



MATERIAL SAFETY DATA SHEET

Revision: 06.06.2022

Version: 04

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

1.1. Product identifier

Mythic 18 Diluent (Cat. No HM18-009-10)
Mythic 18 Diluent (Cat. No HM18-009-20)

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

Identified uses: Laboratory reagents. For professional use only.

Uses advised against: No uses advised against have been identified.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Geneva / Plan-les-Ouates
SWITZERLAND
Phone: +41 22 884 90 90
Fax: +41 22 884 90 99

E-mail address of the person responsible for the safety data sheet: msds@orphee-medical.com

Authorised representative:

PZ CORMAY S.A.
22 Wiosenna Street
05-092 ŁOMIANKI
phone: +48 22 751 79 10
fax +48 22 751 79 11

E-mail address of the person responsible for the safety data sheet: msds@cormay.pl

1.4. Emergency telephone number

The local/in-country emergency telephone number.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Repr. 1B, H360FD

2.2. Label elements

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



Contains boric acid.

Signal word:

Danger

Hazard statement(s):

H360FD - May damage fertility. May damage the unborn child.

Precautionary statement(s):

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P308 + P313 IF exposed or concerned: Get medical advice.

P405 Store locked up.

2.3. Other hazards

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Boric Acid

Contains: < 0.5%

CAS number: 10043-35-3

EC number: 233-139-2

Index number: 005-007-00-2

Registration number: 01-2119486683-25-XXXX

Classification according to Regulation (EC) No 1272/2008 [CLP]:
Repr. 1B, H360FD

The full text of H phrases is given in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of any disorder, get medical advice and show the package or label.
If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. If symptoms occur, consult a physician.
In case of skin contact: Wash contaminated skin immediately with plenty of soap and water. Remove contaminated clothing immediately.
In case of eye contact: Wash thoroughly eyes with plenty of water for at least 15 minutes. If irritation remains, seek medical help.
If swallowed: Rinse mouth with water. Consult a doctor if symptoms occur.

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

No data available.

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

In the case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water, CO₂, dry powder can be used as the extinguish media.
Not recommended extinguishing media: no data available.

5.2. Special hazards arising from the substance or mixture

There is no data about hazardous substances which may occur during fire thermal decomposition of the mixture.

5.3. Advice for firefighters

The rescuers must be equipped with protective clothing and respiratory tract isolating equipment, irrespective of ambient air (in the case of large fire).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Avoid contamination with the preparation.

Notify the effected individuals of the emergency, to be aware of the issues associated.

Do not inhale vapours/aerosols.

Secure the flow of fresh air into closed rooms.

Avoid contact of the mixture with skin and eyes.

Remove contaminated clothing and wash before reuse.

6.1.2. For emergency responders

Wear protective clothing and rubber gloves.

6.2. Environmental precautions

Dilute with plenty of water.

Avoid entering the mixture into drains, surface water and groundwater, reservoirs and waterways.

6.3. Methods and material for containment and cleaning up

Collect small quantities with the use of an absorbing agent (sand, diatomite, acid binders, universal binders, sawdust), rinse with large amount of water if necessary.

Dispose of the collected material to a company with a waste management permit.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS. Refer to section 13 of this MSDS for adequate release measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8).

Avoid contact of the preparation with skin and eyes, as well as inhaling its mists.

Secure efficient local ventilation.

Industrial hygiene:

Eating, drinking or smoking of tobacco is prohibited while working with the preparation, except for places specially designated for this purpose.

Wash your hands after work with the substance carefully with soapy water. Apply skin-protective barrier cream.

7.2. Conditions for safe storage, including any incompatibilities

In accordance with the norms generally accepted for chemicals in laboratories.
Store in original manufacturer containers.
Store in closed containers at temperatures compatible with the information provided on the label.
Protect containers from damage.
Do not store with food or animal feed.

7.3. Specific end use(s)

No information on uses other than those listed in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Do not contain substances with occupational exposure limit values at workplace.

Data for boric acid:

Derived No Effect Level (DNEL):

Worker DNEL, long term	Systemic effects	inhalation	8,3 mg/m ³
Worker DNEL, long term	Systemic effects	dermal	392 mg/kg

Predicted No Effect Concentration (PNEC):

PNEC Fresh water	2,02 mg/l
PNEC Marine water	2,02 mg/l
PNEC Aquatic intermittent release	13,7 mg/l
PNEC Sewage treatment plant	10 mg/l
PNEC Soil	5,4 mg/kg

8.2. Exposure controls

Observe general health and safety rules. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work. Use personal protective equipment.

a) Eye / Face protection:

Avoid direct contact of the mixture with eyes, use glasses as a protection.

b) Skin/Hand protection:

Avoid direct contact of the mixture with skin, immediately take off clothes soiled with the mixture and wash contaminated skin with soapy water, use personal protective, clothing and gloves:

c) Respiratory protection:

