



# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EU) No 2015/830

## Lipase DC FS

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

#### 1.1 Product identifier

Trade name: Lipase DC FS Reagent R2  
As part of the kits: 1 4321 XX XX XXX  
(The positions X code different packages.)

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

General use: Reagent for in-vitro diagnostics in human samples  
For professional use only

#### 1.3 Details of the supplier of the safety data sheet

Company name: PT Prodia Diagnostic Line  
Address: Kawasan Industri Jababeka III  
Jl. Tekno 1 Blok C 2 D-E-F  
Cikarang 17530  
Province: Jawa Barat  
WWW: <http://www.proline.co.id>  
E-mail: [qa@proline.co.id](mailto:qa@proline.co.id)  
Telephone: +62 21 898 42722  
Telefax: +62 21 898 42723  
Department responsible for information:  
Quality Assurance, ext. 107

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

##### Classification according to EC regulation 1272/2008 (CLP)

Eye Irrit. 2; H319 Causes serious eye irritation.

#### 2.2 Label elements

##### Labelling (CLP)



Signal word: **Warning**

Hazard statements: H319 Causes serious eye irritation.

Precautionary Statements:  
P280 Wear protective gloves/protective clothing/eye protection.  
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P337+P313 If eye irritation persists: Get medical advice/attention.

##### Special labelling

EUH208 Contains 2-Chloracetamide. May produce an allergic reaction.



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### 2.3 Other hazards

No risks worthy of mention.  
Results of PBT and vPvB assessment:  
No data available

## SECTION 3: Composition / information on ingredients

3.1 Substances: not applicable

### 3.2 Mixtures

Chemical characterisation: Aqueous solution. Contains surfactants.

Hazardous ingredients:

Ingredient	Designation	Content	Classification
EC No. 200-746-9 CAS 71-23-8	Propan-1-ol	< 3 %	Flam. Liq. 2; H225. Eye Dam. 1; H318. STOT SE 3; H336.
EC No. 201-174-2 CAS 79-07-2	2-Chloracetamide	< 0.1 %	Acute Tox. 3; H301. Skin Sens. 1; H317. Repr. 2; H361f.

Full text of H- and EUH-statements: see section 16.

Additional information: Contains :

Polyethylene glycol. The maximum workplace exposure limits are, where necessary, listed in section 8.  
Contains Sodium azide (0.95 g/L) as preservative.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General information: First aider: Pay attention to self-protection!  
If medical advice is needed, have product container or label at hand.  
Take off contaminated clothing and wash it before reuse.

In case of inhalation: Provide fresh air. If you feel unwell, seek medical advice.

Following skin contact: Change contaminated clothing.  
Immediately clean with water and soap followed by thorough rinsing. In case of skin reactions, consult a physician.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart. Remove contact lenses, if present and easy to do. Continue rinsing. Subsequently consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Induce vomiting.  
Have victim drink large quantities of water, with active charcoal if possible.  
Never give anything by mouth to an unconscious person. Seek medical attention.

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

Causes serious eye irritation.  
May cause allergic reactions in already sensitized persons.

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

Treat symptomatically.



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### SECTION 5: Firefighting measures

#### 5.1 Extinguishing media

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

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

Fires in the immediate vicinity may cause the development of dangerous vapours. In case of fire may be liberated: carbon monoxide and carbon dioxide.

#### 5.3 Advice for firefighters

Special protective equipment for firefighters:

Wear self-contained breathing apparatus.

Additional information:

Hazchem-Code: -

Do not allow fire water to penetrate into surface or ground water.

### SECTION 6: Accidental release measures

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

Avoid contact with skin and eyes. Do not breathe vapours. Wear appropriate protective equipment. In enclosed areas: Provide fresh air. If possible, eliminate leakage. Keep unprotected people away. Take off contaminated clothing and wash it before reuse.

#### 6.2 Environmental precautions

Do not allow to penetrate into soil, waterbodies or drains.

#### 6.3 Methods and material for containment and cleaning up

Soak up with absorbent materials such as sand, siliceous earth, acid- or universal binder. Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of water.

#### 6.4 Reference to other sections

Refer additionally to section 8 and 13.

### SECTION 7: Handling and storage

#### 7.1 Precautions for safe handling

Advices on safe handling: Provide adequate ventilation, and local exhaust as needed. Avoid contact with skin and eyes. Do not breathe vapours. Wear appropriate protective equipment. Keep all containers, equipment and working place clean. Take off contaminated clothing and wash it before reuse. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling. Have eye wash bottle or eye rinse ready at work place.

#### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 °C and 8 °C. Protect from direct sunlight. Do not freeze. Keep sterile.

Hints on joint storage:

Do not store together with: acids, alkalis  
Keep away from food, drink and animal feedingstuffs.



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### 7.3 Specific end use(s)

No information available.

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

Occupational exposure limit values:

CAS No.	Designation	Type	Limit value
71-23-8	Propan-1-ol	Great Britain: WEL-STEL	625 mg/m <sup>3</sup> ; 250 ppm (may be absorbed through the skin)
		Great Britain: WEL-TWA	500 mg/m <sup>3</sup> ; 200 ppm (may be absorbed through the skin)
		Ireland: 8 hours	100 ppm (may be absorbed through the skin)

### 8.2 Exposure controls

Provide good ventilation and/or an exhaust system in the work area.

