

## Safety Data Sheet

# Tadalafil in methanol

Version : V2.0.0.1

Report No. : BWN5625-2016-MSDS-EP

Creation Date : 2025/12/16

Revision Date : -



\*Prepared in accordance with EU REACH Regulation (REACH 1907/2006 with amendment 2020/878)

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

### 1.1 Product identifier

|                           |                          |
|---------------------------|--------------------------|
| Product Name              | Tadalafil in methanol    |
| Cat No.                   | BWN5625-2016             |
| CAS No.                   | Not applicable           |
| EC No.                    | Not applicable           |
| Molecular Formula         | Not applicable           |
| REACH Registration Number | -                        |
| UFI                       | No information available |

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

|                          |                              |
|--------------------------|------------------------------|
| Relevant identified uses | Please consult manufacturer. |
| Uses advised against     | Please consult manufacturer. |

### 1.3 Details of the supplier of the Safety Data Sheet

|                        |                                                                                                      |
|------------------------|------------------------------------------------------------------------------------------------------|
| Name of the company    | Weiyel Inc                                                                                           |
| Address of the company | Hedian Light Industrial Park, Chengguan Town, Shangcheng County, Xinyang City, Henan Province, China |
| Post code              | 465350                                                                                               |
| Telephone number       | 010-58103678                                                                                         |
| Fax number             | 010-84840368                                                                                         |
| E-mail address         | info@weiyel.com                                                                                      |

### 1.4 Emergency telephone number

|                            |              |
|----------------------------|--------------|
| Emergency telephone number | 010-58103678 |
| Opening hours              | 24h          |

## 2 Hazards identification

### 2.1 CLP classification according to Regulation ( EC ) No. 1272/2008 with amendment 2023/707

|                                                  |            |
|--------------------------------------------------|------------|
| Flammable liquids                                | Category 2 |
| Acute Toxicity - Oral                            | Category 3 |
| Acute Toxicity - Dermal                          | Category 3 |
| Acute Toxicity - Inhalation                      | Category 3 |
| Specific target organ toxicity - single exposure | Category 1 |

## 2.2 Label elements

|                   |                                                                                                                                                                                                                                                        |
|-------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Hazard pictograms |    |
| Signal word       | <b>Danger</b>                                                                                                                                                                                                                                          |

## Hazard statements

|      |                                    |
|------|------------------------------------|
| H225 | Highly flammable liquid and vapour |
| H301 | Toxic if swallowed                 |
| H311 | Toxic in contact with skin         |
| H331 | Toxic if inhaled                   |
| H370 | Causes damage to organs            |

## Precautionary statements

### ◆ Prevention

|      |                                                                                                |
|------|------------------------------------------------------------------------------------------------|
| P210 | Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. |
| P233 | Keep container tightly closed.                                                                 |
| P240 | Ground and bond container and receiving equipment.                                             |
| P241 | Use explosion-proof [electrical/ventilating/lighting] equipment.                               |
| P242 | Use non-sparking tools.                                                                        |
| P243 | Take action to prevent static discharges.                                                      |
| P260 | Do not breathe gas/mist/vapour/spray.                                                          |
| P264 | Wash hands and other parts of the body (if related) thoroughly after handling.                 |
| P270 | Do not eat, drink or smoke when using this product.                                            |
| P271 | Use only outdoors or in a well-ventilated area.                                                |
| P280 | Wear protective gloves/protective clothing/eye protection/face protection.                     |

### ◆ Response

|                |                                                                                                                                                                                                                                                                                                                                            |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| P311           | Call a POISON CENTER/ doctor.                                                                                                                                                                                                                                                                                                              |
| P321           | Specific treatment (see related instructions on the label).                                                                                                                                                                                                                                                                                |
| P330           | Rinse mouth.                                                                                                                                                                                                                                                                                                                               |
| P301+P310      | IF SWALLOWED: Immediately call a POISON CENTER/doctor.                                                                                                                                                                                                                                                                                     |
| P302+P352      | IF ON SKIN: Wash with plenty of water.                                                                                                                                                                                                                                                                                                     |
| P304+P340      | IF INHALED: Remove person to fresh air and keep comfortable for breathing.                                                                                                                                                                                                                                                                 |
| P308+P311      | IF exposed or concerned: Call a POISON CENTER/ doctor.                                                                                                                                                                                                                                                                                     |
| P361+P364      | Take off immediately all contaminated clothing and wash it before reuse.                                                                                                                                                                                                                                                                   |
| P370+P378      | Small fire: dry chemical, CO <sub>2</sub> or alcohol-resistant foam; Large fire: alcohol-resistant foam; Fire involving tanks, rail tank cars or highway tanks: Fight fire from maximum distance or use unmanned master stream devices or monitor nozzles. Cool containers with flooding quantities of water until well after fire is out. |
| P303+P361+P353 | IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse affected areas with water [or shower].                                                                                                                                                                                                                         |

