do not empty into drains.

## Waste treatment of containers/packagings

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.

## **SECTION 14: Transport information**

14.1	UN number	not subject to transport regulations
14.2	UN proper shipping name	-
14.3	Transport hazard class(es)	-
14.4	Packing group	-
14.5	Environmental hazards	-
14.6	Special precautions for user	-
14.7	Transport in bulk according to Annex II of MARPOL and the IBC Code	-

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## **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)

Restrictions according to REACH, Annex XVII

Not listed.

List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list

Not listed.

#### **Seveso Directive**

Not assigned.

Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS) - Annex II

Not listed.

Regulation 166/2006/EC concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

Not listed.

Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD)

Not listed.

Regulation 98/2013/EU on the marketing and use of explosives precursors

Not listed.

Regulation 1005/2009/EC on substances that deplete the ozone layer (ODS)

Not listed.

Regulation 649/2012/EU concerning the export and import of hazardous chemicals (PIC)

Not listed.

## 15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance by the supplier.

#### **SECTION 16: Other information**

#### Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)
1.3	Details of the supplier of the safety data sheet: SUMMIT PHARMACEUTICALS EUROPE LTD. Georg-Glock-Straße 8 D-40474 Düsseldorf	Details of the supplier of the safety data sheet: SUMMIT PHARMACEUTICALS EUROPE LTD. Schwannstraße 10 D-40476 Düsseldorf

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Section	Former entry (text/value)	Actual entry (text/value)
	Telephone: +49-2114570 510 Telefax: +49-2114570 518 e-mail: SPE-Germany@sumitomocorp.com	Telephone: +49-2114570 510 Telefax: +49-2114570 518 e-mail: SPE-Germany@sumitomocorp.com
8.1		Relevant PNECs and other threshold levels: change in the listing (table)
8.2		Protective gloves: change in the listing (table)

# Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations	
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 européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)	
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)	
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	
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval	
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-li- cence/)	
EINECS	European Inventory of Existing Commercial Chemical Substances	
ELINCS	European List of Notified Chemical Substances	
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)	
IMDG	International Maritime Dangerous Goods Code	
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval	
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval	
MARPOL	International Convention for the Prevention of Pollution from Ships (abbr. of "Marine Pollutant")	

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Abbr.	Descriptions of used abbreviations	
NLP	No-Longer Polymer	
NOEC	No Observed Effect Concentration	
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 (Regula- tions concerning the International carriage of Dangerous goods by Rail)	
STEL	Short-term exposure limit	
SVHC	Substance of Very High Concern	
TWA	Time-weighted average	
vPvB	Very Persistent and very Bioaccumulative	
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 2015/830/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).

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

Code	Text	
H319	Causes serious eye irritation.	

## Responsible for the safety data sheet

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#### Disclaimer

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

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