



MINISTERUL SANATATII
COMISIA NATIONALA PENTRU PRODUSE BIOCID
MINISTRY OF HEALTH
NATIONAL COMMITTEE FOR BIOCIDAL PRODUCTS

Str. Dr. A. Leonte, Nr. 1 - 3, 050463 Bucuresti, ROMANIA
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Data emiterii: **14.01.2025**

AVIZ DE PRELUNGIRE
Nr. 4968BIO/02/12.30

În conformitate cu Ordinul ministrului sănătății, al ministrului mediului și pădurilor și al președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 10/368/11/2010 privind aprobarea procedurii de avizare a produselor biocide care sunt plasate pe piață pe teritoriul României, cu modificările și completările ulterioare, precum și cu Ordinul ministrului sănătății, al ministrului mediului și pădurilor și al președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 637/2.492/50/2012 privind aprobarea membrilor Comisiei naționale pentru produse biocide și a regulamentului de organizare și funcționare a acesteia, cu modificările și completările ulterioare, în baza cererii de prelungire nr. **1493** din data de **28.11.2024** a firmei **MEDISEPT Sp. Zo.o** și a Avizului Nr. **4968BIO/02/12.24** eliberat în baza dosarului tehnic aprobat în cadrul Comisiei naționale pentru produse biocide, se emite prezentul Aviz de prelungire până la data de **31.12.2030** pentru plasarea pe piață în Romania a produsului biocid **VELOX SPRAY TEA TONIC**, conform prevederilor legale in vigoare.

PREȘEDINTE
Dr. Chim. Gabriela Cîlîncă

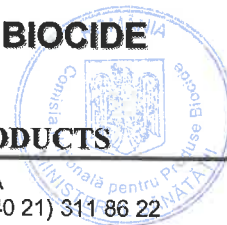




**MINISTERUL SANATATII
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Tel: *(+40 21) 318 36 20, Secretariat tehnic: (+40 21) 311 86 20; Fax: (+40 21) 311 86 22



Data emiterii: 20.06.2023

AVIZ

Nr. 4968BIO/02/12.24

În conformitate cu Ordinul Ministrului Sănătății, al Ministrului Mediului și Pădurilor și al președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 10/368/11/2010, privind aprobarea procedurii de avizare a produselor biocide care sunt plasate pe teritoriul României, cu modificările și completările ulterioare și cu Ordinul Ministrului Sănătății, al Ministrului Mediului și Pădurilor și al Președintelui Autorității Naționale Sanitare Veterinare și pentru Siguranța Alimentelor nr. 637/2492/50/2012, privind aprobarea membrilor Comisiei Naționale pentru Produse Biocide și a regulamentului de organizare și funcționare a acesteia, cu modificările și completările ulterioare, în baza documentelor depuse în dosarul tehnic, CNPB, în sesiunea din data de 26.03.2020 și 15.06.2023 a decis ca produsul biocid poate fi plasat pe piață în România, conform prevederilor legale în vigoare.

I. DENUMIREA COMERCIALĂ ÎN ROMÂNIA

VELOX SPRAY TEA TONIC

Alte denumiri comerciale, după caz

VELOX SPRAY NEUTRAL
DR. MAYER GREEN NEUTRAL
DR. MAYER GREEN TONIC

II. DATE DE IDENTIFICARE ALE PRODUCĂTORULUI (numele, adresa, țara, inclusiv punctul de lucru pentru producătorii din România)

Medisept Sp.Z.o.o – ul. Ludwika Spiessa 4, 20-270 Lublin, Polonia

III. DATE DE IDENTIFICARE ALE SOLICITANTULUI (numele, adresa, țara)

Medisept Sp.Z.o.o – ul. Ludwika Spiessa 4, 20-270 Lublin, Polonia

IV. ÎNCADRAREA PRODUSULUI BIOCID (în conformitate cu anexa V la Regulamentul (UE) nr. 528/2012 al Parlamentului European și al Consiliului din 22 mai 2012 privind punerea la dispoziție pe piață și utilizarea produselor biocide, cu amendamentele ulterioare)

A. Grupa principală:	1
B. Tipul/Tipurile de produs:	2

V. DATE PRIVIND SUBSTANȚA ACTIVĂ / SUBSTANȚE

A. Substanțe chimice

Nr. crt.	Denumirea chimică (IUPAC, ISO sau altele)	Nr. CE	Nr. CAS	Concentrația în unități metrice
1.	Propan-2-ol	200-661-7	67-63-0	6,3g
2.	Ethanol	200-578-6	64-17-5	63,7g

VI. FORMA DE CONDIȚIONARE:

Soluție gata de utilizare.