### ◆ Storage

|      |                  |
|------|------------------|
| P405 | Store locked up. |
|------|------------------|

|                  |                                                                  |
|------------------|------------------------------------------------------------------|
| <b>P403+P233</b> | Store in a well-ventilated place. Keep container tightly closed. |
| <b>P403+P235</b> | Store in a well-ventilated place. Keep cool.                     |

◆ Disposal

|             |                                                                                                     |
|-------------|-----------------------------------------------------------------------------------------------------|
| <b>P501</b> | Dispose of contents/container in accordance with local/regional/national/international regulations. |
|-------------|-----------------------------------------------------------------------------------------------------|

## 2.3 Other hazards

◆ Results of PBT and vPvB assessment

| Component       | Results of PBT and vPvB assessment [according to (EC) No 1907/2006] |
|-----------------|---------------------------------------------------------------------|
| <b>Methanol</b> | Not PBT/vPvB                                                        |
| <b>Cialis</b>   | Insufficient information, temporarily unable to evaluate            |

◆ Results of endocrine disrupting properties assessment

| Component       | Results of endocrine disrupting properties assessment [according to (EU) No 2017/2100 or (EU) No 2018/605] |
|-----------------|------------------------------------------------------------------------------------------------------------|
| <b>Methanol</b> | Insufficient information, temporarily unable to evaluate                                                   |
| <b>Cialis</b>   | Insufficient information, temporarily unable to evaluate                                                   |

◆ Other

|  |                 |
|--|-----------------|
|  | Not applicable. |
|--|-----------------|

## 3 Composition/information on ingredients

### 3.1 Substance

|  |                |
|--|----------------|
|  | Not applicable |
|--|----------------|

### 3.2 Mixture

| Component                                                                      | Weight % content(or range) | Classification according to Regulation ( EC ) No. 1272/2008 with amendment 2023/707 [CLP]                                                                                                                                                                                                                                               | Specific Conc. Limits, M-factors |
|--------------------------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|
| <b>Methanol</b><br>CAS : 67-56-1<br>EC : 200-659-6<br>Index No. : 603-001-00-X | 99.987                     | Flammable liquids, Category 2, H225;<br>Acute Toxicity - Oral, Category 3, H301;<br>Acute Toxicity - Dermal, Category 3, H311;<br>Acute Toxicity - Inhalation, Category 3, H331; Specific target organ toxicity - single exposure, Category 1, H370                                                                                     | H370:C ≥ 10% H371:3% ≤ C < 10%   |
| <b>Cialis</b><br>CAS : 171596-29-5<br>EC : 687-782-2<br>Index No. : -          | 0.013                      | Acute Toxicity - Oral, Category 4, H302;<br>Acute Toxicity - Dermal, Category 4, H312;<br>Skin Corrosion/Irritation, Category 2, H315; Serious eye damage/irritation, Category 2, H319; Acute Toxicity - Inhalation, Category 4, H332; Specific target organ toxicity - single exposure; respiratory tract irritation, Category 3, H335 | -                                |

## 4 First-aid measures

### 4.1 Description of first aid measures

|                       |                                                                                                         |
|-----------------------|---------------------------------------------------------------------------------------------------------|
| <b>General advice</b> | Immediate medical attention is required. Show this safety data sheet (SDS) to the doctor in attendance. |
|-----------------------|---------------------------------------------------------------------------------------------------------|

|                                   |                                                                                                                                                |
|-----------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Eye contact</b>                | First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to a doctor.                        |
| <b>Skin contact</b>               | Remove contaminated clothes. Rinse skin with plenty of water or shower. Refer for medical attention.                                           |
| <b>Ingestion</b>                  | Induce vomiting (ONLY IN CONSCIOUS PERSONS!). Refer for medical attention.                                                                     |
| <b>Inhalation</b>                 | Fresh air, rest. Refer for medical attention.                                                                                                  |
| <b>Protecting of first-aiders</b> | Ensure that medical personnel are aware of the substance involved. Take precautions to protect themselves and prevent spread of contamination. |

#### 4.2 Most important symptoms/effects, acute and delayed

|   |                                                                                                                                        |
|---|----------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Substance accumulation, in the human body, may occur and may cause some concern following repeated or long-term occupational exposure. |
|---|----------------------------------------------------------------------------------------------------------------------------------------|

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

|   |                          |
|---|--------------------------|
| 1 | Treat symptomatically.   |
| 2 | Symptoms may be delayed. |

