


<p align="center"><b>SAFETY DATA SHEET</b> based on Regulation (EC) No. 1907/2006</p>	
<p><b>Fluzone Influenza Vaccine (no preservative)</b> Substance key: REG001458 Version:1.0 (European Community) Revision Date: 18.04.2024<sup>EU</sup></p>	

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

### 1.1 Product identifier

Product name: Fluzone Influenza Vaccine (no preservative)

Synonyms: 371 Trivalent Influenza Vaccine, Types A&B, No Preservative with Triton X-100 Fortification

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

Use of the Substance/Mixture : Drug product for medical use.

This document, established by Sanofi on a voluntary basis, aims at providing available information on the substances contained in our products and on the related risk management measures.

This document is intended for use in the workplace and shall not be used in place of package inserts or other prescribing information, nor in place of any mandatory document (e.g SDS within the meaning of the REACH Regulation).

Although the information contained in the document has been prepared based on the best of our knowledge and is accurate as of the date shown on the document, such document is provided «as is», without any warranty, either expressed or implied.

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

Company : Sanofi

Street address : 46-48 avenue de la Grande-Armée  
(FR) 75017 Paris

Telephone : +33153774000

Telefax : +33153774133

Safety data sheet created by:  
Sanofi Global Product Stewardship (product-stewardship-global@sanofi.com)

**1.4. Emergency telephone number : + 33 1 45 42 59 59 (ORFILA)**

Additional National Emergency Telephone Numbers see Annex.

## SECTION 2: Hazards identification

### 2.1 Classification of the substance or mixture

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

Not a hazardous substance or mixture.

### 2.2 Label elements

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

Not a hazardous substance or mixture.

Supplemental Hazard Statements : EUH210 Safety data sheet available on request.

EUH208 Contains Formaldehyde (CAS-No.: 50-00-0). May produce an allergic reaction.

based on Regulation (EC) No. 1907/2006



Substance key: REG001458 Version:1.0 (European Community) Revision Date: 18.04.2024

Formaldehyd

Physical, chemical and toxicological hazards : Avoid contact with skin and eyes

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.

**Sanofi hazard bands:**

Further information see chapter 16.


Safety : No data available for mixture.

### SECTION 3: Composition/information on ingredients

### 3.2 Mixtures

Product Description : Vaccine indicated for active immunization for the prevention of influenza disease caused by influenza A subtype viruses and type B

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
Formaldehyde	50-00-0 200-001-8 605-001-00-5	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1B; H314 Eye Dam. 1; H318 Skin Sens. 1; H317 Muta. 2; H341 Carc. 1B; H350 <u>Aquatic Chronic 2; H411</u>  specific concentration limit Skin Corr. 1B; H314 >= 25 % Skin Irrit. 2; H315 5 - < 25 % Eye Irrit. 2; H319 5 - < 25 % STOT SE 3; H335 >= 5 % Skin Sens. 1; H317 >= 0,2 %	>= 0,025 - < 0,1

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Non-hazardous ingredients:

SODIUM CHLORIDE

SODIUM DIHYDROGEN PHOSPHATE

DISODIUM HYDROGEN PHOSPHATE

Water

Mixture of 3 strains of inactivated hemagglutinin - placeholder until further data is available

For explanation of abbreviations see section 16.

## SECTION 4: First aid measures

### 4.1 Description of first aid measures

General advice	: Move out of dangerous area. Take off immediately all contaminated clothing. Get immediate medical advice/ attention.
If inhaled	: Move to fresh air. Get immediate medical advice/ attention.
In case of skin contact	: Rinse immediately with plenty of water for at least 15 minutes. Get immediate medical advice/ attention.
In case of eye contact	: Rinse immediately with plenty of water, also under the eyelids, for at least 15 minutes. Get immediate medical advice/ attention.
If swallowed	: Get immediate medical advice/ attention. Do NOT induce vomiting. Rinse mouth with water. If a person vomits when lying on his back, place him in the recovery position.

