

## Safety Data Sheet

acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019

Revision: March 14, 2019

### 1 Identification

- **Product identifier**
- **Trade name:** CyLyse FX
- **Other means of identification:** No other identifiers
- **Recommended use and restriction on use**
- **Recommended use:** Diagnostic testing
- **Restrictions on use:** No relevant information available.
- **Details of the supplier of the Safety Data Sheet**
- **Manufacturer/Supplier:**  
SYSMEX AMERICA, Inc  
577 Aptakisic Road  
Lincolnshire, IL 60069 USA  
Phone: 847-996-4500  
1-800-3SYSMEX (1-800-379-7639)
- **Emergency telephone number:**  
ChemTel Inc.  
(800)255-3924 (North America)  
+1 (813)248-0585 (International)

### 2 Hazard(s) identification

- **Classification of the substance or mixture**  
Acute Tox. 4 H302 Harmful if swallowed.  
Acute Tox. 4 H312 Harmful in contact with skin.  
Acute Tox. 4 H332 Harmful if inhaled.  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2A H319 Causes serious eye irritation.  
Skin Sens. 1 H317 May cause an allergic skin reaction.  
Muta. 2 H341 Suspected of causing genetic defects.  
Carc. 1B H350 May cause cancer. Route of exposure: Inhalation.  
STOT SE 2 H371 May cause damage to the central nervous system and optic nerve.  
STOT SE 3 H335 May cause respiratory irritation.  
STOT RE 2 H373 May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral.

- **Label elements**
- **GHS label elements**  
The product is classified and labeled according to the Globally Harmonized System (GHS).
- **Hazard pictograms:**

(Cont'd. on page 2)

## Safety Data Sheet

acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019

Revision: March 14, 2019

Trade name: CyLyse FX

(Cont'd. of page 1)



GHS07 GHS08

**Signal word:** Danger**Hazard statements:**

H302+H312+H332 Harmful if swallowed, in contact with skin or if inhaled.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H317 May cause an allergic skin reaction.

H341 Suspected of causing genetic defects.

H350 May cause cancer. Route of exposure: Inhalation.

H371 May cause damage to the central nervous system and optic nerve.

H335 May cause respiratory irritation.

H373 May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral.

**Precautionary statements:**

P201 Obtain special instructions before use.

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

P260 Do not breathe dust/fume/gas/mist/vapors/spray.

P264 Wash thoroughly after handling.

P270 Do not eat, drink or smoke when using this product.

P271 Use only outdoors or in a well-ventilated area.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301+P312 If swallowed: Call a poison center/doctor if you feel unwell.

P302+P352 If on skin: Wash with plenty of water.

P321 Specific treatment (see on this label).

P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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

P314 Get medical advice/attention if you feel unwell.

P330 Rinse mouth.

P362+P364 Take off contaminated clothing and wash it before reuse.

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P337+P313 If eye irritation persists: Get medical advice/attention.

P363 Wash contaminated clothing before reuse.

P405 Store locked up.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

### 3 Composition/information on ingredients

**Chemical characterization: Mixtures**

(Cont'd. on page 3)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 2)

**· Components:**

|          |  |        |
|----------|--|--------|
| 111-46-6 | diethylene glycol<br>STOT RE 2, H373<br>Acute Tox. 4, H302   | 25-50% |
| 50-00-0  | Formaldehyde<br>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331<br>Muta. 2, H341; Carc. 1B, H350<br>Skin Corr. 1B, H314<br>Skin Sens. 1, H317 | <25%   |
| 67-56-1  | Methanol<br>Flam. Liq. 2, H225<br>Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331<br>STOT SE 1, H370<br>Eye Irrit. 2B, H320                   | <5%    |

**· Additional information:**

For the listed ingredient(s), the identity and/or exact percentage(s) are being withheld as a trade secret.  
For the wording of the listed Hazard Statements, refer to section 16.

**4 First-aid measures**

**· Description of first aid measures**

**· After inhalation:** Supply fresh air; consult doctor in case of complaints.

**· After skin contact:**

Immediately remove any clothing soiled by the product.  
Immediately wash with water and soap and rinse thoroughly.  
If skin irritation or rash occurs: Get medical advice/attention.

