

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Reference number: 320070 Revision date: 5/2/2022 Supersedes version of: 3/24/2021 Version: 14.0

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

1.1. Product identifier

Product form · Mixture

Product name : May-Grünwald solution

Product code : 320070

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC **FRANCE**

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

<u>commercial@cellavision.com</u> - <u>www.ral-diagnostics.com</u>; <u>www.cellavision.com</u>

1.4. Emergency telephone number

Country	Organisation/Company	Address	Emergency number	Comment
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	
Malta	Medicines & Poisons Info Office	Mater Dei Hospital MSD 2090 Msida	+356 2545 6508	
United Kingdom	National Poisons Information Service (Birmingham Centre) City Hospital	Dudley Road B18 7QH Birmingham	0344 892 0111	Only for healthcare professionals

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Flammable liquids, Category 2 H225 Acute toxicity (oral), Category 3 H301 Acute toxicity (dermal), Category 3 H311 Acute toxicity (inhalation:vapour) Category 3 H331 Specific target organ toxicity - single exposure, Category 1 H370

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Highly flammable liquid and vapour. Causes damage to organs. Toxic in contact with skin. Toxic if inhaled. Toxic if swallowed.

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2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

Hazard pictograms (CLP)







GHS02

GHS06

GHS08

Signal word (CLP) : Danger
Contains : Methanol

Hazard statements (CLP) : H225 - Highly flammable liquid and vapour.

H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.

H370 - Causes damage to organs.

Precautionary statements (CLP) : P210 - Keep away from heat, hot surfaces, sparks, open flames and other

ignition sources. No smoking.

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 - Wash hands thoroughly after handling.

P280 - Wear protective gloves, protective clothing, eye protection, face

protection.

P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor. P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

2.3. Other hazards

Contains no PBT/vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Product identifier	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Methanol substance with national workplace exposure limit(s) (GB, IE, MT); substance with a Community workplace exposure limit	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001- 00-X REACH-no: 01- 2119433307-44	Flam. Liq. 2, H225 Acute Tox. 3 (Inhalation), H331 Acute Tox. 3 (Dermal), H311 Acute Tox. 3 (Oral), H301 STOT SE 1, H370

Specific concentration limits:			
Name	Product identifier	Specific concentration limits	
Methanol	CAS-No.: 67-56-1 EC-No.: 200-659-6 EC Index-No.: 603-001- 00-X REACH-no: 01- 2119433307-44	(3 ≤C < 10) STOT SE 2, H371 (10 ≤C < 100) STOT SE 1, H370	

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a physician immediately.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a doctor. First-aid measures after skin contact : Rinse skin with water/shower. Take off immediately all contaminated clothing.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

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First-aid measures after ingestion : Rinse mouth. Call a physician immediately.

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

No additional information available

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Fire hazard : Highly flammable liquid and vapour.

Hazardous decomposition products in case

of fire

: Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-

contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. No open flames, no sparks, and no smoking. Do not

breathe dust/fume/gas/mist/vapours/spray. Avoid contact with skin, eyes and

clothing.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further

information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Take up liquid spill into absorbent material. Notify authorities if product enters

sewers or public waters.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Keep away from heat, hot surfaces, sparks, open flames and other ignition

sources. No smoking. Wear personal protective equipment. Do not breathe dust/fume/gas/mist/vapours/spray. Do not get in eyes, on skin, or on clothing.

Use only outdoors or in a well-ventilated area.

Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when

using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place. Keep container tightly closed. Store locked up.

Storage temperature : 15 – 25 °C

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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Methanol (67-56-1)			
EU - Indicative Occupational Exposure Limit (IOEL)			
Methanol			
260 mg/m³			
skin			
COMMISSION DIRECTIVE 2006/15/EC			
Methanol [Methyl alcohol]			
260 mg/m³			
200 ppm			
Chemical Agents Code of Practice 2020			
Methanol			
260 mg/m³			
200 ppm			
Skin # Ġilda			
S.L.424.24 - Chemical Agents at Work Regulations (L.N.57 of 2018)			
Methanol			
266 mg/m³			
200 ppm			
333 mg/m³			
250 ppm			
Sk (Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity)			
EH40/2005 (Fourth edition, 2020). HSE			

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

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8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : dark blue.
Odour : alcoholic.