VII. MODUL DE AMBALARE (tipul, capacitate)

Flacoane de 1l și bidoane de 5l.



VIII. DOMENIUL ȘI ARIA DE UTILIZARE

A. Domeniul de utilizare	Dezinfectant care nu este destinat aplicării directe la oameni sau animale.
B. Aria de aplicare	Dezinfectia suprafetelor si amprentelor dentare prin pulverizare.

IX. EFICACITATE

Activitatea	Metoda de testare/ Protocolul de testare	Specia / Tulpina	Concentrații	Timpi de acțiune
Bactericida	EVS-EN 13727:2015 in conditii de curatenie si de murdarie	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Escherichia coli</i> K12 NCTC 15442	Conc. 80%	30 secunde
Levuricida	EVS- EN 13624:2019 (2013) in conditii de curatenie si murdarie	<i>Candida albicans</i> ATCC 10231	Conc. 80%	15 sec.
Bactericida si levuricida	EVS-EN 13697:2015+A1:2019 in conditii de curatenie	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Escherichia coli</i> ATCC 10536 <i>Candida albicans</i> ATCC 10231	Conc. 100%	30 sec.
	EVS-EN 13697:2015+A1:2019 in conditii de murdarie	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Escherichia coli</i> ATCC 10536		60 sec.
Bactericida si levuricida	EVS-EN 16615:2015 in conditii de curatenie si de murdarie	<i>Staphylococcus aureus</i> ATCC 6538 <i>Enterococcus hirae</i> ATCC 10541 <i>Pseudomonas aeruginosa</i> ATCC 15442 <i>Candida albicans</i> ATCC 10231	Conc. 100%	30 sec.
Bactericida si levuricida	EVS-EN 17387:2021 in conditii de murdarie	<i>Staphylococcus aureus</i> CECT 239 = ATCC 6538 <i>Enterococcus hirae</i> CECT 4081 = ATCC 10541 <i>Pseudomonas aeruginosa</i> CECT 116 = ATCC 15442 <i>Escherichia coli</i> K12 NCTC 15442 <i>Candida albicans</i> CECT 1394 - ATCC 10231	Conc. 100%	5 min.
Inactiveaza virusul	EVS-EN 14476:2013+A2:2019 in conditii de murdarie	<i>Vaccinia virus</i> Extindere pe virusurile anvelopate	nediluat	30 secunde

AVIZ Nr. 4968BIO/02/12.24

IX. EFICACITATE



Activitatea	Metoda de testare/ Protocolul de testare	Specia / Tulpina	Concentrații	Timpi de actiune
Inactiveaza virusul	EVS-EN 14476:2013+A2:201 9 in conditii de curatenie si de murdarie	MNV S99	nediluat	1 minut
Tuberculocida	EVS- EN 14348:2005 in conditii de curatenie si de murdarie	<i>Mycobacterium terrae</i> ATCC 15755	Conc. 80%	60 sec.

X. INDICAȚII DE UTILIZARE

Metoda de aplicare	Concentrația soluției de lucru/ doza de aplicare	Timpul de acțiune
Dezinfectia suprafetelor prin pulverizare	Conc.	1 minut

