

# Carbidopa / Levodopa Formulation

Version 4.6      Revision Date: 09.04.2021      SDS Number: 50126-00016      Date of last issue: 10.10.2020  
Date of first issue: 23.01.2015

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

### 1.1 Product identifier

Trade name : Carbidopa / Levodopa Formulation

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

Use of the Sub-stance/Mixture : Pharmaceutical

### 1.3 Details of the supplier of the safety data sheet

Company : Organon & Co.  
30 Hudson Street, 33rd floor  
07302 Jersey City, New Jersey, U.S.A

Telephone : 551-430-6000

E-mail address of person responsible for the SDS : EHSSTEWARD@organon.com

### 1.4 Emergency telephone number

215-631-6999

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## SECTION 2: Hazards identification



### 2.1 Classification of the substance or mixture

#### Classification (REGULATION (EC) No 1272/2008)

Acute toxicity, Category 4	H302: Harmful if swallowed.
Reproductive toxicity, Category 2	H361d: Suspected of damaging the unborn child.
Specific target organ toxicity - repeated exposure, Category 1	H372: Causes damage to organs through prolonged or repeated exposure.
Long-term (chronic) aquatic hazard, Category 3	H412: Harmful to aquatic life with long lasting effects.

### 2.2 Label elements

#### Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :  

Signal word : Danger

Hazard statements : H302 Harmful if swallowed.  
H361d Suspected of damaging the unborn child.  
H372 Causes damage to organs through prolonged or repeated exposure.  
H412 Harmful to aquatic life with long lasting effects.

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Precautionary statements : **Prevention:**  
P201 Obtain special instructions before use.  
P260 Do not breathe dust.  
P270 Do not eat, drink or smoke when using this product.  
P273 Avoid release to the environment.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

**Response:**  
P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Hazardous components which must be listed on the label:

Levodopa  
Carbidopa

### 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.

Dust contact with the eyes can lead to mechanical irritation.

Contact with dust can cause mechanical irritation or drying of the skin.

May form explosive dust-air mixture during processing, handling or other means.

## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Levodopa	59-92-7 200-445-2	Acute Tox. 4; H302 Repr. 2; H361d STOT RE 1; H372 (Central nervous system) Aquatic Chronic 3; H412	>= 70 - < 90
Carbidopa	38821-49-7	Acute Tox. 4; H302 Aquatic Chronic 3; H412	>= 10 - < 20

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately.  
When symptoms persist or in all cases of doubt seek medical advice.

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- Protection of first-aiders : First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).
- If inhaled : If inhaled, remove to fresh air.  
Get medical attention.
- In case of skin contact : In case of contact, immediately flush skin with soap and plenty of water.  
Remove contaminated clothing and shoes.  
Get medical attention.  
Wash clothing before reuse.  
Thoroughly clean shoes before reuse.
- In case of eye contact : If in eyes, rinse well with water.  
Get medical attention if irritation develops and persists.
- If swallowed : If swallowed, DO NOT induce vomiting.  
Get medical attention.  
Rinse mouth thoroughly with water.  
Never give anything by mouth to an unconscious person.

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

- Risks : Harmful if swallowed.  
Suspected of damaging the unborn child.  
Causes damage to organs through prolonged or repeated exposure.
- Contact with dust can cause mechanical irritation or drying of the skin.  
Dust contact with the eyes can lead to mechanical irritation.

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

- Treatment : Treat symptomatically and supportively.
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**SECTION 5: Firefighting measures****5.1 Extinguishing media**

- Suitable extinguishing media : Water spray  
Alcohol-resistant foam  
Carbon dioxide (CO<sub>2</sub>)  
Dry chemical
- Unsuitable extinguishing media : None known.

**5.2 Special hazards arising from the substance or mixture**

- Specific hazards during fire-fighting : Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

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Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Metal oxides

**5.3 Advice for firefighters**

Special protective equipment for firefighters : In the event of fire, wear self-contained breathing apparatus.  
Use personal protective equipment.