### 5 Fire-fighting measures

#### 5.1 Extinguishing media

|                                       |                                                                                                                                                                                                                                                                                                                                            |
|---------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Suitable extinguishing media</b>   | Small fire: dry chemical, CO <sub>2</sub> or alcohol-resistant foam; Large fire: alcohol-resistant foam; Fire involving tanks, rail tank cars or highway tanks: Fight fire from maximum distance or use unmanned master stream devices or monitor nozzles. Cool containers with flooding quantities of water until well after fire is out. |
| <b>Unsuitable extinguishing media</b> | Use of water spray when fighting fire may be inefficient.                                                                                                                                                                                                                                                                                  |

#### 5.2 Specific hazards arising from the substance or mixture

|   |                                                                                                                                         |
|---|-----------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Will form explosive mixtures with air.                                                                                                  |
| 2 | Fire exposed containers may vent contents through pressure relief valves thereby increasing fire intensity and/or vapour concentration. |
| 3 | Vapours may travel to source of ignition and flash back.                                                                                |
| 4 | Liquid and vapour are flammable.                                                                                                        |
| 5 | Development of hazardous combustion gases or vapor possible in the event of fire.                                                       |
| 6 | May expansion or decompose explosively when heated or involved in fire.                                                                 |

#### 5.3 Advice for firefighters

|   |                                                                                                                       |
|---|-----------------------------------------------------------------------------------------------------------------------|
| 1 | As in any fire, wear self-contained breathing apparatus (MSHA/NIOSH approved or equivalent) and full protective gear. |
| 2 | Fight fire from a safe distance, with adequate cover.                                                                 |
| 3 | Prevent fire extinguishing water from contaminating surface water or the ground water system.                         |

### 6 Accidental release measures

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

|   |                                                                                                                                                            |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | Avoid breathing vapours and contacting with skin and eye.                                                                                                  |
| 2 | Beware of vapours accumulating to form explosive concentrations.                                                                                           |
| 3 | Vapours can accumulate in low areas.                                                                                                                       |
| 4 | Emergency personnel wear positive pressure self-contained breathing apparatus. Wear protective and anti-static clothing. Wear chemical impermeable gloves. |

|   |                                                                                                                     |
|---|---------------------------------------------------------------------------------------------------------------------|
| 5 | Use personal protective equipment, do not breathe gas/mist/vapour/spray.                                            |
| 6 | Ensure adequate ventilation. Remove all sources of ignition. Take precautionary measures against static discharges. |
| 7 | Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.                                   |

## 6.2 Environmental precautions

|   |                                                       |
|---|-------------------------------------------------------|
| 1 | Prevent further leakage or spillage if safe to do so. |
| 2 | Discharge into the environment must be avoided.       |

## 6.3 Methods and materials for containment and cleaning up

|    |                                                                                                                                                                                                                                                            |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1  | It is recommended that emergency personnel wear positive pressure self-contained breathing apparatus and wear anti-static clothing.                                                                                                                        |
| 2  | In case of small amount of spillage, use clean non sparking tools to collect absorption materials.                                                                                                                                                         |
| 3  | In case of large amount of spillage, construct cofferdam or dig a hole to collect the spillage. Use foam cover to reduce evaporation. Water spray mist can reduce evaporation, but can not reduce the flammability of the leakage in the restricted space. |
| 4  | Collect absorbent material using a clean, non-sparking tool.                                                                                                                                                                                               |
| 5  | Cover with anti-solvent foam to reduce evaporation.                                                                                                                                                                                                        |
| 6  | Cover with DRY earth, DRY sand or other non-combustible material followed with plastic sheet to minimize spreading or contact with rain.                                                                                                                   |
| 7  | Water spray reduces evaporation but does not reduce the flammability of spills in confined spaces.                                                                                                                                                         |
| 8  | Cut off the source of the leak as much as possible.                                                                                                                                                                                                        |
| 9  | Keep leaks in a ventilated place.                                                                                                                                                                                                                          |
| 10 | Absorb spilled material in dry sand or inert absorbent. In case of large amount of spillage, contain a spill by bunding.                                                                                                                                   |
| 11 | Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.                                                                                                                                                                       |
| 12 | Contain spillage, and then collect with an electrically protected vacuum cleaner or by wet-brushing and place in container.                                                                                                                                |
| 13 | Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment.                                                                                                                                                                       |

## 6.4 Reference to other sections

|   |                                                                            |
|---|----------------------------------------------------------------------------|
| 1 | Personal Protective Equipment advice is contained in Section 8 of the SDS. |
| 2 | Disposal considerations advice is contained in Section 13 of the SDS.      |

