



SECTION 1: Identification

1.1. Product identifier

Mixture identification:

Trade name: EVOLYSE BASIC

Trade code: 2010.21 – 2020.21 – 2030.21

1.2. Recommended use of the chemical and restrictions on use

Recommended use: Aerial disinfectant for non-invasive medical devices and surfaces such as equipments, operating tables and medical units. Professional use only.

Uses advised against: all except those recommended.

1.3. Name, address, and telephone number of the chemical manufacturer, importer, or other responsible party

AMIL CARE CORP

7750 West 26 Ave Unit 8

Hialeah (Miami-Dade)

FL 33016 US

Sito web: www.amil-care.com

E-mail: info@amilcarecorp.com

1.4. Emergency phone number

Ph.: +1 786-674-5505

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

29 CFR 1910.1200:

Classification of this product has been carried out in accordance with paragraph (d) of § 1910.1200.

Eye Irrit. 2A: Eye irritation, Category 2A, H319

2.2. Label elements

29 CFR 1910.1200:



Warning

Hazard statements:

Eye Irrit. 2A: H319 Causes serious eye irritation.

Precautionary statements:

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

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

P337+P313 If eye irritation persists: Get medical advice/attention.

2.3. Hazards not otherwise classified (HNOC):

Non-applicable

SECTION 3: Composition/information on ingredients

3.1. Substances

Non-applicable

3.2. Mixtures

Chemical description: Aqueous mixture composed of hydrogen peroxide

Components:

Remaining components are non-hazardous and/or present at amounts below reportable limits. The specific chemical identity and/or exact percentage (concentration) of composition has been withheld as a trade secret in accordance with paragraph (i) of §1910.1200. Therefore, in accordance with Appendix D to § 1910.1200, the product contains:

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Identification	Chemical name/Classification	Conc.
CAS: 7722-84-1	hydrogen peroxide solution Acute Tox. 4: H302+H332; Ox. Liq. 1: H271; Skin Corr. 1A: H314 - Danger	6%
CAS: 10294-26-5	Disilver(1+) sulphate Eye Dam. 1: H318 - Danger	<0.01 %

To obtain more information on the hazards of the substances consult sections 11, 12 and 16.

Other information:

Classification of the product (see section 2) is calculated considering specific concentration limits (table below).

Specific tests (carried out according to European regulation) linked effects to human health to these concentrations

Identification	Specific concentration limit
hydrogen peroxide solution CAS: 7722-84-1	% (p/p) >=70: Ox. Liq. 1 - H271 50<= % (p/p) <70: Ox. Liq. 2 - H272 % (p/p) >=70: Skin Corr. 1A - H314 50<= % (p/p) <70: Skin Corr. 1B - H314 35<= % (p/p) <50: Skin Irrit. 2 - H315 % (p/p) >=8: Eye Dam. 1 - H318 5<= % (p/p) <8: Eye Irrit. 2 - H319 % (p/p) >=35: STOT SE 3 - H335

SECTION 4: First aid measures**4.1. Description of first aid measures**

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

This product is not classified as hazardous through inhalation, however, it is recommended in case of intoxication symptoms to remove the person affected from the area of exposure, provide clean air and keep at rest. Request medical attention if symptoms persist.

By skin contact:

This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or shower the person affected if necessary thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

By eye contact:

Rinse eyes thoroughly with water for at least 15 minutes. Do not let the person involved rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, as this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration:

Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

4.2. Most important symptoms/effects, acute and delayed

Acute and delayed effects are indicated in sections 2 and 11.

4.3. Indication of immediate medical attention and special treatment needed, if necessary

Not applicable

SECTION 5: Firefighting measures**5.1. Suitable (and unsuitable) extinguishing media****Suitable extinguishing media:**

Product is non-flammable under normal conditions of storage, handling and use. Use preferably water.

Unsuitable extinguishing media:

Chemical extinguishers or foam.

5.2. Specific hazards arising from the chemical:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3. Special protective equipment and precautions for fire-fighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and individual respiratory equipment. Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...).

