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

1.1. Product identifier

Product name: Beyfortus

Synonyms: Nirsevimab (RSV)

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

Identified uses:
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 U.S. Corp**
A Sanofi-aventis U.S. LLC Company

Street address : 55 Corporate Drive
(US) 08807 Bridgewater

24-Hour Transport Emergency, US (Chemtrec):	(800) 424-9300
24-Hour Transport Emergency, outside US (Chemtrec):	(703) 527-3887
US Customer Service	(800) 207-8049
24-Hour Emergency, sanofi-aventis US:	(908) 981-5550

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

1.4. Emergency telephone number : 24h (908) 981-5550

Additional National Emergency Telephone Numbers see Annex.

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture:

OSHA 29 CFR 1910.1200 Classification (Hazard Communication Standard)

Not a hazardous substance or mixture.

2.2. Label elements:

OSHA 29 CFR 1910.1200 Labelling (Hazard Communication Standard)

No labeling elements required.

2.3. Other hazards:

Physical, chemical and : Please read the Physicians Desk Reference for detailed pharmacological

toxicological hazards		information. Avoid contact with skin and eyes
Safety	:	No data available for mixture.

SECTION 3: Composition/information on ingredients

3.2. Mixtures:

Hazardous substance name (CAS-No., EC-No., REACH-No.)	GHS Classification	Concentration
Nirsevimab		(avg. 10.00 %)
Non-hazardous galenic excipients	Not a dangerous substance according to GHS.	(avg. 90.00 %)

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.

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	:	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:

May release toxic, irritating and/or corrosive gases.
In case of fire hazardous decomposition products may be produced such as:
Carbon monoxide
Carbon dioxide (CO2)

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:

No personal respiratory protective equipment normally required. Safety glasses with side-shields Wear suitable gloves. Wear suitable protective clothing.

6.2. Environmental precautions:

Prevent further leakage or spillage. Do not let product enter drains.

6.3. Methods and materials for containment and cleaning up:

General advice	:	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.
Cleaning of contaminated zone	:	After cleaning, flush away traces with water. Clean contaminated floors and objects thoroughly while observing environmental regulations.
Elimination of recovered materials	:	Deliver to the Environmental service of the factory or to any specialized and approved disposal company.

Additional advice:

Only qualified personnel equipped with suitable protective equipment may intervene.

SECTION 7: Handling and storage

7.1. Precautions for safe handling:

Advice on safe handling (industrial scale)	:	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.

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.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters:

8.2. Exposure controls/Engineering controls:

Personal protective equipment

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

General 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.

Industrial workplace

Respiratory protection	:	Usually, no respiratory protection required.
Hand protection	:	Glove material : Nitrile rubber Layer thickness : > 0.1 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
Body Protection	:	Wear suitable protective clothing.
Additional technical information on the plant	:	Not applicable
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.

Laboratory

Respiratory protection	:	Usually, no respiratory protection required.
Hand protection	:	Nitrile rubber Layer thickness > 0.11 mm. Breakthrough time > 480 min.

Eye/face protection	:	Safety glasses
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:

Physical state	:	liquid
Form	:	solution
Colour	:	No data available
Odour	:	No data available
Melting point	:	not determined
Boiling point	:	not determined
Flash point	:	not determined
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
Relative vapour density	:	not determined
Water solubility	:	not determined
Soluble in other solvents (nonaquatic)	:	not determined
pH	:	not determined
Octanol/water partition coefficient	:	not determined
Viscosity, dynamic	:	not determined
Viscosity, kinematic	:	not determined

9.2. Other information:

Impact sensitivity	:	not determined

Combustion Number	:	: not determined
Flammability	:	Note: No data available

SECTION 10: Stability and reactivity

Safety remarks	:	No particular observation.
10.1. Reactivity	:	None known.
10.3. Possibility of hazardous reactions	:	None known.
10.4. Conditions to avoid	:	None known.
10.5. Incompatible materials	:	None known.
10.6. Hazardous decomposition products	:	In case of fire hazardous decomposition products may be produced such as: Carbon dioxide (CO2) Carbon monoxide
Sanofi hazard bands-Safety	:	No data available for mixture. Further information see chapter 16.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute inhalation toxicity	:	No data available for mixture.
Acute dermal toxicity	:	No data available for mixture.
Acute oral toxicity	:	No data available for mixture.
Skin corrosion/irritation	:	No data available for mixture.
Serious eye damage/eye irritation	:	No data available for mixture.
Respiratory or skin sensitisation	:	No data available for mixture.
Repeated dose toxicity	:	No data available for mixture.

SECTION 12: Ecological information

12.1. Toxicity:

Acute Fish toxicity	:	No data available
Toxicity to aquatic invertebrates	:	No data available
Algae toxicity	:	No data available

Bacteria toxicity	:	No data available

12.2. Persistence and degradability:

Biological degradability	:	No data available

12.3. Bioaccumulative potential:

12.4. Mobility in soil:

Behaviour in environmental compartments	:	No data available

12.5. Results of PBT and vPvB assessment:

Results of PBT and vPvB assessment	:	No data available

12.6. Other adverse effects:

SECTION 13: Disposal considerations

13.1. Waste treatment methods:

Product	:	Dispose of contents/ container to an approved waste disposal plant.
Uncleaned empty 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

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
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.

US State Regulations

SECTION 15: Regulatory information

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

SECTION 16: Other information

Version : 1.0 Revision date 06-06-2023

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.

Definition of Sanofi-OEB:
OEB is the occupational exposure band with the following levels:

Occupational Exposure Band	Occupational Exposure Level
OEB 1	> 1000 µg/m³
OEB 2	100 - 1000 µg/m³
OEB 3	10 – 100 µg/m³
OEB 4	1 – 10 µg/m³
OEB 5	< 1 µg/m³

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 persistance, ecotoxicity (EHB)