

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: **5615**
Version: **2.0 en**
Replaces version of: 2017-01-23
Version: (1)

date of compilation: 2017-01-23
Revision: 2022-03-09

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

1.1 Product identifier

Identification of the substance	Cytisine ROTICHROM® TLC
Article number	5615
Registration number (REACH)	It is not required to list the identified uses because the substance is not subject to registration according to REACH (< 1 t/a).
EC number	207-616-0
CAS number	485-35-8

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

Relevant identified uses:	Laboratory chemical Laboratory and analytical use
Uses advised against:	Do not use for products which come into contact with foodstuffs. Do not use for private purposes (household).

1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co KG
Schoemperlenstr. 3-5
D-76185 Karlsruhe
Germany

Telephone: +49 (0) 721 - 56 06 0

Telefax: +49 (0) 721 - 56 06 149

e-mail: sicherheit@carlroth.de

Website: www.carlroth.de

Competent person responsible for the safety data sheet: Department Health, Safety and Environment

e-mail (competent person): sicherheit@carlroth.de

1.4 Emergency telephone number

Name	Street	Postal code/city	Telephone	Website
National Poisons Information Service City Hospital	Dudley Rd	B187QH Birmingham	844 892 0111	

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

Section	Hazard class	Cat-egory	Hazard class and category	Hazard statement
3.1O	Acute toxicity (oral)	3	Acute Tox. 3	H301
3.1D	Acute toxicity (dermal)	3	Acute Tox. 3	H311
3.1I	Acute toxicity (inhal.)	3	Acute Tox. 3	H331

For full text of abbreviations: see SECTION 16

2.2 Label elements

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

Signal word

Danger

Pictograms

GHS06



Hazard statements

H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled

Precautionary statements

Precautionary statements - prevention

P280 Wear protective gloves/protective clothing/eye protection/face protection

Precautionary statements - response

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

Labelling of packages where the contents do not exceed 125 ml

Signal word: **Danger**

Symbol(s)



H301+H311+H331 Toxic if swallowed, in contact with skin or if inhaled.

P280 Wear protective gloves/protective clothing/eye protection/face protection.
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.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance	Cytisine
Molecular formula	C ₁₁ H ₁₄ N ₂ O
Molar mass	190,2 g/mol
CAS No	485-35-8
EC No	207-616-0

Substance, Specific Conc. Limits, M-factors, ATE			
Specific Conc. Limits	M-Factors	ATE	Exposure route
-	-	101 mg/kg 301 mg/kg 0,9 mg/l/4h	oral dermal inhalation: dust/ mist

SECTION 4: First aid measures

4.1 Description of first aid measures



General notes

Take off immediately all contaminated clothing. Self-protection of the first aider.

Following inhalation

Call a physician immediately. If breathing is irregular or stopped, administer artificial respiration.

Following skin contact

After contact with skin, wash immediately with plenty of water.

Following eye contact

Rinse cautiously with water for several minutes. In all cases of doubt, or when symptoms persist, seek medical advice.

Following ingestion

Rinse mouth immediately and drink plenty of water. Call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: **5615**

SECTION 5: Firefighting measures

5.1 Extinguishing media



Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings
water, foam, alcohol resistant foam, dry extinguishing powder, ABC-powder

Unsuitable extinguishing media

water jet

5.2 Special hazards arising from the substance or mixture

Combustible.

Hazardous combustion products

In case of fire may be liberated: Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus. Wear full chemical protective clothing.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures



For non-emergency personnel

Use personal protective equipment as required. Avoid contact with skin, eyes and clothes. Do not breathe dust.

6.2 Environmental precautions

Keep away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains. Take up mechanically.

Advice on how to clean up a spill

Take up mechanically. Control of dust.

Other information relating to spills and releases

Place in appropriate containers for disposal.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Use extractor hood (laboratory). Handle and open container with care. Avoid dust formation. Clear contaminated areas thoroughly.

Advice on general occupational hygiene

When using do not eat or drink. Thorough skin-cleansing after handling the product.

7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep in a cool place.

Incompatible substances or mixtures

Observe hints for combined storage.

Consideration of other advice:

Store locked up.

Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted.

Specific designs for storage rooms or vessels

Recommended storage temperature: 2 – 8 °C

7.3 Specific end use(s)

No information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

National limit values

Occupational exposure limit values (Workplace Exposure Limits)

This information is not available.

