Material Safety Data Sheet

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

PHENOLUM

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Version: 01

MAGIS PHARMA

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

1.1 Product identifier

Product name:	Phenol Phenolum Fenol Phénol Phenol
N° CAS:	108-95-2
N° EC:	203-632-7

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. 3	H301+H311+H331
Skin Corr. 1B	H314
Muta. 2	H341
STOT RE 2	H373

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):

Signal word(s): Danger

Hazard statements:

H301+H311+H331	Toxic if swallowed, in contact with skin or if inhaled.
H314	Causes severe skin burns and eye damage.

H341	Suspected of causing genetic defects.
H373	May cause damage to organs (central nervous system, kidney, liver, skin) through prolonged or repeated exposure.
Precautionary statements:	
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301+P330+P331	IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P302+P352	IF ON SKIN: Wash with plenty of soap and water.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351	IF IN EYES: Rinse cautiously with water for several minutes.
P308+P310	IF exposed or concerned: immediately call a POISON CENTER or doctor/ physician.
Additional applicable label elements:	

2.3 Other hazards

None known.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Phenol
IUPAC name:	Phenol
Synonyms:	Carbolic acid Monohydroxy benzene
N° CAS:	108-95-2
N° EC:	203-632-7
Molecular Formula:	C_6H_6O
Content:	99.0 per cent to 100.5 per cent

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General notes:	First aider needs to protect himself.
After inhalation:	Fresh air. Immediately call in physician. If breathing stops: immediately apply artificial respiration, if necessary also oxygen.
After skin contact:	Rinse out with polyethylene glycol 400 or a mixture of polyethylene glycol 300/ethanol 2:1 and wash with plenty of water. If neither is available wash with plenty of water. Immediately take off contaminated clothing. Call a physician immediately.
After eye contact:	Rinse out with plenty of water. Immediately call in ophthalmologist. Remove contact lenses.

After ingestion:	Give water to drink (two glasses at most). Seek medical advice immediately. In exceptional cases only, if medical care is not available within one hour, induce vomiting (only in persons who are wide awake and fully conscious), administer activated charcoal (20 - 40 g in a 10% slurry) and consult a doctor as quickly as possible. Do not attempt to neutralise.

4.2 Most important symptoms and effects, both acute and delayed

Irritation and corrosion, cough, shortness of breath, drowsiness, dizziness, inebriation, cardiovascular disorders, headache, confusion, respiratory arrest, collapse, unconsciousness, death. Risk of blindness!

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, carbon dioxide (CO_2), foam, dry powder.
Unsuitable extinguishing media:	For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance/mixture

Combustible. Vapours are heavier than air and may spread along floors. Forms explosive mixtures with air on intense heating. Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Surrounding fires:	Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.
Protection against fire:	Stay in danger area only with self-contained breathing apparatus. Prevent skin contact by keeping a safe distance or by wearing suitable 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

Avoid generation and inhalation of dusts in all circumstances. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

For emergency responders

Protective equipment: see section 8.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up carefully. Dispose of properly. Clean up affected area. Avoid generation of dusts.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Observe label precautions. Work under hood. Do not inhale substance/mixture.
Personal protection:	Immediately change contaminated clothing. Apply preventive skin protection. Wash hands and face after working with substance.
Technical protective measures:	Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.
Handling:	Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container. Dry. Keep in a well-ventilated place. Keep locked up or in an area accessible only to qualified or authorised persons.
Conditions for safe storage, including any incompatibilities:	Recommended storage temperature: see product label.
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

Derived No Effect Level (DNEL)

Worker DNEL, long term	Systemic effects	Inhalation	8 mg/m^3
Worker DNEL, long term	Systemic effects	Dermal	1,23 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

PNEC Fresh water	0,0077 mg/l
PNEC Marine water	0,00077 mg/l
PNEC Fresh water sediment	0,0915 mg/kg
PNEC Marine sediment	0,00915 mg/kg
PNEC Soil	0,136 mg/kg
PNEC Sewage treatment plant	2,1 mg/l

