

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

Print Date 07.08.2019

1. Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Tolerase™ L

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

Use of the Substance/Mixture : Ingredient/additive for dietary supplements

1.3 Details of the supplier of the safety data sheet

Company : DSM Nutritional Products Europe Ltd
PO Box 2676
CH-4002 Basel
Telephone : +41618157777
Telefax : +41618157770
E-mail address : sds.nutritionalproducts@dsm.com
Responsible/issuing person

1.4 Emergency telephone number

+41 848 00 11 77 (Carechem 24 International)

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)


Respiratory sensitisation, Category 1 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Classification (67/548/EEC, 1999/45/EC)

Sensitising R42: May cause sensitisation by inhalation.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Danger

Hazard statements : H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

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P342 + P311

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.

Disposal:

P501

Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

9031-11-2

Galactosidase, β -

2.3 Other hazards

Risk of dust explosion.

3. Composition/information on ingredients

Brief description of the product : Mixture (preparation) containing an enzyme and auxiliary substances

3.2 Mixtures

Hazardous components

Chemical Name	CAS-No. EC-No. Registration number	Classification (67/548/EEC)	Classification (REGULATION (EC) No 1272/2008)	Concentration [%]
Galactosidase, β -	9031-11-2 232-864-1	R42	Resp. Sens. 1A; H334	$\geq 5 - < 10$

For the full text of the R-phrases mentioned in this Section, see Section 16.

For the full text of the H-Statements mentioned in this Section, see Section 16.

4. First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
- If inhaled : Move to fresh air.
Consult a physician after significant exposure.
- In case of skin contact : Take off contaminated clothing and shoes immediately.
Wash off with soap and plenty of water.
If symptoms persist, call a physician.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
Obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : Inhalation may provoke the following symptoms:

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

Print Date 07.08.2019

Allergic reactions, Asthma

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : Treat symptomatically.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Water
Foam

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : None known.

5.3 Advice for firefighters

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.
Further information : Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
Consider dust explosion hazard.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Evacuate personnel to safe areas.
Use personal protective equipment.
Ensure adequate ventilation.
Avoid dust formation.
Avoid breathing dust.

6.2 Environmental precautions

Do not flush into surface water or sanitary sewer system.
Prevent further leakage or spillage if safe to do so.
If the product contaminates rivers and lakes or drains inform respective authorities.

6.3 Methods and materials for containment and cleaning up

Pick up and arrange disposal without creating dust.
Keep in suitable, closed containers for disposal.
Avoid formation of dust and aerosols.

6.4 Reference to other sections

For personal protection see section 8.
For disposal considerations see section 13.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

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7. Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Avoid formation of respirable particles.
Avoid exceeding the given occupational exposure limits (see section 8).
For personal protection see section 8.
Provide sufficient air exchange and/or exhaust in work rooms.
Dispose of rinse water in accordance with local and national regulations.
Smoking, eating and drinking should be prohibited in the application area.
- Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.
Take precautionary measures against static discharges.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Keep away from direct sunlight.
: Keep container tightly closed and dry.
- Storage temperature : < 15 °C

7.3 Specific end use(s)

- Specific use(s) : Not applicable

8. Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

- Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.
: Suitable mask with particle filter P3 (European Norm 143)
- Hand protection : Glove material: for example nitrile rubber
: Consider the hazard characteristics of this product and any special workplace conditions when selecting the appropriate type of protective gloves.
- Eye protection : Safety glasses with side-shields
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : When using do not eat or drink.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

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When using do not smoke.
Avoid contact with skin, eyes and clothing.
Do not breathe dust or spray mist.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance	: granular
Colour	: white - brown
Odour	: slight
Odour Threshold	: No information available.
pH	: No data available
Melting point/range	: not determined
Boiling point/boiling range	: not determined
Flash point	: Not applicable
Flammability (solid, gas)	: May form combustible dust concentrations in air
Vapour pressure	: Not applicable
Relative vapour density	: Not applicable
Density	: not determined
Water solubility	: easily soluble
Partition coefficient: n-octanol/water	: Not applicable
Auto-ignition temperature	: No data available
Thermal decomposition	: Decomposes on heating. Potential for exothermic hazard
Explosive properties	: Not explosive
Oxidizing properties	: No data available

