



# Primary Opalescence Suspension. As specified in Chapter 2.2.1. of the European Pharmacopoeia.

## Safety Data Sheet

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

Date of issue: 22/12/2014 Revision date: 25/02/2018 Version: 1.4

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

#### 1.1. Product identifier

Product form : Mixture  
Product name : Primary Opalescence Suspension.  
As specified in Chapter 2.2.1. of the European Pharmacopoeia.  
Product code : OP001

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

##### 1.2.1. Relevant identified uses

Main use category : Professional use, Industrial use  
Use of the substance/mixture : Laboratory chemical  
Function or use category : Laboratory chemicals

##### 1.2.2. Uses advised against

No additional information available

#### 1.3. Details of the supplier of the safety data sheet

##### Spectracer UK Ltd.

Second Floor,  
27 Gloucester Place,  
London,  
W1U 8HU,  
United Kingdom.

Tel: +44 (0) 207 193 9114

Fax: +44 (0) 203 432 4686

Email: [contact@spectracer.co.uk](mailto:contact@spectracer.co.uk)

Web: [www.spectracer.com](http://www.spectracer.com)

#### 1.4. Emergency telephone number

Emergency number : Tel: +44(0)1933 445260 Option 1. Language: English only.  
For Chemical Emergencies Only  
Llewellyn (Safety Advisors) Europe Ltd

| Country        | Organisation/Company                                     | Address   | Emergency number  | Comment |
|----------------|--|---|---|---------|
| Ireland        | National Poisons Information Centre<br>Beaumont Hospital | Beaumont Hospital Beaumont Road<br>9 Dublin           | : +353 1 8379964  |         |
| United Kingdom | National Poisons Information Service (NHS Direct)        | <a href="http://www.npis.org">http://www.npis.org</a> | 111 (England & Wales only) or 112 (EU) or 08454 24 24 24 (Scotland) |         |

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Skin sensitisation, Category 1 H317

Carcinogenicity, Category 1B H350

Hazardous to the aquatic environment — H412

Chronic Hazard, Category 3

Full text of H statements : see section 16

##### Adverse physicochemical, human health and environmental effects

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

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#### 2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

GHS08

Signal word (CLP) :

Danger

Hazardous ingredients :

methenamine, hexamethylenetetramine; hydrazine sulphate

Hazard statements (CLP) :

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

Precautionary statements (CLP) :

P202 - Do not handle until all safety precautions have been read and understood.  
P273 - Avoid release to the environment.  
P280 - Wear protective gloves/protective clothing/eye protection/face 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 hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

#### 2.3. Other hazards

No additional information available

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances

Not applicable

#### 3.2. Mixtures

| Name                                | Product identifier  | %       | Classification according to Regulation (EC) No. 1272/2008 [CLP]   |
|-------------------------------------|---|---------|---|
| methenamine, hexamethylenetetramine | (CAS-No.) 100-97-0<br>(EC-No.) 202-905-8<br>(EC Index-No.) 612-101-00-2   | 5 - 15  | Flam. Sol. 2, H228<br>Skin Sens. 1, H317  |
| hydrazine sulphate                  | (CAS-No.) 10034-93-2<br>(EC-No.) 233-110-4<br>(EC Index-No.) 007-014-00-6 | 0,5 - 1 | Acute Tox. 3 (Oral), H301<br>Acute Tox. 3 (Dermal), H311<br>Acute Tox. 3 (Inhalation), H331<br>Skin Sens. 1, H317<br>Carc. 1B, H350<br>Aquatic Acute 1, H400<br>Aquatic Chronic 1, H410 |

Full text of H-statements: see section 16

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

First-aid measures general : IF exposed or concerned: Get medical advice/attention.  
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.  
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. Wash with plenty of water/... If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. Wash skin with plenty of water. Take off contaminated clothing. If skin irritation or rash occurs: Get medical advice/attention.  
First-aid measures after eye contact : Rinse eyes with water as a precaution.  
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after skin contact : May cause an allergic skin reaction.

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

Treat symptomatically.

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#### SECTION 5: Firefighting measures

##### 5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

##### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

##### 5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

#### SECTION 6: Accidental release measures

##### 6.1. Personal precautions, protective equipment and emergency procedures

###### 6.1.1. For non-emergency personnel

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene. Avoid breathing dust/fume/gas/mist/vapours/spray.

###### 6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

##### 6.2. Environmental precautions

Avoid release to the environment. Notify authorities if product enters sewers or public waters.

##### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

##### 6.4. Reference to other sections

For further information refer to section 13.

#### SECTION 7: Handling and storage

##### 7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Avoid breathing fume, Vapours. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Take all necessary technical measures to avoid or minimize the release of the product on the workplace. Limit quantities of product at the minimum necessary for handling and limit the number of exposed workers. Provide local exhaust or general room ventilation. Wear personal protective equipment. Floors, walls and other surfaces in the hazard area must be cleaned regularly. Avoid contact with skin and eyes. Avoid breathing dust/fume/gas/mist/vapours/spray.

Hygiene measures : Separate working clothes from town clothes. Launder separately. Contaminated work clothing should not be allowed out of the workplace. Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

##### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Keep only in the original container in a cool, well ventilated place away from : Direct sunlight, Heat and ignition sources. Store locked up. Store in a well-ventilated place. Keep cool.

##### 7.3. Specific end use(s)

No additional information available

#### SECTION 8: Exposure controls/personal protection

##### 8.1. Control parameters

| methenamine, hexamethylenetetramine (100-97-0) |                              |  |
|--|------------------------------|--|
| Bulgaria                                       | Local name                   | Уротропин  |
| Bulgaria                                       | OEL TWA (mg/m <sup>3</sup> ) | 2 mg/m <sup>3</sup>  |
| Bulgaria                                       | Regulatory reference         | Наредба № 13 от 30.12.2003 г. за защита на работещите от рискове, свързани с експозиция на химични агенти при работа |
| Estonia  | Local name                   | Heksametüleen-tetraamiin   |
| Estonia  | OEL TWA (mg/m <sup>3</sup> ) | 3 mg/m <sup>3</sup>  |

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| methenamine, hexamethylenetetramine (100-97-0) |   |   |
|--|---|---|
| Estonia  | OEL STEL (mg/m <sup>3</sup> )             | 5 mg/m <sup>3</sup>   |
| Estonia  | Regulatory reference                      | Vabariigi Valitsuse 18. septembri 2001. a määruse nr 293  |
| Lithuania                                      | Local name                                | Heksametilentetraminas  |
| Lithuania                                      | IPRV (mg/m <sup>3</sup> )                 | 3 mg/m <sup>3</sup>   |
| Lithuania                                      | TPRV (mg/m <sup>3</sup> )                 | 5 mg/m <sup>3</sup>   |
| Lithuania                                      | Remark (LT)                               | J (jautrinantis poveikis)   |
| Lithuania                                      | Regulatory reference                      | LIETUVOS HIGIENOS NORMA HN 23:2011  |
| Poland   | Local name                                | 1,3,5,7-Tetraazaadamantan<br>(sześciometylenoczteroamina)   |
| Poland   | NDS (mg/m <sup>3</sup> )                  | 4 mg/m <sup>3</sup>   |
| Poland   | Regulatory reference                      | Dz. U. 2017 poz. 1348   |
| Sweden   | Local name                                | Hexametyletentetramin   |
| Sweden   | nivågränsvärde (NVG) (mg/m <sup>3</sup> ) | 3 mg/m <sup>3</sup>   |
| Sweden   | kortidsvärde (KTV) (mg/m <sup>3</sup> )   | 5 mg/m <sup>3</sup>   |
| Sweden   | Anmärkning (SE)                           | S (Ämnet är sensibiliserande Sensibiliserande ämnen kan ge allergi eller annan överkänslighet. Överkänslighetsbesvären drabbar främst huden eller andningsorganen. Överkänslighet innebär att man reagerar vid kontakt med ämnen som normalt inte ger besvär. Allergi är en undergrupp av överkänslighet som orsakas av reaktioner i kroppens immunsystem. Särskilt låga gränsvärden har fastställts för ämnen med mer uttalat luftvägssensibiliserande egenskaper. Några ämnen med starkt sensibiliserande egenskaper får endast hanteras efter tillstånd från Arbetsmiljöverket, se föreskrifterna om kemiska arbetsmiljörisker. Dessa ämnen har inga gränsvärden men i vissa fall riktvärden); V (Vägledande kortidsgränsvärde ska användas som ett rekommenderat högsta värde som inte bör överskridas) |
| Sweden   | Regulatory reference                      | Hygieniska gränsvärden (AFS 2015:7)   |
| Iceland  | Local name                                | Hexametyletentetramín   |
| Iceland  | OEL (8 hours ref) (mg/m <sup>3</sup> )    | 3 mg/m <sup>3</sup>   |
| Iceland  | Notes (IS)                                | O (efnið er ofnæmisvaldandi)  |
| Iceland  | Regulatory reference                      | Reglugerð um mengunarmörk og aðgerðir til að draga úr mengun á vinnustöðum (Nr. 390/2009)   |
| Norway   | Local name                                | Heksametyletentetramin  |
| Norway   | Grenseverdier (AN) (mg/m <sup>3</sup> )   | 3 mg/m <sup>3</sup>   |
| Norway   | Regulatory reference                      | Arbeidstilsynet. Forskrift, best.nr. 704  |

