

European Pharmacopoeia Reagent Primary Opalescence Solution

Version number: GHS 1.0

Date of compilation: 2021-07-06

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

1.1 Product identifier

Trade name	European Pharmacopoeia Reagent Primary Opalescence Solution
Registration number (REACH)	not relevant (mixture)
Article number	A0282092

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

Relevant identified uses	General use
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1.3 Details of the supplier of the safety data sheet

Chemos GmbH & Co. KG
 Sonnenring 7
 84032 Altdorf
 Germany

Telephone: +49 871-966346-0
 Telefax: +49 871-966346-13
 e-mail: chemos@chemos.de
 Website: <http://www.chemos.de/>

e-mail (competent person) chemos@chemos.de

1.4 Emergency telephone number

Emergency information service	+49 89 1 92 40
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Poison centre				
Country	Name	Postal code/ city	Telephone	Telefax
United Kingdom	National Poison Information Centre Medical Toxicology Unit	SE14 5ER Lon- don	+44 171 635 91 91	

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Category	Hazard class and cat- egory	Hazard state- ment
3.4S	skin sensitisation	1	Skin Sens. 1	H317
3.6	carcinogenicity	1B	Carc. 1B	H350
4.1C	hazardous to the aquatic environment - chronic hazard	3	Aquatic Chronic 3	H412

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects
 Spillage and fire water can cause pollution of watercourses.

2.2 Label elements

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

- Signal word danger

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- Pictograms

GHS07, GHS08



- Hazard statements

H317 May cause an allergic skin reaction.
H350 May cause cancer.
H412 Harmful to aquatic life with long lasting effects.

- Precautionary statements

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
P273 Avoid release to the environment.
P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/
....
P308+P313 IF exposed or concerned: Get medical advice/attention.
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.
P362+P364 Take off contaminated clothing and wash it before reuse.
P501 Dispose of contents/container to industrial combustion plant.

- Hazardous ingredients for labelling

Hydrazine sulfate, Hexamethylenetetramine

2.3 Other hazards

of no significance

SECTION 3: Composition/information on ingredients

3.1 Substances

Not relevant (mixture)

3.2 Mixtures

Description of the mixture

Name of substance	Identifier	Wt%	Classification acc. to GHS	Pictograms
Hexamethylenetetramine	CAS No 100-97-0 EC No 202-905-8 Index No 612-101-00-2	10 – < 25	Flam. Sol. 2 / H228 Skin Sens. 1 / H317	
Hydrazine sulfate	CAS No 10034-93-2 EC No 233-110-4 Index No 007-014-00-6	1 – < 5	Acute Tox. 3 / H301 Acute Tox. 3 / H311 Acute Tox. 3 / H331 Skin Sens. 1 / H317 Carc. 1B / H350 Aquatic Acute 1 / H400 Aquatic Chronic 1 / H410	

Name of substance	Specific Conc. Limits	M-Factors	ATE	Exposure route
Hydrazine sulfate	-	-	100 mg/kg 300 mg/kg 0.5 mg/l/4h	oral dermal inhalation: dust/mist

For full text of abbreviations: see SECTION 16.

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SECTION 4: First aid measures**4.1 Description of first aid measures**

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

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

Following skin contact

Wash with plenty of soap and water.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.

Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

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 spray, BC-powder, Carbon dioxide (CO₂)

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Hazardous combustion products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

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.

SECTION 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

For non-emergency personnel

Remove persons to safety.

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.

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6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains

Advice on how to clean up a spill

Wipe up with absorbent material (e.g. cloth, fleece). Collect spillage: sawdust, kieselgur (diatomite), sand, universal binder

Appropriate containment techniques

Use of adsorbent materials.

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.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

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

Use local and general ventilation. Use only in well-ventilated areas.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Control of effects

Protect against external exposure, such as
frost

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

This information is not available.

Relevant DNELs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
Hexamethylenetetramine	100-97-0	DNEL	5.6 mg/m ³	human, inhalatory	worker (industry)	chronic - systemic effects
Hexamethylenetetramine	100-97-0	DNEL	6.4 mg/kg bw/day	human, dermal	worker (industry)	chronic - systemic effects

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Relevant PNECs of components of the mixture						
Name of substance	CAS No	Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
Hexamethylenetetramine	100-97-0	PNEC	3 mg/l	aquatic organisms	freshwater	short-term (single instance)
Hexamethylenetetramine	100-97-0	PNEC	0.3 mg/l	aquatic organisms	marine water	short-term (single instance)
Hexamethylenetetramine	100-97-0	PNEC	100 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)
Hexamethylenetetramine	100-97-0	PNEC	10.2 mg/kg	aquatic organisms	freshwater sediment	short-term (single instance)
Hexamethylenetetramine	100-97-0	PNEC	1.02 mg/kg	aquatic organisms	marine sediment	short-term (single instance)
Hexamethylenetetramine	100-97-0	PNEC	0.28 mg/kg	terrestrial organisms	soil	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

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.