8.2 Exposure controls

Individual protection measures (personal protective equipment)

Eye/face protection



Use safety goggle with side protection.

Skin protection



Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

• hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. Check leak-tightness/impermeability prior to use. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 ° C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

• type of material

NBR (Nitrile rubber)

• material thickness

>0,11 mm

• breakthrough times of the glove material

>480 minutes (permeation: level 6)

• other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended.

Respiratory protection



Respiratory protection necessary at: Dust formation. Particulate filter device (EN 143). P3 (filters at least 99,95 % of airborne particles, colour code: White).

Environmental exposure controls

Keep away from drains, surface and ground water.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Form	crystals
Colour	colourless
Odour	odourless
Melting point/freezing point	154 – 156 °C
Boiling point or initial boiling point and boiling range	218 °C at 2,67 hPa
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: **5615**

pH (value)	not applicable
Kinematic viscosity	not relevant
<u>Solubility(ies)</u>	
Water solubility	~439 g/l at 16 °C
<u>Partition coefficient</u>	
Partition coefficient n-octanol/water (log value):	0,6 (TOXNET)
Vapour pressure	not determined
<u>Density and/or relative density</u>	
Density	not determined
Relative vapour density	information on this property is not available
Particle characteristics	No data available.
<u>Other safety parameters</u>	
Oxidising properties	none
9.2 Other information	
Information with regard to physical hazard classes:	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics:	There is no additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

10.4 Conditions to avoid

Keep away from heat.

10.5 Incompatible materials

There is no additional information.

10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Toxic if swallowed. Toxic in contact with skin. Toxic if inhaled.

Acute toxicity					
Exposure route	Endpoint	Value	Species	Method	Source
oral	LD50	101 mg/kg	mouse		

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.

Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

Shall not be classified as a specific target organ toxicant (repeated exposure).

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

Symptoms related to the physical, chemical and toxicological characteristics

• If swallowed

Liver and kidney damage

• If in eyes

Irritating to eyes

• If inhaled

causes slight to moderate irritation

• If on skin

Irritating to skin

• Other information

none

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

11.2 Endocrine disrupting properties

Not listed.

11.3 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

Biodegradation

Data are not available.

12.2 Process of degradability

Theoretical Oxygen Demand with nitrification: 2,46 mg/mg

Theoretical Oxygen Demand: 2,102 mg/mg

Theoretical Carbon Dioxide: 2,545 mg/mg

12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n-octanol/water (log KOW)	0,6 (TOXNET)
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12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Not listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

Sewage disposal-relevant information

Do not empty into drains.

Waste treatment of containers/packagings

It is a dangerous waste; only packagings which are approved (e.g. acc. to ADR) may be used.

13.2 Relevant provisions relating to waste

The allocation of waste identity numbers/waste descriptions must be carried out according to the EEC, specific to the industry and process. Waste catalogue ordinance (Germany).

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

13.3 Remarks

Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities. Please consider the relevant national or regional provisions.

SECTION 14: Transport information

14.1 UN number or ID number

ADRRID	UN 1544
IMDG-Code	UN 1544
ICAO-TI	UN 1544

14.2 UN proper shipping name

ADRRID	ALKALOIDS, SOLID, N.O.S.
IMDG-Code	ALKALOIDS, SOLID, N.O.S.
ICAO-TI	Alkaloid salts, solid, n.o.s.
Technical name	Cytisine

14.3 Transport hazard class(es)

ADRRID	6.1
IMDG-Code	6.1
ICAO-TI	6.1

14.4 Packing group

ADRRID	III
IMDG-Code	III
ICAO-TI	III

14.5 Environmental hazards

non-environmentally hazardous acc. to the dangerous goods regulations

14.6 Special precautions for user

Provisions for dangerous goods (ADR) should be complied within the premises.