XI. ETICHETAREA PRODUSULUI BIOCID

A. Produs biocid cu substante active - substante chimice

Pictograme, simboluri si indicarea pericolului	 GHS02  GHS07
Fraze de pericol (H)	H226 Lichid si vapori inflamabili H319 Provoaca o iritare grava a ochilor.
Fraze de precautie (P)	P101 Dacă este necesară consultarea medicului, țineți la îndemână recipientul sau eticheta produsului. (populatie) P102 A nu se lăsa la îndemâna copiilor. (populatie) P210 A se pastra departe de surse de caldura/ scantei/ flacari deschise/ suprafete incinse. – Fumatul interzis. P280 Purtati manusi de protectie/ imbracaminte de protectie/ echipament de protectie a ochilor/ echipament de protectie a fetei. P305+P351+P338 ÎN CAZ DE CONTACT CU OCHII: Clățiți cu atenție cu apă timp de mai multe minute. Scoateți lentilele de contact, dacă este cazul și dacă acest lucru se poate face cu ușurință. Continuați să clățiți. P370+P378 In caz de incendiu: A se utilize stingatorul cu praf ABC pentru a stinge. P403+P233 A se depozita intr-un spatiu bine ventilat. Pastrati recipientul inchis etans. P501 Eliminati continutul/ recipientul in conformitate cu reglementarile privind deseurile periculoase sau ambalajele si respectiv deseurile de ambalaje.

XII. CATEGORIA DE UTILIZATORI

Profesionali si populatie

XIII. RECOMANDARI/ RESTRICTII PRIVIND PROTECTIA SANATATII SI A FACTORILOR DE MEDIU

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Avizul este valabil până la data: 31.12.2024.

Indicatia de utilizare in unitati sanitare este valabila pana la data de 20.06.2026.

Avizul nr. 4967BIO/02/12.24, nr. 4954BIO/02/12.24 si nr. 4955BIO/02/12.24 se anuleaza incepand cu data de 20.06.2023.

Avizul conține – 3 pagini



SECTION 1: Identification of the substance / mixture and company identification**1.1 Product identifier:** DR. MAYER GREEN TONIC**1.2 Relevant identified uses of the substance or mixture and uses advised against:**

Identified use: alcoholic preparation for fast disinfection of surfaces. Professional use only.

The use discouraged: not specified

1.3 Details of the supplier of the safety data sheet**Manufacturer:** MEDISEPT Sp. z o.o.
Konopnica 159C
21-030 Motycz, Poland
tel. 048 81 503 23 77
www.medisept.pl**Distributor:** DENTSTORE SRL
Tepes Voda 89, Sector 2, Bucuresti, Romania
Tel. 021 308 57 51
www.dentstore.roE-mail of the person responsible for the safety data sheet: : g.gromadzki@medisept.pl**1.4 Emergency telephone number:** +48 81 535 22 22 at time: 8.00 a.m. – 4.00 p.m.

112 (general emergency number)

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****In accordance with Regulation 1272/2008:**

Flam. Liq. 3; H225

Eye Irrit.2; H319

STOT SE 3; H336

The threat to human health

Causes serious eye irritation. May cause drowsiness or dizziness

Environmental hazards

No

Physical/chemical hazards

Highly flammable liquid and vapours.

2.2 Label elements:**Pictograms:****Signal word:** Warning**Hazard statements****H225** - Highly flammable liquid and vapour**H319** – Causes serious eye irritation.**H336** - May cause drowsiness or dizziness**Phrases indicating conditions of safe use:**

P102 - Keep out of reach of children.

P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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 –In case of persistent eye irritation: Get medical advice/attention.

P510 - Dispose of contents/container to properly labeled waste containers in accordance with national regulations.

Contains:

Propan-2-ol (CAS: 67-63-0)

In accordance with Regulation 648/2004

Perfume (LIMONENE, LINALOOL, LINALYL ACETATE)

List of components available on website: www.medisep.pl

2.3 Other hazards:

No information as to the compliance with PBT or vPvB criteria, as per Annex XIII to the REACH regulation.

