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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Vanillin

Vanillinum Vanilline Vanilline Vanillin

N° CAS: 121-33-5 N° EC: 204-465-2

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

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: FAC SECUNDUM ARTEM NV

Oostmalsebaan 1c (unit 5)

2960 Sint-Lenaarts

Belgium

Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Skin Sens. 1 H317 Eye Irrit. 2 H319

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.

Precautionary statements:

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

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DOC4	Made alia the manaka di a a ftera le ca di a a
P264	Wash skin thoroughly after handling.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear eye protection/face protection.
P302+P352+P338 IF ON SKIN: Wash with soap and water.

P305+P351 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses,

if present and easy to do. Continue rinsing.

P321 Specific treatment (see on this label).

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

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

P363 Wash contaminated clothing before reuse.

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

national regulation.

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Combustible solid. Divided solid. May form explosive dust-air mixture.

Results of PBT and vPvB assessment: This substance is not considered to be persistent, bioaccumulating and toxic (PBT). This substance is not considered to be very persistent and very bioaccumulating (vPvB).

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name: Vanillin

IUPAC name: 4-hydroxy-3-methoxybenzaldehyde

Synonyms: Vanillaldehyde

p-Vanillin

 N° CAS: 121-33-5 N° EC: 204-465-2 Molecular Formula: $C_8H_8O_3$

Content: Vanillin contains not less than 99.0 per cent and not more than the equivalent of

101.0 per cent of 4-hydroxy-3-methoxybenzaldehyde, calculated with reference to

the dried substance.

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Show this safety data sheet to the doctor in attendance. First aider needs to protect

himself. Place affected clothing in a sealed bag for subsequent decontamination.

After inhalation: Move to fresh air. If breathing is irregular or stopped, administer artificial

respiration. Consult a physician if necessary.

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After skin contact: Take off contaminated clothing and shoes immediately. Wash off with soap and

water. Call a physician if irritation develops or persists.

After eye contact: Rinse immediately with plenty of water, also under the eyelids, for at least 15

minutes. If eye irritation persists, consult a physician.

After ingestion: Do NOT induce vomiting. Rinse mouth with water. If symptoms persist, call a

physician.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray, powder, carbon dioxide (CO₂). Use extinguishing

measures that are appropriate to local circumstances and the

surrounding environment.

Unsuitable extinguishing media: None known.

5.2 Special hazards arising from the substance/mixture

Combustible solid. Risk of dust explosion.

5.3 Advice for firefighters

Surrounding fires: Cool containers/tanks with water spray. Do not inhale fumes.

Protection against fire: Full protective suit. Self-contained breathing apparatus (EN 133).

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Avoid contact with eyes. Do not breathe dust. Personal protective equipment. Boots. Wear suitable protective equipment. Tightly fitting safety goggles. Keep away from flames and hot surfaces.

For emergency responders

Avoid contact with eyes. Do not breathe dust. Personal protective equipment. Boots. Wear suitable protective equipment. Tightly fitting safety goggles. Keep away from flames and hot surfaces.

6.2 Environmental precautions

Do not allow uncontrolled discharge of product into the environment.

6.3 Methods and material for containment and cleaning up

Recovery: Keep in properly labelled containers. Keep in suitable, closed containers for disposal.

Decontamination/cleaning: Wash off with plenty of water. Recover the cleaning water for subsequent disposal.

Disposal: Treat recovered material as described in section "Disposal considerations".

6.4 Reference to other sections

Section 8: Exposure controls/personal protection

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Section 13: Disposal considerations

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Blanket with inert gas. Keep away from fire, sparks and heated

surfaces. Avoid dust formation. Prevent the build-up of electrostatic

charge. Protect from moisture.

Personal protection: Not available.

Technical protective measures: Earth the equipment. Avoid dust formation. Prevent the build-up of

electrostatic charge. Ensure that eyewash stations and safety

showers are close to the workstation location.

Handling: Hygiene measures: Ensure that eyewash stations and safety showers

are close to the workstation location. Use clean, well-maintained personal protection equipment. Wash hands before breaks and at the end of the working day. When using do not eat, drink or smoke.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Not available.

Conditions for safe storage, including any

incompatibilities:

Keep container tightly closed and dry.

Suitable packaging material: Polyethylene. Tinted glass.

Unsuitable packaging material: Aluminium and its alloys. Steel drum.

Storage – away from: Store protected from light. Keep away from heat. Keep away from

alkalis and caustic products.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values above their regulatory reporting threshold.

Predicted No Effect Concentration (PNEC)

Product name	Compartiment	Value	Remarks
Vanillin	Fresh water	0.118 mg/l	
	Marine water	0.0118 mg/l	
	Fresh water sediment	58.22 mg/kg (dw)	
	Mater sediment	5.822 mg/kg (dw)	
	Soil	11.54 mg.kg (dw)	
	STP	10 mg/l	
	Oral (secondary poisoning)		No PNEC derivation as there is no potential for bioaccumulation.