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Additional provisions:

As in any fire, prevent human exposure to fire, smoke, fumes or products of combustion. Only properly trained personnel should be involved in firefighting. Evacuate nonessential personnel from the fire area. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

For emergency responders:

See section 8

6.2. Environmental precautions

This product is not classified as hazardous to the environment. Keep product away from drains, surface and underground water.

6.3. Methods and material for containment and cleaning up

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13

6.4. Reference to other sections

See also section 8 and 13

SECTION 7: Handling and storage

7.1. Precautions for safe handling

A- Precautions for safe manipulation

Comply with the current standards 29 CFR 1910 Occupational Safety and Health Standards. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B- Technical recommendations for the prevention of fires and explosions

It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C- Technical recommendations to prevent ergonomic and toxicological risks.

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3).

7.2. Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location.

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5.

7.3. Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Substances whose occupational exposure limits have to be monitored in the workplace:

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000):

Identification	Occupational exposure limits		
	8-hour TWA PEL	1 ppm	1.4 mg/m ³
hydrogen peroxide solution CAS: 7722-84-1	Ceiling Values - TWA PEL		
Disilver(1+) sulphate CAS: 10294-26-5	8-hour TWA PEL		0.01 mg/m ³
	Ceiling Values - TWA PEL		

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US. ACGIH Threshold Limit Values:

Identification	Occupational exposure limits		
hydrogen peroxide solution CAS: 7722-84-1	TLV-TWA	1 ppm	
	TLV-STEL		
Disilver(1+) sulphate CAS: 10294-26-5	TLV-TWA		0.01 mg/m ³
	TLV-STEL		0.03 mg/m ³

CALIFORNIA- TABLE AC-1 PERMISSIBLE EXPOSURE LIMITS FOR CHEMICAL CONTAMINANTS:

Identification	Occupational exposure limits		
hydrogen peroxide solution CAS: 7722-84-1	PEL	1 ppm	1.4 mg/m ³
	STEL		
Disilver(1+) sulphate CAS: 10294-26-5	PEL		0.01 mg/m ³
	STEL		

8.2. Appropriate engineering controls

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protection Equipment. For more information on Personal Protection Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation, the information on clothing performance must be combined with professional judgment, and a clear understanding of the clothing application, to provide the best protection to the worker. All chemical protective clothing use must be based on a hazard assessment to determine the risks for exposure to chemicals and other hazards. Conduct hazard assessments in accordance with 29 CFR 1910.132


B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable



D.- Ocular and facial protection

Pictogram	PPE	Remarks
 Mandatory face protection	Face shield	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing. Use this PPE in accordance with manufacturer's use limitations and OSHA standard 1910.133 (29CFR).

E.- Bodily protection

Pictogram	PPE	Remarks
	Work clothing	Replace at any sign of deterioration.
	Anti-slip work shoes	Replace at any sign of deterioration.

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

National volatile organic compound emission standards (40 CFR Part 59):

V.O.C. (Subpart C - Consumer): 0 % weight

V.O.C. (Coatings) at 68 °F: 0 kg/m³ (0 g/L)

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:

Physical state at 68 °F: Liquid

Appearance: Not available

Color: Silver

Odor: Odorless

Odour threshold: Non-applicable *

Volatility:

Boiling point at atmospheric pressure: 216 °F

Vapour pressure at 68 °F: 2279 Pa

Vapour pressure at 122 °F: 12019,73 Pa (12.02 kPa)

Evaporation rate at 68 °F: Non-applicable *

Product description:

Density at 68 °F: 1019 kg/m³

Relative density at 68 °F: 1.02

Dynamic viscosity at 68 °F: 1.02 cP

Kinematic viscosity at 68 °F: 0.98 mm²/s

Kinematic viscosity at 104 °F: Non-applicable *

Concentration: Non-applicable *

pH: 3.9 – 4.9

Vapour density at 68 °F: Non-applicable *

Partition coefficient n-octanol/water 68 °F: Non-applicable *

Solubility in water at 68 °F:

