Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

PARACETAMOLUM

Publication: 07/04/2022
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Version: 00

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Paracetamol Paracetamolum Paracetamol Paracétamol Paracetamol
N° CAS:	103-90-2
N° EC:	203-157-5

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

Acute Tox. 4	H302
STOT SE 1	H370
Aquatic Chronic 3	H412

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Danger

Hazard statements:

H302 Harmful if swallowed.

H370	Causes damage to organs.
H412	Harmful to aquatic life with long-lasting effects.
Precautionary statements:	
P260	Do not breathe dust/fumes/gas/mist/vapours/spray.
P264	Wash thoroughly after handling.
P270	Do not eat, drink or smoke when using this product.
P273	Avoid release to the environment.
P301+P312	IF SWALLOWED: Call a POISON CENTER/doctor/…/if you feel unwell.
P330	Rinse mouth.
P501	Dispose of contents/container in accordance with local/regional/national/international regulation.
Additional applicable label elements:	

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Paracetamol
IUPAC name:	N-(4-Hydroxyphenyl)acetamide
Synonyms:	Acetaminophen Tylenol
N° CAS:	103-90-2
N° EC:	203-157-5
Molecular Formula:	$C_8H_9NO_2$
Content:	99.0 per cent to 101.0 per cent (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes: Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen. Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Usual Adult Dose: The usual adult oral dose of acetaminophen is 650 to 1000 mg every six hours, not to exceed 4000 mg per day.

Adverse Effects: Possible allergic reaction to material is inhaled, ingested or in contact with skin.

Overdose Effects: Acute overdose effects in clued gastrointestinal distress and increased sweating. Effects of liver damage (which may be delayed by two or more days) include plain, tenderness, or swelling of the upper abdomen; mental changes; convulsions; respiratory depression; coma; cerebral oedema; bleeding problems; hypoglycaemia; metabolic acidosis; cardiac arrhythmias; and cardiovascular collapse. Kidney failure may also occur.

Acute: Possible eye, skin, gastrointestinal and / or respiratory tract irritation.

Inhalation: May cause irritation. Remove to fresh air.

Eye: May cause irritation. Flush with copious quantities of water.

Skin: May cause irritation. Flush with copious quantities of water.

Ingestion: May cause irritation and toxicity. Flush out mouth with water. This material is readily absorbed from the gastrointestinal tract. The duration of action is 3 to 4 hours.

Medical Conditions Aggravated by Exposure: Hypersensitivity to material, active alcoholism, liver disease, viral hepatitis, and impaired kidney function.

Cross Sensitivity: Rarely, persons sensitive to aspirin may be sensitive to this material as well.

Pregnancy Comments: Chronic toxicity studies in animals have shown that high doses of acetaminophen cause testicular atrophy and inhibition of spermatogenesis; the relevance of this finding to therapeutic use in humans is not known. Pregnancy problems in humans have not been documented.

Pregnancy category: B

4.3 Indication of any immediate medical attention and special treatment needed

Overdose treatment: The recommended treatment for acetaminophen overdose may include:

1. Emptying the stomach via induced vomiting or gastric lavage. Do not administer activated charcoal.
2. Administering acetylcysteine(an antidote used to protect against acetaminophen-induced hepatotoxicity) as soon as possible flowing an overdose.
3. Determining plasma acetaminophen concentration at least 4 hours following ingestion of the overdose. Determinations performed prior to this time are not reliable.
4. Instituting haemodialysis or hemoperfusion to remove acetaminophen from the circulation may be beneficial if acetylcysteine administration cannot be instituted within 24 hours following ingestion of massive overdose.
5. Performing liver function tests every 24 hours for at least 96 hours for at least 96 hours post-ingestion (if the plasma acetaminophen concentration indicates potential hepatotoxicity).
6. Monitoring renal and cardiac function and administering appropriate therapy as required.
7. Instituting supportive treatment, including maintaining fluid and electrolyte balance, correction hypoglycemia, and administering vitamin K1, fresh frozen plasma, or clotting factor concentrate if needed.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media:	Water spray, dry chemical, carbon dioxide or foam as appropriate for surrounding fire and materials.
Unsuitable extinguishing media:	Not available.