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8.2 Exposure controls

Appropriate engineering control

Effective exhaust ventilation system. Dust must be extracted directly at the point of origin.

Hygiene measures: Ensure that eyewash stations and safety showers are close to the workstation location. Use clean, well-maintained personal protection equipment. Wash hands before breaks and at the end of the working day. When using do not eat, drink or smoke.

Protective measures: The protective equipment must be selected in accordance with current CEN standards and in cooperation with the supplier of the protective equipment. Selection of appropriate personal protective equipment should be based on an evaluation of the performance characteristics of the protective equipment relative to the task(s) to be performed, conditions present, duration of use, and the potential hazards and/or risks that may occur during use.

Individual protection measures

Eye/face protection: Tightly fitting safety goggles.

Skin protection: Protective suit.

Hand protection: Where there is a risk of contact with hands, use appropriate gloves. Gloves must be

inspected prior to use. Gloves should be discarded and replaced if there is any

indication of degradation or chemical breakthrough.

Respiratory protection: Use a respirator with an approved filter if a risk assessment indicated this is

necessary. Handling product in bulk: respirator with a particle filter (EN 143).

Thermal hazards: Not determined.

Environmental exposure control

Do not allow uncontrolled discharge of product into the environment.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: White or slightly yellowish, crystalline powder or needles.

Particle size: $< 100 \mu m (10 \%)$

< 393 µm (90 %)

Odour: Vanilla

Odour threshold: Not available. pH: 4.3 (1 % (m/v))

Aqueous solution pKa: 7.3 – 7.4 (25 °C)

Melting/freezing point: Ca. 81 °C – 83 °C
Initial boiling point: 154 °C (13 hPa)

284 °C (1,013 hPa)

Boiling range: Not available.

Flash point: 160 °C (1,022 h Pa), closed cup, Method: EU Test Guideline A9

Evaporation rate: Not available.

Flammability (solid/gas): Not highly flammable. Method: test Directive 92/69/EEC – Annex V part A10

May form combustible dust concentrations in air.

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Combustible solids.

Upper/lower flammability or

explosive limits:

Explosiveness: Not explosive.

Vapour pressure: 0.0029 hPa (25 °C)

0.17 hPa (65 °C)

Vapour density: 5.3 (25 °C)
Relative density: Not available.

Solubility: Freely soluble in alcohol and in methanol. It dissolves in dilute solutions of alkali

hydroxides. Soluble in ethyl acetate and diethylether.

Solubility in water: Slightly soluble in water.

9 g/l (25 °C)

Partition coefficient

(n-octanol/water):

Log Pow: 1.17 - 1.21 (25 °C)

Auto-ignition temperature: Not applicable solid for which the melting point is < 160 °C

Decomposition temperature: Not available.

Viscosity: Not applicable, solid.

Explosive properties: Negative

Method: EU Test Guideline A14 Mechanical sensitivity (shock)

Negative

Method: EU Test Guideline A14 Mechanical sensitivity (friction)

Negative

Method: EU Test Guideline A14

Thermal sensitivity

Oxidising properties: Not considered as oxidising, Structure-activity relationship (SAR)

9.2 Other information

Molecular weight: 152.15 g/mol Sublimation point: 70 °C Density: 1.06 g/cm³ (20 °C) Bulk density: ca. 600 kg/m³ loose

Surface tension: Not considered as surface-active, Structure-activity relationship (SAR)

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable at room temperature.

10.3 Possibility of hazardous reactions

Hazardous polymerisation does not occur.

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10.4 Conditions to avoid

Heat, flames and sparks. Static electricity. Avoid dust formation.

10.5 Incompatible materials

Reacts with the following substances: strong bases, aluminium.

10.6 Hazardous decomposition products

On combustion or on thermal decomposition (pyrolysis) releases: toxic gas, (carbon oxides (CO + CO₂)).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD₅₀: 3 300 mg/kg – rat, for males and females

Method: OECD Test Guideline 401

LD₅₀: 3 978 mg/kg – rat, for males and females

Method: OECD Test Guideline 401

Dermal LD_{50} : > 2000 mg/kg – rat, male and female

Method: OEDC Test Guideline 402

Not classified as hazardous for acute dermal toxicity according to

GHS.

Skin corrosion/irritation: Not irritating to rabbits on cutaneous application.

Serious eye damage/irritation: Rabbit

Causes serious eye irritation.

Method: OECD Test Guideline 405

Respiratory/skin sensitisation: Magnusson and Kligman method – guinea pig

Does not cause skin sensitisation.

Local lymph node assay – mouse

Maximum Stimulation Index < 3

Humans

No cutaneous sensitisation reaction observed.

