

SAFETY DATA SHEET

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Section 1 Identification						
Product Name	Manufacturer	Emergency Contact				
Aniosgel 85 NPC	Laboratoires Anios Pave du Moulin 59260 Lille- Hellemmes France	Angelini Pharma Inc. 8322 Helgerman Court Gaithersburg, MD 20877, USA Phone: (301) 330-7597 Fax: (301) 330-6432				

Recommended Use and Description

Disinfection of healthy skin. For further information on product indication, please see the label.

Section 2 Hazards Identification

Classification of the substance or mixture

• In compliance with EC regulation No. 1272/2008 and its amendments.

Flammable liquid, Category 2 (Flam. Liq. 2, H225). Eye irritation, Category 2 (Eye Irrit. 2, H319).

This mixture does not present an environmental hazard. No known or foreseeable environmental damage under standard conditions of use.

• Label elements

In compliance with EC regulation No. 1272/2008 and its amendments.

• Hazard pictograms:





GHS07 GHS02

Signal Word: DANGER

Hazard statements :

H225 Highly flammable liquid and vapor.

H319 Causes serious eye irritation. Precautionary statements - General:

P102 Keep out of reach of children. Precautionary statements - Prevention:

P210 Keep away from sparks and open flames. No smoking. Precautionary statements - Response:

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Precautionary statements - Storage:

P403 Store in a well-ventilated place. Precautionary statements - Disposal :

P501 Dispose of unused product and its container as hazardous waste.

• Other hazards

The mixture does not contain substances classified as 'Substances of Very High Concern' (SVHC) \geq 0.1% published by the European Chemicals Agency (ECHA) under article 57 of

REACH: http://echa.europa.eu/fr/candidate-list-table

No other hazard identified in the current state of knowledge.

Section 3 Composition & Information on Ingredients



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Title for H and EUH statements: see § 16.

Mixtures Composition

Identification	(EC) 1272/2008	Note	%
CAS: 64-17-5	GHS07, GHS02		50 <= x % < 100
EC: 200-578-6	Dgr		
REACH: 01-2119457610-43	Flam. Liq. 2, H225	[1]	
ETHYL ALCOHOL	Eye Irrit. 2, H319		
INDEX: 603-117-00-0	GHS02, GHS07		$0 \le x \% < 2.5$
CAS: 67-63-0	Dgr		
EC: 200-661-7	Flam. Liq. 2, H225	F43	
REACH: 01-2119457558-25	Eye Irrit. 2, H319	[1]	
PROPAN-2-OL	STOT SE 3, H336		

Information on ingredients:

[1] Substance for which maximum workplace exposure limits are available.

Section 4 First Aid Measures

As a general rule, in case of doubt or if symptoms persist, always call a doctor. NEVER induce swallowing by an unconscious person.

• Description of first aid measures in the event of exposure by inhalation :

Move the person away from the place of exposure and take him/her outside.

In the event of splashes or contact with eyes:

If applicable, remove contact lenses.

Wash thoroughly with soft clean water for 15 minutes, holding the eyelids open.

If there is any redness, pain or visual impairment, consult an ophthalmologist. Show this container or label.

In the event of swallowing:

Rinse out the mouth, do not induce vomiting, keep the person calm and take him/her to a clinic or a doctor's. Show the container or label.

• Most important symptoms and effects, both acute and delayed

Cf. § 11

• Indication of any immediate medical attention and special treatment needed

Refer to the recommendation of the doctor.

Section 5 Fire-fighting measures	Section 6 Accidental Release Measures				
	Personal precautions, protective equipment and emergency				
Flammable.	procedures				
Move oxidizing products away from the fire.					
Move any flammable materials away from the fire.	Consult the safety measures listed under headings 7 and 8. Keep				
5.1. Extinguishing media Suitable methods of extinction	away any unprotected person.				
Prevent the effluent of fire-fighting measures from entering	Move all flammable sources out of danger and keep them away				
drains or waterways.	from the scene. Eliminate any possible source of ignition and				
Use powder or foam extinguishers.	ventilate the premises.				
Special foams for polar liquids, powders and carbon dioxide.	Environmental precautions				
Unsuitable methods of extinction	Contain and control the leaks or spills with non-combustible				
In the event of a fire, do not use:	absorbent materials such as sand, earth, vermiculite,				
- water jet	diatomaceous earth in drums for waste disposal.				