Odour threshold : No data available

pH : 6.5 – 7.5

Relative evaporation rate (butylacetate=1) : No data available

Melting point : Not applicable

Freezing point : No data available

Boiling point : $65 \, ^{\circ}\text{C}$ Flash point : $12 \, ^{\circ}\text{C}$

Auto-ignition temperature : No data available
Decomposition temperature : No data available
Flammability (solid, gas) : Not applicable
Vapour pressure : No data available
Relative vapour density at 20 °C : No data available

Relative density : 0.8

Solubility : No data available

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: No data available

Partition coefficient n-octanol/water (Log

Pow)

Viscosity, kinematic : No data available
Viscosity, dynamic : No data available
Explosive properties : No data available
Oxidising properties : No data available
Explosive limits : No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Highly flammable liquid and vapour.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Avoid contact with hot surfaces. Heat. No flames, no sparks. Eliminate all sources of ignition.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity (oral) : Toxic if swallowed.

Acute toxicity (dermal) : Toxic in contact with skin.

Acute toxicity (inhalation) : Toxic if inhaled.

May-Grünwald solution		
ATE CLP (oral)	100.422 mg/kg bodyweight	
ATE CLP (dermal)	301.265 mg/kg bodyweight	
ATE CLP (vapours)	3.013 mg/l/4h	
Methanol (67-56-1)		

Methanol (67-56-1)		
LD50 oral rat	1187 – 2769 mg/kg bodyweight Animal: rat	
LD50 dermal rabbit	300 mg/kg Source: ECHA	
LC50 Inhalation - Rat (Vapours)	131.5 mg/l/4h	

Skin corrosion/irritation : Not classified pH: 6.5 – 7.5

Serious eye damage/irritation : Not classified

pH: 6.5 – 7.5

Respiratory or skin sensitisation : Not classified
Germ cell mutagenicity : Not classified
Carcinogenicity : Not classified
Reproductive toxicity : Not classified

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Methanol (67-56-1)		
LOAEL (animal/male, F0/P)	1700 mouse	
NOAEL (animal/male, F0/P)	< 1000 mg/kg bodyweight Animal: mouse, Animal sex: male	
STOT-single exposure	: Causes damage to organs	

STOT-single exposure : Causes damage to organs.

Methanol (67-56-1)

STOT-single exposure Causes damage to organs.

STOT-repeated exposure : Not classified
Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-

term adverse effects in the environment.

Hazardous to the aquatic environment,

short-term (acute)

: Not classified

Hazardous to the aquatic environment, long-

term (chronic)

: Not classified

Methanol (67-56-1)		
LC50 - Fish [1]	15400 mg/l Source: ECHA	
EC50 - Crustacea [1]	> 10000 mg/l Daphnia magna	
EC50 96h - Algae [1]	22000 mg/l Source: ECHA	
NOEC (chronic)	208 mg/l Test organisms (species): Daphnia magna Duration: '21 d'	
NOEC chronic fish	15800 mg/l Oryzias latipes	

12.2. Persistence and degradability

Methanol (67-56-1)	
Persistence and degradability	Readily biodegradable.

12.3. Bioaccumulative potential

Methanol (67-56-1)		
Partition coefficient n-octanol/water (Log Pow)	-0.77 Source: HSDB,CHemIDplus	
Bioaccumulative potential	No bioaccumulation.	

12.4. Mobility in soil

Methanol (67-56-1)	
Mobility in soil	2.75 Source: HSDB

12.5. Results of PBT and vPvB assessment

Component	
Methanol (67-56-1)	This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

12.6. Other adverse effects

Other adverse effects : Not release to the environment.

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting

instructions. Dispose in a safe manner in accordance with local/national

regulations.

Additional information : Flammable vapours may accumulate in the container.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID	
14.1. UN number					
UN 1230	UN 1230	UN 1230	UN 1230	UN 1230	
14.2. UN proper shipping	14.2. UN proper shipping name				
METHANOL	METHANOL	Methanol	METHANOL	METHANOL	
Transport document descr	Transport document description				
UN 1230 METHANOL, 3 (6.1), II, (D/E)	UN 1230 METHANOL, 3 (6.1), II (12°C c.c.)	UN 1230 Methanol, 3 (6.1), II	UN 1230 METHANOL, 3 (6.1), II	UN 1230 METHANOL, 3 (6.1), II	
14.3. Transport hazard class(es)					
3 (6.1)	3 (6.1)	3 (6.1)	3 (6.1)	3 (6.1)	
e e	3 6 6	3 6	6	3	
14.4. Packing group					
II	II	II	II	II	
14.5. Environmental hazards					
Dangerous for the environment: No	Dangerous for the environment: No Marine pollutant: No	Dangerous for the environment: No	Dangerous for the environment: No	Dangerous for the environment: No	