Diluted product.

Germ cell mutagenicity: Genotoxicity in vitro In vitro tests did not show mutagenic effects.

Genotoxicity in vivo In vivo micronucleus test – mouse

Female Oral

Method: OECD Test Guideline 474

Negative Gavage

Carcinogenicity: Oral toxicity tests on rats and mice did not reveal any carcinogenic potential.

Reproductive toxicity: Toxicity to No effect observed in male or female reproductive

reproduction/Fertility system in repeated dose tox studies.

The product is not considered to affect fertility.

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Developmental

toxicity/Teratogenicity No embryotoxic or teratogenic effect have been

observed.

Rat

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: The substance or mixture is not classified as specific target organ toxicant, single

exposure according to GHS criteria.

STOT-repeated exposure: The substance or mixture is not classified as specific target organ toxicant, repeated

exposure according to GHS criteria.

Oral exposure 6 months – rat, male

NOAEL: 650 mg/kg

Aspiration Hazard: Not applicable.

Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Causes serious eye irritation.

Skin contact: May cause an allergic skin reaction.

Inhalation: Not available.
Ingestion: Not available.
Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Acute toxicity to fish LC₅₀ – 96 h: 57 mg/l – *Pimephales promelas* (fathead minnow)

Flow-through test

Analytical monitoring: yes Measured concentration

Harmful to fish.

Acute toxicity to daphnia and other

aquatic invertebrates

EC₅₀ – 48 h: 36.8 mg/l – Daphnia magna (water flea)

Static test

Analytical monitoring: yes

Method: OECD Test Guideline 202

Measured concentration

Harmful to aquatic invertebrates.

Toxicity to aquatic plants $ErC_{50} - 72 \text{ h: } 120 \text{ mg/l} - Pseudokirchneriella subcapitata (green algae)}$

Static test

Analytical monitoring: yes End point: Growth rate

Method: OECD Test Guideline 201

Measured concentration

Not harmful to algae (EC/EL₅₀ > 100 mg/l)

NOEC - 72 h: 47 mg/l - Pseudokirchneriella subcapitata (green algae)

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Static test

Analytical monitoring: yes End point: Growth rate

Method: OECD Test Guideline 201

No adverse chronic effect observed up to and including the threshold of 1

mg/l

Toxicity to microorganisms NOEC: 100 mg/l

Respiration inhibition

Method: OECD Test Guideline 301C

Chronic toxicity to daphnia and other

aquatic invertebrates

NOEC: 5.9 mg/l – 21 days – Daphnia magna (water flea)

Semi-static test

Analytical monitoring: yes

Method: OECD Test Guideline 212

No adverse chronic effect observed up to and including the threshold of 1

mg/l

Chronic toxicity to aquatic plants NOEC: 47 mg/l – 72 h - Pseudokirchneriella subcapitata (green algae)

Method: OECD Test Guideline 201

Growth rate

12.2 Persistence and degradability

Biodegradability Ready biodegradability study:

Method: OECD Test Guideline 301C

97 – 100 % - 14 days

The substance fulfils the criteria for ultimate aerobic biodegradability and

ready biodegradability.

Inoculum: activated sludge

Degradability assessment The product is considered to be rapidly degradable in the environment.

12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water Not potentially bioaccumulable.

12.4 Mobility in soil

Adsorption potential (Koc) Adsorption/soil

Koc: 4898

12.5 Results of PBT and vPvB assessment

This substance is not considered to be persistent, bioaccumulating and toxic (PBT).

This substance is not considered to be very persistent and very bioaccumulating (vPvB)

12.6 Other adverse effects

Ecotoxicity assessment

Acute aquatic toxicity Harmful to aquatic life.

Chronic aquatic toxicity No adverse chronic effect observed up to and including the threshold of 1 mg/l.

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product disposal: Avoid release to the environment. Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities.

Advice on cleaning and disposal of packaging: Cleaning is not required prior to disposal. Must be incinerated in a suitable incineration plant holding a permit delivered by the competent authorities. Dispose of in accordance with local regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

ADR, RID, IMDG, IATA, ADN/ADNR: Not regulated.

Note: The above regulatory prescriptions are those valid on the date of publication of this sheet. Given the possible evolution of transport regulations for hazardous materials, it would be advisable to check their validity with your sales office.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Legita et

Risk phrases: R36 Irritating to eyes.

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R43 May cause sensitisation by skin contact.

Safety phrases: S26 In case of contact with eyes, rinse immediately with plenty of water and seek

medical advice.

S28 After contact with skin, wash immediately with soap and water.

S39 Wear eye/face protection.

15.2 Chemical safety assessment

A chemical safety assessment has been carried out for this substance.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods
 IUPAC: International Union of Pure and Applied Chemistry
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation

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(EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be