

**SAFETY DATA SHEET**  
in accordance with OSHA 29 CFR 1910.1200

**sanofi**

**Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation**

Substance key: REG003356 Version:1,1 (United States of America) Revision Date: 02-12-2026

**SECTION 1. IDENTIFICATION**

Product name: Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation

Synonyms: Dulcolax Daily Gut Support Gummies Orange

**Manufacturer or supplier's details**

Company : Sanofi

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

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

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

**Recommended use of the chemical and restrictions on use**

Recommended use : 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 OSHA 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.

**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

**GHS label elements**

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required, Labeling of the finished drug product is not required according to OSHA 29 CFR 1910.1200.

**Other hazards**

None known.

Physical, chemical and toxicological hazards : Substance pharmacologically active.  
Avoid contact with skin and eyes  
Please read the Physicians Desk Reference for detailed pharmacological information.

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**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	>= 30 - < 50
Starch	9005-25-8	>= 1 - < 5
Citric acid anhydrous	77-92-9	>= 1 - < 5

Actual concentration is withheld as a trade secret

**SECTION 4. 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.
- Most important symptoms and effects, both acute and delayed : No information available.  
No information available.
- Notes to physician : Treat symptomatically.

**SECTION 5. FIREFIGHTING MEASURES**

- Suitable extinguishing media : Water spray jet  
Dry powder.  
Carbon dioxide.  
Foam.
- Hazardous combustion products : Carbon oxides
- Further information : Fire residues and contaminated firefighting water must be disposed of in accordance with the local regulations.
- Special protective equipment for firefighters : Use self-contained breathing apparatus.

**SECTION 6. ACCIDENTAL RELEASE MEASURES**

- Personal precautions, protective equipment and emergency procedures : Avoid dust formation.  
Use personal protective clothing.
- Environmental precautions : Do not allow to enter drains or waterways.
- Methods and materials for containment and cleaning up : Take up mechanically
- Avoid raising dust
- Clean contaminated floors and objects thoroughly, observing environmental regulations

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When picked up, treat material as prescribed under heading "Disposal".

**SECTION 7. HANDLING AND STORAGE**

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.

Advice on safe handling : Avoid the formation and deposition of dust. Provide exhaust ventilation if dust is formed.

Conditions for safe storage : Keep only in the original container

Further information on storage conditions : Keep container tightly closed and dry


Protect from light.

Materials to avoid : Keep away from food, drink and animal feeding stuffs.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
Starch	9005-25-8	TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0
		TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1

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		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0

**Personal protective equipment**

Respiratory protection : Use the indicated respiratory protection if the occupational exposure limit is exceeded and/or in case of product release (dust).  
Suitable mask with particle filter P3 (European Norm 143)

Hand protection

Material : Dermatril® (KCL)  
Break through time : > 480 min  
Glove thickness : > 0.11 mm

Remarks : Nitrile rubber gloves.  
Eye protection : Safety glasses with side-shields  
Skin and body protection : Protective clothing  
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.

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.

**Laboratory**

Respiratory protection : Usually, no respiratory protection required.

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.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Form : tablet

Physical state : solid

Odour Threshold : No data available

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pH : not determined

Melting point/range : not determined

Flash point : Not applicable

Vapour pressure : not determined

Solubility(ies)  
Water solubility : not determined

Ignition temperature : not determined

**SECTION 10. STABILITY AND REACTIVITY**

Reactivity : None known.

Possibility of hazardous reactions : No hazardous reactions known.

Conditions to avoid : None known.

Incompatible materials : None known.

Hazardous decomposition products : No hazardous decomposition products are known.