Solubility properties: Soluble in water

Decomposition temperature: Non-applicable *

Melting point/freezing point: Non-applicable *

Flammability:

Flash Point: Non Flammable (>199.4 °F)

Heat of combustion: Non-applicable *

Flammability (solid, gas): Non-applicable *

Autoignition temperature: Non-applicable *

Lower flammability limit: Non-applicable *

Upper flammability limit: Non-applicable *

Particle characteristics:

Median equivalent diameter: Non-applicable

9.2. Other information

Information with regard to physical hazard classes:

Explosive properties: Non-applicable *

Oxidising properties: Non-applicable *

Corrosive to metals: Non-applicable *

Heat of combustion: Non-applicable *

Aerosols-total percentage (by mass) of flammable components: Non-applicable *

Other safety characteristics:

Surface tension at 68 °F: Non-applicable *

Refraction index: Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: Stability and reactivity

10.1. Reactivity

No hazardous reactions are expected if follow technical instructions storage of chemicals. See section 7.

10.2. Chemical stability

Chemically stable under the conditions of storage, handling and use.

10.3. Possibility of hazardous reactions

Under the conditions no hazardous reactions are expected to produce a pressure or excessive temperatures

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10.4. Conditions to avoid

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5. Incompatible materials

Acids	Water	Oxidising materials	Combustible materials	Others
Avoid strong acids	Not applicable	Precaution	Precaution	Avoid alkalis or strong bases

10.6. Hazardous decomposition products

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds

SECTION 11: Toxicological information

11.1. Information on toxicological effects

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than recommended by the occupational exposure limits, it may result in adverse effects on health depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, however, it contains substances classified as dangerous for consumption. For more information see section 3

- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for inhalation. For more information see section 3.

- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.

- Contact with the eyes: Produces eye damage after contact.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3..

IARC: hydrogen peroxide solution (3)

- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitizing effects. For more information see section 3.

- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3. - Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

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Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
hydrogen peroxide solution CAS: 7722-84-1	LD50 oral	500 mg/kg (ATEi)	
	LD50 dermal	>5000 mg/kg	
	LC50 inhalation	11 mg/L (4 h) (ATEi)	
Disilver(1+) sulphate CAS: 10294-26-5	LD50 oral	>5000 mg/kg	
	LD50 dermal	>5000 mg/kg	
	LC50 inhalation	>5 mg/L	

Acute Toxicity Estimate (ATE mix):

	ATE mix	Ingredient(s) of unknown toxicity
Oral	8333,33 mg/kg (Calculation method)	0 %
Dermal	>5000 mg/kg (Calculation method)	Non-applicable
Inhalation	183,33 mg/L (4 h) (Calculation method)	0 %

SECTION 12: Ecological information

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1. Ecotoxicity (aquatic and terrestrial, where available)

Acute toxicity:

Identification	Concentration		Species	Genus
hydrogen peroxide solution CAS: 7722-84-1	LC50	16,4 mg/L (96 h)	Pimephales promelas	Fish
	EC50	7,7 mg/L (24 h)	Daphnia magna	Crustacean
	EC50	2,5 mg/L (72 h)	Chlorella vulgaris	Alga
Disilver(1+) sulphate CAS: 10294-26-5	LC50	0.0012 mg/L (96 h)	Pimephales promelas	Fish
	EC50	0.00022 mg/L (48 h)	Daphnia magna	Crustacean
	EC50	Non-applicable		

12.2. Persistence and degradability

Not available

12.3. Bioaccumulative potential

Identification	Bioaccumulation potential	
Disilver(1+) sulphate CAS: 10294-26-5	BCF	70
	Log POW	
	Potential	Moderate

12.4. Mobility in soil

Not available

12.5. Results of PBT and vPvB assessment

Not available

12.6. Other adverse effects

Not described

SECTION 13: Disposal considerations

13.1. Disposal methods

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations. In case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommended disposal down the drain. See epigraph 6.2.