Apply in rooms with efficiently working ventilation, avoid inhaling the mixture mists, respiratory tract-protective agents are not required.

d) Thermal hazards:

Thermal hazards have not been identified.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Physical state:	<i>clear liquid</i>
b) Colour:	<i>colourless</i>
c) Odour:	<i>no data available</i>
d) Melting point/freezing point:	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>
f) Flammability:	<i>no data available</i>
g) Lower and upper explosion limit:	<i>no data available</i>
h) Flash point:	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>
k) pH:	<i>7.45</i>
l) Kinematic viscosity:	<i>no data available</i>
m) Solubility:	<i>no data available</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>
p) Density and/or relative density:	<i>1.009 g/cm³</i>
q) Relative vapour density:	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The mixture is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The mixture is stable when normal handling and with anticipated warehousing and storage conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The mixture is stable in conditions provided by the manufacturer. Avoid heat.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known. In the event of fire: see section 5.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicity of the mixture:

a) acute toxicity:

Based on available data, the classification criteria are not met.

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met.

d) respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

e) germ cell mutagenicity:

Based on available data, the classification criteria are not met.

f) carcinogenicity:

Based on available data, the classification criteria are not met.

g) reproductive toxicity:

May damage fertility. May damage the unborn child.

h) STOT-single exposure:

Based on available data, the classification criteria are not met.

i) STOT-repeated exposure:

Based on available data, the classification criteria are not met.

j) aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

No ecotoxicological studies conducted for the entire mixture.

Ecotoxicity effects of the mixture:

The mixture is not classified as hazardous to the aquatic environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

No other adverse effect have been identified.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Transfer waste to a company with a waste management permit. Avoid releasing to the drains and to the environment.

Reagent	Waste classification	UE waste code reagent	UE waste code direct packaging
MYTHIC 18 DILUENT	hazardous	18 01 06*	15 01 10*

List of Waste referred to in Article 7 of Directive 2008/98/EC:

18 01 06* chemicals consisting of or containing hazardous substances

15 01 10* packaging containing residues of or contaminated by hazardous substances

SECTION 14: Transport information

14.1. UN number or ID number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

No limits.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

Material Safety Data Sheet was prepared in accordance with:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) in its current version.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 53/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (Text with EEA relevance) in its current version.

Council regulation (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic' (Text with EEA relevance) in its current version.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance) in its current version.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the mixture.

SECTION 16: Other information

Full text of abbreviations and acronyms:

PBT - persistent, bioaccumulative and toxic substances
vPvB - very persistent and very bioaccumulative substances
Repr. 1B - Reproductive toxicity (category 1B)

Text of H-code(s):

H360FD - May damage fertility. May damage the unborn child.

Methods of evaluating information for the purpose of classification: calculation method.

Key literature references and data sources: the material safety data sheet for the mixture have been prepared on the basis of safety data sheets for individual components of the mixture, data from

the ECHA website and the available knowledge and experience, taking into account the current legislation.

The foregoing information is based on the present state of our knowledge. It characterizes the mixture with respect to the appropriate safety measures. They do not guarantee the properties of the mixture.

We do not take responsibility for damage and losses that may result from inappropriate use of the mixture.

Reason of changes:

Adaptation of the format of the safety data sheet to the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020.

Change to the document number.

Changes in the classification and labelling (section 2).

Changes of the physical and chemical properties (section 9.1).

Change of the waste classification (section 13.1).

Update of legal regulations (section 15.1).

Add information about the authorised representative (section 1.3).



MATERIAL SAFETY DATA SHEET

Revision: 06.06.2022

Version: 03

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

1.1. Product identifier

Mythic 18 Cyanide Free Lytic Solution (Cat. No HM18-008-05)
Mythic 18 Cyanide Free Lytic Solution (Cat. No HM18-008-1)

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

Identified uses: Laboratory reagents. For professional use only.

Uses advised against: No uses advised against have been identified.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Geneva / Plan-les-Ouates
SWITZERLAND
Phone: +41 22 884 90 90
Fax: +41 22 884 90 99

E-mail address of the person responsible for the safety data sheet: msds@orphee-medical.com

Authorised representative:

PZ CORMAY S.A.
22 Wiosenna Street
05-092 ŁOMIANKI
phone: +48 22 751 79 10
fax +48 22 751 79 11

E-mail address of the person responsible for the safety data sheet: msds@cormay.pl

1.4. Emergency telephone number

The local/in-country emergency telephone number.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Aquatic Acute 1; H400

2.2. Label elements

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



Signal word:

Warning

Hazard statement(s):

H400 - Very toxic to aquatic life.

Precautionary statement(s):

P273 Avoid release to the environment.

P391 Collect spillage.