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

Symptoms	: No information available.
Risks	: No information available.

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

Treatment	: Treat symptomatically.
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## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.
Unsuitable extinguishing media	: Do NOT use water jet.

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

Hazardous combustion products	: Carbon oxides
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### 5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear an approved positive pressure self-contained breathing apparatus in addition to standard fire fighting gear.
- Further information : Prevent fire extinguishing water from contaminating surface water or the ground water system.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

- Personal precautions : No personal respiratory protective equipment normally required.  
Safety glasses with side-shields  
Wear suitable gloves.  
Wear suitable protective clothing.  
Only qualified personnel equipped with suitable protective equipment may intervene.

### 6.2 Environmental precautions

- Environmental precautions : Prevent further leakage or spillage.  
Do not let product enter drains.

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

- Methods for cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Sweep up and shovel into suitable containers for disposal.  
Close and label thoroughly.

### 6.4 Reference to other sections

Information regarding Safe handling, see chapter 7., For further information see Section 8 of the safety data sheet., For disposal considerations see section 13.


## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

- Advice on safe handling : No special handling advice required.
- Advice on protection against fire and explosion : To avoid ignition of vapours by static electricity discharge, all metal parts of the equipment must be grounded. Keep away from sources of ignition - No smoking.
- Hygiene measures : When using, do not eat, drink or smoke. Keep away from foodstuffs and beverages. Wash hands before breaks and at the end of workday.

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

- Further information on storage conditions : Keep tightly closed in a dry and cool place. Keep away from direct sunlight.

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Storage temperature : Recommended storage temperature: +2°C to +8°C.

### 7.3 Specific end use(s)

## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

#### Occupational Exposure Limits

Components	CAS-No.	Value type (Form of exposure)	Control parameters	Basis
Formaldehyde	50-00-0	TWA	0,3 ppm 0,37 mg/m3	2004/37/EC
Further information: Dermal sensitisation, Carcinogens or mutagens				
		STEL	0,6 ppm 0,74 mg/m3	2004/37/EC
Further information: Dermal sensitisation, Carcinogens or mutagens				

#### Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

Substance name	End Use	Exposure routes	Potential health effects	Value
SODIUM DIHYDROGEN PHOSPHATE	Workers	Inhalation	Long-term systemic effects	13,07 mg/m3

### 8.2 Exposure controls

#### Personal protective equipment

Eye protection : Safety glasses with side-shields conforming to EN166

Hand protection

Material : Nitrile rubber  
Rate of permeability : > 480 min  
Glove thickness : > 0,1 mm

Remarks : The protective gloves to be used must comply with the specifications of EC directive 89/686/EEC and the resultant standard EN374.  
This recommendation applies only to the product stated in this safety data sheet and supplied by us as well as to the purpose specified by us. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves.


Skin and body protection : Wear suitable protective clothing.

Respiratory protection : Usually, no respiratory protection required.

Protective measures : Avoid contact with skin and eyes.  
A workplace risk assessment must be carried out in order to determine the correct engineering control measures and personal protective equipment.

#### Laboratory

Respiratory protection : Usually, no respiratory protection required.

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Hand protection	:	Nitrile rubber Layer thickness > 0.11 mm. Breakthrough time > 480 min.
Eye/face protection	:	Safety glasses with side-shields conforming to EN166
Body Protection	:	Wear suitable protective clothing.
Hygiene measures	:	Wash hands before breaks and at the end of workday.

