

Paracetamol

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
Date of issue: 19/06/2012 Revision date: 08/03/2017

753173 / 424528

Version: 2.0

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

1.1. Product identifier

Product form : Substance
Substance name : Paracetamol
IUPAC name : N-(4-Hydroxyphenyl)acetamide
EC No : 203-157-5
CAS No : 103-90-2
Product code : 753173 / 424528
Formula : C₈H₉NO₂
Synonyms : Acetaminophen, N-Acetyl-p-aminophenol
Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
United Kingdom	Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Centre Hospitalier Universitaire de Constantine	Avonley Road SE14 5ER London	0870 243 2241	

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
Specific target organ toxicity — Single exposure, Category 3, H335

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Respiratory tract irritation
Specific target organ toxicity — Repeated exposure, Category 2 H373
Hazardous to the aquatic environment — Chronic Hazard, Category 3 H412

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS08

GHS07

Signal word (CLP) : Warning

Hazard statements (CLP) : H302 - Harmful if swallowed
H335 - May cause respiratory irritation
H373 - May cause damage to organs through prolonged or repeated exposure
H412 - Harmful to aquatic life with long lasting effects

Precautionary statements (CLP) : P261 - Avoid breathing dust
P280 - Wear eye protection, face protection, protective clothing, protective gloves
P273 - Avoid release to the environment

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Paracetamol	(CAS No) 103-90-2 (EC No) 203-157-5	99 - 101	Acute Tox. 4 (Oral), H302 STOT SE 3, H335 STOT RE 2, H373 Aquatic Chronic 3, H412

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing. Get medical advice and attention if you feel unwell.

- 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. Seek medical attention if ill effect or irritation develops.
- First-aid measures after eye contact : Rinse immediately with plenty of water. If eye irritation persists, take medical advice.
- First-aid measures after ingestion : Rinse mouth. Give water to drink. Never give anything by mouth to an unconscious person. Induce vomiting if person is conscious. Seek medical advice.

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

- Symptoms/injuries : Exposure may produce an allergic reaction. Dizziness. Headache. Nervous system disorder. Blurred vision. Causes depression of the respiratory system.

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

Treat symptomatically.

SECTION 5: Fire-fighting measures

5.1. Extinguishing media

- Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.
- Explosion hazard : Large amounts: Risk of dust explosion.

5.3. Advice for firefighters

- Firefighting instructions : 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 : Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

- Protective equipment : Wear proper protective equipment. Wear respiratory protection.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

- Methods for cleaning up : Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water. Detergent.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area. Keep container tightly closed. Protect from sunlight.

Maximum storage period : 5 year

7.3. Specific end use(s)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Paracetamol (103-90-2)		
United Kingdom	WEL TWA (mg/m³)	100000 mg/m³

8.2. Exposure controls

Hand protection:

Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Dust production: dust mask with filter type P2

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Crystalline powder.
Molecular mass	: 151.2 g/mol
Colour	: White.
Odour	: odourless.
Odour threshold	: No data available
pH	: 5.5 - 6.5 in H ₂ O
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: 168 - 172 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: 540 - 590 °C

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Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: 0 kPa 25°C
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water. Soluble in : Alcohol. Water: 14 g/l
Log Pow	: 0.46 - 0.51
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: Potential dust explosion hazard.
Oxidising properties	: No data available
Explosive limits	: 50 - 60 g/m³

9.2. Other information

No additional information available

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

None known.

10.4. Conditions to avoid

High temperature. Light (daylight). Moisture.

10.5. Incompatible materials

Strong oxidizers. Strong bases. Strong acids.

10.6. Hazardous decomposition products

Carbon dioxide. Carbon monoxide. Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Oral: Harmful if swallowed.

Paracetamol (103-90-2)	
LD50 oral rat	1944 mg/kg

Skin corrosion/irritation	: Not classified pH: 5.5 - 6.5 in H2O
Serious eye damage/irritation	: Not classified pH: 5.5 - 6.5 in H2O
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified

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Reproductive toxicity	: Not classified
STOT-single exposure	: May cause respiratory irritation.
STOT-repeated exposure	: May cause damage to organs through prolonged or repeated exposure.
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Paracetamol (103-90-2)	
LC50 fish 1	814 mg/l 96 h
EC50 Daphnia 1	50 mg/l 48 h

12.2. Persistence and degradability

Paracetamol (103-90-2)	
Biodegradation	57 %

12.3. Bioaccumulative potential

Paracetamol (103-90-2)	
Log Pow	0.46 - 0.51

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
Not applicable	Not applicable
14.2. UN proper shipping name	
Not applicable	Not applicable
14.3. Transport hazard class(es)	
Not applicable	Not applicable
Not applicable	Not applicable
14.4. Packing group	
Not applicable	Not applicable
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

- Overland transport

No data available

- Air transport

No data available

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

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

No REACH Annex XVII restrictions

Paracetamol is not on the REACH Candidate List

Paracetamol is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.1	Product code	Removed	Removed article number 411574, paracetamol (180), from SDS as this version of the product has been discontinued.
1.4	Emergency telephone	Modified	Added additional information
2	Classification (DSD/DPD)	Removed	Obsolete
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

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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.

Full text of H- and EUH-statements:

Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
Aquatic Chronic 3	Hazardous to the aquatic environment — Chronic Hazard, Category 3
STOT RE 2	Specific target organ toxicity — Repeated exposure, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H302	Harmful if swallowed
H335	May cause respiratory irritation
H373	May cause damage to organs through prolonged or repeated exposure
H412	Harmful to aquatic life with long lasting effects

SDS EU (REACH Annex II) Version 2017

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