14.7 Maritime transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

Proper shipping name	ALKALOIDS, SOLID, N.O.S.
Particulars in the transport document	UN1544, ALKALOIDS, SOLID, N.O.S., (Cytisine), 6.1, III, (E)
Classification code	T2
Danger label(s)	6.1



Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: **5615**

Special provisions (SP)	43, 274, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	2
Tunnel restriction code (TRC)	E
Hazard identification No	60
Emergency Action Code	2X

Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) Additional information

Classification code	6.1
Danger label(s)	6.1



Special provisions (SP)	43, 274, 802(ADN)
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
Transport category (TC)	2
Hazard identification No	60

International Maritime Dangerous Goods Code (IMDG) - Additional information

Proper shipping name	ALKALOIDS, SOLID, N.O.S.
Particulars in the shipper's declaration	UN1544, ALKALOIDS, SOLID, N.O.S., (Cytisine), 6.1, III
Marine pollutant	-
Danger label(s)	6.1



Special provisions (SP)	43, 223, 274
Excepted quantities (EQ)	E1
Limited quantities (LQ)	5 kg
EmS	F-A, S-A
Stowage category	A

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Proper shipping name	Alkaloid salts, solid, n.o.s.
Particulars in the shipper's declaration	UN1544, Alkaloid salts, solid, n.o.s., (Cytisine), 6.1, III
Danger label(s)	6.1



Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

Special provisions (SP)	A3, A5, A6
Excepted quantities (EQ)	E1
Limited quantities (LQ)	10 kg

SECTION 15: Regulatory information

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

Relevant provisions of the European Union (EU)

Restrictions according to REACH, Annex XVII

not listed

List of substances subject to authorisation (REACH, Annex XIV)/SVHC - candidate list

Not listed.

Seveso Directive

2012/18/EU (Seveso III)

No	Dangerous substance/hazard categories	Qualifying quantity (tonnes) for the application of lower and upper-tier requirements		Notes
H2	acute toxic (cat. 2 + cat. 3, inhal.)	50	200	41)

Notation

- 41) - Category 2, all exposure routes
- category 3, inhalation exposure route

Deco-Paint Directive

VOC content	100 %
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Industrial Emissions Directive (IED)

VOC content	0 %
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Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS)

not listed

Regulation concerning the establishment of a European Pollutant Release and Transfer Register (PRTR)

not listed

Water Framework Directive (WFD)

not listed

Regulation on the marketing and use of explosives precursors

not listed

Regulation on drug precursors

not listed

Regulation on substances that deplete the ozone layer (ODS)

not listed

Regulation concerning the export and import of hazardous chemicals (PIC)

not listed

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

Regulation on persistent organic pollutants (POP)

not listed

Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

National inventories

Country	Inventory	Status
CA	NDSL	substance is listed
EU	ECSI	substance is listed
NZ	NZIoC	substance is listed
TW	TCSI	substance is listed
US	TSCA	substance is listed

Legend

ECSI	EC Substance Inventory (EINECS, ELINCS, NLP)
NDSL	Non-domestic Substances List (NDSL)
NZIoC	New Zealand Inventory of Chemicals
TCSI	Taiwan Chemical Substance Inventory
TSCA	Toxic Substance Control Act

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Indication of changes (revised safety data sheet)

Alignment to regulation: Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU

Restructuring: section 9, section 14

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.1		Classification according to Regulation (EC) No 1272/2008 (CLP): change in the listing (table)	yes
2.1	Remarks: For full text of Hazard- and EU Hazard-statements: see SECTION 16.		yes
2.2		Pictograms: change in the listing (table)	yes
2.2		Precautionary statements - response: change in the listing (table)	yes
2.2	Precautionary statements - storage		yes
2.2		Precautionary statements - storage: change in the listing (table)	yes
2.2		Labelling of packages where the contents do not exceed 125 ml: change in the listing (table)	yes
2.3	Other hazards: There is no additional information.	Other hazards	yes

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: 5615

Section	Former entry (text/value)	Actual entry (text/value)	Safety-relevant
2.3		Results of PBT and vPvB assessment: According to the results of its assessment, this substance is not a PBT or a vPvB.	yes

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord relatif au transport international des marchandises dangereuses par route (Agreement concerning the International Carriage of Dangerous Goods by Road)
ATE	Acute Toxicity Estimate
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EmS	Emergency Schedule
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
ICAO-TI	Technical instructions for the safe transport of dangerous goods by air
IMDG	International Maritime Dangerous Goods Code
IMDG-Code	International Maritime Dangerous Goods Code
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
SVHC	Substance of Very High Concern
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative

Safety data sheet

according to Regulation (EC) No. 1907/2006 (REACH)



Cytisine ROTICHROM® TLC

article number: **5615**

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Agreement concerning the International Carriage of Dangerous Goods by Road (ADR). Regulations concerning the International Carriage of Dangerous Goods by Rail (RID). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in section 2 and 3)

Code	Text
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.