5.2 Special hazards arising from the substance/mixture

Fire and Explosion Hazards: This material is assumed to be combustible. As with all dry powders, it is advisable to ground mechanical equipment in contact with dry material to dissipate the potential build-up of static electricity.

5.3 Advice for firefighters

Surrounding fires:	As with all fires, evacuate personnel to a safe area.

Protection against fire:	Firefighters should us self-contained breathing equipment and protective clothing.
Hazardous combustion products:	Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear approved respirator and chemically compatible gloves. Avoid breathing dust.

For emergency responders

Wear approved respirator and chemically compatible gloves. Avoid breathing dust.

6.2 Environmental precautions

Not available.

6.3 Methods and material for containment and cleaning up

Vacuum/sweep up spillage, avoid breathing dust. Place in appropriate container. Ventilate and wash spill site.

6.4 Reference to other sections

Not available.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	Not available.
Technical protective measures:	Not available.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	Store in tight, light-resistant container.
Conditions for safe storage, including any incompatibilities:	Not available.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Not available.

8.2 Exposure controls

Appropriate engineering control

Ventilation: No special ventilation requirements.

Work hygienic practices: Remove/launder contaminated clothing before reuse.

Individual protection measures

Eye/face protection:	Safety glasses.
Skin protection:	Protect exposed skin.
Hand protection:	Gloves: rubber.
Respiratory protection:	Approved dust mask.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, crystalline powder.
Odour:	Odourless.
Odour threshold:	Not available.
pH:	Not available.
Melting/freezing point:	168 °C to 172 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Freely soluble in ethanol (96 per cent). Very slightly soluble in methylene chloride.
Solubility in water:	Sparingly soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

9.2 Other information

Specific gravity: 1.293

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable.

Polymerisation hazard: no polymerisations.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid direct sunlight, conditions that might generate heat and dispersion as a dust cloud.

10.5 Incompatible materials

Strong acids. Strong bases. Strong oxidizing agents.

10.6 Hazardous decomposition products

Decomposing material: CO, CO_2, NO.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Oral LD_{50} (rat): 1 944 mg/kg Oral LD_{50} (mouse): 338 mg/kg
Skin corrosion/irritation:	Not available.
Serious eye damage/irritation:	Not available.
Respiratory/skin sensitisation:	Not available.
Germ cell mutagenicity:	Not available.
Carcinogenicity:	Not listed as a carcinogen (NTP, IARC, OSHA). This material is not classifiable as to its carcinogenicity in humans. NTP Carcinogenesis studies (feed): Equivocal evidence (female rat); No evidence (Mal rat, mouse).
Reproductive toxicity:	Not available.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Not available.
STOT-repeated exposure:	Not available.
Aspiration Hazard:	Not available.
Other:	Target organ(s): liver.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Products of Biodegradation: Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation: The products of degradation are more toxic.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Not available.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Burn and control the waste gas.

Remove the NO materials with syringe.

Dispose of waste in accordance with all applicable national/federal, state and local laws.

SECTION 14: TRANSPORT INFORMATION

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

14.1 UN Number

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not available.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not available.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not available.

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not available.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	Not available.

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

Packing: Primary packaging: PE bags; Secondary packaging: woven bags or fibre drums, seal well.

Transportation: The MSDS should be accompanied with each shipment, which could be the reference for emergency cases. Check the seals and the completeness of the packages before shipment, and ensure no spills, collapses, falling, or damages during transportation. Prevent from shipping with acid, oxidants, food or food additives. Protect from insolation, rain, and high temperature.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Irritant
Harmful

Risk phrases:

R22 Harmful if swallowed

R52 Harmful to aquatic organisms

Safety phrases:

S20/21 When using do not eat, drink or smoke.

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

S36/37 Wear suitable protective clothing and gloves.

S61 Avoid release to the environment. Refer to special instructions/safety data sheet.

15.2 Chemical safety assessment

Not available.

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 (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
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