SAFETY DATA SHEET



In accordance with 453/2010 and 1272/2008

(All references to EU regulations and directives are abbreviated into only the numeric term)

Issued 2015-06-04

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Trade name

Monosialoganglioside GM2 (human Tay-Sachs)

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

Identified uses Laboratory chemicals

1.3. Details of the supplier of the safety data sheet

Company Larodan AB

Karolinska Institutet Science Park

Retzius väg 8 SE-171 65 SOLNA

Sweden

 Telephone
 +46 20 15 22 00

 E-mail
 info@larodan.com

 Website
 www.larodan.com

1.4. Emergency telephone number

In case of emergency contact toxicological information, emergency tel 112 (within Europe) or 1-800-222-1222 (for USA). For other countries, use the built-in emergency number in your cell phone

For non-emergency poison information, see http://www.who.int/gho/phe/chemical_safety/poisons_centres/en/

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification in accordance with 1272/2008

Upon assessment, this substance is not classified as hazardous according to 1272/2008.

2.2. Label elements

Label information in accordance with 1272/2008

Hazard pictograms Not applicable Signal words Not applicable Hazard statements Not applicable

2.3. Other hazards

Not relevant.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

This product is composed of a pure or almost pure substance.

3.1. Substances

Synonyms GM2-ganglioside, Sialosylganglio-N-triaosylceramide, Tay-Sachs ganglioside

Chemical formula $C_{67}H_{121}N_3O_{26} \cdot NH_3$ Molecular weight 1385 + NH3 (stearoyl)

Constituent			Purity	
Monosialoganglioside GM2 (human Tay-Sachs)				
CAS No	19600-01-2		>98%	

Occurrence of any impurity, stabilising additive, or individual ingredients other than the main ingredient is indicated by the chemical name and the purity level.

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal

SECTION 4: FIRST AID MEASURES

4.1. Description of first aid measures

Generally

In case of concern, or if symptoms persist, call doctor/physician.

Upon breathing in

Inhalation of fumes from heated product: let the injured rest at a warm place with fresh air. Contact the doctor if symptoms persist.

Upon contact with the eyes

As a precaution, rinse the eye thoroughly with water; If symptoms occur, call a doctor/physician.

Upon skin contact

Normal washing of the skin is considered sufficient; If nevertheless symptoms do occur, contact a physician.

Remove contaminated clothes.

Upon ingestion

Flush nose, mouth and throat with water.

Upon ingestion of larger amounts, consult a doctor/physician.

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

Ingestion of large amounts of the product may cause nausea and vomiting.

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

Symptomatic treatment.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Recommended extinguishing agents

Extinguish with materials intended for the surrounding fire.

Unsuitable extinguishing agents

Among common extinguishing agents there are none that are overtly unsuitable.

5.2. Special hazards arising from the substance or mixture

Produces fumes containing harmful gases (carbon monoxide and carbon dioxide) when burning.

The product is not hazardous in the flammable sense.

5.3. Advice for fire-fighters

In case of fire use a respirator mask.

Wear full protective clothing.

Protective measures should be taken regarding other material at the site of the fire.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Use recommended safety equipment, see section 8.

Note that there is a risk of slipping if product is leaking/spilling.

6.2. Environmental precautions

At amounts considered in this case, the product may be released into the natural environment without serious environmental consequences. Large emissions should however be reported to the emergency services and the Environment Agency.

6.3. Methods and material for containment and cleaning up

Small spills can be wiped up with a cloth or similar. Then flush the spill site with water. Larger spills should first be covered with sand or earth and then be collected. Collected material should be disposed according to Section 13.

6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for safe handling

Read and follow the manufacturer's instructions.

Avoid spillage, inhalation and contact with eyes and skin.

Keep well closed.

The usual precautions for handling chemicals should be observed.

7.2. Conditions for safe storage, including any incompatibilities

Store in dry and cool area.

Store in a ventilated space.

7.3. Specific end uses

See identified uses in Section 1.2.

SECTION 8: EXPOSURE CONTROLS/PERSONAL

PROTECTION

8.1. Control parameters

8.1.1. National limit values, United Kingdom

All ingredients (cf. Section 3) lack occupational exposure limit values.

8.2. Exposure controls

In terms of minimizing risks, no special attention is needed for this product besides the general obligations that follow EU directive 89/391 and national occupational legislation.

Eye protection is not necessary during normal use.

Protective gloves are normally not needed due to the properties of this product, but may be necessary for other reasons, e.g. mechanical risks, temperature conditions or microbiological risks.

Special measures for protection of the skin are necessary only in rare working situations. In case of doubt, consult occupational expertise. Show this safety data sheet.

