


<p style="text-align: center;"><b>SAFETY DATA SHEET</b> according to Regulation (EC) No. 1907/2006</p>	
<p><b>Thyrotropin alfa</b> Substance key: SXR123724 Version:1.0 (European Community) Revision Date: 24.01.2025<sup>EU</sup></p>	

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

### 1.1. Product identifier

Product name: Thyrotropin alfa

Synonyms: Recombinant human thyroid stimulating hormone (rhTSH)

CAS-No.: 194100-83-9

#### REACH-No.:

A registration number is not available for this substance as the substance or its use are exempted from registration according to Article 2 REACH Regulation (EC) No 1907/2006, the annual tonnage does not require a registration or registration is envisaged for a later registration deadline.

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

Identified uses:  
Active Pharmaceutical Ingredient

#### Therapeutic class:

Hypothalamic hormone.



### 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:

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

This substance is not classified as dangerous according to European Union legislation.


### 2.2. Label elements:

**CLP/GHS-Labeling (REGULATION (EC) No 1272/2008)**

Hazard warning labelling not compulsory

### 2.3. Other hazards:

Physical, chemical and : Avoid contact with skin and eyes

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<p><b>Thyrotropin alfa</b> Substance key: SXR123724 Version:1.0 (European Community) Revision Date: 24.01.2025<sup>EU</sup></p>	

toxicological hazards

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.

Environmental Effects : No data available on environmental effects.

### SECTION 3: Composition/information on ingredients

#### 3.1. Substances:

Product Description : Thyrotropin (human  $\beta$ -subunit) complex with chorionic gonadotropin (human  $\alpha$ -subunit) (9CI)  
CAS-No. : 194100-83-9

### SECTION 4: First aid measures

#### 4.1. Description of first aid measures:

General advice : Remove contaminated clothing immediately and dispose of safely.  
If inhaled : When dust is intensively inhaled, seek medical help immediately.  
In case of skin contact : In case of contact with skin wash off immediately with plenty of water.  
In case of eye contact : In case of contact with eyes rinse thoroughly with plenty of water and seek medical advice  
If swallowed : When swallowed seek medical aid immediately and show the physician the packaging or the label of the packaging.

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

Symptoms : No information available.  
Hazards : No information available.

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


Treatment : Treat symptomatically.

### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media:

Suitable extinguishing media : All means (e.g. water, carbon dioxide, dry chemical extinguisher).  
Unsuitable extinguishing media : Strong water jet.

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

<p align="center"><b>SAFETY DATA SHEET</b></p> <p align="center">according to Regulation (EC) No. 1907/2006</p>	
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In case of combustion, evolution of dangerous gases possible.

### 5.3. Advice for firefighters:

Special protective equipment for firefighters : Use self-contained breathing apparatus.

Further information : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.

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## SECTION 6: Accidental release measures

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

Avoid dust formation. Use personal protective clothing. If ventilation insufficient, use a respiratory protection apparatus.

### 6.2. Environmental precautions:

Do not allow to enter drains or waterways.

### 6.3. Methods and materials for containment and cleaning up:

General advice : Take up mechanically  
Avoid raising dust  
Clean contaminated floors and objects thoroughly, observing environmental regulations  
When picked up, treat material as prescribed under heading "Disposal".

### 6.4. Reference to other sections:

Information regarding Safe handling, see chapter 7. Information regarding personal protective measures see, chapter 8.  
Information regarding Waste Disposal, see chapter 13.

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## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling:


Advice on safe handling (industrial scale) : Avoid the formation and deposition of dust. Provide exhaust ventilation if dust is formed. Keep away from sources of ignition --- No smoking.

Advice on safe handling (laboratory scale) : Handling in a fume cupboard.

Advice on protection against fire and explosion : Take precautionary measures against electrostatic loading. Render equipment and apparatus inert (nitrogen, inert gases) and earth before putting into operation  
Avoid formation of dust  
Observe the general rules of industrial fire protection.