9.2 Other information

Combustibility index for deposited dust	: 3 (22 °C)
	: 3 (100 °C)
Dust explosion class	: St(H)1 (Milled sample, Median value of the tested sample 0,053 mm, Loss on drying 0,5 %; The value was determined in the modified Hartmann tube.)
Minimum ignition energy	: 10 - 30 mJ (Milled sample, Median value of the tested sample 0,053 mm, Loss on drying 0,5 %, EN 13821) The Minimum ignition energy (MIE) of a dust/air mix depends on the particle size the water content and the temperature of the dust. The finer and the dryer the dust the lower the MIE.
	: General remark: The indicated dust explosion characteristics are only valid for this product and are sensitive to the sample's parameters.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

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Powder volume resistivity : ca. 9E+12 Ohmm (Product sample, Median value of the tested sample 0,161 mm, Loss on drying 5,5 %)
The material can accumulate static charge and can therefore cause electrical ignition.

Minimum ignition : 400 °C (Median value of the tested sample 0,161 mm)
temperature of a dust/air mix Product sample, determined in the BAM oven

Bulk density : ca. 420 kg/m³

10. Stability and reactivity

10.1 Reactivity

No hazards to be specially mentioned.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Dust may form explosive mixture in air.

10.4 Conditions to avoid

Heat.

10.5 Incompatible materials

Strong acids and strong bases
Strong oxidizing agents

10.6 Hazardous decomposition products

No decomposition if used as directed.

11. Toxicological information

11.1 Information on toxicological effects

Acute oral toxicity : LD50 (Rat): > 2 000 mg/kg
(calculated from LD50 of components)

Skin corrosion/irritation : Prolonged skin contact may cause skin irritation.

Serious eye damage/eye irritation : Dust contact with the eyes can lead to mechanical irritation.

Respiratory or skin sensitisation
Galactosidase, β- : May cause sensitisation by inhalation.

Carcinogenicity : No indication for carcinogenicity known.

Reproductive toxicity : No indication for adverse effects on fertility known.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

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STOT - repeated exposure : This information is not available.

Experience with human exposure: Inhalation

Galactosidase, β - : Inhalation may induce sensitization and may cause allergic reactions in sensitized individuals.

12. Ecological information

12.1 Toxicity

No data is available on the product itself.

12.2 Persistence and degradability

No data is available on the product itself.

12.3 Bioaccumulative potential

Bioaccumulation : No data available
Partition coefficient: n-octanol/water : Not applicable

12.4 Mobility in soil

Distribution among environmental compartments : No data available

12.5 Results of PBT and vPvB assessment

Assessment : not determined

12.6 Other adverse effects

Additional ecological information : There is no data available for this product.

13. Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.
Do not dispose of waste into sewer.
Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging : Dispose of as unused product.
Do not re-use empty containers.

14. Transport information

14.1 UN number

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

5014549

Version 2.1

Revision Date 03.02.2015

Print Date 07.08.2019

Not dangerous goods

IATA

Not dangerous goods

14.2 Proper shipping name

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.3 Transport hazard class

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.4 Packing group

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.5 Environmental hazards

ADR

Not dangerous goods

RID

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.6 Special precautions for user

Storage conditions in Section 7 should also be met during transportation.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

No data available

15. Regulatory information

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Tolerase™ L

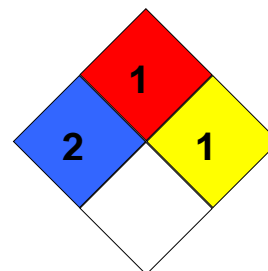
5014549

Version 2.1

Revision Date 03.02.2015

Print Date 07.08.2019

NFPA Classification : Health hazard: 2
Fire Hazard: 1
Reactivity Hazard: 1



15.2 Chemical Safety Assessment

Not applicable

16. Other information

Full text of R-phrases referred to under sections 2 and 3

R42 May cause sensitisation by inhalation.

Full text of H-Statements referred to under sections 2 and 3.

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

Abbreviations: 67/548/EEC= Dangerous Substances Directive. 1999/45/EC= Dangerous Preparations Directive. Regulation (EC) No. 1272/2008= Regulation on classification, labelling and packaging of substances and mixtures. DNEL= Derived No-Effect Level. PNEC= Predicted No-Effect Concentration. NFPA= National Fire Protection Association (USA). IATA= International Air Transport Association. IMDG= International Maritime Dangerous Goods. RID= International Rule for Transport of Dangerous Substances by Railway; ADR= European Agreement concerning the International Carriage of Dangerous Goods by Road. TWA= Time Weighted Average. STEL= Short term exposure limit. WEL = Workplace Exposure Limit.