**· After eye contact:**

Remove contact lenses if worn.  
Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

**· After swallowing:**

Rinse out mouth and then drink plenty of water.  
Do not induce vomiting; immediately call for medical help.

**· Most important symptoms and effects, both acute and delayed:**

Headache  
Allergic reactions  
Irritating to eyes, respiratory system and skin.  
Gastric or intestinal disorders when ingested.  
Nausea in case of ingestion.  
Acidosis  
Cramp

**· Danger:**

Harmful if swallowed, in contact with skin or if inhaled.  
Danger of gastric perforation.  
Danger of convulsion.  
Danger of disturbed cardiac rhythm.

(Cont'd. on page 4)

## Safety Data Sheet

acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019

Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 3)

May cause cancer. Route of exposure: Inhalation.  
Suspected of causing genetic defects.  
May cause damage to the central nervous system and optic nerve.

May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral.

**· Indication of any immediate medical attention and special treatment needed:**

Contains Formaldehyde. May produce an allergic reaction.  
Treat skin and mucous membrane with antihistamine and corticoid preparations.  
If swallowed, gastric irrigation with added, activated carbon.  
Medical supervision for at least 48 hours.  
Monitor circulation, possible shock treatment.

### 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Fight larger fires with water spray.
- **For safety reasons unsuitable extinguishing agents:** None.
- **Special hazards arising from the substance or mixture**  
Formation of toxic gases is possible during heating or in case of fire.
- **Advice for firefighters**
- **Protective equipment:**  
Wear self-contained respiratory protective device.  
Wear fully protective suit.

### 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures**  
Use respiratory protective device against the effects of fumes/dust/aerosol.  
Wear protective equipment. Keep unprotected persons away.  
Ensure adequate ventilation.
- **Environmental precautions** Avoid release to the environment.
- **Methods and material for containment and cleaning up**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Send for recovery or disposal in suitable receptacles.
- **Reference to other sections**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protection equipment.  
See Section 13 for disposal information.

### 7 Handling and storage

- **Handling**
- **Precautions for safe handling:**

(Cont'd. on page 5)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 4)

Avoid splashes or spray in enclosed areas.  
Use only in well ventilated areas.  
Avoid contact with the eyes and skin.  
Open and handle receptacle with care.

- **Conditions for safe storage, including any incompatibilities**
- **Requirements to be met by storerooms and receptacles:**  
Use only receptacles specifically permitted for this substance/product.  
Avoid storage near extreme heat, ignition sources or open flame.  
Store in cool, dry conditions in well sealed receptacles.
- **Information about storage in one common storage facility:** Store away from foodstuffs.
- **Specific end use(s)** No relevant information available.

**8 Exposure controls/personal protection**

· **Control parameters**

· **Components with limit values that require monitoring at the workplace:**

**50-00-0 Formaldehyde**

|                     |   |
|---------------------|---|
| PEL (USA)           | Short-term value: 2 ppm<br>Long-term value: 0.75 ppm<br>see 29 CFR 1910.1048(c)                                       |
| REL (USA)           | Long-term value: 0.016 ppm<br>Ceiling limit value: 0.1* ppm<br>*15-min; See Pocket Guide App. A                       |
| TLV (USA)           | Short-term value: 0.37 mg/m <sup>3</sup> , 0.3 ppm<br>Long-term value: 0.12 mg/m <sup>3</sup> , 0.1 ppm<br>DSEN; RSEN |
| EL (Canada)         | Long-term value: 0.3 ppm<br>Ceiling limit value: 1 ppm<br>ACGIH A1; IARC 1; S(D), S(R)                                |
| EV (Canada)         | Short-term value: 1.0 ppm   |
| Ceiling limit value | 1.5 ppm   |
| LMPE (Mexico)       | Ceiling limit value: 0.3 ppm<br>A2, SEN   |