SECTION 3: Composition/information on ingredients

3.1 Substance: Not applicable

3.2 Mixture: Hazardous components

Product identifier	Content %	Classification CLP	
		Hazard class and category codes	Codes hazard statements
Propan-2-ol CAS: 67-63-0 EC: 200-661-7 Index No.: 603-117-00-0 No REACH: 01-2119457558-25-XXXX	<10	Flam. Liq. 2 Eye Irrit. 2 STOT SE 3	H225 H319 H336
Ethanol CAS: 64-17-5 EC: 200-578-6 Index no: 603-002-00-5 <u>REACH no:</u> 01-2119457610-43-XXXX	<70	Flam. Liq. 2 Eye Irrit. 2	H225 H319

Full text of H phrases In Section 16

SECTION 4: First Aid Measures

4.1 Description of first aid measures

Skin contact:

Remove contaminated clothing, wash affected skin with soap and water, rinse thoroughly with water. In the event of an irritation, erythema, contact your doctor.

Eye contact:

Rinse eyes for several minutes (approx. 15) with plenty of water, holding the eyelids apart. Avoid strong stream, due to the risk of cornea damage, consult a doctor.

Inhalation:

In case of dizziness or nausea, remove casualty to fresh air, in the absence of rapid improvement, seek medical advice.

Ingestion:

Do not induce vomiting, rinse your mouth. Immediately contact your doctor.

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

Respiratory system: In case of dizziness or nausea, remove casualty to fresh air, in the absence of rapid improvement, seek medical advice.

Digestive tract: Ingestion causes irritation of the mucous membranes of the gastrointestinal tract, abdominal pain, stomach cramps, nausea, vomiting, diarrhea, malaise, headaches and dizziness - symptoms of food poisoning.

Eye contact: Causes eye irritation.

Skin contact: Cause skin irritation, redness.

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

Decision on the rescue procedure is taken by a doctor following thorough examination of victim's condition

SECTION 5: Fire fighting measures**5.1 Extinguishing media:**

Suitable extinguishing media: : Alcohol-resistant foam or dry chemicals (A, B, C), carbon dioxide (fire-extinguisher), sand or soil, water spray. Use fire extinguishing methods suitable to the environment.

Unsuitable extinguishing media: A strong stream of water.

5.2 Special hazards arising from the substance or mixture:

During a fire, under the action of heat release toxic decomposition products containing min. carbon oxides.

5.3 Advice for fire-fighters:

Cool containers with spray water. If possible remove from the danger zone. As in any fire, wear self-contained breathing apparatus and full protective gear. Prevent fire-fighting water from entering surface water, ground water and sanitation.

SECTION 6: Accidental release measures**6. Personal precautions, protective equipment and emergency procedures:**

For non-emergency personnel: Inform the appropriate service. Remove from the hazardous area people not involved in liquidation of failure.

For emergency responders: Ensure adequate ventilation, use personal protective equipment. Do not breathe vapors.

6.2 Environmental precautions:

Prevent from spreading or entering into drains and reservoirs, to inform local authorities if you fail to provide protection.

6.3 Methods and material for containment and cleaning up :

Absorb with liquid-binding material (sand, sawdust, diatomaceous earth, universal absorbent). Contaminated material placed in properly labeled containers. The contaminated material placed in properly labeled containers for disposal in accordance with applicable regulations.

6.4 Reference to other sections:

Waste product handling – see section 13 of the Safety Data Sheet.

Individual protection measures – see section 8 of the Safety Data Sheet.

SECTION 7: Handling and Storage**7.1 Precautions for safe handling:**

Use in well-ventilated area. Avoid contact with eyes. Avoid prolonged or repeated contact with skin. Avoid spilling or splashing. Avoid breathing vapors. Avoid sources of ignition, heat, hot surfaces and open flames. Work in accordance with safety and hygiene: Do not eat, drink and smoke in the workplace, wash hands after use, remove contaminated clothing and protective equipment before entering eating areas.

7.2 Conditions for safe storage, including any incompatibilities:

Store in a cool, dry, well-ventilated properly labeled original container tightly closed. Avoid direct sunlight and heat sources, hot surfaces and open flames.

7.3 Specific end use(s):

alcoholic preparation for fast disinfection of surfaces. Professional use only.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters:

Exposure standards for occupational hazards in accordance with the Regulation of the Minister of Labour and Social Policy of 12 June 2018 on maximum permissible concentration and intensity of harmful factors in the work environment (polish Journal of Laws, item. 1286).