## SECTION 9: Physical and chemical properties

### 9.1 Information on basic physical and chemical properties

Form	:	solution
Physical state	:	liquid (20 °C, 1.013 hPa)
Colour	:	No data available
Odour	:	No data available
Melting point/range	:	not determined
Boiling point	:	not determined
Flash point	:	not determined
Auto-ignition temperature	:	not determined
Decomposition temperature	:	not determined
pH	:	approx. 7,6 (20 °C)
Viscosity		
Viscosity, dynamic	:	1,2 mPa.s (20 °C)
Viscosity, kinematic	:	not determined
Solubility(ies)		
Water solubility	:	not determined
Solubility in other solvents	:	not determined
Partition coefficient: n-octanol/water	:	not determined
Vapour pressure	:	not determined
Density	:	1,008 g/cm <sup>3</sup> (20 °C)
Relative vapour density	:	not determined
Auto-ignition temperature	:	not determined
Lower explosion limit	:	not determined
Upper explosion limit	:	not determined

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Minimum ignition energy : not determined

Impact sensitivity : not determined

Safety remarks : No particular observation.

None known.

**Possibility of hazardous reactions**  
Hazardous reactions : None known.

Conditions to avoid : None known.

Materials to avoid : None known.

In case of fire hazardous decomposition products may be produced such as:

Carbon dioxide (CO<sub>2</sub>)

Carbon monoxide

**Sanofi Safety Hazard Band Components (Further information see chapter 16.):**


Fluzone Influenza Vaccine (no preservative)	: No data available for mixture.
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## SECTION 11: Toxicological information

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

### Acute toxicity

Product name (CAS-No.)	Test Type	Species	Result	Method, Symptoms	Remarks
Product name (CAS-No.)	Test Type	Species	Result	Method, Symptoms	Remarks
Formaldehyde (50-00-0)	Acute oral toxicity	LD50 (Rat, male)	460 mg/kg	Method: OECD Test Guideline 401	
Formaldehyde (50-00-0)	Acute inhalation toxicity	LC50 (Rat, male and female)	463 ppm	Exposure time: 4 h Test atmosphere: vapour	

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#### Skin corrosion/irritation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone Influenza Vaccine (no preservative)				No data available for mixture.
Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Formaldehyde (50-00-0)	Rabbit (20 h)	Causes burns.	OECD Test Guideline 404	

#### Serious eye damage/eye irritation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone Influenza Vaccine (no preservative)				No data available for mixture.

#### Respiratory or skin sensitisation

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Fluzone Influenza Vaccine (no preservative)				No data available for mixture.
Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Formaldehyde (50-00-0)		The product is a skin sensitiser, sub-category 1A.		

#### Carcinogenicity/Germ cell mutagenicity/Reproductive toxicity - Assessment

Product name (CAS-No.)	Carcinogenicity	Germ cell mutagenicity	Reproductive toxicity	Remarks
Fluzone Influenza Vaccine (no preservative)	not determined	not determined	Reproduction: not determined Teratogenicity: not determined	

#### Carcinogenicity/Germ cell mutagenicity/Reproductive toxicity - Assessment

Product name (CAS-No.)	Carcinogenicity	Germ cell mutagenicity	Reproductive toxicity	Remarks
Formaldehyde (50-00-0)	Positive evidence from human epidemiological studies No data available	Classification not possible No data available	Reproduction: No data available No data available Teratogenicity: No data available	

#### STOT - single exposure

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Fluzone Influenza Vaccine (no preservative)	STOT-single exposure				No data available for mixture.
Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Formaldehyde (50-00-0)	STOT-single exposure				No data available

#### STOT - repeated exposure

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Fluzone Influenza Vaccine (no preservative)	STOT - repeated				No data available



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Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
preservative)	exposure				for mixture.
Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Formaldehyde (50-00-0)	STOT - repeated exposure				No data available

#### Aspiration toxicity

Product name (CAS-No.)	Test Type	Result	Remarks
Fluzone Influenza Vaccine (no preservative)	Aspiration toxicity	No data available for mixture.	
Product name (CAS-No.)	Test Type	Result	Remarks
Formaldehyde (50-00-0)	Aspiration toxicity	No data available	

### 11.2 Information on other hazards

#### Endocrine disrupting properties

Product name (CAS-No.)	Remarks
Fluzone Influenza Vaccine (no preservative)	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. Source: Calculated

#### Further information

Product name (CAS-No.)	Remarks
Formaldehyde (50-00-0)	Remarks: The data we have is not sufficient for an industrial toxicological evaluation. Usual hygienic measures must be taken as the case is when dealing with chemicals. LD50 values are not known. Health hazard effects cannot be ruled out because of skin contact, inhalation or swallowing of the product.