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

Sucrose : SHB 5

Starch : SHB 5

Citric acid anhydrous : SHB 1

**SECTION 11. TOXICOLOGICAL INFORMATION**

**Acute toxicity**

Product name (CAS-No.)	Test Type	Species	Result	Method, Symptoms	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Acute oral toxicity	Acute toxicity estimate	> 5,000 mg/kg	Method: Calculation method	Source: Calculated
Product name (CAS-No.)	Test Type	Species	Result	Method, Symptoms	Remarks
Sucrose (57-50-1)	Acute oral toxicity	LD50 (Rat)	> 29,700 mg/kg		Source: SDS of Supplier
Sucrose (57-50-1)	Acute toxicity (other routes of administration)	LD50 (Mouse)	14,000 mg/kg	Application Route: Acute intraperitoneal toxicity (IP)	Source: literature value
Starch (9005-25-8)	Acute oral toxicity	LD50 (Rat)	> 50,000 mg/kg		Source: SDS of Supplier

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Starch (9005-25-8)	Acute toxicity (other routes of administration)	LD50 (Mouse)	6,600 mg/kg	Application Route: Acute intraperitoneal toxicity (IP)	
Citric acid anhydrous (77-92-9)	Acute oral toxicity	LD50 (Rat)	3,000 mg/kg		
Citric acid anhydrous (77-92-9)	Acute dermal toxicity	(Rat)	> 2,000 mg/kg		

**Skin corrosion/irritation**

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation				No data available for mixture.
Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Sucrose (57-50-1)				No data available
Citric acid anhydrous (77-92-9)	rabbit (24 h)	Mild skin irritation		

**Serious eye damage/eye irritation**

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation				No data available for mixture.
Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Sucrose (57-50-1)				No data available
Starch (9005-25-8)				No data available
Citric acid anhydrous (77-92-9)	rabbit (24 h)	Eye irritation		

**Respiratory or skin sensitisation**

Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation				No data available for mixture.
Product name (CAS-No.)	Species	Result	Method, Symptoms	Remarks
Sucrose (57-50-1)				No data available
Starch (9005-25-8)				No data available
Citric acid anhydrous (77-92-9)		negative		May produce an allergic reaction.


**Carcinogenicity**

**IARC**

No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

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**NTP** No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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

Product name (CAS-No.)	Carcinogenicity	Germ cell mutagenicity	Reproductive toxicity	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	not determined	not determined	Reproduction: not determined Teratogenicity: not determined	

**STOT - single exposure**

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	STOT-single exposure				No data available for mixture.
Sucrose (57-50-1)	STOT-single exposure				No data available
Starch (9005-25-8)	STOT-single exposure				No data available
Citric acid anhydrous (77-92-9)	STOT-single exposure	Inhalation		May cause respiratory irritation.	

**STOT - repeated exposure**

Product name (CAS-No.)	Test Type	Exposure routes	Target Organs	Assessment	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	STOT - repeated exposure				No data available for mixture.
Sucrose (57-50-1)	STOT - repeated exposure				No data available
Starch (9005-25-8)	STOT - repeated exposure				No data available
Citric acid anhydrous (77-92-9)	STOT - repeated exposure				No data available

**Aspiration toxicity**

Product name (CAS-No.)	Test Type	Result	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Aspiration toxicity	Not applicable	
Sucrose (57-50-1)	Aspiration toxicity	Not applicable	
Starch (9005-25-8)	Aspiration toxicity	Not applicable	
Citric acid anhydrous (77-92-9)	Aspiration toxicity	Not applicable	

**11.2 Information on other hazards**

**Endocrine disrupting properties**

Product name (CAS-No.)	Remarks
Sucrose	The substance/mixture does not contain components considered to have endocrine disrupting properties according to

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Product name (CAS-No.)	Remarks
(57-50-1)	REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
Starch (9005-25-8)	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.
Citric acid anhydrous (77-92-9)	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**

Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Toxicity to fish				No data available for mixture.
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Toxicity to daphnia and other aquatic invertebrates				No data available for mixture.
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Toxicity to algae/aquatic plants				No data available for mixture.
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Toxicity to microorganisms				No data available for mixture.
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Toxicity to soil dwelling organisms				No data available for mixture.