Exposure limits (ACGIH):

Name / type of substance	TWA	STEL
	ppm	
Propan-2-ol	900	1200
Ethanol	1900	-

DNEL Values for Propan-2-ol

Worker, skin, long exposure systemic effect: 888 mg/kg/d

Worker, inhalation, long exposure, systemic effect: 500mg/m³

User, skin, long exposure, systemic effect: 319 mg/kg/d

User, inhalation, long exposure, local effect: 89mg/m³

User, oral, long exposure, systemic effect: 26 mg/kg/d

PNEC Values for Propan-2-ol

Fresh water: 140,9mg/l

Seawater: 140,9mg/

Periodic release: 190mg/l

Fresh water sludge: 552mg/kg

Seawater sludge: 552mg/kg

Sewage plant: 2251 mg/l

Soil: 28mg/kg

DNEL Values for ethanol

Worker, skin, long exposure systemic effect: 343 mg/kg/d

Worker, inhalation, long exposure, systemic effect: 950mg/m³

User, skin, long exposure, systemic effect: 206 mg/kg/d

User, inhalation, long exposure, local effect: 114mg/m³

User, oral, long exposure, systemic effect: 87 mg/kg/d

PNEC Values for ethanol

Fresh water: 0,96mg/l

Seawater: 0,79mg/

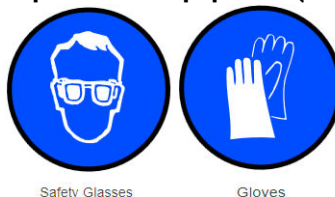
Periodic release: 190mg/l

Fresh water sludge: 580mg/kg

8.2 Exposure controls:

Technical solutions: recommended well-ventilated areas.

Individual protection measures, such as personal protective equipment (if working with concentrated product):



Eye and face protection:

Wear safety glasses or full face mask (according to EN 166).

Skin protection:

Hand protection:

Wear protective gloves resistant to chemicals made of nitrile rubber, natural rubber or PVC, in accordance with EN-PN 374: 2005.

Gloves material:

Choice of suitable gloves do not depend only on material but brand and quality. Material resistance can be defined after testing. Exact destruction time must be declared by manufacturer.

Other:

Wear appropriate protective work wear (according to EN 344) - wash regularly.

Respiratory protection:

Not necessary. Do not breath vaporous

Thermal hazards:

Not applicable.

Environmental exposure controls:

Do not allow to spread in the environment and enter drains and watercourses.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance	Liquid
Colour	transparent
Odour	Alcoholic, citrus
Odour threshold	Not specified
pH	8,0-9,0
Melting point/range	>-5°C
Boiling point/range	approx 80 °C
Flash point	21 °C
Ignition	Not specified
Evaporation rate	Not specified
Flammability (solid, gas)	Not specified
Vapour pressure at 20 ° C	Not specified
Relative vapor density	Not specified

Density at 20 °C	0,880 – 0,890g/cm ³
Solubility in solvents	Completely soluble in water
Coefficient of n-octanol / water	Not specified
Auto-ignition temperature	>420°C
Temperature of decomposition	Not specified
Refractive index (Na)	1,366 +/- 0,002

9.2 Other information: No additional test results.

SECTION 10: Stability and reactivity

10.1 Reactivity :

Unknown

10.2 Chemical stability:

The product is stable under normal conditions of use, storage and transport.

10.3 Possibility of hazardous reactions:

No

10.4 Conditions to avoid :

Avoid high temperature, direct sunlight, hot surfaces and open fire.

10.5 Incompatible materials :

Strong alkali and acids, ammonia, strong oxidizers or reductors

10.6 Hazardous decomposition products :

At high temperatures, they release toxic products of decomposition - carbon oxides.