2.3. Other hazards

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Dodecyltrimethylammonium chloride (DTAC)

Contains: < 2.4%

CAS number: 112-00-5

EC number: 203-927-0

Index number -

Registration number: not applicable

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

Acute Tox 4, H302

Skin Irrit. 2, H315

Eye Irrit. 2, H319

STOT SE 3, H335

Aquatic Acute 1, H400

Tetradonium bromide (TTAB)

Contains: < 0.2%

CAS number: 1119-97-7
EC number: 214-291-9
Index number -
Registration number: not applicable

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

Acute Tox. 4, H302
Skin Irrit. 2, H315
Eye Dam. 1, H318
STOT SE 3, H335
STOT RE 2, H373
Aquatic Acute 1, H400

M-factor:

M = 100

The full text of H phrases is given in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of any disorder, get medical advice and show the package or label.
If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. If symptoms occur, consult a physician.
In case of skin contact: Wash contaminated skin immediately with plenty of soap and water. Remove contaminated clothing immediately.
In case of eye contact: Wash thoroughly eyes with plenty of water for at least 15 minutes. If irritation remains, seek medical help.
If swallowed: Rinse mouth with water. Consult a doctor if symptoms occur.

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

No data available.

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

In the case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water, CO₂, dry powder can be used as the extinguish media.
No data available on resources not recommended for firefighting.

5.2. Special hazards arising from the substance or mixture

There is no data about hazardous substances which may occur during fire thermal decomposition of the mixture.

5.3. Advice for firefighters

The rescuers must be equipped with protective clothing and respiratory tract isolating equipment, irrespective of ambient air (in the case of large fire).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

- Avoid contamination with the preparation.
- Notify the effected individuals of the emergency, to be aware of the issues associated.
- Do not inhale vapours/aerosols.
- Secure the flow of fresh air into closed rooms.
- Avoid contact of the mixture with skin and eyes.
- Remove contaminated clothing and wash before reuse.

6.1.2. For emergency responders

- Wear protective clothing and rubber gloves.

6.2. Environmental precautions

Dilute with plenty of water.
Avoid entering the mixture into drains, surface water and groundwater, reservoirs and waterways.

6.3. Methods and material for containment and cleaning up

Collect small quantities with the use of an absorbing agent (sand, diatomite, acid binders, universal binders, sawdust), rinse with large amount of water if necessary.
Dispose of the collected material to a company with a waste management permit.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS. Refer to section 13 of this MSDS for adequate release measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8).

Avoid contact of the preparation with skin and eyes, as well as inhaling its mists.

Secure efficient local ventilation.

Industrial hygiene:

Eating, drinking or smoking of tobacco is prohibited while working with the preparation, except for places specially designated for this purpose.

Wash your hands after work with the substance carefully with soapy water. Apply skin-protective barrier cream.

7.2. Conditions for safe storage, including any incompatibilities

In accordance with the norms generally accepted for chemicals in laboratories.

Store in original manufacturer containers.

Store in closed containers at temperatures compatible with the information provided on the label.

Protect containers from damage.

Do not store with food or animal feed.

7.3. Specific end use(s)

No information on uses other than those listed in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No exposure limit value known.

8.2. Exposure controls

Observe general health and safety rules. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work. Use personal protective equipment.

a) Eye / Face protection:

Avoid direct contact of the mixture with eyes, use glasses as a protection.

b) Skin/Hand protection:

Avoid direct contact of the mixture with skin, immediately take off clothes soiled with the mixture and wash contaminated skin with soapy water, use personal protective, clothing and gloves:

c) Respiratory protection:

Apply in rooms with efficiently working ventilation, avoid inhaling the mixture mists, respiratory tract-protective agents are not required.

d) Thermal hazards:

Thermal hazards have not been identified.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Physical state:	<i>clear liquid</i>
b) Colour:	<i>colourless</i>
c) Odour:	<i>no data available</i>
d) Melting point/freezing point:	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>
f) Flammability:	<i>no data available</i>
g) Lower and upper explosion limit:	<i>no data available</i>
h) Flash point:	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>
k) pH:	<i>7.32</i>
l) Kinematic viscosity:	<i>no data available</i>
m) Solubility:	<i>miscible with water</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>
p) Density and/or relative density:	<i>0,998 g/cm³</i>
q) Relative vapour density:	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The mixture is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The mixture is stable when normal handling and with anticipated warehousing and storage conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The mixture is stable in conditions provided by the manufacturer. Avoid heat.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known. In the event of fire: see section 5.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicity of the mixture:

a) acute toxicity:

ATE_{mix} (oral) > 2000

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met.

d) respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

e) germ cell mutagenicity:

Based on available data, the classification criteria are not met.

f) carcinogenicity:

Based on available data, the classification criteria are not met.

g) reproductive toxicity:

Based on available data, the classification criteria are not met.

h) STOT-single exposure:

Based on available data, the classification criteria are not met.

i) STOT-repeated exposure:

Based on available data, the classification criteria are not met.

j) aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

Quantitative data on the ecological effect of this mixture are not available

Ecotoxicity effects of the components:

Dodecyltrimethylammonium chloride (DTAC)