14.6. Special precautions for user

Overland transport

Classification code (ADR) : FT1
Special provisions (ADR) : 279
Limited quantities (ADR) : 11
Excepted quantities (ADR) : E2

Packing instructions (ADR) : P001, IBC02

Mixed packing provisions (ADR) : MP19
Portable tank and bulk container instructions : T7

(ADR)

Portable tank and bulk container special : TP2

provisions (ADR)

Tank code (ADR) : L4BH
Tank special provisions (ADR) : TU15
Vehicle for tank carriage : FL
Transport category (ADR) : 2

Special provisions for carriage - Loading, : CV13, CV28

unloading and handling (ADR)

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Special provisions for carriage - Operation

(ADR)

Hazard identification number (Kemler No.) : 336

Orange plates :

336 1230

: S2, S19

Tunnel restriction code (ADR) : D/E
EAC code : •2WE
APP code : A(fl)

Transport by sea

Special provisions (IMDG) : 279 Limited quantities (IMDG) : 1 L Excepted quantities (IMDG) : E2 Packing instructions (IMDG) : P001 IBC packing instructions (IMDG) : IBC02 Tank instructions (IMDG) : T7 Tank special provisions (IMDG) : TP2 : F-E EmS-No. (Fire) EmS-No. (Spillage) : S-D Stowage category (IMDG) : B Stowage and handling (IMDG) : SW2 Flash point (IMDG) : 12°C c.c.

Properties and observations (IMDG) : Colourless, volatile liquid. Flashpoint: 12°C c.c. Explosive limits: 6% to

36.5% Miscible with water. Toxic if swallowed; may cause blindness. Avoid skin

contact.

MFAG-No : 131

Air transport

PCA Excepted quantities (IATA) : E2 PCA Limited quantities (IATA) : Y341 PCA limited quantity max net quantity (IATA) : 1L PCA packing instructions (IATA) : 352 PCA max net quantity (IATA) : 1L CAO packing instructions (IATA) : 364 CAO max net quantity (IATA) : 60L Special provisions (IATA) : A113 ERG code (IATA) : 3L

Inland waterway transport

Classification code (ADN) : FT1
Special provisions (ADN) : 279, 802
Limited quantities (ADN) : 1 L
Excepted quantities (ADN) : E2

Equipment required (ADN) : PP, EP, EX, TOX, A

Ventilation (ADN) : VE01, VE02

Number of blue cones/lights (ADN) : 2

Rail transport

Classification code (RID) : FT1
Special provisions (RID) : 279
Limited quantities (RID) : 1L

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Excepted quantities (RID) : E2

: P001, IBC02 Packing instructions (RID) Mixed packing provisions (RID) : MP19 : T7

Portable tank and bulk container instructions

(RID)

: TP2

Portable tank and bulk container special

provisions (RID)

Tank codes for RID tanks (RID) : L4BH : TU15 Special provisions for RID tanks (RID) Transport category (RID) : 2

Special provisions for carriage - Loading,

unloading and handling (RID)

: CW13, CW28

Colis express (express parcels) (RID) : CE7 Hazard identification number (RID) : 336

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

Contains no substance subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 July 2012 concerning the export and import of hazardous chemicals.

Contains no substance subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to REGULATION (EU) No 1005/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 September 2009 on substances that deplete the ozone layer.

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

Contains no substance subject to Regulation (EC) 273/2004 of the European Parliament and of the Council of 11 February 2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Supersedes	Modified	
	Revision date	Modified	
2.2	Precautionary statements (CLP)	Modified	
15.2	Chemical safety assessment	Added	
16	Abbreviations and acronyms	Added	

Abbreviations and acronyms:	
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road

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Abbreviations and acronyms:	
ATE	Acute Toxicity Estimate
BCF	Bioconcentration factor
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PBT	Persistent Bioaccumulative Toxic
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
SDS	Safety Data Sheet
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Full text of H- and EUH-statements:	
Acute Tox. 3 (Dermal)	Acute toxicity (dermal), Category 3
Acute Tox. 3 (Inhalation)	Acute toxicity (inhal.), Category 3
Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
Flam. Liq. 2	Flammable liquids, Category 2
H225	Highly flammable liquid and vapour.

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Full text of H- and EUH-statements:	
H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H331	Toxic if inhaled.
H370	Causes damage to organs.
H371	May cause damage to organs.
STOT SE 1	Specific target organ toxicity – single exposure, Category 1
STOT SE 2	Specific target organ toxicity – Single exposure, Category 2

The classification complies with

: ATP 12

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.