Protective breathing equipment should only be required in extreme work-situations. Consult the manufacturer if this is the case. For limitation of environmental exposure, see Section 12.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

a)	Appearance	Form: solid
		Colour: white
b)	Odour	Not applicable
c)	Odour threshold	Not applicable
d)	pH	Not applicable
e)	Melting point/freezing point	Not applicable
f)	Initial boiling point and boiling range	Not applicable
g)	Flash point	Not applicable
h)	Evaporation rate	Not applicable
i)	Flammability (solid, gas)	Not applicable
j)	Upper/lower flammability or explosive limits	Not applicable
k)	Vapour pressure	Not applicable
1)	Vapour density	Not applicable
m)	Relative density	Not applicable
n)	Solubility	chloroform/methanol/water, 2:1:0.1; forms micellar solution in water
o)	Partition coefficient: n-octanol/water	Not applicable
p)	Auto-ignition temperature	Not applicable
q)	Decomposition temperature	Not applicable
r)	Viscosity	Not applicable
s)	Explosive properties	Not applicable
t)	Oxidising properties	Not applicable

9.2. Other information

No data available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity

The product contains no substances which can lead to hazardous reactions at normal use.

10.2. Chemical stability

The product is stable at normal storage and handling conditions.

10.3. Possibility of hazardous reactions

Not indicated

10.4. Conditions to avoid

Not indicated

10.5. Incompatible materials

Avoid contact with oxidizers.

10.6. Hazardous decomposition products

Carbon monoxide (CO), carbon dioxide (CO2) and harmful and irritating substances.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

General or unspecific toxicity

The product is not classified as toxic.

Acute effects

Not classified as an acutely toxic substance.

Harmfulness

The product is not classified as harmful to health.

Repeated dose toxicity

No chronic effects have been reported for this product.

Carcinogenicity

No carcinogenic effects have been reported for this product.

CMR effects

No mutagenic or reproductive toxic effects have been reported for this substance.

Sensibilisation

Not sensitising.

Corrosive and irritating effects

The product is not corrosive. Minor irritation may arise for persons who are prone/susceptible.

Synergism and antagonism

No information is available.

Effect on judgement and other psychological effects

Does not affect the judgement.

Relevant toxicological properties

Monosialoganglioside GM2 (human Tay-Sachs) No information available

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Monosialoganglioside GM2 (human Tay-Sachs)

No information available

No ecological damage is known or expected in the event of normal use.

12.2. Persistence and degradability

The components of the product degrades in the natural environment.

Not applicable

12.4. Mobility in soil

The product is not soluble in water and will spread on aquatic surfaces.

12.5. Results of PBT and vPvB assessment

No chemical safety report has been executed.

12.6. Other adverse effects

Not indicated

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Waste handling for the product

The product is not classified as hazardous waste.

Also take local regulations for dealing with waste into account.

Avoid discharge into sewers.

Recycling of the product

This product is not usually recycled.

Send to landfill.

Transportation of waste

Waste class J(0) - Does not have adverse effects on health or the environment.

SECTION 14: TRANSPORT INFORMATION

This product is only supposed to be transported by road or railway and just the transport regulations ADR/RID thus apply. If other means of transport are to be used, contact the publisher of this safety data sheet.

14.1. UN number

Not classified as dangerous goods

14.2. UN proper shipping name

Not applicable

14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

Not applicable

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable

SECTION 15: REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture Not applicable.

15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

SECTION 16: OTHER INFORMATION

16a. Indication of where changes have been made to the previous version of the safety data sheet Revisions of this document

This is the first version.

16b. Legend to abbreviations and acronyms used in the safety data sheet

Full texts for Hazard Class and Category Code mentioned in section 3

No tox haz Not classified as toxic

No phys haz Non-assigned physical hazard

No environmental hazard Not classified as being environmentally hazardous

Explanations of the abbreviations in Section 14

ADR European Agreement concerning the International Transport of Dangerous Goods by Road

RID Regulations concerning the International Transport of Dangerous Goods by Rail

16c. Key literature references and sources for data

Sources for data

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2015-06-05.

Where such data was lacking, on the second hand the documentation on which this official classification is based was used, e.g. IUCLID (International Uniform Chemical Information Database). On the third hand, information was used from reputable international chemical suppliers, and on the fourth hand from other available information, e.g. safety data sheets from other suppliers or information from non-profit associations, whereby the reliability of the source was judged by an expert. If, in spite of this, reliable information was not found, the hazards were judged by expert opinions based on the known properties of similar substances, and according to the principles in 1907/2006 and 1272/2008.

Full texts for Regulations mentioned in this Safety Data Sheet

- 453/2010 COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- 1272/2008 REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16
 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing
 Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
- 89/391 COUNCIL DIRECTIVE (89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work
- 1907/2006 REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18
 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),
 establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation
 (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and
 Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC Annex I

16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification

The calculation of the hazards of this mixture has been performed as an evaluation by applying a weight of evidence determination using expert judgement in accordance with 1272/2008 Annex I, weighing all available information having a bearing on the determination of the hazards of the mixture, and in accordance with 1907/2006 Annex XI.

16e. List of relevant hazard statements and/or precautionary statements

16f. Advice on any training appropriate for workers to ensure protection of human health and the environment Warning for misuse

This product is not expected to cause severe harm to humans or the environment. However the manufacturer, the distributor or the supplier cannot be responsible for unusual or criminal use of the product.

Other relevant information