

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006, as amended by  
Commission Regulation (EU) 2020/878



## Propentofylline Formulation

Version  
5.0

Revision Date:  
14.04.2025

SDS Number:  
2935920-00020

Date of last issue: 28.09.2024  
Date of first issue: 25.06.2018

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

#### 1.1 Product identifier

Trade name : Propentofylline Formulation  
Other means of identification : Vivitonin (A005114)  
VIVITONIN 50 TABLETS FOR AGED DOGS (51394)  
VIVITONIN 100 TABLETS FOR AGED DOGS (49892)

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

Use of the Substance/Mixture : Veterinary product  
Recommended restrictions on use : Not applicable

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

Company : MSD  
Drynam Road  
K67 P263 Dublin, Ireland  
Telephone : +1-908-740-4000  
E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

#### 1.4 Emergency telephone number

+1-908-423-6000

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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.  
Specific target organ toxicity - repeated exposure, Category 2 : H373: May cause damage to organs through prolonged or repeated exposure.

#### 2.2 Label elements

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

Hazard pictograms :    
Signal word : Warning

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Hazard statements : H302      Harmful if swallowed.  
H373      May cause damage to organs through prolonged or repeated exposure.

Precautionary statements : **Prevention:**  
P260      Do not breathe dust.  
P264      Wash skin thoroughly after handling.  
P270      Do not eat, drink or smoke when using this product.

**Response:**

P301 + P312 + P330      IF SWALLOWED: Call a POISON CENTER/ doctor if you feel unwell. Rinse mouth.  
P314      Get medical advice/ attention if you feel unwell.

### Hazardous components which must be listed on the label:

Propentofylline

### Additional Labelling

The following percentage of the mixture consists of ingredient(s) with unknown hazards to the aquatic environment: 50 %

### 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.

Dust contact with the eyes can lead to mechanical irritation.

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

May form combustible dust concentrations in air during processing, handling or other means.

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## SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

#### Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Propentofylline	55242-55-2	Acute Tox. 4; H302 STOT RE 2; H373	>= 50 - < 70

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For explanation of abbreviations see section 16.

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## 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.
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 if symptoms occur.
In case of skin contact	: Wash with water and soap. Get medical attention if symptoms occur.
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 unless directed to do so by medical personnel. 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	: Contact with dust can cause mechanical irritation or drying of the skin. Dust contact with the eyes can lead to mechanical irritation.  Harmful if swallowed. May cause damage to organs through prolonged or repeated exposure.
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### 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
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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.  
Exposure to combustion products may be a hazard to health.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NOx)

### 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 deter-

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mine 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

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 in accordance with the particular national regulations.
Advice on common storage	: Do not store with the following product types: Strong oxidizing agents

### 7.3 Specific end use(s)

Specific use(s)	: No data available
	No data available

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

dusts non-specific

4 mg/m<sup>3</sup>

Value type (Form of exposure): OELV - 8 hrs (TWA) (Respirable dust)  
Basis: IE OEL

10 mg/m<sup>3</sup>

Value type (Form of exposure): OELV - 8 hrs (TWA) (inhalable dust)  
Basis: IE OEL

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Propentofylline	55242-55-2	TWA	1000 µg/m <sup>3</sup> ( OEB 1)	Internal
Starch	9005-25-8	OELV - 8 hrs (TWA) (Respirable dust)	4 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m <sup>3</sup>	IE OEL
Talc	14807-96-6	OELV - 8 hrs (TWA) (Respirable dust)	0.8 mg/m <sup>3</sup>	IE OEL
		OELV - 8 hrs (TWA) (inhalable dust)	10 mg/m <sup>3</sup>	IE OEL

### 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/face 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  
Respiratory protection : Work uniform or laboratory coat.  
: If adequate local exhaust ventilation is not available or expo-

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Filter type : Particulates type (P)  
sure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.  
Equipment should conform to I.S. EN 143

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Physical state : tablet, powder  
Colour : No data available  
Odour : No data available  
Odour Threshold : No data available  
Melting point/freezing point : No data available  
Initial boiling point and boiling range : No data available  
Flammability (solid, gas) : May form combustible dust concentrations in air during processing, handling or other means.  
Flammability (liquids) : Not applicable  
Upper explosion limit / Upper flammability limit : No data available  
Lower explosion limit / Lower flammability limit : No data available  
Flash point : Not applicable  
Auto-ignition temperature : No data available  
Decomposition temperature : No data available  
pH : Not applicable  
Viscosity  
Viscosity, kinematic : Not applicable  
Solubility(ies)  
Water solubility : No data available  
Solubility in other solvents : No data available  
Partition coefficient: n- : Not applicable

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octanol/water

Vapour pressure : Not applicable  
Relative density : No data available  
Density : No data available  
Relative vapour density : Not applicable  
Particle characteristics  
    Particle size : No data available

### 9.2 Other information

Explosives : Not explosive  
Oxidizing properties : The substance or mixture is not classified as oxidizing.  
Evaporation rate : Not applicable  
Molecular weight : Not applicable

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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

Hazardous reactions : May form combustible dust concentrations in air 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 hazard classes as defined in Regulation (EC) No 1272/2008

Information on likely routes of : Inhalation

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exposure      Skin contact  
Ingestion  
Eye contact

### Acute toxicity

||| Harmful if swallowed.