8.2 Exposure controls

Appropriate engineering control

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection:	Tightly fitting safety goggles.		
Skin protection:	Flame retardant antistatic protective clothing.		
Hand protection:	Full contact:	Glove material:	Viton (R)
		Glove thickness:	0,70 mm
		Break through time:	> 480 min
	Splash contact:	Glove material:	Viton (R)
		Glove thickness:	0,70 mm
		Break through time:	> 480 min

The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 890 Vitoject® (full contact), KCL 890 Vitoject® (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet<(>,<)> supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Respiratory protection: Required when dusts/vapours/aerosols are generated.

Recommended Filter type: Filter A-(P3)

The entrepeneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

Thermal hazards: Not determined.

Environmental exposure control

Do not let product enter drains.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	Colourless or faintly pink or faintly yellowish, crystals or crystalline masses, deliquescent.
Odour:	Characteristic.
Odour threshold:	0,005 - 5,2 ppm
pH:	Ca. 5 at 50 g/l, 20 °C
Melting point:	40,8 °C
Initial boiling point:	181,8 °C at 1.013 hPa
Boiling range:	Not available.

Flash point:	81 °C at ca. 1.013 hPa (Method: DIN 51758)
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Upper explosion limit: 9,5% (V) Lower explosion limit: 1,3% (V)
Vapour pressure:	0,2 hPa at 20 °C
Vapour density:	1,07 g/cm^3 at 20 °C (Method: DIN 51757)
Relative density:	3,2 at 20 °C (Air = 1.0)
Solubility:	Very soluble in ethanol (96 per cent), in glycerol and in methylene chloride.
Solubility in water:	Soluble in water. 84 g/l at 20 °C
Partition coefficient (n-octanol/water):	log Pow: 1,47 (30 °C) (ECHA) Bioaccumulation is not expected.
Auto-ignition temperature:	715 °C at ca.1.013 hPa
Decomposition temperature:	Not available.
Viscosity:	Viscosity, dynamic: 3,437 mPa.s at 50 °C
Explosive properties:	Not classified as explosive.
Oxidising properties:	None.

9.2 Other information

Ignition temperature:	595 °C (Method: DIN 51794-
Bulk density:	ca. 620 kg/m^3

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Forms explosive mixtures with air on intense heating. A range from approx. 15 Kelvin below the flash point is to be rated as critical. The following applies in general to flammable organic substances and mixtures: in correspondingly fine distribution, when whirled up a dust explosion potential may generally be assumed.

10.2 Chemical stability

Sensitivity to light.

10.3 Possibility of hazardous reactions

Exothermic reaction with: aluminium, aldehydes, halogens, hydrogen peroxide, iron(III) compounds, oxidizing agents, strong acids, strong bases, formaldehyde.

Risk of explosion with: nitrites, nitrates, salts of oxyhalogenic acids, peroxy compounds.

10.4 Conditions to avoid

Strong heating.

10.5 Incompatible materials

Rubber, various plastics, various alloys, various metals.