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• Special hazards arising from the substance or mixture

A fire will often produce a thick black smoke. Exposure to decomposition products may be hazardous to health. Do not breathe in smoke.

Advice for firefighters

Fire-fighting personnel are to be equipped with autonomous insulating breathing apparatus.

Full protective suit.

Do not get rid in natural spaces (waterways, ground and vegetation, etc.)

- Methods and material for containment and cleaning up Absorb any spilled product with absorbent non-combustible materials, and sweep away or remove with a shovel. Put any waste in drums for disposal. Do not mix with any other waste. Wash the contaminated surface thoroughly with water. Do not put any spilt product back into its original container with the intention of re-use.
- Reference to other sections Disposal considerations: see section 13.

Section 7 Handling & Storage

Precautions for safe handling

- Product for external use do not swallow.
- Handle in accordance with user instructions on label. Handle at a temperature not exceeding 45° C. Handle in well-ventilated premises.

• Fire prevention :

- Keep packages tightly closed and away from sources of heat, sparks and naked flames. Do not use tools which may produce sparks. Do not smoke.
- Keep away from flammable materials
- Keep away from sources of ignition no smoking.

• Recommended equipment and procedures:

- For personal protection, see section 8.
- Observe precautions stated on label and also industrial safety regulations. Avoid eye contact with this mixture.
- Packages which have been opened must be reclosed carefully and stored in an upright position. Water source nearby.
- Prohibited equipment and procedures:
- No smoking, eating or drinking in areas where the mixture is used.

• Conditions for safe storage, including any incompatibilities

- Keep the container tightly closed
- Keep in the original container only, in a cool and well-ventilated place, away from all sources of ignition, heat and direct sunlight. Recommended storage temperature: from +5°C to +25°C.
- Do not use after the expiry date mentioned on the packaging. Keep out of the reach of children
- Store away from incompatible materials (see section 10) Splash pan for high quantities' storage
- Always transport and store the containers upright

• Specific end use(s)

- For professional use only
- Refer to paragraph 1 for product indication

Section 8 Exposure Controls/ Personal Protection

Exposure Controls
OSHA PEL: 400 ppm
ACGIH TLV: 400 ppm
ACGIH STEL: 500 ppm

Exposure controls

Suitable technical inspections: Ensure the rooms are well-ventilated. Atmospheric concentrations at the workplace must not exceed the limit values given for normal conditions of use.

- Eye / face protection Avoid contact with eyes. Water source nearby.
- Hand protection: Not applicable.
- Body protection

Not applicable.



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HEALTH MEASURES:

Do not eat, drink or smoke during use.

Respiratory protection: Not applicable in normal conditions of use.
 Avoid product's inhalation

Section 9 Physical & Chemical Properties

Information on basic physical and chemical properties

General information:

Physical state:	Viscous liquid
Color:	Colorless
Odor:	Typical of alcohol
pH:	5.25
	Neutral
Boiling point/boiling range:	> 35°C
Flash Point:	22.50 °C
Vapor pressure (50°C):	Not relevant
Density:	+/- 0.86
Water solubility:	Soluble
Melting point/melting range:	Not specified
Self-ignition temperature :	Not specified
Decomposition point/decomposition range:	Not specified

Section 10 Stability & Reactivity

Reactivity

No hazardous reaction if the instructions/indications for storage and handling are respected.

- Chemical stability: This mixture is stable under the recommended handling and storage conditions in section 7.
- Possibility of hazardous reactions: Cf. § 10.1 and 10.2
- Conditions to avoid: Avoid exposure to heat.
- **Incompatible materials:** Do not mix with other products.

Keep away from combustible material

Hazardous decomposition products: At high temperatures, dangerous decomposition products may be produced, such
as fumes, carbon dioxide and carbon monoxide, nitrogen oxide.

Section 11 Toxicological Information

Information on toxicological effects

- Substances: Not specified
- Mixture

Acute toxicity: Acute toxicity estimate (ATE)*:

Oral ATE: > 2000 mg/kg

* According to the method of calculation describe in the CLP regulation (Classification, Labelling, Packaging) Part 3 Chapter 3.1 based on the data of the different components present in the product.

Ingestion may lead to irritation of the digestive system, abdominal pain, headaches and nausea.

- Serious damage to eyes/eye irritation :
- Ocular irritation: notably redness of the conjunctivae and lacrimation.
- Other information: Assessment of cutaneous tolerance in healthy volunteer: Very good cutaneous tolerance (48 h occlusive patch in 10 volunteers).