## SECTION 12: Ecological information

### 12.1 Toxicity

Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Fluzone Influenza Vaccine (no preservative)	Toxicity to fish				No data available for mixture.
Fluzone Influenza Vaccine (no preservative)	Toxicity to daphnia and other aquatic invertebrates				No data available for mixture.
Fluzone Influenza Vaccine (no preservative)	Toxicity to algae/aquatic plants				No data available for mixture.
Fluzone Influenza Vaccine (no preservative)	Toxicity to microorganisms				No data available for mixture.
Fluzone Influenza Vaccine (no preservative)	Toxicity to soil dwelling organisms				No data available for mixture.

#### Components:

Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Formaldehyde (50-00-0)	Toxicity to fish	LC50 (Fish)	6,18 mg/l Exposure time: 96 h		

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Formaldehyde (50-00-0)	Toxicity to fish	NOEC (Oryzias latipes (Orange-red killifish))	> 48 mg/l Exposure time: 28 d		
Formaldehyde (50-00-0)	Toxicity to daphnia and other aquatic invertebrates	EC50 (Daphnia magna (Water flea))	5,8 mg/l Exposure time: 48 h		
Formaldehyde (50-00-0)	Toxicity to daphnia and other aquatic invertebrates	NOEC (Daphnia magna Straus)	> 6,4 mg/l Exposure time: 21 d		
Formaldehyde (50-00-0)	Toxicity to algae/aquatic plants Exposure time: 72 h	EC50 (Desmodesmus subspicatus (green algae))	4,89 mg/l		
Formaldehyde (50-00-0)	Toxicity to fish (Chronic toxicity)				No data available
Formaldehyde (50-00-0)	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)	Daphnia magna (Water flea)	EC10: 6,4 mg/l		
Formaldehyde (50-00-0)	Toxicity to microorganisms				No data available

## 12.2 Persistence and degradability

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Fluzone Influenza Vaccine (no preservative)	Biodegradability				No data available for mixture.

### Components:

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Formaldehyde (50-00-0)	Biodegradability				No data available

## 12.3 Bioaccumulative potential

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Fluzone Influenza Vaccine (no preservative)	Bioaccumulation				No data available for mixture.

### Components:

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Formaldehyde (50-00-0)	Bioaccumulation				No data available
Formaldehyde (50-00-0)	Partition coefficient: n-octanol/water		log Pow: 0,35 (25 °C)		


## 12.4 Mobility in soil

No data available

## 12.5 Results of PBT and vPvB assessment

Product name (CAS-No.)	Result
Fluzone Influenza Vaccine (no preservative)	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 Endocrine disrupting properties

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Product name (CAS-No.)	Result
Fluzone Influenza Vaccine (no preservative)	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.

## 12.7 Other adverse effects

Product name (CAS-No.)	Test Type	Result
Formaldehyde (50-00-0)	Additional ecological information	No information on ecology is available. Do not allow uncontrolled discharge of product into the environment.

## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

- Product : Dispose of contents/ container to an approved waste disposal plant.
- Contaminated packaging : Dispose of contents/ container to an approved waste disposal plant.  
Do not re-use empty containers.

## SECTION 14: Transport information

### 14.1 UN number or ID 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

### 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

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 - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable
- REACH - List of substances subject to authorisation (Annex XIV) : Not listed
- Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not listed
- Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not listed
- Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not listed

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REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered:  
Formaldehyde (Number on list 72, 28)

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

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)  
Not applicable

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

TCSI : Not in compliance with the inventory

TSCA : Product contains substance(s) not listed on TSCA inventory.