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

Requirements for storage areas and containers : Keep only in the original container

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Further information on storage conditions : Keep container tightly closed and dry  
Protect from light.

### 7.3. Specific end use(s):

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## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters:

### 8.2. Exposure controls:

#### Personal protective equipment

**(IMPORTANT: to be adapted following the workplace risk assessment.)**

General protective measures : Do not inhale dust. Avoid contact with eyes and skin.  
A workplace risk assessment must be carried out in order to determine the correct engineering control measures and personal protective equipment. Protective clothing should be selected specifically for the working place, depending on concentration and quantity of the hazardous substances handled. The resistance of the protective clothing to chemicals should be ascertained with the respective supplier.

#### Industrial workplace

Respiratory protection : Particle filter half mask, filter P3.  
Powered Air-purifying respirator (PAPR) - mounted airhat

Hand protection : Nitrile rubbergloves.

Glove material :	Dermatril® (KCL)
Layer thickness :	0,11 mm
Permeation time :	> 480 min

Glove material :	Camatril® (KCL)
Layer thickness :	0,5 mm
Permeation time :	> 480 min


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.

Eye/face protection : Safety glasses with side protection shield.

Body Protection : Protective clothing  
Disposable suit (Typ 5)

Additional technical information on the plant : Use under strictly controlled conditions.

Hygiene measures : Do not eat, drink or smoke during work time.  
Keep away from foodstuffs and beverages.  
After worktime and during work intervals the affected skin areas must be thoroughly cleaned.

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#### Laboratory


Respiratory protection	: Handling in a fume cupboard.
Hand protection	: Nitrile rubber gloves. Layer thickness > 0.11 mm. Breakthrough time > 480 min.
Eye/face protection	: Safety glasses with side protection shield.
Body Protection	: Dedicated working clothes.
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:

Physical state	: solid
Melting point/range	: not determined
Flash point	: Not applicable
Ignition temperature	: not determined
Auto-ignition temperature	: not determined
Thermal decomposition	: not determined
Lower explosion limit	: not determined
Upper explosion limit	: not determined
Minimum ignition energy	: not determined
Vapour pressure	: not determined
Density	: not determined
Bulk density	: not determined
Water solubility	: not determined
pH	: not determined
Octanol/water partition coefficient	: not determined
Viscosity, dynamic	: Not applicable
Viscosity, kinematic	: Not applicable
Oxidizing potential	: No data available

#### 9.2. Other information:

<p align="center"><b>SAFETY DATA SHEET</b> according to Regulation (EC) No. 1907/2006</p>	
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Impact sensitivity : No data available

Combustion Number : : not determined

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## SECTION 10: Stability and reactivity

**10.1. Reactivity** : No decomposition if used as directed.

**10.2. Chemical stability** : No decomposition if stored normally.

**10.3. Possibility of hazardous reactions** : No hazardous reactions known.

**10.4. Conditions to avoid** : No data available

**10.5. Incompatible materials** : None known.

**10.6. Hazardous decomposition products** : No hazardous decomposition products known.

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## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute inhalation toxicity : not determined

Acute dermal toxicity : not determined

Acute oral toxicity : not determined

Skin corrosion/irritation : not determined

Serious eye damage/eye irritation : not determined

Respiratory or skin sensitisation : not determined

Specific target organ toxicity (STOT) - Single exposure : not determined

Aspiration hazard : Not applicable

### Chronic/Long-term toxicity

Repeated dose toxicity : This information is not available.


Germ cell mutagenicity : not determined

Carcinogenicity : not determined

Reproductive toxicity : not determined

Specific target organ toxicity (STOT) - repeated exposure : not determined

**Further information:**

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Other toxicity data : 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.

Endocrine disrupting properties:  
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.

## SECTION 12: Ecological information

### 12.1. Toxicity:

Acute Fish toxicity : not determined  
Chronic fish toxicity : not determined  
Toxicity to aquatic invertebrates : not determined  
Chronic invertebrates toxicity : not determined  
Algae toxicity : No data available  
Bacteria toxicity : not determined

### 12.2. Persistence and degradability:

Biological degradability : not determined

### 12.3. Bioaccumulative potential:

Bioaccumulation : No data available

### 12.4. Mobility in soil:

Behaviour in environmental compartments : No known data.