# 7 Handling and storage

## 7.1 Precautions for safe handling

### ◆ Protective measures

|   |                                                   |
|---|---------------------------------------------------|
| 1 | Handling is performed in a well ventilated place. |
| 2 | Wear suitable protective equipment.               |
| 3 | Avoid contact with skin and eyes.                 |

### ◆ Measures to prevent fire

|   |                                                                                                           |
|---|-----------------------------------------------------------------------------------------------------------|
| 1 | Use only non-sparking tools.                                                                              |
| 2 | To prevent fire caused by electrostatic discharge steam, equipment on all metal parts should be grounded. |
| 3 | Use explosion proof equipment.                                                                            |
| 4 | Keep away from heat/sparks/open flames/ hot surfaces.                                                     |

### ◆ Measures to prevent aerosol and dust generation

|   |                 |
|---|-----------------|
| 1 | Not applicable. |
|---|-----------------|

◆ Advice on general occupational hygiene

|   |                                                 |
|---|-------------------------------------------------|
| 1 | Wash hands and face after using the substances. |
| 2 | Replace the contaminated clothing immediately.  |

| 7.2 Conditions for safe storage, including any incompatibilities

|   |                                                                  |
|---|------------------------------------------------------------------|
| 1 | Keep containers tightly closed.                                  |
| 2 | Keep containers in a dry, cool and well-ventilated place.        |
| 3 | Keep away from heat/sparks/open flames/hot surfaces.             |
| 4 | Store away from incompatible materials and foodstuff containers. |

| 7.3 Specific end use(s)

|   |                                                                                      |
|---|--------------------------------------------------------------------------------------|
| 1 | In addition to use mentioned in the Section 1.2, unforeseen other specific end uses. |
|---|--------------------------------------------------------------------------------------|

**8** Exposure controls/personal protection

| 8.1 Control parameters

◆ Occupational exposure limit values

| Component | Country/Region                                              | Limit value - Eight hours |                   | Limit value - Short term |                   |
|-----------|-------------------------------------------------------------|---------------------------|-------------------|--------------------------|-------------------|
|           |                                                             | ppm                       | mg/m <sup>3</sup> | ppm                      | mg/m <sup>3</sup> |
| Methanol  | Japan - JSOH(2024–2025)                                     | 200                       | 260               | -                        | -                 |
|           | Permissible exposure standards for workers in the workplace | 200                       | 262               | 250                      | 327.5             |
|           | European Union                                              | 200                       | 260               | -                        | -                 |
|           | France                                                      | 200                       | 260               | -                        | -                 |
|           | Germany (AGS)                                               | 100                       | 130               | 200                      | 260               |
|           | Germany (DFG)                                               | 100                       | 130               | 200                      | 260               |

◆ Biological limit values

| Component | Standard   | Biological monitoring index | Biological limits value | Sampling time | Remark |
|-----------|------------|-----------------------------|-------------------------|---------------|--------|
| Methanol  | USA -ACGIH | Methanol(Urine)             | 15mg/L                  | End of shift  |        |

◆ Monitoring methods

|   |                                                                                                                                                   |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | EN 14042 Workplace atmospheres. Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents. |
| 2 | GBZ/T 300 and GBZ/T 160 series standard Determination of toxic substances in workplace air.                                                       |

◆ Derived No effect level (DNEL)

| Component | Route of exposure | DNEL for Workers      |                          |                         |                            |
|-----------|-------------------|-----------------------|--------------------------|-------------------------|----------------------------|
|           |                   | Acute effects (local) | Acute effects (systemic) | Chronic effects (local) | Chronic effects (systemic) |
| Methanol  | Inhalation        | No data available     | No data available        | 130 mg/m3               | 130 mg/m3                  |
|           | Oral              | No data available     | No data available        | No data available       | No data available          |
|           | Dermal            | No data available     | No data available        | No data available       | No data available          |
| Cialis    | Inhalation        | No data available     | No data available        | No data available       | No data available          |
|           | Oral              | No data available     | No data available        | No data available       | No data available          |
|           | Dermal            | No data available     | No data available        | No data available       | No data available          |

◆ Predicted No Effect Concentration (PNEC)

| Component | A                    | B                    | C                    | D                    | E                    | F                    | G                    | H                                |
|-----------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------------------|
| Methanol  | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No hazard identified | No potential for bioaccumulation |

**Note 1:**

A: Freshwater; B: Seawater; C: Sewage treatment plant; D: Sediment (freshwater); E: Sediment (seawater); F: Air; G: Soil; H: Secondary poisoning(Hazard for Predators).