SECTION 11: Toxicological information

11.1 Information on toxicological effects:

a) Acute toxicity: not recognized

Propan-2-ol

LD50 (oral, rat): 5280mg/kg

LD50 (rat,skin): 12800mg/kg

LC50 (rat, respiratory): 72,6mg/l, 4h

Ethanol

LD50 (oral, rat): 6200mg/kg

LD50 (rabbit,skin): 20000mg/kg

LC50 (rat, respiratory): 124,7mg/l, 4h

Irritation: skin, rabbit, exposition 3 min, OECD404

Allergy: no, Buehler method

b) irritation effect: not recognized

c) corrosive effect: causes eye irritation

d) allergic effect: not recognized

e) repeated dose toxicity: not recognized

f) carcinogenicity: not recognized

g) mutagenicity: not recognized

h) reproductive toxicity: not recognized

Information on likely routes of exposure:

The respiratory system. Inhalation of concentrated vapours may cause irritation of the mucous membranes of the nose, throat and downstream sections of the respiratory system, cough, shortness of breath, trouble breathing. May cause drowsiness or dizziness

The digestive tract: May cause irritation of the mucous membranes of the gastrointestinal tract, abdominal pain, stomach cramps, nausea, vomiting, diarrhea, malaise, headache and dizziness – symptoms of food poisoning.

Eye contact: Causes eye irritation.

Contact with skin: Not known

Delayed, immediate and chronic effects from short-and long-term exposure:

No data.

Interaction effect:

No data.

SECTION 12: Ecological information

Detailed studies of the environmental effects were not carried out. Harmful to aquatic life with long-lasting effects.

12.1 Toxicity:**Ethanol**

Toxicity to fish (Alburnus al burnus): LC50: 1100mg/l, 96h

Toxicity for crustacean (Daphnia magna): EC50 9268mg/l, 48h

Toxicity to algae (Microcystis aeruginosa): EC50 1450mg/l, 192h

Propan-2-ol

Toxicity to fish (Pimephales promelas): LC50: 9640mg/l, 96h

Toxicity for crustacean (Daphnia magna): EC50 1299mg/l, 48h

Toxicity to algae (Scenedesmus subspicatus): EC50 1000mg/l, 72h

12.2 Persistence and degradability:

Surfactants are included in the product are consistent with the regulations concerning biodegradation.

Propan-2-ol

Biological need for: 1,19gO₂/g

Chemical need for oxygen: 2,23g O₂/g

Ethanol

Biodegradability: 89% in 14d (100mg/l)

12.3 Bioaccumulative potential:**Propan-2-ol**

BCF: 3

Log Po/w: 0,05

Bioaccumulative potential: low

Ethanol

BCF: 3

Log Po/w: -0,31

Bioaccumulative potential: low

12.4 Mobility in soil:

Mobile in the soil, dissolved in water and spread in an aquatic environment.

Propan-2-ol

Ko/c: 1,5: high mobility

Ethanol:

Ko/c: 1,0: high mobility

12.5 Results of PBT and vPvB assessment:

No data.

12.6 Other adverse Effects:


No data.

SECTION 13: Disposal considerations**13.1 Waste treatment methods:**

Hazard of environmental contamination; dispose of the waste in accordance with the local and/or national regulations. Proceed in accordance with valid regulations on waste disposal. Any unused product and contaminated packaging should be put in labelled containers for waste collection and submitted for disposal to a person authorized for waste removal (a specialized company) that is entitled for such activity. Do not empty unused product in drainage systems. The product must not be disposed with municipal waste. Empty containers may be used at waste

incinerators or deposited in a dump with appropriate classification. Perfectly cleaned containers can be submitted for recycling

SECTION 14: Transport information

	ADR/RID	IMDG	IATA
Transport route	Road/Rail	Maritime	Air
14.1 – UN number	1987	1987	1987
14.2 – Proper transport name UN	ALCOHOLS N.O.S. (propan-2-ol, ethanol)	ALCOHOLS N.O.S. (propan-2-ol, ethanol)	Alcohols n.o.s.: (propan-2-ol, ethanol)
14.3 – Transport hazard class(es):			
14.4 – Packing group	III	III	III
14.5 – Environmental hazards	No		
14.6 – Special precautions for users	Transport in sealed containers, vertical, labelled.		
Detailed rules	274,601	223,274	A3, A180
Packing instructions	P001, IBC03, LP01, R001	P001, LP01	Civil airplanes: - Packaging instructions: 355 -max netto package volume: 60L Transport airplanes: - Packaging instructions: 366- max netto package volume: 220 L
LQ	5L	5L	- Packaging instructions Y344 - max count, netto package volume:10 L
EQ	E1	E1	E1
EmS	Not applicable	F-E, S-D	Not applicable
14.7 – Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	Not applicable, the product is not classified as hazardous during transport	Not applicable, the product is not classified as hazardous during transport	Not applicable, the product is not classified as hazardous during transport