10.6 Hazardous decomposition products

Not available.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity:	Acute oral toxicity:	Symptoms: If ingested, severe burns of the mouth and throat, as well as a danger of perforation of the oesophagus and the stomach.
	Acute inhalation toxicity:	Symptoms: mucosal irritations, cough, shortness of breath, possible damages:, damage of respiratory tract.
	Acute dermal toxicity:	LD50 Rat: 660 mg/kg (OECD Test Guideline 402)
Skin corrosion/irritation:	In vitro study, result: Causes burns. (OECD Test Guideline 431) Causes burns.	
Serious eye damage/irritation:	Causes serious eye damage. Risk of blindness! Rabbit; result: Corrosive (OECD Test Guideline 405)	
Respiratory/skin sensitisation:	Sensitisation test: Guinea pig, result: negative. (IUCLID)	
Germ cell mutagenicity:	*Genotoxicity in vitro* Mutagenicity (mammal cell test): chromosome aberration. Result: positive Method: OECD Test Guideline 473 Mutagenicity (mammal cell test): micronucleus. Result: positive Method: OECD Test Guideline 487	
Carcinogenicity:	Not available.	
Reproductive toxicity:	Not available.	
Summary of evaluation of the CMR properties:	Mutagenicity: Suspected of causing genetic defects.	
STOT-single exposure:	Not available.	
STOT-repeated exposure:	May cause damage to organs through prolonged or repeated exposure. Target Organs: nervous system, kidney, liver, skin.	
Aspiration Hazard:	Not available.	
Other:	After absorption: Systemic effects: headache, drowsiness, inebriation, confusion, dizziness, cardiovascular disorders, changes in the blood count, respiratory arrest, collapse, unconsciousness, death. Damage to: Liver, kidney, cardiac. Other dangerous properties cannot be excluded. This substance should be handled with particular care.	

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Not available.
Ingestion:	Not available.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Toxicity to fish:	LC_{50} *Oncorhynchus mykiss* (rainbow trout): 5,0 mg/l; 96 h (ECOTOX Database)
Toxicity to daphnia and other aquatic invertebrates:	Static test EC_{50} *Ceriodaphnia dubia* (water flea): 3,1 mg/l; 48 h US-EPA
Toxicity to algae:	IC_5 *Scenedesmus quadricauda* (Green algae): 7,5 mg/l; 8 d (IUCLID) (maximum permissible toxic concentration) static test EC50 *Pseudokirchneriella subcapitata* (algae): 61,1 mg/l; 96 h US-EPA
Toxicity to bacteria:	EC_{50} activated sludge: 766 mg/l; 3 h OECD Test Guideline 209
Toxicity to fish (Chronic toxicity):	Semi-static test NOEC *Poecilia reticulata* (guppy): 4 mg/l; 14 d OECD Test Guideline 204
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):	Semi-static test EC10 *Daphnia magna* (Water flea): 0,46 mg/l; 16 d (ECHA)

12.2 Persistence and degradability

Biodegradability:	100 %; 6 d (OECD Test Guideline 302B): Easily eliminable. 85 %; 14 d (OECD Test Guideline 301C): Readily biodegradable.
Biochemical Oxygen Demand (BOD):	1.680 mg/g (5 d) (IUCLID)
Chemical Oxygen Demand (COD):	2.300 mg/g (IUCLID)

12.3 Bioaccumulative potential

Log Pow: 1,47 (30 °C)
(ECHA) Bioaccumulation is not expected.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

12.6 Other adverse effects

Surface tension:	71,3 mN/m at 20 °C
Additional ecological information:	Forms corrosive mixtures with water even if diluted. Endangers drinking-water supplies if allowed to enter soil or water. Change in the flavour characteristics of fish protein. Discharge into the environment must be avoided.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Not available.

Material Safety Data Sheet

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

PHENOLUM

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) :	UN 1671

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	PHENOL, SOLID

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	6.1

14.4 Packing group

ADR/ RID(Land),IMDG(Sea), IATA/ICAO (Air) :	II

14.5 Environmental hazards

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

14.6 Special precautions for user

ADR/RID:	Tunnel restriction code:	D/E
IMDG:	EmS:	F-A S-A

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

Not relevant.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:

Risk phrases:

R23/24/25 Toxic by inhalation, in contact with skin and if swallowed.

R35 Causes severe skin burns.

R48 Danger of serious damage to health by prolonged exposure.

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 plenty of soap and water.

S36/37/39 Wear suitable protective clothing, gloves and eye/face protection.

S62 If swallowed, do not induce vomiting: seek medical advice immediately and show this container or label where possible.

S63 In case of accident by inhalation: remove casualty to fresh air and keep at rest.

S64 If swallowed, rinse mouth with water (only if the person is conscious).

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

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

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