**Note 2:**

The PNEC values of the remaining components not shown in the product are not available yet.

## 8.2 Exposure controls

### 8.2.1 Engineering controls

|   |                                                                                        |
|---|----------------------------------------------------------------------------------------|
| 1 | Ensure adequate ventilation, especially in confined areas.                             |
| 2 | Ensure that eyewash stations and safety showers are close to the workstation location. |
| 3 | Use explosion-proof electrical/ventilating/lighting/equipment.                         |
| 4 | Set up emergency exit and necessary risk-elimination area.                             |

### 8.2.2 Personal protection equipment

| General requirement      |      |
|--------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Eye protection           | Must wear appropriate safety goggles.                                                                                                                                                                                                                                                                                                                                                                                                  |
| Hand protection          | Must wear anti static chemical protective gloves.                                                                                                                                                                                                                                                                                                                                                                                      |
| Respiratory protection   | Must wear appropriate personal dust proof gas mask.                                                                                                                                                                                                                                                                                                                                                                                    |
| Skin and body protection | Must wear anti static chemical protective clothing and anti static shoes.                                                                                                                                                                                                                                                                                                                                                              |

### 8.2.3 Environmental exposure controls

|                                 |                          |
|---------------------------------|--------------------------|
| Environmental exposure controls | No information available |
|---------------------------------|--------------------------|

## 9 Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

|                |                  |
|----------------|------------------|
| Physical state | colorless liquid |
|----------------|------------------|

|                                                    |                                                              |
|----------------------------------------------------|--------------------------------------------------------------|
| <b>Colour</b>                                      | colorless liquid                                             |
| <b>Odor</b>                                        | No information available                                     |
| <b>Odor threshold</b>                              | No information available                                     |
| <b>pH</b>                                          | No information available                                     |
| <b>Melting point/freezing point(°C)</b>            | -98 ( Methanol )                                             |
| <b>Initial boiling point and boiling range(°C)</b> | 65 ( Methanol )                                              |
| <b>Flash point(Closed cup,°C)</b>                  | 9 ( Methanol )                                               |
| <b>Evaporation rate</b>                            | No information available                                     |
| <b>Flammability</b>                                | No information available                                     |
| <b>Upper/lower explosive limits[% (v/v)]</b>       | Upper limit : 50 ( Methanol ) ; Lower limit : 6 ( Methanol ) |
| <b>Vapor pressure</b>                              | 12.9 kPa ( 20°C,Methanol )                                   |
| <b>Vapor density(Air = 1)</b>                      | 1.1 ( Methanol )                                             |
| <b>Relative density(Water=1)</b>                   | 0.79 ( 20°C,Methanol )                                       |
| <b>Solubility</b>                                  | Miscible with water ( Methanol )                             |
| <b>n-octanol/water partition coefficient</b>       | -0.74 ( Methanol )                                           |
| <b>Auto-ignition temperature(°C)</b>               | 440 ( Methanol )                                             |
| <b>Decomposition temperature(°C)</b>               | No information available                                     |
| <b>Kinematic viscosity</b>                         | 0.544 mPa ( 25°C,Methanol )                                  |
| <b>Explosive properties</b>                        | No information available                                     |
| <b>Oxidizing properties</b>                        | No information available                                     |
| <b>Particle characteristics</b>                    | Not applicable                                               |

## 9.2 Other information

### 9.2.1 Information with regard to physical hazard classes

|                                                           |                          |
|-----------------------------------------------------------|--------------------------|
| <b>Information with regard to physical hazard classes</b> | No information available |
|-----------------------------------------------------------|--------------------------|

### 9.2.2 Other safety characteristics

|                                     |                          |
|-------------------------------------|--------------------------|
| <b>Other safety characteristics</b> | No information available |
|-------------------------------------|--------------------------|

## 10 Stability and reactivity

### Stability and reactivity

|                                                |                                                                                                      |
|------------------------------------------------|------------------------------------------------------------------------------------------------------|
| <b>10.1 Reactivity</b>                         | Contact with incompatible substances can cause decomposition or other chemical reactions.            |
| <b>10.2 Chemical stability</b>                 | Stable under proper operation and storage conditions.                                                |
| <b>10.3 Possibility of hazardous reactions</b> | In contact with oxidants causes severe reactions, and may cause a fire or explosion.                 |
| <b>10.4 Conditions to avoid</b>                | Incompatible materials, heat, flame and spark.                                                       |
| <b>10.5 Incompatible materials</b>             | Oxidants, alkali metals, alkaline earth metals and aluminum.                                         |
| <b>10.6 Hazardous decomposition products</b>   | Under normal conditions of storage and use, hazardous decomposition products should not be produced. |