**67-56-1 Methanol**

|           |  |
|-----------|--|
| PEL (USA) | Long-term value: 260 mg/m <sup>3</sup> , 200 ppm   |
| REL (USA) | Short-term value: 325 mg/m <sup>3</sup> , 250 ppm<br>Long-term value: 260 mg/m <sup>3</sup> , 200 ppm<br>Skin      |
| TLV (USA) | Short-term value: 328 mg/m <sup>3</sup> , 250 ppm<br>Long-term value: 262 mg/m <sup>3</sup> , 200 ppm<br>Skin; BEI |

(Cont'd. on page 6)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

|                               |                          |
|-------------------------------|--------------------------|
| Printing date: March 14, 2019 | Revision: March 14, 2019 |
|-------------------------------|--------------------------|

**Trade name: CyLyse FX**

(Cont'd. of page 5)

|               |   |
|---------------|---|
| EL (Canada)   | Short-term value: 250 ppm<br>Long-term value: 200 ppm<br>Skin   |
| EV (Canada)   | Short-term value: 325 mg/m <sup>3</sup> , 250 ppm<br>Long-term value: 260 mg/m <sup>3</sup> , 200 ppm<br>Skin |
| LMPE (Mexico) | Short-term value: 250 ppm<br>Long-term value: 200 ppm<br>PIEL, IBE  |

**111-46-6 diethylene glycol**

|            |                                       |
|------------|---------------------------------------|
| WEEL (USA) | Long-term value: 10 mg/m <sup>3</sup> |
|------------|---------------------------------------|

**· Ingredients with biological limit values:**

**67-56-1 Methanol**

|           |   |
|-----------|---|
| BEI (USA) | 15 mg/L<br>Medium: urine<br>Time: end of shift<br>Parameter: Methanol (background, nonspecific) |
|-----------|---|

**· Exposure controls**

**· General protective and hygienic measures:**

- The usual precautionary measures for handling chemicals should be followed.
- Keep away from foodstuffs, beverages and feed.
- Immediately remove all soiled and contaminated clothing.
- Wash hands before breaks and at the end of work.
- Do not inhale gases / fumes / aerosols.
- Avoid contact with the eyes and skin.

**· Engineering controls:** No relevant information available.

**· Breathing equipment:**

- Use suitable respiratory protective device in case of insufficient ventilation.
- Use suitable respiratory protective device when aerosol or mist is formed.
- For spills, respiratory protection may be advisable.

**· Protection of hands:**



Protective gloves

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

**· Eye protection:**



Safety glasses

**· Body protection:** Protective work clothing

**· Limitation and supervision of exposure into the environment**

No relevant information available.

(Cont'd. on page 7)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX** (Cont'd. of page 6)

· **Risk management measures** No relevant information available.

**9 Physical and chemical properties**

· **Information on basic physical and chemical properties**

· **Appearance:**  
    **Form:** Liquid  
    **Color:** Clear  
    Colorless to pale yellow.  
· **Odor:** Mild  
· **Odor threshold:** Not determined.

· **pH-value:** Not determined.  
· **Melting point/Melting range:** Not determined.  
· **Boiling point/Boiling range:** Not determined.

· **Flash point:** Not applicable.

· **Flammability (solid, gaseous):** Not applicable.

· **Auto-ignition temperature:** Not determined.

· **Decomposition temperature:** Not determined.

· **Danger of explosion:** Product does not present an explosion hazard.

· **Explosion limits**  
    **Lower:** Not determined.  
    **Upper:** Not determined.  
· **Oxidizing properties:** Non-oxidizing.

· **Vapor pressure:** Not determined.

· **Density:**  
    **Relative density:** Not determined.  
    **Vapor density:** Not determined.  
    **Evaporation rate:** Not determined.

· **Solubility in / Miscibility with Water:** Fully miscible.

· **Partition coefficient (n-octanol/water):** Not determined.

· **Viscosity**  
    **Dynamic:** Not determined.  
    **Kinematic:** Not determined.  
· **Other information** No relevant information available.