Regulations related to waste management:

Legislation related to waste management: 40 CFR Part 261- IDENTIFICATION AND LISTING OF HAZARDOUS WASTE

SECTION 14: Transport information

Transport of dangerous goods by ground:

With regard to 49 CFR on the Transport of Dangerous Goods:

14.1	UN number:	Non-applicable
14.2	UN proper shipping name:	Non-applicable
14.3	Transport hazard class(es):	Non-applicable
	Labels:	Non-applicable
14.4	Packing group, if applicable:	Non-applicable
14.5	Marine pollutant:	No
14.6	Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:	
	Physico-Chemical properties:	see section 9
14.7	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):	Non-applicable

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Transport of dangerous goods by sea:

With regard to IMDG 39-18:

14.1	UN number:	Non-applicable
14.2	UN proper shipping name:	Non-applicable
14.3	Transport hazard class(es):	Non-applicable
	Labels:	Non-applicable
14.4	Packing group, if applicable:	Non-applicable
14.5	Marine pollutant:	No
14.6	Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:	
	Special regulations:	Non-applicable
	EmS Codes:	Non-applicable
	Physico-Chemical properties:	see section 9
	Limited quantities:	Non-applicable
	Segregation group:	Non-applicable
14.7	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):	Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2021:

14.1	UN number:	Non-applicable
14.2	UN proper shipping name:	Non-applicable
14.3	Transport hazard class(es):	Non-applicable
	Labels:	Non-applicable
14.4	Packing group, if applicable:	Non-applicable
14.5	Marine pollutant:	No
14.6	Special precautions which a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises:	
	Physico-Chemical properties:	see section 9
14.7	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code):	Non-applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations specific for the product in question

Toxic chemical release reporting under EPCRA section 313 (40 CFR Part 372): Disilver(1+) sulphate
 California Proposition 65 (the Safe Drinking Water and Toxic Enforcement Act of 1986): Non-applicable
 The Toxic Substances Control Act (TSCA) : hydrogen peroxide solution ; Disilver(1+) sulphate ; Water
 Massachusetts RTK - Substance List: hydrogen peroxide solution ; Disilver(1+) sulphate
 New Jersey Worker and Community Right-to-Know Act: hydrogen peroxide solution ; Disilver(1+) sulphate
 New York RTK - Substance list: hydrogen peroxide solution ; Disilver(1+) sulphate
 Pennsylvania Worker and Community Right-to-Know Law: hydrogen peroxide solution ; Disilver(1+) sulphate
 CANADA-Domestic Substances List (DSL): hydrogen peroxide solution ; Disilver(1+) sulphate ; Water
 CANADA-Non-Domestic Substances List (NDSL): Non-applicable
 NTP (National Toxicology Program): Non-applicable
 Minnesota - Hazardous substances ERTK: hydrogen peroxide solution ; Disilver(1+) sulphate
 Rhode Island - Hazardous substances RTK: Non-applicable
 OSHA Specifically Regulated Substances (29 CFR 1910.1001-1096): Non-applicable
 Hazardous Air Pollutants (Clean Air Act): Non-applicable
 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantities:
 Disilver(1+) sulphate (1 pounds)

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, use, storage and disposal of this product.

Other legislation:

Take into consideration other applicable federal, state, and local laws and local regulations.

Evolyse basic is a medical device Class I, registered and listed by the FDA (under the jurisdiction of the FDA) Reg. # 3011684996.

SECTION 16: Other information

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with Appendix d to §1910.1200 - Safety data sheets

Texts of the legislative phrases mentioned in section 2:

H319: Causes serious eye irritation.

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

29 CFR 1910.1200:

Acute Tox. 4: H302+H332 - Harmful if swallowed or if inhaled.

Eye Dam. 1: H318 - Causes serious eye damage.

Ox. Liq. 1: H271 - May cause fire or explosion, strong oxidiser.

Skin Corr. 1A: H314 - Causes severe skin burns and eye damage.

Advice related to training:

Minimal training is recommended to prevent industrial risks for staff using this product, in order to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

Occupational Safety & Health Administration (OSHA).

Abbreviations and acronyms:

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

IARC: International Agency for Research on Cancer

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