



SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended

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

1.1 Product identifier

Trade name : Gadobutrol Monohydrate
Product code : G0503
CAS RN : 198637-52-4

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

Use of the Substance/Mixture : Use as laboratory reagent

1.3 Details of the supplier of the safety data sheet

Company : TCI EUROPE N.V.
Address : Boereveldseweg 6 - Haven 1063, B-2070 Zwijndrecht, Belgium
Telephone : +32 (0)3 735 07 00
Telefax : +32 (0)3 735 07 01
E-mail address of person responsible for the SDS : sales-eu@tcichemicals.com

1.4 Emergency telephone number

Emergency telephone number : +44 844 892 0111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.1 Substances

Substance name : Gadobutrol Monohydrate
CAS RN : 198637-52-4

Components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

- | | | |
|-------------------------|---|--|
| If inhaled | : | Remove person to fresh air and keep comfortable for breathing.
Get medical advice/ attention if you feel unwell. |
| In case of skin contact | : | Take off all contaminated clothing immediately.
If on skin, rinse well with water.
If skin irritation or rash occurs: Get medical advice/ attention. |
| In case of eye contact | : | Rinse with plenty of water.
If easy to do, remove contact lens, if worn.
If eye irritation persists: Get medical advice/ attention. |
| If swallowed | : | Get medical advice/ attention.
Rinse mouth. |

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

None known.

SECTION 5: Firefighting measures

5.1 Extinguishing media

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|------------------------------|---|--|
| Suitable extinguishing media | : | Dry powder, Foam, Water spray, Carbon dioxide (CO ₂) |
|------------------------------|---|--|

5.2 Special hazards arising from the substance or mixture

- | | | |
|---------------------------------------|---|---------------------------|
| Specific hazards during fire-fighting | : | No information available. |
|---------------------------------------|---|---------------------------|

5.3 Advice for firefighters

- | | | |
|---|---|--|
| Special protective equipment for firefighters | : | Use personal protective equipment. |
| Specific extinguishing methods | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Immediately evacuate personnel to safe areas. Remove undamaged containers from fire area if it is safe to do so. |

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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|----------------------|---|--|
| Personal precautions | : | Wear suitable protective equipment. Keep people away from and upwind of spill/leak. Entry to non-involved personnel should be controlled around the leakage area by roping off, etc. |
|----------------------|---|--|

6.2 Environmental precautions

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|---------------------------|---|---------------------------------------|
| Environmental precautions | : | Prevent product from entering drains. |
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6.3 Methods and material for containment and cleaning up

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|-------------------------|---|---|
| Methods for cleaning up | : | Pick up and arrange disposal without creating dust. |
|-------------------------|---|---|

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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|-------------------------|---|--|
| Technical measures | : | Prevent dispersion of dust. |
| Local/Total ventilation | : | Ensure adequate ventilation.
Use a local exhaust ventilation. |
| Advice on safe handling | : | Avoid contact with skin, eyes and clothing.
Wear personal protective equipment.
Wash hands and face thoroughly after handling. |

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed. Store in a refrigerator. Protect from moisture. Keep under inert gas.

Storage class (TRGS 510) : 11

7.3 Specific end use(s)

Specific use(s) : No information available.

SECTION 8: Exposure controls/personal protection**8.1 Control parameters**

Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Engineering measures**

Install a closed system or local exhaust.
Also install safety shower and eye bath.

Personal protective equipment

Eye/face protection : Safety glasses, Face-shield
Hand protection : Protective gloves
Skin and body protection : Protective suit

Respiratory protection : Dust mask

*Use personal protective equipment(PPE) approved under appropriate government standards and follow local and national regulations.

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

Physical state : Solid form
Colour : white
Odour : No data available
Odour Threshold : No data available

Melting point/freezing point : No data available
Boiling point/boiling range : No data available
Flammability : No data available
Upper explosion limit/Upper flammability limit : No data available
Lower explosion limit/Lower flammability limit : No data available
Flash point : No data available
Auto-ignition point : No data available
Decomposition temperature : No data available
pH : No data available

Viscosity
Viscosity, dynamic : No data available
Viscosity, kinematic : No data available

Solubility(ies)
Water solubility : very soluble
Solubility in other solvents : Solvent: Ethanol
insoluble

Partition coefficient: n-octanol/water (log value) : -5,4
Vapour pressure : No data available
Relative density : No data available
Relative vapour density : No data available
Particle characteristics : No data available

9.2 Other information

Molecular weight : 622,74 g/mol

SECTION 10: Stability and reactivity**10.1 Reactivity**

No data available

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions : None under normal processing.

10.4 Conditions to avoid

Conditions to avoid : Heat, Exposure to moisture

10.5 Incompatible materials

Materials to avoid : Oxidizing agents,

10.6 Hazardous decomposition products

Carbon monoxide, Carbon dioxide (CO₂), Nitrogen oxides (NO_x)

SECTION 11: Toxicological information**11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008**

Acute toxicity : No information available.

Skin corrosion/irritation : No information available.

Serious eye damage/eye irritation : No information available.

Respiratory or skin sensitisation : No information available.

Germ cell mutagenicity : No information available.

Carcinogenicity : No information available.

Reproductive toxicity : No information available.

STOT - single exposure : No information available.

STOT - repeated exposure : No information available.

Repeated dose toxicity : No information available.

Aspiration hazard : No information available.

11.2 Information on other hazards**Endocrine disrupting properties****Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 12: Ecological information**12.1 Toxicity**

No data available

12.2 Persistence and degradability

No data available

12.3 Bioaccumulative potential

No data available

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment**Product:**

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties**Product:**

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

No data available

SECTION 13: Disposal considerations**13.1 Waste treatment methods**

Product : Disposal in accordance with local and national regulations.
Entrust disposal to a licensed waste disposal company.

Contaminated packaging : Disposal in accordance with local and national regulations.
Before disposal of used container, remove contents completely.

SECTION 14: Transport information**14.1 UN number or ID number**

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good

IMDG : Not regulated as a dangerous good

IATA (Cargo) : Not regulated as a dangerous good

IATA (Passenger) : Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

Remarks : Not classified as dangerous in the meaning of transport regulations.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

SECTION 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles (Annex XVII) : Not applicable

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59). : Not applicable

Regulation (EC) on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EU) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Water hazard class (Germany) : WGK 3 highly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

The components of this product are reported in the following inventories:

CH BAGREG	: Not in compliance with the inventory
TSCA	: Substance(s) not listed on TSCA inventory
AICS	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Gadobutrol Monohydrate
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
NZIoC	: Not in compliance with the inventory

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance.

SECTION 16: Other information

Full text of other abbreviations

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

This SDS was prepared sincerely based on the information obtained, however, any warranty shall not be given regarding the data contained and the assessment of hazards and toxicity. Prior to use, please investigate not only the hazards and toxicity information but also the laws and regulations of the organization, area and country where the products are to be used, which shall be given the first priority. The products are supposed to be used promptly after purchase in consideration of safety. Some new information or amendments may be added afterwards. If the products are to be used far behind the expected time of use or you have any questions, please feel free to contact us. The stated cautions are for normal handling only. In case of special handling operations, sufficient care should be taken, in addition to the safety measures suitable for the given situation. All chemical products should be treated with the recognition of "having unknown hazards and toxicity", which differ greatly depending on the conditions and handling when in use and/or the conditions and duration of storage. The products must be handled only by those who are familiar with specialized knowledge and have experience or under the guidance of those specialists throughout use from opening to storage and disposal. Safe usage conditions shall be set up on each user's own responsibility.

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