## 11 Toxicological information

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



**2023/707**

| Tadalafil in methanol                |                                                                  |
|--------------------------------------|------------------------------------------------------------------|
| <b>Skin corrosion/irritation</b>     | Based on available data, the classification criteria are not met |
| <b>Serious eye damage/irritation</b> | Based on available data, the classification criteria are not met |
| <b>Skin sensitization</b>            | Based on available data, the classification criteria are not met |
| <b>Respiratory sensitization</b>     | Based on available data, the classification criteria are not met |
| <b>Reproductive toxicity</b>         | Based on available data, the classification criteria are not met |
| <b>STOT-single exposure</b>          | Causes damage to organs(Category 1)                              |
| <b>STOT-repeated exposure</b>        | Based on available data, the classification criteria are not met |
| <b>Aspiration hazard</b>             | Based on available data, the classification criteria are not met |
| <b>Germ cell mutagenicity</b>        | Based on available data, the classification criteria are not met |

**| Acute toxicity**

| Component       | LD <sub>50</sub> (oral) | LD <sub>50</sub> (dermal) | LC <sub>50</sub> (inhalation,4h) |
|-----------------|-------------------------|---------------------------|----------------------------------|
| <b>Methanol</b> | 5628mg/kg(Rat)          | 15800mg/kg(Rabbit)        | 83.867mg/L(Rat)                  |

**| Carcinogenicity**

| Component       | List of carcinogens by the IARC Monographs | Report on Carcinogens by NTP |
|-----------------|--------------------------------------------|------------------------------|
| <b>Methanol</b> | Not Listed                                 | Not Listed                   |
| <b>Cialis</b>   | Not Listed                                 | Not Listed                   |

**| 11.2 Information on other hazards****| 11.2.1 Endocrine disrupting properties**

| Component       | Endocrine disrupting properties |
|-----------------|---------------------------------|
| <b>Methanol</b> | No information available        |
| <b>Cialis</b>   | No information available        |

**| 11.2.2 Other Information**

|                          |                  |
|--------------------------|------------------|
| <b>Other Information</b> | See Section 11.1 |
|--------------------------|------------------|

**12 Ecological information****| 12.1 Toxicity****| Acute aquatic toxicity**

| Component       | Fish                                        | Crustaceans                                        | Algae or other aquatic plants |
|-----------------|---------------------------------------------|----------------------------------------------------|-------------------------------|
| <b>Methanol</b> | LC <sub>50</sub> : 24000mg/L<br>(96h)(Fish) | EC <sub>50</sub> : 24500mg/L<br>(48h)(Crustaceans) | No information available      |

**| Chronic aquatic toxicity**

|                                 |                          |
|---------------------------------|--------------------------|
| <b>Chronic aquatic toxicity</b> | No information available |
|---------------------------------|--------------------------|

**| 12.2 Persistence and degradability**

| Component | Persistence (water/soil) | Persistence (air) |
|-----------|--------------------------|-------------------|
| Methanol  | Low                      | Low               |

### 12.3 Bioaccumulative potential

| Component | Bioaccumulative potential | Comments |
|-----------|---------------------------|----------|
| Methanol  | Low                       | BCF=10   |

### 12.4 Mobility in soil

| Component | log Koc | Remark |
|-----------|---------|--------|
| Methanol  | 0.000   |        |

### 12.5 Results of PBT and vPvB assessment

| Component | Results of PBT and vPvB assessment [according to (EC) No 1907/2006] |
|-----------|---------------------------------------------------------------------|
| Methanol  | Not PBT/vPvB                                                        |
| Cialis    | Insufficient information, temporarily unable to evaluate            |

### 12.6 Endocrine disrupting properties

| Component | Endocrine disrupting properties |
|-----------|---------------------------------|
| Methanol  | No information available        |
| Cialis    | No information available        |

### 12.7 Other adverse effects

|  |                          |
|--|--------------------------|
|  | No information available |
|--|--------------------------|

## 13 Disposal considerations

### 13.1 Waste treatment methods

|                          |                                                                                                                                                        |
|--------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| Waste chemicals          | Before disposal should refer to the relevant national and local laws and regulation. Recommend the use of incineration disposal.                       |
| Contaminated packaging   | Containers may still present chemical hazard when empty. Keep away from hot and ignition source of fire. Return to supplier for recycling if possible. |
| Disposal recommendations | Refer to section waste chemicals and contaminated packaging.                                                                                           |

## 14 Transport information

### Label and Mark

|                    |                                                                                     |
|--------------------|-------------------------------------------------------------------------------------|
| Transporting Label |  |
|--------------------|-------------------------------------------------------------------------------------|