#### Product:

Acute oral toxicity : Acute toxicity estimate: 1,880 mg/kg  
Method: Calculation method

#### Components:

##### Propentofylline:

||| Acute oral toxicity : LD50 (Rat): 940 mg/kg  
Symptoms: Breathing difficulties, Convulsions, Lachrymation  
LD50 (Mouse): 780 mg/kg  
LD50 (Rabbit): 405 mg/kg

##### Skin corrosion/irritation

||| Not classified based on available information.

##### Serious eye damage/eye irritation

||| Not classified based on available information.

##### Respiratory or skin sensitisation

##### Skin sensitisation

||| Not classified based on available information.

##### Respiratory sensitisation

||| Not classified based on available information.

##### Germ cell mutagenicity

||| Not classified based on available information.

##### Carcinogenicity

||| Not classified based on available information.

##### Reproductive toxicity

||| Not classified based on available information.

#### Components:

##### Propentofylline:

||| Effects on foetal development : Test Type: Development  
Species: Mouse  
Application Route: Ingestion  
Developmental Toxicity: NOAEL: 500 mg/kg body weight  
Result: No adverse effects

Test Type: Development

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Species: Rabbit  
Application Route: Ingestion  
Developmental Toxicity: NOAEL: 150 mg/kg body weight  
Result: No teratogenic effects

### STOT - single exposure

Not classified based on available information.

### STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

### Components:

#### Propentofylline:

Exposure routes	:	Oral
Assessment	:	May cause damage to organs through prolonged or repeated exposure.
Remarks	:	Based on human experience.

### Aspiration toxicity

Not classified based on available information.

## 11.2 Information on other hazards

### Endocrine disrupting properties

Not classified based on available information.

### 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.
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### Experience with human exposure

### Components:

#### Propentofylline:

Ingestion	:	Target Organs: Blood Target Organs: Lungs Target Organs: Cardiovascular Target Organs: Gastro-intestinal system Symptoms: Gastrointestinal discomfort, Nausea Target Organs: Nervous system Symptoms: Dizziness, Headache
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## SECTION 12: Ecological information

### 12.1 Toxicity

#### Components:

#### Propentofylline:

##### **Ecotoxicology Assessment**

Acute aquatic toxicity	: Toxic effects cannot be excluded
Chronic aquatic toxicity	: Toxic effects cannot be excluded

### 12.2 Persistence and degradability

No data available

### 12.3 Bioaccumulative potential

#### Components:

#### Propentofylline:

Partition coefficient: n-octanol/water	: log Pow: 1.540
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### 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.
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### 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.
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### 12.7 Other adverse effects

No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product	: Dispose of in accordance with local regulations.
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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.

Do not dispose of waste into sewer.

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.

## SECTION 14: Transport information

### 14.1 UN number or ID number

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : 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

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : 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)

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : Not regulated as a dangerous good  
IMDG : Not regulated as a dangerous good  
IATA : Not regulated as a dangerous good

### 14.4 Packing group

ADN : Not regulated as a dangerous good  
ADR : Not regulated as a dangerous good  
RID : 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

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### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Not applicable

### 14.7 Maritime transport in bulk according to IMO instruments

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

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 (EU) No 2024/590 on substances that deplete the ozone layer	: Not applicable
Regulation (EU) 2019/1021 on persistent organic pollutants (recast)	: 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
Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.	
	Not applicable

#### Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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

DSL	: not determined
AICS	: 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.
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### Full text of H-Statements

H302 : Harmful if swallowed.  
H373 : May cause damage to organs through prolonged or repeated exposure if swallowed.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
STOT RE : Specific target organ toxicity - repeated exposure  
IE OEL : Ireland. List of Chemical Agents and Carcinogens with Occupational Exposure Limit Values - Code of Practice, Schedule 1 and 2  
IE OEL / OELV - 8 hrs (TWA) : Occupational exposure limit value (8-hour reference period)

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

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/>

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### Classification of the mixture:

Acute Tox. 4 H302  
STOT RE 2 H373

### Classification procedure:

Calculation method  
Calculation method

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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.

IE / EN