## 8.2. Exposure controls

### Appropriate engineering controls:

Provide adequate general and local exhaust ventilation. Ensure good ventilation of the work station.

### Personal protective equipment:

Protective goggles. Gloves. Protective clothing.

### Hand protection:

Protective gloves

### Eye protection:

Safety glasses

### Skin and body protection:

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Wear suitable protective clothing

#### Respiratory protection:

Where exposure through inhalation may occur from use, respiratory protection equipment is recommended. [In case of inadequate ventilation] wear respiratory protection.

#### Personal protective equipment symbol(s):



#### Environmental exposure controls:

Avoid release to the environment.

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

|  |                     |
|--|---------------------|
| Physical state                             | : Liquid            |
| Colour                                     | : No data available |
| Odour                                      | : No data available |
| Odour threshold                            | : No data available |
| pH   | : No data available |
| Relative evaporation rate (butylacetate=1) | : No data available |
| Melting point                              | : Not applicable    |
| Freezing point                             | : No data available |
| Boiling point                              | : No data available |
| Flash point                                | : No data available |
| Auto-ignition temperature                  | : No data available |
| Decomposition temperature                  | : No data available |
| Flammability (solid, gas)                  | : Not applicable    |
| Vapour pressure                            | : No data available |
| Relative vapour density at 20 °C           | : No data available |
| Relative density                           | : No data available |
| Solubility                                 | : No data available |
| Log Pow                                    | : No data available |
| Viscosity, kinematic                       | : No data available |
| Viscosity, dynamic                         | : No data available |
| Explosive properties                       | : No data available |
| Oxidising properties                       | : No data available |
| Explosive limits                           | : No data available |

### 9.2. Other information

No additional information available

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

### 10.2. Chemical stability

Stable under normal conditions.

### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

### 10.5. Incompatible materials

No additional information available

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#### 10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

|                             |  |
|-----------------------------|--|
| Acute toxicity (oral)       | : Not classified   |
| Acute toxicity (dermal)     | : Not classified   |
| Acute toxicity (inhalation) | : Not classified   |
| Additional information      | : Based on available data, the classification criteria are not met |

#### methenamine, hexamethylenetetramine (100-97-0)

|                                   |  |
|-----------------------------------|--|
| LD50 oral rat                     | > 5000 mg/kg (Rat)                     |
| Skin corrosion/irritation         | : Not classified                       |
| Serious eye damage/irritation     | : Not classified                       |
| Respiratory or skin sensitisation | : May cause an allergic skin reaction. |
| Germ cell mutagenicity            | : Not classified                       |
| Carcinogenicity                   | : May cause cancer.                    |
| Reproductive toxicity             | : Not classified                       |
| STOT-single exposure              | : Not classified                       |
| STOT-repeated exposure            | : Not classified                       |
| Aspiration hazard                 | : Not classified                       |

### SECTION 12: Ecological information

#### 12.1. Toxicity

|                          |  |
|--------------------------|--|
| Ecology - general        | : Harmful to aquatic life with long lasting effects. |
| Acute aquatic toxicity   | : Not classified                                     |
| Chronic aquatic toxicity | : Harmful to aquatic life with long lasting effects. |

#### methenamine, hexamethylenetetramine (100-97-0)

|                |                         |
|----------------|-------------------------|
| LC50 fish 1    | 49800 mg/l (LC50; 96 h) |
| EC50 Daphnia 1 | 36000 mg/l (EC50; 48 h) |

#### 12.2. Persistence and degradability

#### methenamine, hexamethylenetetramine (100-97-0)

|                                 |   |
|---------------------------------|---|
| Persistence and degradability   | Hydrolysis in water.                                  |
| Biochemical oxygen demand (BOD) | 0,026 g O <sub>2</sub> /g substance                   |
| ThOD                            | 1,37 g O <sub>2</sub> /g substance (NH <sub>3</sub> ) |
| BOD (% of ThOD)                 | 0,01897   |