### IMDG-CODE

|                              |                          |
|------------------------------|--------------------------|
| 14.1 UN number               | 1993                     |
| 14.2 UN proper shipping name | FLAMMABLE LIQUID, N.O.S. |
| 14.3 Transport hazard class  | 3                        |

|                                           |    |
|-------------------------------------------|----|
| 14.4 Packing group                        | II |
| 14.5 Environmental hazards<br>(Yes or no) | No |

### IATA-DGR

|                                           |                          |
|-------------------------------------------|--------------------------|
| 14.1 UN number                            | 1993                     |
| 14.2 UN proper shipping name              | FLAMMABLE LIQUID, N.O.S. |
| 14.3 Transport hazard class               | 3                        |
| 14.4 Packing group                        | II                       |
| 14.5 Environmental hazards<br>(Yes or no) | No                       |

### UN-ADR

|                                           |                          |
|-------------------------------------------|--------------------------|
| 14.1 UN number                            | 1993                     |
| 14.2 UN proper shipping name              | FLAMMABLE LIQUID, N.O.S. |
| 14.3 Transport hazard class               | 3                        |
| 14.4 Packing group                        | II                       |
| 14.5 Environmental hazards<br>(Yes or no) | No                       |

### Special precautions for user

|  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>Shipment of the goods vehicle exhaust pipe must be equipped with fire retardant devices, prohibit using mechanical equipment and tools of which easy to produce sparks. Transit should be anti-exposure, anti-rain, anti-high temperature. Transportation used tank (tank) cars should be grounded chain, tank can be installed to reduce the partition hole static electricity shocks. Strictly prohibited shipping or transportation with oxidants, acids, food and food additives etc. When bulk transport, Prohibit the use of cement or wooden boats. Transport vehicles should be equipped with the appropriate variety and quantity of fire equipment and emergency equipment leakage during transport. Before transport, should be preceded by checking whether container integrity, sealing. The transport unit must be placarded and marked in accordance with relevant transporting requirements.</p> |
|--|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Maritime transport in bulk according to IMO instruments

- ◆ Transport in bulk according to Annex II of MARPOL and the IBC code

|  |               |
|--|---------------|
|  | Not Available |
|--|---------------|

- ◆ Transport in bulk in accordance with MARPOL Annex V and the IMSBC Code

|  |               |
|--|---------------|
|  | Not Available |
|--|---------------|

- ◆ Transport in bulk in accordance with the IGC Code

|  |               |
|--|---------------|
|  | Not Available |
|--|---------------|

## 15 Regulatory information

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

#### International chemical inventory

| Component | A | B | C | D | E | F | G | H | I | J | K | L | M |
|-----------|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Methanol  | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ | √ |

|               |   |   |   |   |   |   |   |   |   |   |   |   |   |   |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| <b>Cialis</b> | x | x | x | x | x | x | x | x | x | x | x | x | ✓ | ✓ |
|---------------|---|---|---|---|---|---|---|---|---|---|---|---|---|---|

- [A] China Inventory of Existing Chemical Substances(IECSC)  
 [B] European Inventory of Existing Commercial Chemical Substances(EC inventory)  
 [C] United States Toxic Substances Control Act Inventory(TSCA)  
 [D] Canadian Domestic Substances List(DSL)  
 [E] New Zealand Inventory of Chemicals(NZIoC)  
 [F] Philippines Inventory of Chemicals and Chemical Substances(PICCS)  
 [G] Korea Existing Chemicals Inventory(KECL)  
 [H] Australian. Inventory of Industrial Chemical (AIICS)  
 [I] Japan Inventory of Existing & New Chemical Substances(ENCS)  
 [J] Thailand Existing Chemicals Inventory(TECI)  
 [K] Mexico National Inventory of Chemical Substances (INSQ)  
 [L] Russia Inventory of Existing Substances(DRAFT)  
 [M] Inventory of Existing Chemical Substances in Taiwan, China (TCSI)

## List of Chemical Substances under International Conventions

| Component       | A | B | C |
|-----------------|---|---|---|
| <b>Methanol</b> | x | x | x |
| <b>Cialis</b>   | x | x | x |

- [A] The Montreal Protocol on Substances that Deplete the Ozone Layer  
 [B] Stockholm Convention on Persistent Organic Pollutants (POPs)  
 [C] Rotterdam Convention on the prior informed consent procedure for certain hazardous chemicals and pesticides in international trade

## European chemical inventory

| Component       | A | B | C | D | E | F | G | H | I |
|-----------------|---|---|---|---|---|---|---|---|---|
| <b>Methanol</b> | x | x | ✓ | ✓ | ✓ | ✓ | x | x | x |
| <b>Cialis</b>   | x | x | x | x | x | x | x | x | x |

