

Bio Marking Dye - Blue**Information Sheet****SECTION 1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Code: **05-014-030**
Product name **Bio Marking Dye - Blue**

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

Intended use **In vitro medical-diagnostic disposable. Reagent for microscopy.**

1.3. Details of the supplier of the safety data sheet

Name **BIO-OPTICA MILANO SPA**
Full address **via San Faustino, 58**
District and Country **20134 Milano (MI)**
Italia
Tel. **0039 02 2127131**
Fax **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Tossicology and Antivenin Center**

SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients**3.1. Substances**

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Blue**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Blue**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|----------------|
| Appearance | viscous liquid |
| Colour | blue |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Blue

SECTION 9. Physical and chemical properties ... / >>

9.2. Other information

| | |
|------------------------------|--------|
| VOC (Directive 2010/75/EC) : | 0,96 % |
| VOC (volatile carbon) : | 0,38 % |

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Blue

SECTION 11. Toxicological information ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Blue

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Blue**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Blue

SECTION 16. Other information ... / >>

02 / 03 / 08 / 11 / 12.

Bio Marking Dye - Black

Information Sheet

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

1.1. Product identifier

Code: **05-015-030**
Product name **Bio Marking Dye - Black**

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

Intended use **In vitro medical-diagnostic disposable. Reagent for microscopy.**

1.3. Details of the supplier of the safety data sheet

Name **BIO-OPTICA MILANO SPA**
Full address **via San Faustino, 58**
District and Country **20134 Milano (MI)**
Italia
Tel. **0039 02 2127131**
Fax **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Toxicology and Antivenin Center**

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulation 1907/2006 and subsequent amendments.

Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Hazardous to the aquatic environment, chronic toxicity, category 4 H413 May cause long lasting harmful effects to aquatic life.

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:

H413 May cause long lasting harmful effects to aquatic life.

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

Bio Marking Dye - Black**SECTION 3. Composition/information on ingredients ... / >>****3.2. Mixtures**

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

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

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Black**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Information not available

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | black |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower inflammability limit | Not available |
| Upper inflammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Black**SECTION 9. Physical and chemical properties** ... / >>**9.2. Other information**

VOC (Directive 2010/75/EC) : 0,96 %
VOC (volatile carbon) : 0,38 %

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information**11.1. Information on toxicological effects**

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Black**SECTION 11. Toxicological information** ... / >>GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

This product may damage the structure and/or the functions of the aquatic ecosystems in the long and/or delayed term.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

SECTION 13. Disposal considerations

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

13.1. Waste treatment methods

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Black

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Aquatic Chronic 4 Hazardous to the aquatic environment, chronic toxicity, category 4
H413 May cause long lasting harmful effects to aquatic life.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
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7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
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9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
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- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current

Bio Marking Dye - Black**SECTION 16. Other information ... / >>**

health and safety laws and regulations. The producer is relieved from any liability arising from improper uses. Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:
The following sections were modified:
02 / 08 / 11 / 12 / 13 / 15 / 16.

Bio Marking Dye - Green

Information Sheet

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

1.1. Product identifier

Code: 05-016-030
Product name: Bio Marking Dye - Green

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

Intended use: In vitro medical-diagnostic disposable. Reagent for microscopy.

1.3. Details of the supplier of the safety data sheet

Name: BIO-OPTICA MILANO SPA
Full address: via San Faustino, 58
District and Country: 20134 Milano (MI)
Italia
Tel. 0039 02 2127131
Fax 0039 02 2153000

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: Bio-Optica Milano S.p.a.

1.4. Emergency telephone number

For urgent inquiries refer to: Please contact the nearest Toxicology and Antivenin Center

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Green**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Green**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | green |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Green**SECTION 9. Physical and chemical properties** ... / >>**9.2. Other information**

VOC (Directive 2010/75/EC) : 1,21 %
VOC (volatile carbon) : 0,50 %

SECTION 10. Stability and reactivity**10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Green**SECTION 11. Toxicological information** ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Green

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Green**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Green

SECTION 16. Other information ... / >>

09.

Bio Marking Dye - Yellow**Information Sheet****SECTION 1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Code: **05-017-030**
Product name **Bio Marking Dye - Yellow**

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

Intended use **In vitro medical-diagnostic disposable. Reagent for microscopy.**

1.3. Details of the supplier of the safety data sheet

Name **BIO-OPTICA MILANO SPA**
Full address **via San Faustino, 58**
District and Country **20134 Milano (MI)**
Italia
Tel. **0039 02 2127131**
Fax **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Tossicology and Antivenin Center**

SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients**3.1. Substances**

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Yellow**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Yellow**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | yellow |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Yellow

SECTION 9. Physical and chemical properties ... / >>

9.2. Other information

VOC (Directive 2010/75/EC) : 0,96 %
VOC (volatile carbon) : 0,38 %

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Yellow**SECTION 11. Toxicological information** ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Yellow

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Yellow**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Yellow

SECTION 16. Other information ... / >>

09 / 14.

Bio Marking Dye - Orange

Information Sheet

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

1.1. Product identifier

Code: 05-018-030
Product name: Bio Marking Dye - Orange

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

Intended use: In vitro medical-diagnostic disposable. Reagent for microscopy.

1.3. Details of the supplier of the safety data sheet

Name: BIO-OPTICA MILANO SPA
Full address: via San Faustino, 58
District and Country: 20134 Milano (MI)
Italia
Tel. 0039 02 2127131
Fax 0039 02 2153000

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: Bio-Optica Milano S.p.a.