Toxicity to fish (*Carassius auratus*) LC₅₀ – 0.35 mg/l - 24 h

Toxicity to daphnia (*Daphnia magna*) and other aquatic invertebrates LC₅₀ – 0.06 mg/l - 24 h

Toxicity to algae EC₅₀ – 0.09 mg/l - 96 h

Tetradonium bromide (TTAB)

Toxicity to *Danio rerio* fish (zebrafish), semi-static test LC₅₀ – 1.81 mg/l - 96 h

Toxicity to daphnia (*Daphnia magna*) and other aquatic invertebrates, semi-static test EC₅₀ – 0.022 mg/l - 48 h

Toxicity to algae (*Pseudokirchneriella subcapitata*) EC₅₀ – 0.00538 mg/l - 72 h

Ecotoxicity effects of the mixture:

Very toxic to aquatic life.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 20127/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

No other adverse effect have been identified.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Transfer waste to a company with a waste management permit. Avoid releasing to the drains and to the environment.

Reagent	Waste classification	UE waste code reagent	UE waste code direct packaging
MYTHIC 18 CYANIDE FREE LYTIC SOLUTION	hazardous	18 01 06*	15 01 10*

List of Waste referred to in Article 7 of Directive 2008/98/EC:

18 01 06* chemicals consisting of or containing hazardous substances

15 01 10* packaging containing residues of or contaminated by hazardous substances

SECTION 14: Transport information

14.1. UN number or ID number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

No limits.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

Material Safety Data Sheet was prepared in accordance with:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) in its current version.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 53/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (Text with EEA relevance) in its current version.

Council regulation (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic' (Text with EEA relevance) in its current version.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance) in its current version.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the mixture.

SECTION 16: Other information

Full text of abbreviations and acronyms:

PBT - persistent, bioaccumulative and toxic substances

vPvB - very persistent and very bioaccumulative substances

Acute Tox. 4 - Acute toxicity (category 4)
Aquatic Acute 1 - Hazardous to the aquatic environment - acute hazard (category 1)
Eye Irrit. 2 - Eye irritation (category 2)
Eye Dam. 1 - Serious eye damage (category 1)
Skin Irrit. 2 - Skin irritation (category 2)
STOT RE 2 - Specific target organ toxicity — repeated exposure (category 2)
STOT SE 3 - Specific target organ toxicity — single exposure (category 3)

Text of H-code(s):

H302 - Harmful if swallowed
H315 - Causes skin irritation
H318 - Causes serious eye damage
H319 - Causes serious eye irritation
H335 - May cause respiratory irritation
H373 - May cause damage to organs through prolonged or repeated exposure through the ingestion
H400 - Very toxic to aquatic life

Methods of evaluating information for the purpose of classification: calculation method.

Key literature references and data sources: the material safety data sheet for the mixture have been prepared on the basis of safety data sheets for individual components of the mixture, data from the ECHA website and the available knowledge and experience, taking into account the current legislation.

The foregoing information is based on the present state of our knowledge. It characterizes the mixture with respect to the appropriate safety measures. They do not guarantee the properties of the mixture.

We do not take responsibility for damage and losses that may result from inappropriate use of the mixture.

Reason of changes:

Adaptation of the format of the safety data sheet to the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020.
Change to the document number.
Changes in the classification and labelling (section 2).
Changes of the physical and chemical properties (section 9.1).
Change of the waste classification (section 13.1).
Update of legal regulations (section 15.1).
Add information about the authorised representative (section 1.3).



MATERIAL SAFETY DATA SHEET

Revision: 06.06.2022

Version: 05

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

1.1. Product identifier

Mythic 18-22 Enzymatic Cleaning Solution (Cat. No HM18-007-1)

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

Identified uses: Laboratory reagents. For professional use only.

Uses advised against: No uses advised against have been identified.

1.3. Details of the supplier of the safety data sheet

Manufacturer:

**Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Geneva / Plan-les-Ouates
SWITZERLAND
Phone: +41 22 884 90 90
Fax: +41 22 884 90 99**

E-mail address of the person responsible for the safety data sheet: msds@orphee-medical.com

Authorised representative:

**PZ CORMAY S.A.
22 Wiosenna Street
05-092 ŁOMIANKI
phone: +48 22 751 79 10
fax +48 22 751 79 11**

E-mail address of the person responsible for the safety data sheet: msds@cormay.pl

1.4. Emergency telephone number

The local/in-country emergency telephone number.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Repr. 1B, H360FD

2.2. Label elements

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



Contains boric acid.

Signal word:

Danger

Hazard statement(s):

H360FD - May damage fertility. May damage the unborn child.

Precautionary statement(s):

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P308 + P313 IF exposed or concerned: Get medical advice.

P405 Store locked up.

2.3. Other hazards

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable.