SECTION 15: Regulatory information

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

1. The ordinance 1907/2006 (EC) of the European Parliament and Council, dated in 18 December 2006, on registration, evaluation, permissions and restrictions for chemicals (REACH), along with later modifications.
2. Commission Regulation (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance).
3. Law of 25 February 2011 on chemical substances and their mixtures (Journal of Laws No. 63, item. 322, along with later modifications)
4. European Parliament and Council Regulation of 16 December 2008 no. 1272/2008 (CLP) along with later modifications.
5. Ministry of Health Regulation of 20 April 2012 on dangerous substances and mixtures container labelling and certain mixtures (Journal of Laws 2012 No. 0 item. 445, along with later modifications)
6. Ministry of Health Regulation of 10 August 2012 on classification types and criteria of chemical substances and their mixtures (Journal of Laws 2012 item. 1018, along with later modifications)

7. Law of 9 December 2012 on waste list (Journal of Laws 2013 No. 0, item.21).
8. The Law of 13 June 2013 on packaging and packaging waste (Journal of Laws 2013, item. 888).
9. Regulation of the the Minister of Environment of 9 december 2014 on waste catalog (Journal of Laws No. 1923)
10. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste, as amended.
11. The Law of 19 August 2011. on the transport of dangerous goods (Journal of Laws No. 227, item. 1367)
12. Government Statement of 23 March 2015. On the entry into force of amendments to Annexes A and B of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR), done at Geneva on 30 September 1957. (Journal of Laws 2015 , item. 882).
13. Regulation of the Minister of Labour and Social Policy of 12 June 2018 on maximum permissible concentration and intensity of harmful factors in the work environment (Journal item. 1286).
14. Regulation of the Minister of the Environment of 9 December 2003 on substances posing a particular threat to the environment (Journal of Laws No. 217, item.2141).

15.2 Chemical safety assessment: No chemical safety assessment for the mixture.

SECTION 16: Other information

Phrases H:

H225 Highly flammable liquid and vapour

H319 Causes serious eye irritation

H336 May cause drowsiness or dizziness

Description of used abbreviations, acronyms and symbols:

Flam. Liq.2 Highly flammable liquid and vapors cat 2

Eye Irrit.2 – eye irritation cat. 2

STOT SE 3 Specific target organ toxicity - single exposure – cat 3

LC50 – (ang. *lethal concentration*) medium mortality dose of 50% in population of test organisms in long exposure

LC50 – (ang. *lethal concentration*) medium mortality dose of 50% in population of test organisms in 1 time exposure

TWA – Time weighted Average exposure limit

STEL – Acceptable Ceiling

DNEL - (Derived no-effect level) is the level of exposure to a substance above which humans should not be exposed.

PNEC (Predicted No Effect Concentration) is the concentration of a chemical which marks the limit at which below no adverse effects of exposure in an ecosystem are measured.

IATA International Air Transport Association

ADR a treaty governing transport of hazardous materials

IMDG International Maritime Dangerous Goods Code is accepted as an international guideline to the safe transportation or shipment of dangerous goods or hazardous materials by water on vessel

Training:

Before working with product carry out OSH training for staff related to the presence of chemical factor in the work environment. Carry out, register and inform employees about the evaluation of professional risk of working in presence of chemical factors

MATERIAL SAFETY DATA SHEET – Dr. Mayer Green Tonic

- Issued date 18.10.2018
- Version ENG 2.0 of 15.05.2019
- Changes: section 1, 8, 15

SOURCE MATERIALS

Appendix I of EC Regulation 2015/830 of 28 May 2015

Regulations detailed in Section 15 of this document

MSDS – DR. MAYER GREEN TONIC v 1.0 EN

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