No evidence of skin sensitization (HRIPT)

Section 12 Ecological Information

- Toxicity
 - Mixtures: The mixture has not been classified as an environmental hazard, in compliance with EC regulation 1272/2008.
- **Persistence and degradability:** No data available.
- **Bioaccumulative potential:** No data available.
- Mobility in soil: No data available.



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- **Results of PBT and vPvB assessment:** No data available.
- Other adverse effects: No data available.

Section 13 Waste Disposal Considerations

Proper waste management of the mixture and/or its container must be determined in accordance with Directive 2008/98/EC.

The packages must not be reused.

Do not pour into waterways.

• Waste treatment methods

Waste: Waste management is carried out without endangering human health, without harming the environment and, in particular without risk to water, air, soil, plants or animals.

Recycle or dispose of waste in compliance with current legislation, preferably via a certified collector or company.

Soiled packaging: Empty container completely. Keep label(s) on container.

Give to a certified disposal contractor.

Codes of wastes (Decision 2001/573/EC, Directive 2006/12/EEC, Directive 94/31/EEC on hazardous waste):

18 01 06 * chemicals consisting of or containing dangerous substances

20 01 29 *detergents containing dangerous substances

For information:

The following waste code is given for indicative purposes only.

The waste code must be determined by the user, according to the application of the product.

18 = Wastes from human or animal health care and/or related research (except kitchen and restaurant wastes not arising from immediate health care)

20 = Municipal wastes and similar commercial, industrial and institutional wastes including separately collected fractions

Section 14 Transport Information

Transport product in compliance with provisions of the ADR for road, RID for rail, IMDG for sea and ICAO/IATA for air transport (ADR 2015 - IMDG 2014 - ICAO/IATA 2015).

- UN number: 1170
- UN proper shipping name: UN1170=ETHANOL SOLUTION (ETHYL ALCOHOL SOLUTION)
- Transport hazard class(es)
 - Classification:



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- Packing group: II
- Environmental hazards: None
- Special precautions for user

ADR/RID	Class	Code	Pack gr.	Label	Ident.	LQ	Provis.	EQ	Cat.	Tunnel
	3	F1	II	3	33	1 L	144 601	E2	2	D/E
IMDG	Class	2°Label	Pack gr.	LQ	EMS	Provis.	EQ			
	3	-	II	1 L	F-E,S-D	144	E2			
IATA	Class	2°Label	Pack gr.	Passager	Passager	Cargo	Cargo	note	EQ	
	3	-	II	353	5 L	364	60 L	A3 A58	E2	
								A180		
	3	-	II	Y341	1 L	-	-	A3 A58	E2	
								A180		

Section 15 Regulatory Information

• Safety, health and environmental regulations/legislation specific for the substance or mixture

Classification and labelling information included n section 2: The following regulations have been used:



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- Regulation EC 1272/2008 modified by regulation EC 618/2012
- EU Regulation No. 1271/2008 amended by EU Regulation No. 758/2013
- Chemical safety assessment

Information from the chemical safety assessment of substances present in the product is included in the appropriate sections of this safety data sheet, whenever necessary.

Section 16 Other Information

Since the user's working conditions are not known by us, the information supplied on this safety data sheet is based on our current level of knowledge and on national and community regulations.

It is at all times the responsibility of the user to take all necessary measures to comply with legal requirements and local regulations.

The information in this safety data sheet must be regarded as a description of the safety requirements relating to the mixture. It is recommended that the information contained in this safety data sheet is provided to the users, if necessary in an appropriate form.

This information relates to the specifically designated product and may not be valid in combination with any another product. The product must not be used for applications other than those specified in heading 1 without having first obtained written handling instructions.

UPDATES SINCE PREVIOUS VERSION

- Implementation of classification and labeling in compliance with EC regulation 1272/2008.

Wording of the phrases mentioned in section 3:

H225 Highly flammable liquid and vapor.

H319 Causes serious eve irritation.

H336 May cause drowsiness or dizziness.

Abbreviations:

ADR: European agreement concerning the international carriage of dangerous goods by Road.

IMDG: International Maritime Dangerous Goods. IATA: International Air Transport Association. ICAO: International Civil Aviation Organization

RID: Regulations concerning the International carriage of Dangerous goods by rail.

GHS02 : Flame

GHS07: Exclamation mark