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : Not in compliance with the inventory

PICCS : Not in compliance with the inventory

IECSC : Not in compliance with the inventory

NZIoC : Not in compliance with the inventory

## 15.2 Chemical safety assessment

### SECTION 16: Other information

Date of first issue: 18.04.2024

Date of last issue: -

**Full text of H-Statements**

H301 : Toxic if swallowed.

H311 : Toxic in contact with skin.

H314 : Causes severe skin burns and eye damage.

H317 : May cause an allergic skin reaction.

H318 : Causes serious eye damage.

H330 : Fatal if inhaled.

H341 : Suspected of causing genetic defects.

H350 : May cause cancer.


H411 : Toxic to aquatic life with long lasting effects.

**Full text of other abbreviations**

Acute Tox. : Acute toxicity

Aquatic Chronic : Long-term (chronic) aquatic hazard

Carc. : Carcinogenicity

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Eye Dam.	: Serious eye damage
Muta.	: Germ cell mutagenicity
Skin Corr.	: Skin corrosion
Skin Sens.	: Skin sensitisation
2004/37/EC	: Europe. Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work
2004/37/EC / STEL	: Short term exposure limit
2004/37/EC / TWA	: Long term exposure 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; AIC - 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; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

#### Further information

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.

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Definition of Sanofi-OEB:

OEB is the occupational exposure band with the following levels:


Occupational Exposure Band	Occupational Exposure Level
OEB 1	> 1000 µg/m <sup>3</sup>
OEB 2	100 - 1000 µg/m <sup>3</sup>
OEB 3	10 – 100 µg/m <sup>3</sup>
OEB 4	1 – 10 µg/m <sup>3</sup>
OEB 5	< 1 µg/m <sup>3</sup>

Additional notations may be applied as suffixes to the OEL/OEB and are used to communicate additional information that is not directly indicated by the OEL/OEB classifications. This information is necessary to perform an efficient risk assessment and determine the correct exposure controls. The meanings of the suffixes is explained in this way:

Notation/Suffixes	Danger
G1	Reprotoxic hazard for pregnant women. Exposure below the OEL is acceptable.
G2	Reprotoxic hazard for pregnant women. Exposure even below the OEL is not acceptable.
Sr	Respiratory sensitization hazard with serious potential consequences (anaphylactic reactions).
Sk	Specific dermal hazard (High dermal absorption / Danger of skin sensitization).
Cor	Corrosive compound - Important dermal and ocular hazard If corrosive compounds.

Definition of SHB and EHB:

Substances are classified on a scale from 1, the less hazardous, to 5, the most hazardous, according to their safety properties, eg explosivity, flammability, etc. (SHB) and ecotoxicological properties, eg persistence, ecotoxicity (EHB)

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### **National Emergency Telephone Number:**

**Austria:**

Notruf 0–24 Uhr: +43 1 406 43 43

Vergiftungsinformationszentrale (VIZ)

**Belgium/Luxemburg:**

+32 (0) 70 245 245

((+352) 8002-5500, vanuit Groothertogdom Luxemburg)

BELGISCH ANTIGIFCENTRUM

Note: the public and the health professionals of the Grand Duchy of Luxembourg have access to the Belgian Poison Center via the free number

**Bulgaria:**

Emergency phone 24 hours: +359 2 915 44 09

Hospital for Active Medical Treatment and Emergency Medicine 'N.I.Pirigov', Bul. Tottleben 21, 1606 Sofia Center, Sofia, Bulgaria

**Croatia:**

+385 12348342

Centar za kontrolu otrovanja Ksaverska cesta 2, 10000 Zagreb

**Czech Republic:**

Tel: +420 224 919 293, +420 224 915 402

Toxikologické informační středisko

Na Bojišti 1, 120 00 Praha 2

**Denmark:**

Tel: +45 82 12 12 12

Akuthjælp ved forgiftning - Døgnet rundt

**Estonia:**

16662

Välisriigist helistades +372 7943 794 .