1.4. Emergency telephone number

For urgent inquiries refer to: Please contact the nearest Toxicology and Antivenin Center

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Orange**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Orange

SECTION 7. Handling and storage**7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | orange |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Orange

SECTION 9. Physical and chemical properties ... / >>

9.2. Other information

| | |
|------------------------------|--------|
| VOC (Directive 2010/75/EC) : | 0,96 % |
| VOC (volatile carbon) : | 0,38 % |

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Orange

SECTION 11. Toxicological information ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Orange

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Orange**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Orange

SECTION 16. Other information ... / >>

09 / 14.

Bio Marking Dye - Red

Information Sheet

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

1.1. Product identifier

Code: 05-019-030
Product name: Bio Marking Dye - Red

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

Intended use: In vitro medical-diagnostic disposable. Reagent for microscopy.

1.3. Details of the supplier of the safety data sheet

Name: BIO-OPTICA MILANO SPA
Full address: via San Faustino, 58
District and Country: 20134 Milano (MI)
Italia
Tel. 0039 02 2127131
Fax 0039 02 2153000

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: Bio-Optica Milano S.p.a.

1.4. Emergency telephone number

For urgent inquiries refer to: Please contact the nearest Toxicology and Antivenin Center

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Red**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Red**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | red |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Red

SECTION 9. Physical and chemical properties ... / >>

9.2. Other information

VOC (Directive 2010/75/EC) : 1,21 %
VOC (volatile carbon) : 0,50 %

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Red

SECTION 11. Toxicological information ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Red

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Red**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Red

SECTION 16. Other information ... / >>

08 / 09.

Bio Marking Dye - Purple**Information Sheet****SECTION 1. Identification of the substance/mixture and of the company/undertaking****1.1. Product identifier**

Code: **05-020-030**
Product name **Bio Marking Dye - Purple**

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

Intended use **In vitro medical-diagnostic disposable. Reagent for microscopy.**

1.3. Details of the supplier of the safety data sheet

Name **BIO-OPTICA MILANO SPA**
Full address **via San Faustino, 58**
District and Country **20134 Milano (MI)**
Italia
Tel. **0039 02 2127131**
Fax **0039 02 2153000**

e-mail address of the competent person responsible for the Safety Data Sheet

info@bio-stain.it

Product distribution by: **Bio-Optica Milano S.p.a.**

1.4. Emergency telephone number

For urgent inquiries refer to **Please contact the nearest Toxicology and Antivenin Center**

SECTION 2. Hazards identification**2.1. Classification of the substance or mixture**

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements).

Hazard classification and indication: --

2.2. Label elements

Hazard pictograms: --

Signal words: --

Hazard statements: --

Precautionary statements: --

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

SECTION 3. Composition/information on ingredients**3.1. Substances**

Information not relevant

3.2. Mixtures

The product does not contain substances classified as being hazardous to human health or the environment pursuant to the provisions Regulation (EU) 1272/2008 (CLP) (and subsequent amendments and supplements) in such quantities as to require the statement.

Bio Marking Dye - Purple**SECTION 4. First aid measures****4.1. Description of first aid measures**

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

Specific information on symptoms and effects caused by the product are unknown.

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

Information not available

SECTION 5. Firefighting measures**5.1. Extinguishing media****SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture**HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE**

Do not breathe combustion products.

5.3. Advice for firefighters**GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

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

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

Bio Marking Dye - Purple**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

TLV of solvent mixture: 25 mg/m³

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

RESPIRATORY PROTECTION

None required, unless indicated otherwise in the chemical risk assessment.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties**9.1. Information on basic physical and chemical properties**

| | |
|--|------------------|
| Appearance | viscous liquid |
| Colour | violet |
| Odour | characteristic |
| Odour threshold | Not available |
| pH | Not available |
| Melting point / freezing point | Not available |
| Initial boiling point | Not available |
| Boiling range | Not available |
| Flash point | > 60 °C |
| Evaporation Rate | Not available |
| Flammability of solids and gases | Not available |
| Lower flammability limit | Not available |
| Upper flammability limit | Not available |
| Lower explosive limit | Not available |
| Upper explosive limit | Not available |
| Vapour pressure | Not available |
| Vapour density | Not available |
| Relative density | Not available |
| Solubility | soluble in water |
| Partition coefficient: n-octanol/water | Not available |
| Auto-ignition temperature | Not available |
| Decomposition temperature | Not available |
| Viscosity | Not available |
| Explosive properties | Not available |
| Oxidising properties | Not available |

Bio Marking Dye - Purple

SECTION 9. Physical and chemical properties ... / >>

9.2. Other information

VOC (Directive 2010/75/EC) : 0,96 %
VOC (volatile carbon) : 0,38 %

SECTION 10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on toxicological effects

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

| | |
|-----------------------------------|---|
| LC50 (Inhalation) of the mixture: | Not classified (no significant component) |
| LD50 (Oral) of the mixture: | Not classified (no significant component) |
| LD50 (Dermal) of the mixture: | Not classified (no significant component) |

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

Bio Marking Dye - Purple**SECTION 11. Toxicological information** ... / >>RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects

Information not available

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

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.

CONTAMINATED PACKAGING

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

Bio Marking Dye - Purple

SECTION 14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number

Not applicable

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

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

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EC: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Information not available

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains.

Bio Marking Dye - Purple**SECTION 16. Other information****LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation
- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

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2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
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5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
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10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

Bio Marking Dye - Purple

SECTION 16. Other information ... / >>

09 / 14.