**Components:**

Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Sucrose (57-50-1)	Toxicity to daphnia and other aquatic invertebrates				No data available
Sucrose (57-50-1)	Toxicity to algae/aquatic plants				No data available
Sucrose (57-50-1)	Toxicity to fish (Chronic toxicity)				No data available
Sucrose (57-50-1)	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)				No data available
Sucrose (57-50-1)	Toxicity to microorganisms				No data available
Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Starch (9005-25-8)	Toxicity to fish	LC50 (fish)	> 5,000 mg/l Exposure time: 96 h		
Starch (9005-25-8)	Toxicity to daphnia and other aquatic invertebrates				No data available
Starch (9005-25-8)	Toxicity to algae/aquatic plants				No data available
Starch (9005-25-8)	Toxicity to fish (Chronic toxicity)				No data available
Starch	Toxicity to daphnia and				No data available

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(9005-25-8)	other aquatic invertebrates (Chronic toxicity)				
Starch (9005-25-8)	Toxicity to microorganisms				No data available
Product name (CAS-No.)	Test Type	Species	Result	Method	Remarks
Citric acid anhydrous (77-92-9)	Toxicity to fish	LC50 (Leuciscus idus)	440 mg/l Exposure time: 96 h		
Citric acid anhydrous (77-92-9)	Toxicity to daphnia and other aquatic invertebrates	EC50 (Daphnia magna)	ca. 120 mg/l Exposure time: 72 h		Source: SDS of Supplier
Citric acid anhydrous (77-92-9)	Toxicity to algae/aquatic plants Exposure time: 192 h	NOEC (Scenedesmus quadricauda)	425 mg/l		
Citric acid anhydrous (77-92-9)	Toxicity to fish (Chronic toxicity)				No data available
Citric acid anhydrous (77-92-9)	Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)				No data available
Citric acid anhydrous (77-92-9)	Toxicity to microorganisms Exposure time: 72 h	EC5 (Entosiphon sulcatum (Protozoen))	485 mg/l		Source: SDS of Supplier
Citric acid anhydrous (77-92-9)	Toxicity to microorganisms Exposure time: 15 min	EC50 (Photobacterium phosphoreum / Vibrio fisheri)	14 mg/l		Source: SDS of Supplier

**12.2 Persistence and degradability**

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Biodegradability				No data available for mixture.
Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Starch (9005-25-8)	Biodegradability		Readily biodegradable.		Source: SDS of Supplier
Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Citric acid anhydrous (77-92-9)	Biodegradability Exposure time: 30 d		Readily biodegradable. Biodegradation: 90 %	OECD TG 301 D	The product is readily biodegradable according to OECD criteria.
Citric acid anhydrous (77-92-9)	Biochemical Oxygen Demand (BOD)		Biochemical oxygen demand within 5 days 526 mg/g		Source: SDS of Supplier
Citric acid anhydrous (77-92-9)	Chemical Oxygen Demand (COD)		0,728 g/g		Source: SDS of Supplier

**12.3 Bioaccumulative potential**

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
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Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Bioaccumulation				No data available for mixture.

**Components:**

Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Sucrose (57-50-1)	Bioaccumulation				Unlikely to be bioaccumulable in living organisms (Log Pow < 4).
Sucrose (57-50-1)	Partition coefficient: n-octanol/water		log Pow: -3.70	Experimental determination.	Source: literature value
Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Starch (9005-25-8)	Bioaccumulation				No data available
Starch (9005-25-8)	Partition coefficient: n-octanol/water				No data available
Product name (CAS-No.)	Test Type	Conditions	Result	Method	Remarks
Citric acid anhydrous (77-92-9)	Bioaccumulation				Unlikely to be bioaccumulable in living organisms (Log Pow < 4).
Citric acid anhydrous (77-92-9)	Partition coefficient: n-octanol/water		log Pow: -1.72 - 1.64 (20 °C)	Experimental determination.	

**12.4 Mobility in soil**

No data available

**12.5 Results of PBT and vPvB assessment**

Product name (CAS-No.)	Result
Sucrose (57-50-1)	Remarks: No data available


Product name (CAS-No.)	Result
Starch (9005-25-8)	Remarks: No data available

Product name (CAS-No.)	Result
Citric acid anhydrous (77-92-9)	Remarks: No data available

**12.6 Endocrine disrupting properties**

**12.7 Other adverse effects**

Product name (CAS-No.)	Test Type	Result	Remarks
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Ozone-Depletion Potential	Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances	Warning: Manufactured with .? , a substance which harms public health and environment by destroying ozone in

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Product name (CAS-No.)	Test Type	Result	Remarks
			the upper atmosphere.