3.2. Mixtures

Boric Acid		Contains: < 0.5%
CAS number:	10043-35-3	
EC number:	233-139-2	
Index number:	005-007-00-2	
Registration number:	01-2119486683-25-XXXX	

Classification according to Regulation (EC) No 1272/2008 [CLP]:
Repr. 1B, H360FD

The full text of H phrases is given in section 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: In case of any disorder, get medical advice and show the package or label.
If inhaled: If breathed in, move person into fresh air. If not breathing, give artificial respiration. If symptoms occur, consult a physician.
In case of skin contact: Wash contaminated skin immediately with plenty of soap and water. Remove contaminated clothing immediately.
In case of eye contact: Wash thoroughly eyes with plenty of water for at least 15 minutes. If irritation remains, seek medical help.
If swallowed: Rinse mouth with water. Consult a doctor if symptoms occur.

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

No data available.

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

No data available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

In the case of fire use extinguishing media suitable for materials stored in immediate vicinity. Water, CO₂, dry powder can be used as the extinguish media.
Not recommended extinguishing media: no data available.

5.2. Special hazards arising from the substance or mixture

There is no data about hazardous substances which may occur during fire thermal decomposition of the mixture.

5.3. Advice for firefighters

The rescuers must be equipped with protective clothing and respiratory tract isolating equipment, irrespective of ambient air (in the case of large fire).

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Avoid contamination with the preparation.

Notify the effected individuals of the emergency, to be aware of the issues associated.

Do not inhale vapours/aerosols.

Secure the flow of fresh air into closed rooms.

Avoid contact of the mixture with skin and eyes.

Remove contaminated clothing and wash before reuse.

6.1.2. For emergency responders

Wear protective clothing and rubber gloves.

6.2. Environmental precautions

Dilute with plenty of water.

Avoid entering the product into drains, surface water and groundwater, reservoirs and waterways.

6.3. Methods and material for containment and cleaning up

Collect small quantities with the use of an absorbing agent (sand, diatomite, acid binders, universal binders, sawdust), rinse with large amount of water if necessary.

Dispose of the collected material to a company with a waste management permit.

6.4. Reference to other sections

Use the control measures and personal protective equipment described in section 8 of this MSDS. Refer to section 13 of this MSDS for adequate release measures.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

While working with the preparation, one should use appropriate means of personal protection (see pt. 8).

Avoid contact of the preparation with skin and eyes, as well as inhaling its mists.

Secure efficient local ventilation.

Industrial hygiene:

Eating, drinking or smoking of tobacco is prohibited while working with the preparation, except for places specially designated for this purpose.

Wash your hands after work with the substance carefully with soapy water. Apply skin-protective barrier cream.

7.2. Conditions for safe storage, including any incompatibilities

In accordance with the norms generally accepted for chemicals in laboratories.
Store in original manufacturer containers.
Store in closed containers at temperatures compatible with the information provided on the label.
Protect containers from damage.
Do not store with food or animal feed.

7.3. Specific end use(s)

No information on uses other than those listed in section 1.2.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Do not contain substances with occupational exposure limit values at workplace.

Data for boric acid:

Derived No Effect Level (DNEL):

Worker DNEL, long term	Systemic effects	inhalation	8,3 mg/m ³
Worker DNEL, long term	Systemic effects	dermal	392 mg/kg

Predicted No Effect Concentration (PNEC):

PNEC Fresh water	2,02 mg/l
PNEC Marine water	2,02 mg/l
PNEC Aquatic intermittent release	13,7 mg/l
PNEC Sewage treatment plant	10 mg/l
PNEC Soil	5,4 mg/kg

8.2. Exposure controls

Observe general health and safety rules. Do not eat, drink or smoke while working. Wash hands before breaks and at the end of work. Use personal protective equipment.

a) Eye/Face protection:

Avoid direct contact of the product with eyes, use glasses as a protection.

b) Skin/Hand protection:

Avoid direct contact of the product with skin, immediately take off clothes soiled with the preparation and wash contaminated skin with soapy water, use personal protective, clothing and gloves:

c) Respiratory protection:

Apply in rooms with efficiently working ventilation, avoid inhaling product mists, respiratory tract-protective agents are not required.

d) Thermal hazards:

Thermal hazards have not been identified.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a) Physical state:	<i>clear liquid</i>
b) Colour:	<i>colourless</i>
c) Odour:	<i>no data available</i>
d) Melting point/freezing point :	<i>no data available</i>
e) Boiling point or initial boiling point and boiling range:	<i>no data available</i>
f) Flammability:	<i>no data available</i>
g) Lower and upper explosion limit:	<i>no data available</i>
h) Flash point:	<i>no data available</i>
i) Auto-ignition temperature:	<i>no data available</i>
j) Decomposition temperature:	<i>no data available</i>
k) pH:	<i>7.62</i>
l) Kinematic viscosity:	<i>no data available</i>
m) Solubility:	<i>miscible with water</i>
n) Partition coefficient n-octanol/water (log value):	<i>no data available</i>
o) Vapour pressure:	<i>no data available</i>
p) Density and/or relative density:	<i>1,0042 g/cm³</i>
q) Relative vapour density:	<i>no data available</i>
r) Particle characteristics:	<i>not applicable</i>

9.2. Other information

No other relevant information.