Specific extinguishing methods : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Use water spray to cool unopened containers.  
Remove undamaged containers from fire area if it is safe to do so.  
Evacuate area.

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**SECTION 6: Accidental release measures****6.1 Personal precautions, protective equipment and emergency procedures**

Personal precautions : Use personal protective equipment.  
Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

**6.2 Environmental precautions**

Environmental precautions : Avoid release to the environment.  
Prevent further leakage or spillage if safe to do so.  
Retain and dispose of contaminated wash water.  
Local authorities should be advised if significant spillages cannot be contained.

**6.3 Methods and material for containment and cleaning up**

Methods for cleaning up : Sweep up or vacuum up spillage and collect in suitable container for disposal.  
Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air).  
Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration.  
Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable.  
Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

**6.4 Reference to other sections**

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

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**SECTION 7: Handling and storage****7.1 Precautions for safe handling**

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- Technical measures : Static electricity may accumulate and ignite suspended dust causing an explosion.  
Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.
- Local/Total ventilation : Use only with adequate ventilation.
- Advice on safe handling : Do not breathe dust.  
Do not swallow.  
Avoid contact with eyes.  
Avoid prolonged or repeated contact with skin.  
Wash skin thoroughly after handling.  
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment  
Minimize dust generation and accumulation.  
Keep container closed when not in use.  
Keep away from heat and sources of ignition.  
Take precautionary measures against static discharges.  
Do not eat, drink or smoke when using this product.  
Take care to prevent spills, waste and minimize release to the environment.
- Hygiene measures : If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use.  
The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

**7.2 Conditions for safe storage, including any incompatibilities**

- Requirements for storage areas and containers : Keep in properly labelled containers. Store locked up. Store in accordance with the particular national regulations.
- Advice on common storage : Do not store with the following product types:  
Strong oxidizing agents  
Organic peroxides  
Explosives  
Gases

**7.3 Specific end use(s)**

- Specific use(s) : No data available

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

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Levodopa	59-92-7	TWA	500 µg/m <sup>3</sup> (OEB 2)	Internal
Carbidopa	38821-49-7	TWA	2,000 µg/m <sup>3</sup> (OEB 1)	Internal
Cellulose	9004-34-6	TWA OEL-RL	5 mg/m <sup>3</sup>	ZA OEL

# SAFETY DATA SHEET



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		(Respirable dust)		
	Further information: Recommended Limit			
		TWA OEL-RL (inhalable dust)	10 mg/m <sup>3</sup>	ZA OEL
	Further information: Recommended Limit			
		STEL OEL-RL (Dust)	20 mg/m <sup>3</sup>	ZA OEL
	Further information: Recommended Limit			
Starch	9005-25-8	TWA OEL-RL (Respirable dust)	5 mg/m <sup>3</sup>	ZA OEL
	Further information: Recommended Limit			
		TWA OEL-RL (inhalable dust)	10 mg/m <sup>3</sup>	ZA OEL
	Further information: Recommended Limit			

### 8.2 Exposure controls

#### Engineering measures

Use feasible engineering controls to minimize exposure to compound.  
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.

#### Personal protective equipment

- Eye protection : Wear safety glasses with side shields or goggles.  
If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles.  
Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.
- Hand protection  
Material : Chemical-resistant gloves
- Skin and body protection : Work uniform or laboratory coat.
- Respiratory protection : If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.
- Filter type : Particulates type (P)

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

- Appearance : powder
- Colour : No data available
- Odour : odourless
- Odour Threshold : No data available
- pH : No data available
- Melting point/freezing point : No data available
- Initial boiling point and boiling range : No data available
- Flash point : No data available

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Evaporation rate	:	No data available
Flammability (solid, gas)	:	May form explosive dust-air mixture during processing, handling or other means.
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

### 9.2 Other information

Flammability (liquids)	:	No data available
Molecular weight	:	No data available
Particle size	:	No data available

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## SECTION 10: Stability and reactivity

### 10.1 Reactivity

Not classified as a reactivity hazard.

