



Safety data sheet

REACH: Regulation (EC) No 2021/849 (in particular as amended by Regulation (EU) No. 1907/2006 & 2015/830 with respect to SDSs) & CLP: Regulation (EC) No 1272/2008

Printing date Jul 17, 2025

Version number 2

Revision: Jul 17, 2025

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

1.1 Product identifier:

- Trade name: VALIDATE® pTau181 CSF, VALIDATE® tTau CSF, AccuTrak™ Abeta42 CSF
- Product number: 804re, 805re, 2400-0258
- REACH Registration number: Not relevant
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:
- Product category Calibration Verification and/or Linearity Set. For *in vitro* diagnostic use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

LGC Clinical Diagnostics Inc.

221 US Route 1

Cumberland Foreside, ME 04110 - USA

800-377-9684; 207-892-1300

Hours: 8:30 AM to 5:00 PM, Eastern Time, Monday through Thursday. 8:30 AM to 4:00 PM on Friday.

www.lgcgroup.com

1.4 Emergency telephone number:

CHEMTREC, 24 hours

Inside the US or Canada: 1-800-424-9300

Outside of the US or Canada: +1-703-527-3887

Contact the CHEMTREC® Emergency Call Center for assistance with transportation or hazardous materials emergencies (24 hours/day, 7 days/week). Refer to LGC Clinical Diagnostics, Inc. customer number 798037.

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

- Classification according to Regulation (EC) No 1272/2008



GHS05 corrosion

Eye Dam. 1 H318 Causes serious eye damage.

2.2 Label elements

- Labelling according to Regulation (EC) No 1272/2008

The product is classified and labelled according to the CLP regulation.

- Hazard pictograms



GHS05

- Signal word: Danger

- Hazard-determining components of labelling:

Hydrochloric acid

- Hazard statements:

H318 Causes serious eye damage.

- Precautionary Statements:

P280 Wear eye protection / face 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.

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P310 Immediately call a POISON CENTER/doctor.

· **Additional information:**

This value refers to knowledge of known, established toxicological or ecotoxicological values.

0 % of the mixture consists of component(s) of unknown toxicity.

Contains 0 % of components with unknown hazards to the aquatic environment.

· **2.3 Other hazards:** None known

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

SECTION 3: Composition/information on ingredients

· **3.2 Mixtures**

· **Description:**

Mixture of substances listed below with nonhazardous additions not included on the SDS. All listed components and non-hazardous unlisted components equal 100%.

· **Dangerous components:**

CAS: 7647-01-0 EINECS: 231-595-7	Hydrochloric acid ⚠ Skin Corr. 1B, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H302; Acute Tox. 4, H332; STOT SE 3, H335 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 25 % Skin Irrit. 2; H315: 10 % ≤ C < 25 % Eye Irrit. 2; H319: 10 % ≤ C < 25 % STOT SE 3; H335: C ≥ 10 %	2-12%
	Artificial Cerebrospinal Fluid	30-60%
	Fibrinogen Stripped Human Pooled Plasma	≤2.5%

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

SECTION 4: First aid measures

· **4.1 Description of first aid measures**

· **General information:**

Caution: Contains human plasma. Handle as if capable of transmitting infectious agents.

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

· **After skin contact:**

Wash with soap and water.

If skin irritation occurs, consult a doctor.

· **After eye contact:**

Rinse opened eye for several minutes under running water.

If easy to do so, remove contact lenses if worn.

If eye irritation occurs, consult a doctor.

· **After swallowing:**

Rinse mouth with water.

If swallowed and symptoms occur, consult a doctor.

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

No further relevant information available.