Terviseameti mürgistusteabekeskuse infoliin

Infoliin on avatud ööpäevaringselt kõikidel nädalapäevadel nii elanikele kui ka tervishoiutöötajatele.

Telefoniliinile helistamine on anonüümne ning kohaliku kõne hinnaga.

**Finland:**

+358 9 471 977 (normaalihintainen puhelu)

Myrkytystietokeskus

Avoimna 24 h/vrk

**France:**

+33 (0)1 45 42 59 59

ORFILA (INRS)

**Greece:**

+30 2107793777

Emergency number, Poison Information Centre

Children's Hospital P&A Kyriakou

Athens 11762

Greece

**Hungary:**

+36 80 201 199

Az Egészségügyi Toxikológiai Tájékoztató Szolgálat (ETTSZ)


Információs szolgálat akut mérgezés esetén

**Iceland:**

+354 543 2222

+354 112

+354 543 1000

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Eitrunarmiðstöð

Eitt af helstu hlutverkum hennar er að veita upplýsingar um eiturefni og ráðgjöf um viðbrögð og meðferð þegar eitranir verða

Ireland:

+353 (0) 1 809 2166

National Poisons Information Centre

Public Poisons Information Line between 8am and 10pm for members of the public who are concerned about accidental poisoning

Ireland:

+353 (0) 809 2566

National Poisons Information Centre

24 hour service to assist doctors and healthcare professionals in the management of poisoning

Italy:

+39 668593726

CAV Osp. Pediatrico Bambino Gesù Dip. Emergenza e Accettazione DEA Roma Piazza Sant'Onofrio, 4 165

Italy:

+39 800183459

Az. Osp. Univ. Foggia Foggia V.le Luigi Pinto, 1 71122

Italy:

+39 817472901

Az. Osp. A. Cardarelli Napoli Via A. Cardarelli, 9 80131

Italy:

+39 06-49978000

CAV Policlinico Umberto I Roma V.le del Policlinico, 155 161

Italy:

+39 06-3054343

CAV Policlinico A. Gemelli Roma Largo Agostino Gemelli, 8 168

Italy:

+39 055-7947819

Az. Osp. Careggi U.O. Tossicologia Medica Firenze Largo Brambilla, 3 50134

Italy:

+39 0382-24444

CAV Centro Nazionale di Informazione Tossicologica Pavia Via Salvatore Maugeri, 10 27100

Italy:

+39 02-66101029

Osp. Niguarda Ca' Granda Milano Piazza Ospedale Maggiore, 320162

Italy:

+39 800883300

Azienda Ospedaliera Papa Giovanni XXII Bergamo Piazza OMS, 1 24127

Latvia:

112

Valsts ugunsdzēsības un glābšanas dienests

Latvia:


+371 67042473

Toksikoloģijas un sepses klīnikas Saindēšanās un zāļu informācijas centrs, Hipokrāta 2, Rīga, Latvija, LV-1038

Service is available 24 hours.

Lithuania:



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+370 85 236 2052  
Poison Information Bureau (PIB)

Netherlands:  
+31 30 274 88 88  
Het Nationaal Vergiftigingen Informatie Centrum (NVIC) is het kenniscentrum voor de klinische toxicologie in Nederland. Het NVIC informeert artsen, apothekers en andere professionele hulpverleners over de mogelijke gezondheidseffecten en behandelingsmogelijkheden bij vergiftigingen.

Norway:  
+47 22 59 13 00  
Giftinformasjon

Portugal:  
+351 800 250 250  
CIAV

Slovakia:  
+421 2 54 774 166  
NTIC

Spain:  
Teléfono: +34 91 562 04 20 (solo emergencias toxicológicas)  
Servicio de Información Toxicológica  
Información en español (24h/365 días)

Sweden:  
112 – ask for Poisons Information ( 112 – begär Giftinformation)  
Giftinformationscentralen

Switzerland:  
145  
Swiss Toxicological Information Centre (Tox Info Swiss)