### 10.2 Chemical stability

Stable under normal conditions.

### 10.3 Possibility of hazardous reactions

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Hazardous reactions : May form explosive dust-air mixture during processing, handling or other means.  
Can react with strong oxidizing agents.

**10.4 Conditions to avoid**

Conditions to avoid : Heat, flames and sparks.  
Avoid dust formation.

**10.5 Incompatible materials**

Materials to avoid : Oxidizing agents

**10.6 Hazardous decomposition products**

No hazardous decomposition products are known.

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**SECTION 11: Toxicological information****11.1 Information on toxicological effects**

Information on likely routes of exposure : Inhalation  
Skin contact  
Ingestion  
Eye contact

**Acute toxicity**

Harmful if swallowed.

**Product:**

Acute oral toxicity : Acute toxicity estimate: 1.952 mg/kg  
Method: Calculation method

**Components:****Levodopa:**

Acute oral toxicity : LD50 (Rat): 1.780 mg/kg  
LD50 (Mouse): 2.363 mg/kg

**Carbidopa:**

Acute oral toxicity : LD50 (Rat): 4.810 mg/kg  
LD50 (Mouse): 1.750 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****Carbidopa:**

Species : Rabbit  
Result : No skin irritation



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**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****Carbidopa:**

Species : Rabbit  
Result : Mild eye irritation

**Respiratory or skin sensitisation****Skin sensitisation**

Not classified based on available information.

**Respiratory sensitisation**

Not classified based on available information.

**Components:****Levodopa:**

Species : Guinea pig  
Result : Not a skin sensitizer.

**Carbidopa:**

Remarks : No data available

**Germ cell mutagenicity**

Not classified based on available information.

**Components:****Levodopa:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: negative

Test Type: Chromosomal aberration  
Test system: mouse lymphoma cells  
Result: equivocal

Test Type: Micronucleus test  
Test system: Chinese hamster lung cells  
Result: positive

Test Type: sister chromatid exchange assay  
Test system: Chinese hamster lung cells  
Result: positive

**Carbidopa:**

Genotoxicity in vitro : Test Type: Bacterial reverse mutation assay (AMES)  
Result: positive

Test Type: In vitro mammalian cell gene mutation test  
Result: positive

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Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse  
Application Route: Oral  
Result: negative

**Carcinogenicity**

Not classified based on available information.

**Components:****Levodopa:**

Species : Rat  
Application Route : Oral  
Exposure time : 2 Years  
Result : negative

**Carbidopa:**

Species : Rat  
Application Route : Oral  
Exposure time : 96 weeks  
: 135 mg/kg body weight  
Result : negative

**Reproductive toxicity**

Suspected of damaging the unborn child.

**Components:****Levodopa:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 100 mg/kg body weight  
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: LOAEL: 125 mg/kg body weight  
Symptoms: Skeletal malformations, Visceral malformations  
Result: positive

Test Type: Development  
Species: Rat  
Application Route: Oral  
Developmental Toxicity: LOAEL: 10 mg/kg body weight

Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: LOAEL: 500 mg/kg body weight  
Symptoms: Effects on foetal development  
Result: positive

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Reproductive toxicity - Assessment : Some evidence of adverse effects on development, based on animal experiments.

**Carbidopa:**

Effects on fertility : Test Type: Fertility  
Species: Rat  
Application Route: Oral  
Fertility: NOAEL: 120 mg/kg body weight  
Symptoms: Reduced body weight  
Result: Animal testing did not show any effects on fertility.

Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Oral  
Developmental Toxicity: NOAEL: 120 mg/kg body weight  
Result: No teratogenic effects

Test Type: Development  
Species: Rabbit  
Application Route: Oral  
Developmental Toxicity: NOAEL: 120 mg/kg body weight  
Result: No teratogenic effects

**STOT - single exposure**

Not classified based on available information.