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable in conditions provided by the manufacturer.

10.2. Chemical stability

The mixture is stable when normal handling and with anticipated warehousing and storage conditions.

10.3. Possibility of hazardous reactions

Not known.

10.4. Conditions to avoid

The mixture is stable in conditions provided by the manufacturer. Avoid heat.

10.5. Incompatible materials

Not known.

10.6. Hazardous decomposition products

Not known. In the event of fire: see section 5.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Toxicity of the mixture:

a) acute toxicity:

Based on available data, the classification criteria are not met.

b) skin corrosion/irritation:

Based on available data, the classification criteria are not met.

c) serious eye damage/irritation:

Based on available data, the classification criteria are not met.

d) respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

e) germ cell mutagenicity:

Based on available data, the classification criteria are not met.

f) carcinogenicity:

Based on available data, the classification criteria are not met.

g) reproductive toxicity:

May damage fertility. May damage the unborn child.

h) STOT-single exposure:

Based on available data, the classification criteria are not met.

i) STOT-repeated exposure:

Based on available data, the classification criteria are not met.

j) aspiration hazard:

Based on available data, the classification criteria are not met.

11.2 Information on other hazards

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605.

SECTION 12: Ecological information

12.1. Toxicity

No ecotoxicological studies conducted for the entire mixture.

Ecotoxicity effects of the mixture:

The mixture is not classified as hazardous to the aquatic environment.

12.2. Persistence and degradability

No data available.

12.3. Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The mixture does not contain any substances meeting the criteria for PBT or vPvB in accordance with Annex XIII of REACH in its current version.

12.6. Endocrine disrupting properties

The mixture does not contain substances with endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 20127/2100 or Commission Regulation (EU) 2018/605.

12.7 Other adverse effects

No other adverse effect have been identified.

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

Transfer waste to a company with a waste management permit. Avoid releasing to the drains and to the environment.

Reagent	Waste classification	UE waste code reagent	UE waste code direct packaging
MYTHIC 18-22 ENZYMATIC CLEANING SOLUTION	hazardous	18 01 06*	15 01 10*

List of Waste referred to in Article 7 of Directive 2008/98/EC:
18 01 06* chemicals consisting of or containing hazardous substances

15 01 10* packaging containing residues of or contaminated by hazardous substances

SECTION 14: Transport information

14.1. UN number or ID number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

No limits.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.

14.7. Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

Material Safety Data Sheet was prepared in accordance with:

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance) in its current version.

Commission Regulation (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 53/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) in its current version.

Commission Regulation (EU) No 1357/2014 of 18 December 2014 replacing Annex III to Directive 2008/98/EC of the European Parliament and of the Council on waste and repealing certain Directives (Text with EEA relevance) in its current version.

Council regulation (EU) 2017/997 of 8 June 2017 amending Annex III to Directive 2008/98/EC of the European Parliament and of the Council as regards the hazardous property HP 14 'Ecotoxic' (Text with EEA relevance) in its current version.

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance) in its current version.

15.2. Chemical safety assessment

Chemical safety assessment has been no carried out for the product.

SECTION 16: Other information

Full text of abbreviations and acronyms:

PBT - persistent, bioaccumulative and toxic substances

vPvB - very persistent and very bioaccumulative substances

Repr. 1B - Reproductive toxicity (category 1B)

Text of H-code(s):

H360FD - May damage fertility. May damage the unborn child.

Methods of evaluating information for the purpose of classification: calculation method.

Key literature references and data sources: the material safety data sheet for the mixture have been prepared on the basis of safety data sheets for individual components of the mixture, data from the ECHA website and the available knowledge and experience, taking into account the current legislation.

The foregoing information is based on the present state of our knowledge. It characterizes the mixture with respect to the appropriate safety measures. They do not guarantee the properties of the mixture.

We do not take responsibility for damage and losses that may result from inappropriate use of the mixture.

Reason of changes:

Adaptation of the format of the safety data sheet to the requirements of Commission Regulation (EU) 2020/878 of 18 June 2020.