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

In case of inadequate ventilation wear respiratory protection.

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	liquid
Colour	not determined
Odour	characteristic
Melting point/freezing point	0 °C

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Boiling point or initial boiling point and boiling range	100 °C
Flammability	non-combustible
Lower and upper explosion limit	not determined
Flash point	not determined
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	not determined
Kinematic viscosity	not determined
Solubility(ies)	not determined

Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	23 hPa at 20 °C
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Density and/or relative density

Density	1.012 g/cm ³
Relative vapour density	information on this property is not available

Particle characteristics	not relevant (liquid)
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
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Other safety characteristics

Solvent content	94.5 %
Solid content	11 %

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SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

See below "Conditions to avoid".

10.3 Possibility of hazardous reactions

No known hazardous reactions.

10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

10.5 Incompatible materials

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 hazard classes as defined in Regulation (EC) No 1272/2008

Test data are not available for the complete mixture.

Classification procedure

The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Acute toxicity

Shall not be classified as acutely toxic.

Acute toxicity estimate (ATE) of components of the mixture

Name of substance	CAS No	Exposure route	ATE
Hydrazine sulfate	10034-93-2	oral	100 mg/kg
Hydrazine sulfate	10034-93-2	dermal	300 mg/kg
Hydrazine sulfate	10034-93-2	inhalation: dust/mist	0.5 mg/l/4h

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

May cause an allergic skin reaction.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

May cause cancer.

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Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Harmful to aquatic life with long lasting effects.

Aquatic toxicity (chronic) of components of the mixture

Name of substance	CAS No	Endpoint	Value	Species	Exposure time
Hexamethylenetetramine	100-97-0	ErC50	3 g/l	algae	14 d
Hexamethylenetetramine	100-97-0	EC50	>100 mg/l	microorganisms	2 h

12.2 Persistence and degradability

Degradability of components of the mixture

Name of substance	CAS No	Process	Degradation rate	Time	Method	Source
Hexamethylenetetramine	100-97-0	oxygen depletion	35 %	28 d		ECHA
Hexamethylenetetramine	100-97-0	DOC removal	39 %	28 d		ECHA

12.3 Bioaccumulative potential

Data are not available.

Bioaccumulative potential of components of the mixture

Name of substance	CAS No	BCF	Log KOW	BOD5/COD
Hexamethylenetetramine	100-97-0		-2.18 (20 °C)	

12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

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12.6 Endocrine disrupting properties

Information on this property is not available.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

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. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- | | |
|---|---|
| 14.1 UN number or ID number | not subject to transport regulations |
| 14.2 UN proper shipping name | not relevant |
| 14.3 Transport hazard class(es) | none |
| 14.4 Packing group | not assigned |
| 14.5 Environmental hazards | non-environmentally hazardous acc. to the dangerous goods regulations |
| 14.6 Special precautions for user | There is no additional information. |
| 14.7 Maritime transport in bulk according to IMO instruments | The cargo is not intended to be carried in bulk. |

Information for each of the UN Model Regulations**Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information**

Not subject to ADR, RID and ADN.

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

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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)

Deco-Paint Directive

VOC content	0 %
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Industrial Emissions Directive (IED)

VOC content	0 %
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15.2 Chemical Safety Assessment

Chemical safety assessments for substances in this mixture were not carried out.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
Acute Tox.	Acute toxicity
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)
Aquatic Acute	Hazardous to the aquatic environment - acute hazard
Aquatic Chronic	Hazardous to the aquatic environment - chronic hazard
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BOD	Biochemical Oxygen Demand
Carc.	Carcinogenicity
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
COD	Chemical oxygen demand
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)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control

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Abbr.	Descriptions of used abbreviations
Flam. Sol.	Flammable solid
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)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
index No	The Index number is the identification code given to the substance in Part 3 of Annex VI to Regulation (EC) No 1272/2008
log KOW	n-Octanol/water
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
Skin Sens.	Skin sensitisation
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

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 2020/878/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).

Classification procedure

Physical and chemical properties: The classification is based on tested mixture.

Health hazards, Environmental hazards: The method for classification of the mixture is based on ingredients of the mixture (additivity formula).

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

Code	Text
H228	Flammable solid.
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H317	May cause an allergic skin reaction.
H331	Toxic if inhaled.
H350	May cause cancer.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

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Code	Text
H412	Harmful to aquatic life with long lasting effects.

Disclaimer

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