### Personal protection equipment

#### Occupational exposure controls

- Respiratory protection: Respiratory protection must be worn whenever the WEL levels have been exceeded. Use a breathing protection against vapours/aerosol. Use combination filter type A/P according to EN 14387.
- Hand protection: Protective gloves according to EN 374. Glove material: Nitrile rubber. Breakthrough time: >480 min. Observe glove manufacturer's instructions concerning penetrability and breakthrough time.
- Eye protection: Tightly sealed goggles according to EN 166.
- Body protection: Wear suitable protective clothing.
- General protection and hygiene measures: Do not breathe vapours. Avoid contact with skin and eyes. Take off contaminated clothing and wash it before reuse. Wash hands before breaks and after work. Do not eat, drink or smoke when using this product. Have eye wash bottle or eye rinse ready at work place.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance: Physical state at 20 C and 101.3 kPa: liquid  
Colour: colourless, clear (R1) and slightly turbid, orange-red (R2)
- Odour: no characteristic odour (R1) and characteristic odour (R2)
- Odour threshold: No data available
- pH value: at 25 C: 8.0 (R1) and 4.0 (R2)
- Melting point/freezing point: No data available
- Initial boiling point and boiling range: No data available
- Flash point/flash point range: not combustible
- Evaporation rate: No data available



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Flammability:	No data available
Explosion limits:	No data available
Vapour pressure:	No data available
Vapour density:	No data available
Density:	at 20 C: 1.007 g/mL (R1) and 1.0238 g/mL (R2)
Water solubility:	completely miscible
Partition coefficient: n-octanol/water:	No data available
Auto-ignition temperature:	No data available
Decomposition temperature:	No data available
Viscosity, kinematic:	No data available
Explosive properties:	No data available
Oxidizing characteristics:	No data available

### 9.2 Other information

Additional information: No data available

## SECTION 10: Stability and reactivity

### 10.1 Reactivity

refer to 10.3

### 10.2 Chemical stability

Stable under recommended storage conditions.

### 10.3 Possibility of hazardous reactions

No hazardous reactions known.

### 10.4 Conditions to avoid

Protect from frost, heat and sunlight.

### 10.5 Incompatible materials

Acids, alkalis

### 10.6 Hazardous decomposition products

No decomposition when used properly.

Thermal decomposition: No data available



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## SECTION 11: Toxicological information

### 11.1 Information on toxicological effects

Toxicological effects: The statements are derived from the properties of the single components. No toxicological data is available for the product as such.

Acute toxicity (oral): Lack of data.

Acute toxicity (dermal): Lack of data.

Acute toxicity (inhalative): Lack of data.

Skin corrosion/irritation: Based on available data, the classification criteria are not met.

Serious eye damage/irritation: Eye Irrit. 2; H319 = Causes serious eye irritation.

Sensitisation to the respiratory tract: Lack of data.

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

Contains 2-Chloracetamide. May produce an allergic reaction.

Germ cell mutagenicity/Genotoxicity: Lack of data.

Carcinogenicity: Lack of data.

Reproductive toxicity: Lack of data.

Effects on or via lactation: Lack of data.

Specific target organ toxicity (single exposure): Lack of data.

Specific target organ toxicity (repeated exposure): Lack of data.

Aspiration hazard: Lack of data.

### Symptoms

After eye contact: Upon direct contact with eyes may cause burning, tearing, redness.

## SECTION 12: Ecological information

### 12.1 Toxicity

Further details: No data available

### 12.2 Persistence and degradability

Further details: No data available

### 12.3 Bioaccumulative potential

Partition coefficient: n-octanol/water:  
No data available

### 12.4 Mobility in soil

No data available

### 12.5 Results of PBT and vPvB assessment

No data available

### 12.6 Other adverse effects

General information: Do not allow to enter into ground-water, surface water or drains.



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### SECTION 13: Disposal considerations

#### 13.1 Waste treatment methods

##### Product

Waste key number: 16 05 06\* = Laboratory chemicals, consisting of or containing hazardous substances, including mixtures of laboratory chemicals.  
\* = Evidence for disposal must be provided.

Recommendation: Special waste. Dispose of waste according to applicable legislation.

##### Contaminated packaging

Waste key number: 15 01 02 = Plastic packaging

Recommendation: Dispose of waste according to applicable legislation.  
Non-contaminated packages may be recycled.

### SECTION 14: Transport information

#### 14.1 UN number

ADR/RID, IMDG, IATA-DGR:  
not applicable

#### 14.2 UN proper shipping name

ADR/RID, IMDG, IATA-DGR:  
Not restricted

#### 14.3 Transport hazard class(es)

ADR/RID, IMDG, IATA-DGR:  
not applicable

#### 14.4 Packing group

ADR/RID, IMDG, IATA-DGR:  
not applicable

#### 14.5 Environmental hazards

Marine pollutant: no

#### 14.6 Special precautions for user

No dangerous good in sense of these transport regulations.

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

No data available

### SECTION 15: Regulatory information

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

##### National regulations - Indonesia

Hazchem-Code: -  
No data available

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### National regulations - EC member states

Further regulations, limitations and legal requirements:

Use restriction according to REACH annex XVII, no.: 3

### 15.2 Chemical Safety Assessment

For this mixture a chemical safety assessment is not required.

## SECTION 16: Other information

### Further information

Wording of the H-phrases under paragraph 2 and 3:

H225 = Highly flammable liquid and vapour.

H301 = Toxic if swallowed.

H317 = May cause an allergic skin reaction.

H318 = Causes serious eye damage.

H319 = Causes serious eye irritation.

H336 = May cause drowsiness or dizziness.

H361f = Suspected of damaging fertility.

EUH208 = Contains 2-Chloracetamide. May produce an allergic reaction.

Reason of change: -

Date of first version: 1/4/2020

### Department issuing data sheet

Contact person: see section 1: Department responsible for information

For abbreviations and acronyms, see: ECHA Guidance on information requirements and chemical safety assessment, chapter R.20 (Table of terms and abbreviations).

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.