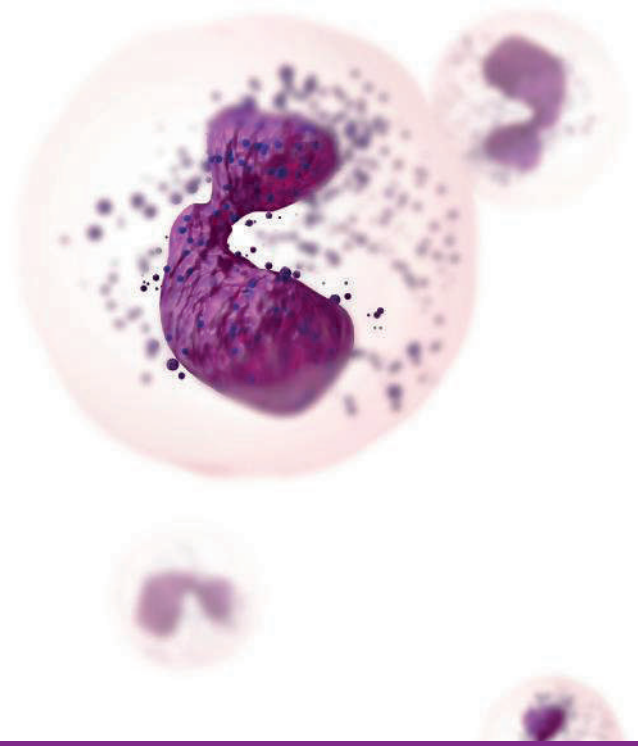
Change to the document number.

Changes in the classification and labelling (section 2).

Changes of the physical and chemical properties (section 9.1).

Change of the waste classification (section 13.1).

Update of legal regulations (section 15.1).
Add information about the authorised representative (section 1.3).



Hematology Catalogue

Reagents and Analyzers



SWISS HAEMATOLOGY
SOLUTION

The Mythic™ Family Multi-Patented Hematology Analyzers

First launched in 2004, the Mythic family of hematology analyzers has become the flagship of our Swiss hematology company, Orphée. Simplistic in design, our compact Mythic analyzers feature superior technology offering unsurpassed TRUE 5-DIFF diagnostic performance, unstoppable reliability and unmatched cost savings.



Mythic™ 60

28 Parameters
60 Tests per Hour
5-DIFF Hematology Analyzer

- True 5-DIFF technology
- LED-based flow cytometry single cell measurement
- Dynamic Clustering for individualized results for each patient
- Only 3 reagents
- Modern, compact design with 8.4 inch LED touch screen
- User-friendly software
- New parameters: ALY #, ALY %, IMM #, IMM %
- Pre-diluted mode with automatic diluent dosage
- Sampling volume 15.6 μ l
- Low reagents consumption
- Improved fluidic system and electronic design
- 98,5 % uptime



Perfect PoCT solution: reliable tests results
+ low reagents mconsumption



Mythic™ 18

20 Parameters
60 Tests per Hour
3-DIFF Hematology Analyzer

- Compact, space saving design
- Sample volume <10 µl
- Low reagents consumption
- Easy maintenance



Mythic™ 22 OT

24 Parameters
Open Tube System
Up to 50 Tests per Hour
5-DIFF Hematology Analyzer

- Light weight and easy maintenance
- Sample volume 15.7 µl
- Multi-patented, reliable technology
- 100% optical differentiation with only 3 reagents
- Low reagents consumption for affordable 5-Diff hematology testing



Mythic™ 22 AL

24 Parameters
Auto Loading System
Up to 50 Tests per Hour
5-DIFF Fully Automated Analyzer

- 50 samples continuous loading system with STAT mode
- Sample volume 18.2 µl
- Multi-patented, reliable technology
- 100% optical differentiation with only 3 reagents
- Low reagents consumption for affordable 5-Diff hematology testing

REAGENTS FOR MYTHIC 18

Reagent name	Cat. No	Volume per bottle	Shelf-life
MYTHIC 18 Diluent	HM 18-009-10	10 L	24 months
MYTHIC 18 Diluent	HM 18-009-20	20 L	24 months
MYTHIC 18 Cyanide Free Lytic Solution	HM 18-008-1	1 L	24 months
MYTHIC 18 Cyanide Free Lytic Solution	HM 18-008-05	500 ml	24 months
MYTHIC 18-22 Cleaning Solution (Mythic 18 Only)	HM 18-007-1	1 L	24 months

REAGENTS FOR MYTHIC 22 OT, MYTHIC 22 AL, MYTHIC 60

Reagent name	Cat. No	Volume per bottle	Shelf-life
Diluent for MYTHIC 22	HM 22-003-10	10 L	36 months
OnlyOne	HM 22-002-1	500 ml	24 months
Cleaner for MYTHIC 22	HM 22-001-1	1 L	24 months



CONTROL BLOOD

Reagent name	Cat. No	Volume per vial	Mythic 18	Mythic 22	Mythic 22AL	Mythic 60
MYT-3D Tri Level	MYT 302	(2L, 2N, 2H) x 2,5 ml	████████			
MYT-3D Normal Level	MYT 306N	6 x 2,5 ml	████████			
MYT-5D Tri Level	MYT 502	(2L, 2N, SH) x 3 ml		████████	████████	████████
MYT-5D Normal Level	MYT 506N	6 x 3 ml		████████	████████	████████
MYT-CAL	MYT CAL2	2 x 2,5 ml	████████	████████	████████	████████

MYT-3D - unopened tubes/vials are stable through the expiration date (open vials shelf-life 14 days at 2-8°C).
 MYT-5D - unopened tubes/vials are stable through the expiration date (open vials shelf-life 15 days at 2-8°C).
 MYT-CAL - unopened tubes/vials are stable through the expiration date (open vials shelf-life 7 days at 2-8°C).