- [A] Candidate list of Substances of Very High Concern for authorization under EU REACH regulation  
 [B] Substances requiring authorisation under EU REACH regulation  
 [C] Substances restricted under EU REACH  
 [D] Pre-registered substances under EU REACH  
 [E] Registered substances under EU REACH  
 [F] Substance Evaluation – CoRAP under EU REACH  
 [G] List of priority substances under EU water policy ( Directive 2455/2001/EC )  
 [H] Substances subject to POPs Regulation  
 [I] Substances proposed as POPs

Note:

- “✓” Indicates that the substance included in the regulations.  
 “x” No data or not included in the regulations.

## German water hazard class(WGK)

| Component       | WGK   | Remark |
|-----------------|-------|--------|
| <b>Methanol</b> | WGK 2 |        |

- [WGK 1] slightly hazardous to water  
 [WGK 2] obviously hazardous to water  
 [WGK 3] highly hazardous to water  
 [nwg] non-hazardous to water  
 [awg] hazardous to water in general

## German technical instructions on air quality control(TA LUFT)

| Component | TA LUFT                                                                                                                                                                             | Remark |
|-----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------|
| Methanol  | Chapter 5.2.5 Organic Substances, class I. The following values are in all not allowed to be exceeded in the exhaust gas: Mass flow: 0,10 kg/hr or Mass conc.: 20 mg/m <sup>3</sup> |        |

### German technical rules for hazardous substances (TRGS)

| Component | TRGS                                                                                                                                   | Remark |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------|--------|
| Methanol  | TRGS 201 TRGS 400 TRGS 555 TRGS 600 TRGS 402 TRGS 401 TRGS 500 TRGS 509 TRGS 510 TRGS 800 TRGS 720 TRGS 721 TRGS 722 TRGS 723 TRGS 724 |        |

### 15.2 Chemical safety assessment

|  |                                                                                                |
|--|------------------------------------------------------------------------------------------------|
|  | No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier. |
|--|------------------------------------------------------------------------------------------------|

## 16 Other information

### Information on revision

|                     |            |
|---------------------|------------|
| Creation Date       | 2025/12/16 |
| Revision Date       | -          |
| Reason for revision | -          |

### Reference

- [1] IPCS: The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>.
- [2] IARC, website: <http://www.iarc.fr/>.
- [3] OECD: The Global Portal to Information on Chemical Substances, website: <https://www.echemportal.org/echemportal/>.
- [4] CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>.
- [5] NLM: ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>.
- [6] EPA: Integrated Risk Information System, website: <http://cfpub.epa.gov/iris/>.
- [7] U.S. Department of Transportation: ERG, website: <http://www.phmsa.dot.gov/hazmat/library/erg>.
- [8] Germany GESTIS-database on hazard substance, website: <http://gestis-en.itrust.de/>.

### Abbreviations and acronyms

|                  |                                      |           |                                                           |
|------------------|--------------------------------------|-----------|-----------------------------------------------------------|
| CAS              | Chemical Abstracts Service           | UN        | The United Nations                                        |
| PC-STEL          | Short term exposure limit            | OECD      | Organization for Economic Co-operation and Development    |
| PC-TWA           | Time Weighted Average                | IMDG-CODE | International Maritime Dangerous Goods CODE               |
| MAC              | Maximum Allowable Concentration      | IARC      | International Agency for Research on Cancer               |
| DNEL             | Derived No Effect Level              | ICAO      | International Civil Aviation Organization                 |
| PNEC             | Predicted No Effect Concentration    | IATA      | International Air Transportation Association              |
| NOEC             | No Observed Effect Concentration     | ACGIH     | American Conference of Governmental Industrial Hygienists |
| LC <sub>50</sub> | Lethal Concentration 50%             | NFPA      | National Fire Protection Association                      |
| LD <sub>50</sub> | Lethal Dose 50%                      | NTP       | National Toxicology Program                               |
| EC <sub>50</sub> | Effective Concentration 50%          | PBT       | Persistent, Bioaccumulative, Toxic                        |
| EC <sub>x</sub>  | Effective Concentration X%           | vPvB      | very Persistent, very Bioaccumulative                     |
| P <sub>OW</sub>  | Partition coefficient Octanol: Water | CMR       | Carcinogens, mutagens or substances toxic to reproduction |
| BCF              | Bioconcentration factor              | RPE       | Respiratory Protective Equipment                          |
| ED               | Endocrine disruptor                  |           |                                                           |

### Disclaimer

This Safety Data Sheet (SDS) was prepared according to REACH Regulation. The data included was derived from

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