Product name (CAS-No.)	Test Type	Result
Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation	Additional ecological information	Do not allow uncontrolled discharge of product into the environment.

Product name (CAS-No.)	Test Type	Result
Citric acid anhydrous (77-92-9)	Additional ecological information	Do not dispose of in the environment.

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

Sucrose	: EHB 1 (preliminary)
Starch	: EHB 1 (preliminary)
Citric acid anhydrous	: EHB 1 (preliminary)

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues	: Dispose of contents/ container to an approved waste disposal plant.
Contaminated packaging	: Packaging that cannot be cleaned should be disposed off as product waste

**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

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

Not applicable for product as supplied.

**National Regulations**

**SECTION 15. REGULATORY INFORMATION**

**EPCRA - Emergency Planning and Community Right-to-Know Act**

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

Components	CAS-No.	Component TPQ (lbs)
Organic Tapioca syrup and Tapioca syrup	Not Assigned	

**SARA 311/312 Hazards** : No SARA Hazards

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

Warning: Manufactured with Organic Tapioca syrup and Tapioca syrup, a substance which harms public health and environment by destroying ozone in the upper atmosphere.

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40 CFR Protection of Environment; Part 82

Protection of Stratospheric Ozone - CAA Section 602 Class I Substances Ozone-

Depletion Potential

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

The following chemical(s) are listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F):

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMII Intermediate or Final VOC's (40 CFR 60.489):

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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**Clean Water Act**

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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This product contains the following toxic pollutants listed under the U.S. Clean Water Act Section 307

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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This product contains the following priority pollutants related to the U.S. Clean Water Act:

Organic Tapioca syrup and Tapioca syrup	Not Assigned	>= 30 - < 50 %
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**US State Regulations**

**Massachusetts Right To Know**

Organic Tapioca syrup and Tapioca syrup	Not Assigned
Sucrose	57-50-1
Starch	9005-25-8

**Pennsylvania Right To Know**

Agar Agar	9002-18-0
Organic Tapioca syrup and Tapioca syrup	Not Assigned
Sucrose	57-50-1
Trimagnesium dicitrate nonahydrate	153531-96-5
Starch	9005-25-8

**Maine Chemicals of High Concern**

Organic Tapioca syrup and Tapioca syrup	Not Assigned
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**Vermont Chemicals of High Concern**

Organic Tapioca syrup and Tapioca syrup	Not Assigned
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**Washington Chemicals of High Concern**

Organic Tapioca syrup and Tapioca syrup	Not Assigned
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**California Prop. 65**

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

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**California Permissible Exposure Limits for Chemical Contaminants**

Sucrose 57-50-1  
Starch 9005-25-8

TCSI : On the inventory, or in compliance with the inventory

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

AIIC : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL

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 : On the inventory, or in compliance with the inventory

NZIoC : Not in compliance with the inventory

TECI : Not in compliance with the inventory

**TSCA list**

The following substance(s) is/are subject to a Significant New Use Rule:

Organic Tapioca syrup and Tapioca syrup Not Assigned

The following substance(s) is/are subject to TSCA 12(b) export notification requirements:

Organic Tapioca syrup and Tapioca syrup Not Assigned

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**SECTION 16. OTHER INFORMATION**

**Full text of other abbreviations**

ACGIH : USA. ACGIH Threshold Limit Values (TLV)

NIOSH REL : USA. NIOSH Recommended Exposure Limits

OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)

OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants

ACGIH / TWA : 8-hour, time-weighted average

NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek

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**sanofi**

**Dulcolax Daily Gut Support Gummies Orange - Pharmaceutical preparation**

Substance key: REG003356 Version:1,1 (United States of America) Revision Date: 02-12-2026

OSHA P0 / TWA : 8-hour time weighted average  
OSHA Z-1 / TWA : 8-hour time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECI - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Revision Date : 02-12-2026

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.

US / EN

**SAFETY DATA SHEET**  
**in accordance with OSHA 29 CFR 1910.1200**



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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.