**STOT - repeated exposure**

Causes damage to organs through prolonged or repeated exposure.

**Components:****Levodopa:**

Exposure routes : Oral  
Target Organs : Central nervous system  
Assessment : Causes damage to organs through prolonged or repeated exposure.

**Repeated dose toxicity****Components:****Levodopa:**

Species : Rat  
LOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 106 Weeks  
Target Organs : Central nervous system  
Symptoms : Salivation

Species : Monkey  
LOAEL : 100 mg/kg  
Application Route : Oral  
Exposure time : 22 Weeks  
Target Organs : Central nervous system

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**Carbidopa:**

Species : Rat  
 LOAEL : 25 mg/kg  
 Application Route : Oral  
 Exposure time : 96 Weeks  
 Remarks : No significant adverse effects were reported

Species : Monkey  
 NOAEL : 135 mg/kg  
 Application Route : Oral  
 Exposure time : 1 yr  
 Remarks : No significant adverse effects were reported

Species : Dog  
 NOAEL : 5 mg/kg  
 LOAEL : 15 mg/kg  
 Application Route : Oral  
 Exposure time : 238 d  
 Symptoms : Diarrhoea, Vomiting, Tremors

**Aspiration toxicity**

Not classified based on available information.

**Experience with human exposure****Components:****Levodopa:**

Ingestion : Symptoms: Nausea, central nervous system effects, Drowsiness

**Carbidopa:**

Ingestion : Symptoms: involuntary movement

**SECTION 12: Ecological information****12.1 Toxicity****Components:****Levodopa:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 16 mg/l  
 Exposure time: 48 h

**Carbidopa:**

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 35,3 mg/l  
 Exposure time: 48 h  
 Method: OECD Test Guideline 202

**12.2 Persistence and degradability**

No data available

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**12.3 Bioaccumulative potential****Components:****Levodopa:**

Partition coefficient: n-octanol/water : log Pow: -2,39

**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 Other adverse effects****Product:**

Endocrine disrupting potential : 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.

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

Product : Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.  
If not otherwise specified: Dispose of as unused product.

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

Not regulated as a dangerous good

**14.2 UN proper shipping name**

Not regulated as a dangerous good

**14.3 Transport hazard class(es)**

Not regulated as a dangerous good

**14.4 Packing group**

Not regulated as a dangerous good

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**14.5 Environmental hazards**

Not regulated as a dangerous good

**14.6 Special precautions for user**

Not applicable

**14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Remarks : Not applicable for product as supplied.

**SECTION 15: Regulatory information****15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****The components of this product are reported in the following inventories:**

AICS : not determined

DSL : not determined

IECSC : not determined

**15.2 Chemical safety assessment**

A Chemical Safety Assessment has not been carried out.

**SECTION 16: Other information**

Other information : Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

**Full text of H-Statements**

H302 : Harmful if swallowed.

H361d : Suspected of damaging the unborn child.

H372 : Causes damage to organs through prolonged or repeated exposure if swallowed.

H412 : Harmful to aquatic life with long lasting effects.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Repr. : Reproductive toxicity

STOT RE : Specific target organ toxicity - repeated exposure

ZA OEL : South Africa. Hazardous Chemical Substances Regulations, Occupational Exposure Limits

ZA OEL / TWA OEL-RL : Long term occupational exposure limits - recommended limit

ZA OEL / STEL OEL-RL : Short term occupational exposure limits - recommended limit

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AIIC - 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 - Con-

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centration 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; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

Sources of key data used to compile the Safety Data Sheet : Internal technical data, data from raw material SDSs, OECD eChem Portal search results and European Chemicals Agency, <http://echa.europa.eu/>

**Classification of the mixture:**

Acute Tox. 4	H302
Repr. 2	H361d
STOT RE 1	H372
Aquatic Chronic 3	H412

**Classification procedure:**

Calculation method
Calculation method
Calculation method
Calculation method

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 is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user's end product, if applicable.

ZA / EN