PERIODIC MAINTENANCE

Reagent name	Cat. No	Volume per bottle	Shelf life	Mythic 18	Mythic 22	Mythic 22AL	Mythic 60
Mythic 18-22 Flush Cleaner	HM18-011-025	250 ml	12 months	████████	████████	████████	████████

CALIBRATORS

Optical calibrator	Cat. No	Shelf-life	Description	Mythic 18	Mythic 22	Mythic 22AL	Mythic 60
G-CAL	G-CAL	1 month	Used for final optic adjustment		████████	████████	████████

Open vial shelf life – 7 days at 2-8°C.

Gain calibrators	Cat. No	Description	Mythic 18	Mythic 22	Mythic 22AL	Mythic 60
LATEX RBC/PLT	465-0110-20	Used for adjustment of RBC/PLT channel	████████	████████	████████	
LATEX WBC	465-0110-10	Used for adjustment of amplification in WBC channel	████████	████████	████████	████████
KIT LATEX	465-0110-05	1 x LATEX RBC/PLT and 1 x LATEX WBC	████████	████████	████████	
KIT LATEX M60	465-0110-60	1 x LATEX RBC and 1 x LATEX WBC				████████



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phone: +41 22 884 90 90
fax: +41 22 884 90 99

www.orphee-medical.com
contact@orphee-medical.com



EU DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Plan-les-Ouates / Geneva
Switzerland

Authorized representative:

PZ CORMAY S.A.
22 Wiosenna Str.
05-092 Lomianki
Poland

We, Orphée SA, declare that the following device:

Device name: Mythic 18 Cyanide free Lytic solution

Device catalogue numbers: HM18-008-05, HM18-008-1

Basic UDI-DI: 764014248HM18-0082Z

Device class: A

Classification rule: 5a

Intended use: Mythic 18 Cyanide free Lytic solution is intended to lyse of erythrocytes for hemoglobin release to allow further hemoglobin's assay on hematological analyzer MYTHIC 18. It prepares leukocytes for subpopulations differentiation process. It is only for in vitro diagnostics, for healthcare professional users.

complies with General Safety and Performance Requirements of the ANNEX I – Regulation (EU) 2017/746 of the European Parliament and of the Council and their Conformity Assessment has been made accordingly to the ANNEX IX – Regulation (EU) 2017/746 of the European Parliament and of the Council.

This Declaration of Conformity is issued under the sole responsibility of Orphée SA.

Signature:

Anna Smolira

Person responsible for regulatory compliance
of Orphée SA

Signature:

Robert Wiśniewski

Person responsible for regulatory compliance
of Orphée SA

Place: Lublin

Date: 10 June 2022



EU DECLARATION OF CONFORMITY

In accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Plan-les-Ouates / Geneva
Switzerland

Authorized representative:

PZ CORMAY S.A.
22 Wiosenna Str.
05-092 Lomianki
Poland

We, Orphée SA, declare that the following device:

Device name: Mythic 18 Diluent

Device catalogue numbers: HM18-009-10, HM18-009-20

Basic UDI-DI: 764014248HM18-00933

Device class: A

Classification rule: 5a

Intended use: Mythic 18 Diluent is intended to dilute blood samples before assay and to maintain appropriate environment during assay on hematology analyzers MYTHIC 18. It is only for in vitro diagnostics, for healthcare professional users.

complies with General Safety and Performance Requirements of the ANNEX I – Regulation (EU) 2017/746 of the European Parliament and of the Council and their Conformity Assessment has been made accordingly to the ANNEX IX – Regulation (EU) 2017/746 of the European Parliament and of the Council.

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Manufacturer:

Orphée SA
19 chemin du Champ-des-Filles
CH-1228 Plan-les-Ouates / Geneva
Switzerland

Authorized representative:

PZ CORMAY S.A.
22 Wiosenna Str.
05-092 Lomianki
Poland

We, Orphée SA, declare that the following device:

Device name: Mythic 18-22 Enzymatic Cleaning Solution

Device catalogue number: HM18-007-1

Basic UDI-DI: 764014248HM18-0072X

Device class: A

Classification rule: 5a

Intended use: Mythic 18-22 Enzymatic Cleaning Solution is intended to remove biological material's residues from the measurement system of the hematology analyzer MYTHIC 18. It is only for in vitro diagnostics, for healthcare professional users.

complies with General Safety and Performance Requirements of the ANNEX I – Regulation (EU) 2017/746 of the European Parliament and of the Council and their Conformity Assessment has been made accordingly to the ANNEX IX – Regulation (EU) 2017/746 of the European Parliament and of the Council.

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