



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 10.11.2024

Version number 1

Revision: 10.11.2024

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

· **1.1 Product identifier:**

· **Trade name:** VALIDATE® Methotrexate

· **Product number:** 310ro

· **REACH Registration number:** Not relevant

· **1.2 Relevant identified uses of the substance or mixture and uses advised against:**

Intended for in vitro diagnostic use in the determination of linearity, calibration verification and verification of reportable range in automated, semi-automated and manual instrument systems.

· **Product category** Calibration Verification/Linearity Set

· **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

* SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008**

The product is not classified, according to the CLP regulation.

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008** Non-Regulated Material

· **Hazard pictograms** Non-Regulated Material

· **Signal word:** Non-Regulated Material

· **Hazard-determining components of labelling:**

3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone

· **Hazard statements:** Non-Regulated Material

· **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

· **3.1 Mixtures**

· **Description:** Mixture of substances listed below with nonhazardous additions.

(Contd. on page 2)

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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: VALIDATE® Methotrexate

(Contd. of page 1)

· Dangerous components:		
9007-83-4	γ -Globulins From Human Blood ⚠ Eye Irrit. 2, H319; STOT SE 3, H335	2-12%
55965-84-9	3(2H)-Isothiazolone, 5-chloro-2-methyl-, mixt. with 2-methyl-3(2H)-isothiazolone ⚠ Acute Tox. 3, H301; Acute Tox. 3, H311; Acute Tox. 3, H331; ⚠ Skin Corr. 1B, H314; ⚠ Aquatic Acute 1, H400; Aquatic Chronic 1, H410; ⚠ Skin Sens. 1, H317 Specific concentration limits: Skin Corr. 1B; H314: C ≥ 0.6 % Skin Irrit. 2; H315: 0.06 % ≤ C < 0.6 % Eye Irrit. 2; H319: 0.06 % ≤ C < 0.6 % Skin Sens. 1; H317: C ≥ 0.0015 %	≤0.5%
70024-90-7	Human Albumin	0.2-15%

· **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:** If symptoms persist, call a physician.

· **After inhalation:**

If symptoms are experienced remove source of contamination or move victim to fresh air. Obtain medical advice.

· **After skin contact:**

No health effects expected. If irritation does occur, flush with lukewarm, gently flowing water for 5 minutes or until chemical is removed.

· **After eye contact:**

No effects expected. If irritation does occur, flush contaminated eye(s) with lukewarm, gently flowing water for 5 minutes or until the chemical is removed. If irritation persists, obtain medical advice.

· **After swallowing:** If irritation or discomfort occurs, obtain medical advice immediately.

· **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.

SECTION 5: Firefighting measures

· **5.1 Extinguishing media**

· **Suitable extinguishing agents:**

Class B: dry chemical, carbon dioxide, foam, steam or water fog.

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 particular fire or explosion hazard. In case of fire it can release carbon oxides, nitrogen oxides, hydrogen chloride and/or chlorine gases, disodium oxide and other toxic and irritating fumes.

· **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.

(Contd. on page 3)



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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: **VALIDATE® Methotrexate**

(Contd. of page 2)

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Wear suitable protective clothing, gloves and eye/face protection.
- **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).
Ensure adequate ventilation.
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**
Ensure good ventilation/exhaustion at the workplace.
Prevent formation of aerosols.
Avoid all unnecessary exposure. Handle as a biohazard.
- **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:**
Keep container tightly closed and dry. Store in well ventilated area. Keep cool.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:** Keep container tightly sealed.
- **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:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** The lists valid during the making were used as basis.
- **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.
Keep away from foodstuffs, beverages and feed.
Immediately remove all soiled and contaminated clothing.
Wash hands before breaks and at the end of work.
Avoid contact with the eyes and skin.
- **Respiratory protection:** Not required.

(Contd. on page 4)

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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: **VALIDATE® Methotrexate**

(Contd. of page 4)

· Hand protection



Protective gloves

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



Tightly sealed goggles

- **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

Fluid

· Colour:

Amber

· Odour:

Odourless

· 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.

· Vapour pressure @ 20 °C:

≤23 hPa (7732-18-5 Water, distilled water, deionized water)

· Density and/or relative density

· Density:

Not determined.

· Relative density:

Not determined.

· Vapour density:

Not determined.

· 9.2 Other information

· Appearance:

· Form:

Fluid

(Contd. on page 5)



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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: **VALIDATE® Methotrexate**

(Contd. of page 5)

· **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

· **Oxidising 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

· **Oxidising liquids**

Non-Regulated Material

· **Oxidising 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:** No further relevant information available.

· **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.

· **LD/LC50 values relevant for classification:** No data available.

· **Primary irritant effect:**

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

· **Serious eye damage/irritation** Based on available data, the classification criteria are not met.

· **Sensitisation:** 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.

(Contd. on page 6)



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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: **VALIDATE® Methotrexate**

(Contd. of page 6)

- **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:** No further relevant information available.
- **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.
- **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.
- **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

(Contd. on page 7)



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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: **VALIDATE® Methotrexate**

(Contd. of page 7)

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.
- **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.
- **Regulation (EC) No 273/2004 on drug precursors**
None of the ingredients are listed.
- **Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors**
None of the ingredients are listed.
- **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**
H301 Toxic if swallowed.
H311 Toxic in contact with skin.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H331 Toxic if inhaled.
H335 May cause respiratory irritation.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
- **Date of previous version:** 10.11.2024
- **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

(Contd. on page 8)



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 10.11.2024

Version number 1

Revision: 10.11.2024

Trade name: VALIDATE® Methotrexate

(Contd. of page 8)

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. 3: Acute toxicity – Category 3

Skin Corr. 1B: Skin corrosion/irritation – Category 1B

Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

Skin Sens. 1: Skin sensitisation – Category 1

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1

Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1

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

SDS created by MSDS Authoring Services www.msdsauthoring.com +1-877-204-9106