(Cont'd. on page 8)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 7)

**10 Stability and reactivity**

- **Reactivity:** No relevant information available.
- **Chemical stability:**
- **Thermal decomposition / conditions to be avoided:**  
No decomposition if used and stored according to specifications.
- **Possibility of hazardous reactions**  
Toxic fumes may be released if heated above the decomposition point.  
Reacts with strong acids and oxidizing agents.  
Reacts with strong alkali.
- **Conditions to avoid** Excessive heat.
- **Incompatible materials** Oxidizers, strong bases, strong acids
- **Hazardous decomposition products**  
Under fire conditions only:  
Carbon monoxide and carbon dioxide

**11 Toxicological information**

- **Information on toxicological effects**
- **Acute toxicity:** Harmful if swallowed, in contact with skin or if inhaled.

· **LD/LC50 values that are relevant for classification:**

**111-46-6 diethylene glycol**

Oral LD50 1120 mg/kg (man)  
12565 mg/kg (rat)  
Dermal LD50 11890 mg/kg (rabbit)

**50-00-0 Formaldehyde**

Oral LD50 >200 mg/kg (rat)

- **Primary irritant effect:**
- **On the skin:** Irritant to skin and mucous membranes.
- **On the eye:** Causes eye irritation.
- **Sensitization:** Contains Formaldehyde. May produce an allergic reaction.

· **IARC (International Agency for Research on Cancer):**

|         |              |   |
|---------|--------------|---|
| 50-00-0 | Formaldehyde | 1 |
|---------|--------------|---|

· **NTP (National Toxicology Program):**

|         |              |   |
|---------|--------------|---|
| 50-00-0 | Formaldehyde | K |
|---------|--------------|---|

· **OSHA-Ca (Occupational Safety & Health Administration):**

|         |              |  |
|---------|--------------|--|
| 50-00-0 | Formaldehyde |  |
|---------|--------------|--|

· **Probable route(s) of exposure:**

Ingestion.  
Inhalation.  
Eye contact.

(Cont'd. on page 9)



**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 8)

- Skin contact.
- **Germ cell mutagenicity:** Suspected of causing genetic defects.
- **Carcinogenicity:** May cause cancer. Route of exposure: Inhalation.
- **Reproductive toxicity:** Based on available data, the classification criteria are not met.
  
- **STOT-single exposure:** May cause damage to the central nervous system and optic nerve.
- **STOT-repeated exposure:**  
May cause damage to the kidneys through prolonged or repeated exposure. Route of exposure: Oral.
- **Aspiration hazard:** Based on available data, the classification criteria are not met.

**12 Ecological information**

- **Toxicity**
- **Aquatic toxicity** No relevant information available.
- **Persistence and degradability** No relevant information available.
- **Bioaccumulative potential:** No relevant information available.
- **Mobility in soil:** No relevant information available.
- **Additional ecological information**
- **General notes:** Avoid release to the environment.
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **Other adverse effects** No relevant information available.

**13 Disposal considerations**

- **Waste treatment methods**
- **Recommendation:**  
The user of this material has the responsibility to dispose of unused material, residues and containers in compliance with all relevant local, state and federal laws and regulations regarding treatment, storage and disposal for hazardous and nonhazardous wastes.
- **Uncleaned packagings**
- **Recommendation:** Disposal must be made according to official regulations.

**14 Transport information**

- |   |                |
|---|----------------|
| <ul style="list-style-type: none"> <li>· <b>UN-Number</b></li> <li>· <b>DOT, ADR/RID/ADN, IMDG, IATA</b></li> </ul>               | Not regulated. |
| <ul style="list-style-type: none"> <li>· <b>UN proper shipping name</b></li> <li>· <b>DOT, ADR/RID/ADN, IMDG, IATA</b></li> </ul> | Not regulated. |

(Cont'd. on page 10)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019 Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 9)

|  |                 |
|--|-----------------|
| · <b>Transport hazard class(es)</b>  |                 |
| · DOT, ADR/RID/ADN, IMDG, IATA   |                 |
| · <b>Class</b>   | Not regulated.  |
| · <b>Packing group</b>   |                 |
| · DOT, ADR/RID/ADN, IMDG, IATA   | Not regulated.  |
| · <b>Environmental hazards</b>   |                 |
| · <b>Marine pollutant:</b>   | No              |
| · <b>Special precautions for user</b>  | Not applicable. |
| · <b>Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code</b> | Not applicable. |