#### hydrazine sulphate (10034-93-2)

|                               |                        |
|-------------------------------|------------------------|
| Persistence and degradability | Biodegradable in soil. |
|-------------------------------|------------------------|

#### 12.3. Bioaccumulative potential

#### methenamine, hexamethylenetetramine (100-97-0)

|         |               |
|---------|---------------|
| Log Pow | -4,15 - -2,13 |
|---------|---------------|

#### hydrazine sulphate (10034-93-2)

|                           |                    |
|---------------------------|--------------------|
| Bioaccumulative potential | No data available. |
|---------------------------|--------------------|

#### 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

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#### SECTION 13: Disposal considerations

##### 13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.  
 Product/Packaging disposal recommendations : Dispose of contents/container to a licensed waste centre in accordance with local/regional/national/international regulations.

#### SECTION 14: Transport information

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

| ADR                                     | IMDG          | IATA          | ADN           | RID           |
|---|---------------|---------------|---------------|---------------|
| <b>14.1. UN number</b>                  |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.2. UN proper shipping name</b>    |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.3. Transport hazard class(es)</b> |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.4. Packing group</b>              |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.5. Environmental hazards</b>      |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available  |               |               |               |               |

##### 14.6. Special precautions for user

###### - Overland transport

Not regulated

###### - Transport by sea

Not regulated

###### - Air transport

Not regulated

###### - Inland waterway transport

Not regulated

###### - Rail transport

Not regulated

##### 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

The following restrictions are applicable according to Annex XVII of the REACH Regulation (EC) No 1907/2006:

|  |  |
|--|--|
| 3. Liquid substances or mixtures which are regarded as dangerous in accordance with Directive 1999/45/EC or are fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008   | Primary Opalescence Suspension.<br>As specified in Chapter 2.2.1. of the European Pharmacopoeia. |
| 3(b) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10 | Primary Opalescence Suspension.<br>As specified in Chapter 2.2.1. of the European Pharmacopoeia. |
| 3(c) Substances or mixtures fulfilling the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008: Hazard class 4.1   | Primary Opalescence Suspension.<br>As specified in Chapter 2.2.1. of the European Pharmacopoeia. |

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40. Substances classified as flammable gases category 1 or 2, flammable liquids categories 1, 2 or 3, flammable solids category 1 or 2, substances and mixtures which, in contact with water, emit flammable gases, category 1, 2 or 3, pyrophoric liquids category 1 or pyrophoric solids category 1, regardless of whether they appear in Part 3 of Annex VI to Regulation (EC) No 1272/2008 or not.

methenamine, hexamethylenetetramine

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

#### 15.1.2. National regulations

##### Germany

Reference to AwSV : Water hazard class (WGK) 3, severe hazard to waters (Classification according to AwSV, Annex 1)

Storage class (LGK) : LGK 6.1D - Non-combustible substances of acute toxicity, category 3 / hazardous substances that are toxic or produce chronic effects

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

##### Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

##### Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product  
Pregnant/breastfeeding women working with the product must not be in direct contact with the product  
The requirements from the Danish Working Environment Authorities regarding work with carcinogens must be followed during use and disposal

#### 15.2. Chemical safety assessment

No chemical safety assessment has been carried out

### SECTION 16: Other information

Full text of H- and EUH-statements:

|                           |   |
|---------------------------|---|
| Acute Tox. 3 (Dermal)     | Acute toxicity (dermal), Category 3                               |
| Acute Tox. 3 (Inhalation) | Acute toxicity (inhal.), Category 3                               |
| Acute Tox. 3 (Oral)       | Acute toxicity (oral), Category 3                                 |
| Aquatic Acute 1           | Hazardous to the aquatic environment — Acute Hazard, Category 1   |
| Aquatic Chronic 1         | Hazardous to the aquatic environment — Chronic Hazard, Category 1 |
| Aquatic Chronic 3         | Hazardous to the aquatic environment — Chronic Hazard, Category 3 |
| Carc. 1B                  | Carcinogenicity, Category 1B                                      |
| Flam. Sol. 2              | Flammable solids, Category 2                                      |
| Skin Sens. 1              | Skin sensitisation, Category 1                                    |
| 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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|      |  |
|------|--|
| H412 | Harmful to aquatic life with long lasting effects. |
|------|--|

SDS EU Mod H F (REACH ANNEX II)

*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.*