· **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 agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **For safety reasons unsuitable extinguishing agents:** No further relevant information.
- **5.2 Special hazards arising from the substance or mixture:** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:**
As in any fire, wear self-contained breathing apparatus pressure-demand and full protective gear to prevent contact with skin and eyes.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Use standard laboratory good practices.
- **6.2 Environmental precautions:**
Dilute with plenty of water.
Do not allow to enter sewers, surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
Dispose of the material collected according to regulations.
- **6.4 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.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Handle as if capable of transmitting infectious agents. Use universal precautions. Avoid contact with skin, eyes, and mucous membranes. Follow applicable biosafety and waste disposal regulations.
- **Information about fire and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** Store at the recommendation of manufacturer.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** None.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**

7647-01-0 Hydrochloric acid

OEL	Short-term value: 15 mg/m ³ , 10 ppm
	Long-term value: 8 mg/m ³ , 5 ppm
IOELV	

- **Additional information:** The lists valid during the making were used as basis.

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- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
The usual precautionary measures are to be adhered to when handling chemicals.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**



Protective gloves

- **Material of gloves:** Not applicable.
- **Penetration time of glove material:** Not applicable.
- **Eye/face protection**



Safety glasses

- **Body protection:** Not required.
- **Environmental exposure controls** None

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Liquid
- **Color:** Clear, Colorless
- **Odor:** Odorless
- **Melting point/freezing point:** Not determined.
- **Boiling point or initial boiling point and boiling range** Not determined.
- **Flammability** Not applicable.
- **Lower and upper explosion limit**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Flash point:** Not applicable.
- **Auto-ignition temperature:** Not applicable
- **Decomposition temperature:** Not determined.
- **pH** Not determined.
- **Viscosity:**
- **Kinematic viscosity** Not determined.
- **Dynamic:** Not determined.
- **Solubility**
- **water:** Fully miscible.
- **Partition coefficient n-octanol/water (log value)** Not determined.
- **Vapor pressure:** Not determined.
- **Density and/or relative density**
- **Density:** Not determined.

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- **Relative density:** Not determined.
- **Vapor density:** Not determined.
- **9.2 Other information**
- **Appearance:**
- **Form:** Fluid
- **Important information on protection of health and environment, and on safety.**
- **Ignition temperature:** Product is not self-igniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Change in condition**
- **Evaporation rate:** Not determined.
- **Information with regard to physical hazard classes**
- **Explosives** Non-Regulated Material
- **Flammable gases** Non-Regulated Material
- **Aerosols** Non-Regulated Material
- **Oxidizing gases** Non-Regulated Material
- **Gases under pressure** Non-Regulated Material
- **Flammable liquids** Non-Regulated Material
- **Flammable solids** Non-Regulated Material
- **Self-reactive substances and mixtures** Non-Regulated Material
- **Pyrophoric liquids** Non-Regulated Material
- **Pyrophoric solids** Non-Regulated Material
- **Self-heating substances and mixtures** Non-Regulated Material
- **Substances and mixtures, which emit flammable gases in contact with water** Non-Regulated Material
- **Oxidizing liquids** Non-Regulated Material
- **Oxidizing solids** Non-Regulated Material
- **Organic peroxides** Non-Regulated Material
- **Corrosive to metals** Non-Regulated Material
- **Desensitised explosives** Non-Regulated Material

SECTION 10: Stability and reactivity

- **10.1 Reactivity:** No further relevant information available.
- **10.2 Chemical stability:** Product is stable under normal conditions.
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions:** No dangerous reactions known.
- **10.4 Conditions to avoid:** No further relevant information available.
- **10.5 Incompatible materials:**
Strong bases
Strong acids
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

SECTION 11: Toxicological information

- **11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Based on available data, the classification criteria are not met.

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· LD/LC50 values relevant for classification:		
7647-01-0 Hydrochloric acid		
Oral	LD50	700 mg/kg (Rat) 900 mg/kg (rabbit)
Dermal	LD50	5,010 mg/kg (rabbit)
Inhalative	LC50/4 h	6.41 mg/l (Rat)

- **Primary irritant effect:**
- **Skin corrosion/irritation**
Based on available data, the classification criteria are not met.

7647-01-0 Hydrochloric acid		
Irritation of skin	Skin Irritation	(rabbit)

- **Serious eye damage/irritation**
Causes serious eye irritation.

