

SAFETY DATA SHEETS

This SDS packet was issued with item:

078945155

N/A

	SAFETY DATA SHEET <i>According to 1907/2006/EC, Article 31</i> MONOBLUE SafR
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Printing date 16.10.2017

Version 0 Revision: 16.10.2017

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

- **1.1 Product identifier**
- **Trade name:** **MONOBLUE SafR**
- **1.2 Relevant identified uses of the substance or mixture and uses advised against**
Dye for ophthalmic use.
- **Application of the substance / the preparation:**
Class IIa medical device.
Complies with Council Directive 93/42 / EEC of 14 June 1993 on medical devices
- **1.3 Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
ARCADOPHTA
11, rue Antoine Ricord
31100 TOULOUSE - FRANCE
www.arcadophta.com
Tel.: +33 (0)5 61 40 52 35
Fax: +33 (0)5 61 40 84 66
Email: pascaledavid@arcadophta.com
- **1.4 Emergency telephone number:**
France (INRS 24h/24) - Tel: +33 (0)1 45 42 59 59
Ireland - Tel: 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112
Belgium - Tel: 32 070/245 245
UK : +44 (0)-870-190-6777 (CARECHEM24)

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008:**
The product is not classified according to the CLP regulation.
- **2.2 Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** Not classified as hazardous
- **Hazard pictograms** Not classified as hazardous
- **Signal word** Not classified as hazardous
- **Hazard statements** Not classified as hazardous
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** Mixture: consisting of the following components.
- **Dangerous components:** Not classified as hazardous

- **Other components:**

CAS: 72-57-1	Tetrasodium 3,3'-[(3,3'-dimethyl[1,1'-biphenyl]-4,4'-diyl)bis(azo)]bis[5-amino-4-hydroxynaphthalene-2,7-disulphonate]
EINECS: 200-786-7	

- **SVHC No**

- **Additional information:** For the wording of the listed risk phrases, refer to section 16.

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SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After excessive inhalation:** Provide fresh air; consult a doctor in case of medical complaints.
- **After skin contact:** Generally, the product does not irritate the skin.
- **After eye contact:** No special measures required
- **After swallowing:** Do not induce vomiting; call for medical help immediately.
- **4.2 Most important symptoms and effects, both acute and delayed:**
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed:**
No further relevant information available.

SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **5.2 Special hazards arising from the substance or mixture:** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures:** Not required.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow the product to enter sewers/ surface water or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections:**
See Section 7 for information on safe handling.
See Section 8 for information on personal protective equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling:** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Store at ambient temperature, protected from light.
- **Further information about storage conditions:** Protect from frost.
- **7.3 Specific end use(s):** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **Additional information about design of technical facilities:** No further data; see section 7.

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- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**
The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**
The most current valid lists have been used as a basis for the production of this document.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:** Gloves recommended.
- **Gloves material:** -
- **Eye protection:** Goggles recommended.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

Form:	Liquid
Colour:	Light blue
Odour:	Characteristic
Odour threshold:	Not determined.
- **pH-value at 20 °C:** 7-7,5
- **Change in condition**

Melting point/freezing point:	0 °C
Initial boiling point and boiling range:	100 °C
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not self-igniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.
- **Vapour pressure at 20 °C:** 23 hPa
- **Density:** Not determined.
- **Relative density:** Not determined.
- **Vapour density:** Not determined.
- **Evaporation rate:** Not determined.
- **Solubility in / Miscibility with water:** Fully miscible.

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- **Segregation coefficient (n-octanol/water):** Not determined.
- **Viscosity:**
 - Dynamic:** Not determined.
 - Kinematic:** Not determined.
- **9.2 Other information:** No further relevant information available.

SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions:** No dangerous reactions known.
- **10.4 Conditions to avoid:** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.
- **On the eyes:** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **Additional ecological information:**
- **General notes:**
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· **12.6 Other adverse effects:** No further relevant information available.**SECTION 13: Disposal considerations**· **13.1 Waste treatment methods**· **Recommendation:** Smaller quantities can be disposed of with household waste.· **Uncleaned packaging:**· **Recommendation:** Disposal must be made according to official regulations.· **Recommended cleansing agents:** Water, if necessary together with cleansing agents.**SECTION 14: Transport information**· **14.1 UN-Number**· **ADR, ADN, IMDG, IATA**

Not classified as hazardous for transport

· **14.2 UN proper shipping name**· **ADR, ADN, IMDG, IATA**

Not classified as hazardous for transport

· **14.3 Transport hazard class(es)**· **ADR, ADN, IMDG, IATA**· **Class**

Not classified as hazardous for transport

· **14.4 Packing group**· **ADR, IMDG, IATA**

Not classified as hazardous for transport

· **14.5 Environmental hazards:**

Not applicable.

· **14.6 Special precautions for user**

Not applicable.

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

Not applicable.

· **UN "Model Regulation":**

Not classified as hazardous for transport

SECTION 15: Regulatory information· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture Directive 2012/18/EU**· **Named dangerous substances - ANNEX I** None of the ingredients is listed.· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.**SECTION 16: Other information**

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonised System of Classification and Labelling of Chemicals

EINECS: European Inventory of Existing Commercial Chemical Substances

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ELINCS: European List of Notified Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
PBT: Persistent, Bioaccumulative and Toxic
SVHC: Substances of Very High Concern
vPvB: very Persistent and very Bioaccumulative

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