**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **United States (USA)**
- **SARA**

|  |                                     |       |
|--|-------------------------------------|-------|
| · <b>Section 302 (extremely hazardous substances):</b>                                     | None of the ingredients are listed. |       |
| · <b>Section 355 (extremely hazardous substances):</b>                                     | 50-00-0   Formaldehyde              |       |
| · <b>Section 313 (Specific toxic chemical listings):</b>                                   | 50-00-0   Formaldehyde              |       |
|  | 67-56-1   Methanol                  |       |
| · <b>TSCA (Toxic Substances Control Act)</b>   | All ingredients are listed.         |       |
| · <b>Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130):</b> | 50-00-0   Formaldehyde              | 15000 |
| · <b>Proposition 65 (California)</b>   |                                     |       |
| · <b>Chemicals known to cause cancer:</b>  | 50-00-0   Formaldehyde              |       |
| · <b>Chemicals known to cause developmental toxicity for females:</b>                      | None of the ingredients are listed. |       |
| · <b>Chemicals known to cause developmental toxicity for males:</b>                        | None of the ingredients are listed. |       |

(Cont'd. on page 11)

**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

|                               |                          |
|-------------------------------|--------------------------|
| Printing date: March 14, 2019 | Revision: March 14, 2019 |
|-------------------------------|--------------------------|

**Trade name: CyLyse FX**

(Cont'd. of page 10)

|  |  |
|--|--|
| <b>· Chemicals known to cause developmental toxicity:</b>                  |  |
| 67-56-1  | Methanol   |
| <b>· EPA (Environmental Protection Agency):</b>                            |  |
| 50-00-0  | Formaldehyde <span style="float:right">B1</span> |
| <b>· IARC (International Agency for Research on Cancer):</b>               |  |
| 50-00-0  | Formaldehyde <span style="float:right">1</span>  |
| <b>· Canadian Domestic Substances List (DSL) (Substances not listed.):</b> |  |
| All ingredients are listed.  |  |

**16 Other information**

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

**· Abbreviations and acronyms:**

- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- IMDG: International Maritime Code for Dangerous Goods
- DOT: US Department of Transportation
- IATA: International Air Transport Association
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bio-accumulable, Toxic
- vPvB: very Persistent and very Bioaccumulative
- OSHA: Occupational Safety & Health Administration
- Flam. Liq. 2: Flammable liquids – Category 2
- Acute Tox. 3: Acute toxicity – Category 3
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Corr. 1B: Skin corrosion/irritation – Category 1B
- Skin Irrit. 2: Skin corrosion/irritation – Category 2
- Eye Irrit. 2A: Serious eye damage/eye irritation – Category 2A
- Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B
- Skin Sens. 1: Skin sensitisation – Category 1
- Muta. 2: Germ cell mutagenicity – Category 2
- Carc. 1B: Carcinogenicity – Category 1B
- STOT SE 1: Specific target organ toxicity (single exposure) – Category 1
- STOT SE 2: Specific target organ toxicity (single exposure) – Category 2
- STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

**· Sources**

- Website, European Chemicals Agency (echa.europa.eu)
- Website, US EPA Substance Registry Services (ofmpub.epa.gov/sor internet/registry/substreg/home/overview/home.do)
- Website, Chemical Abstracts Registry, American Chemical Society (www.cas.org)
- Patty's Industrial Hygiene, 6th ed., Rose, Vernon, ed. ISBN: 978-0-470-07488-6
- Casarett and Doull's Toxicology: The Basic Science of Poisons, 8th Ed., Klaassen, Curtis D., ed., ISBN: 978-0-07-176923-5.
- Safety Data Sheets, Individual Manufacturers

SDS Prepared by:  
ChemTel Inc.

(Cont'd. on page 12)



**Safety Data Sheet**  
acc. to OSHA HCS (29CFR 1910.1200) and WHMIS 2015 Regulations

Printing date: March 14, 2019

Revision: March 14, 2019

**Trade name: CyLyse FX**

(Cont'd. of page 11)

1305 North Florida Avenue  
Tampa, Florida USA 33602-2902  
Toll Free North America 1-888-255-3924 Intl. +01 813-248-0573  
Website: [www.chemtelinc.com](http://www.chemtelinc.com)