7647-01-0 Hydrochloric acid		
Irritation of eyes	Eye Irritation	(rabbit)

- **Sensitization:** Based on available data, the classification criteria are not met.
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT (Specific target organ toxicity)-single exposure**
Based on available data, the classification criteria are not met.
- **STOT (Specific target organ toxicity)-repeated exposure**
Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

· **11.2 Information on other hazards**

· Endocrine disrupting properties		
None of the ingredients are listed.		

SECTION 12: Ecological information

· **12.1 Toxicity**

· Aquatic toxicity:		
7647-01-0 Hydrochloric acid		
EC50	3.6 mg/l (Bluegill/sunfish)	>56 mg/l (Daphnia)

- **12.2 Persistence and degradability:** No further relevant information available.
- **12.3 Bioaccumulative potential:** No further relevant information available.
- **12.4 Mobility in soil:** No further relevant information available.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.

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- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:** Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**
- **Recommendation:** Observe all federal, state and local environmental regulations when disposing of this material. Dispose under directive 2008/98/EC (Waste Framework Directive) and local biosafety waste disposal regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agents:** Water, if necessary together with cleansing agents.

SECTION 14: Transport information

- **14.1 UN number or ID number**
- **ADR/ADN, IMDG, IATA** Non-Regulated Material
- **14.2 UN proper shipping name**
- **ADR/ADN, IMDG, IATA** Non-Regulated Material
- **14.3 Transport hazard class(es)**
- **ADR/ADN, ADN, IMDG, IATA**
- **Class** Non-Regulated Material
- **14.4 Packing group**
- **ADR/ADN, IMDG, IATA** Non-Regulated Material
- **14.5 Environmental hazards:** Not applicable.
- **14.6 Special precautions for user** Not applicable.
- **14.7 Maritime transport in bulk according to IMO instruments** Not applicable.
- **UN "Model Regulation":** Non-Regulated Material

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU** Substance is not listed.
- **Named dangerous substances - ANNEX I** None of the ingredients are listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

· **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**

None of the ingredients are listed.

· **REGULATION (EU) 2019/1148**

· **Annex I - RESTRICTED EXPLOSIVES PRECURSORS (Upper limit value for the purpose of licensing under Article 5(3))**

None of the ingredients are listed.

· **Annex II - REPORTABLE EXPLOSIVES PRECURSORS**

None of the ingredients are listed.

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· Regulation (EC) No 273/2004 on drug precursors		
7647-01-0	Hydrochloric acid	3
· Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors		
7647-01-0	Hydrochloric acid	3
· National regulations:		
The product is not subject to be labelled according with the prevailing version of the regulations on hazardous substances.		

· **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

SECTION 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.

· **Relevant phrases**

- H302 Harmful if swallowed.
- H314 Causes severe skin burns and eye damage.
- H315 Causes skin irritation.
- H318 Causes serious eye damage.
- H319 Causes serious eye irritation.
- H332 Harmful if inhaled.
- H335 May cause respiratory irritation.

· **Date of previous version:** 23.04.2025

· **Abbreviations and acronyms:**

- ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
- ADN: The European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
- IMDG: International Maritime Code for Dangerous Goods
- IATA: International Air Transport Association
- GHS: Globally Harmonised System of Classification and Labelling of Chemicals
- EINECS: European Inventory of Existing Commercial Chemical Substances
- ELINCS: European List of Notified Chemical Substances
- CAS: Chemical Abstracts Service (division of the American Chemical Society)
- LC50: Lethal concentration, 50 percent
- LD50: Lethal dose, 50 percent
- PBT: Persistent, Bioaccumulative and Toxic
- vPvB: very Persistent and very Bioaccumulative
- Acute Tox. 4: Acute toxicity – Category 4
- Skin Corr. 1B: Skin corrosion/irritation – Category 1B
- Eye Dam. 1: Serious eye damage/eye irritation – Category 1
- STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· *** Data compared to the previous version altered.**

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