### 12.5. Results of PBT and vPvB assessment:

Results of PBT and vPvB assessment : No data available

### 12.6. Other adverse effects:

Endocrine disrupting properties:  
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.

Note : Do not allow to enter soil, waterways or waste water

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## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods:

- Product : Dispose of contents/ container to an approved waste disposal plant.
- Uncleaned empty packaging : Packaging that cannot be cleaned should be disposed off as product waste

## SECTION 14: Transport information

### 14.1. UN number

#### ADN

Not classified as dangerous in the meaning of transport regulations.

#### ADR

Not classified as dangerous in the meaning of transport regulations.

#### RID

Not classified as dangerous in the meaning of transport regulations.

#### IMDG

Not classified as dangerous in the meaning of transport regulations.

#### IATA

Not classified as dangerous in the meaning of transport regulations.

### 14.2. UN proper shipping name

#### ADN

Not classified as dangerous in the meaning of transport regulations.

#### ADR

Not classified as dangerous in the meaning of transport regulations.

#### RID

Not classified as dangerous in the meaning of transport regulations.

#### IMDG

Not classified as dangerous in the meaning of transport regulations.

#### IATA

Not classified as dangerous in the meaning of transport regulations.

### 14.3. Transport hazard class

#### ADN

Not classified as dangerous in the meaning of transport regulations.

#### ADR

Not classified as dangerous in the meaning of transport regulations.

#### RID

Not classified as dangerous in the meaning of transport regulations.

#### IMDG

Not classified as dangerous in the meaning of transport regulations.

#### IATA

Not classified as dangerous in the meaning of transport regulations.

### 14.4. Packing group

#### ADN

Not classified as dangerous in the meaning of transport regulations.

#### ADR

Not classified as dangerous in the meaning of transport regulations.

#### RID


Not classified as dangerous in the meaning of transport regulations.

#### IMDG

Not classified as dangerous in the meaning of transport regulations.

#### IATA



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<p><b>Thyrotropin alfa</b> Substance key: SXR123724 Version:1.0 (European Community) Revision Date: 24.01.2025<sup>EU</sup></p>	

Not classified as dangerous in the meaning of transport regulations.

#### 14.5. Environmental hazards

##### ADN

Not classified as dangerous in the meaning of transport regulations.

##### ADR

Not classified as dangerous in the meaning of transport regulations.

##### RID

Not classified as dangerous in the meaning of transport regulations.

##### IMDG

Not classified as dangerous in the meaning of transport regulations.

##### IATA

Not classified as dangerous in the meaning of transport regulations.

#### 14.6. Special precautions for user

For personal protection see section 8.

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

No data available

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### SECTION 15: Regulatory information

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

#### 15.2. Chemical safety assessment:


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### SECTION 16: Other information

Version : 1.0 Revision date 24.01.2025

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.

Note: major information modified since the last version of the sheet is marked by a vertical line in front of the relevant change.

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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.

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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)


Információszolgáltatás akut mérgezés esetén

**Iceland:**

+354 543 2222

+354 112

+354 543 1000

<p align="center"><b>SAFETY DATA SHEET</b></p> <p align="center">according to Regulation (EC) No. 1907/2006</p>	
<p><b>Thyrotropin alfa</b></p> <p>Substance key: SXR123724 Version:1.0 (European Community) Revision Date: 24.01.2025<sup>EU</sup></p>	

**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<sup>®</sup> 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:**

<p align="center"><b>SAFETY DATA SHEET</b></p> <p align="center">according to Regulation (EC) No. 1907/2006</p>	
<p><b>Thyrotropin alfa</b></p> <p>Substance key: SXR123724 Version:1.0 (European Community) Revision Date: 24.01.2025<sup>EU</sup></p>	

+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)