

SAFETY DATA SHEET

[In accordance with the criteria of Regulation No 1907/2006 (REACH) as amended]

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

1.1 Product identifier

Viral Stop Gel

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

Relevant identified uses: hand and skin disinfectant for everyday use.

Uses advised against: not determined.

1.3 Details of the supplier of the safety data sheet

Supplier: **Empire Pharma Sp. z o.o.**

Address: Al. Jana Pawła II 54 C, 05-250 Radzymin, Poland

Telephone: +48 608755665

E-mail address for a competent person responsible for SDS: Daniel.palonek@empire.org.pl

1.4 Emergency telephone number

112

Section 2: Hazards identification

2.1 Classification of the substance or mixture

Flam. Liq. 2 H225, Eye Irrit. 2 H319

Highly flammable liquid and vapour. Causes serious eye irritation.

2.2 Label elements

Hazard pictograms and signal words



The names of substances on the label

None.

Hazard statements

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements

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.

P403+P235 Store in a well-ventilated place. Keep cool.

P501 Dispose of contents/container to properly labeled waste containers in accordance with national legislation.

2.3 Other hazards

Product does not contain ingredients, which meet criteria for PBT or vPvB in accordance with Annex XIII of REACH Regulation.

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Section 3: Composition/information on ingredients

3.1 Substances

Not applicable.

3.2 Mixtures

CAS number: 64-17-5 EC number: 200-578-6 Index number: 603-002-00-5 Registration number: 01-2119457610-43-XXXX	<u>ethanol</u> Flam. Liq. 2 H225, Eye Irrit. 2 H319 <u>Specific concentration limit:</u> ≥ 50 % Eye Irrit. 2 H319	< 75 %
CAS number: 67-63-0 EC number: 200-661-7 Index number: 603-117-00-0 Registration number: 01-2119457558-25-XXXX	<u>propan-2-ol</u> Flam. Liq. 2 H225, Eye Irrit. 2 H319, STOT SE 3 H336	< 5 %
CAS number: 75-65-0 EC number: 200-889-7 Index number: 603-005-00-1 Registration number: 01-2119444321-51-XXXX	<u>2-methylpropan-2-ol</u> Flam. Liq. 2 H225, Eye Irrit. 2 H319, Acute Tox. 4 H332, STOT SE 3 H335	< 1 %
CAS number: 123-92-2 EC number: 204-662-3 Index number: 607-130-00-2 Registration number:-	<u>isopentyl acetate</u> ¹⁾ Flam. Liq. 3 H226, Skin Irrit. 2 H315, EUH066 ²⁾	< 0.1 %

¹⁾ Substance with occupational exposure limits defined on the European Union level

²⁾ Additional hazard statement

Full text of each relevant H phrases is given in section 16 of SDS.

Section 4: First aid measures

4.1 Description of first aid measures

Skin contact: product intended for skin disinfection. Consult a doctor if disturbing symptoms occur.

Eye contact: wash eyes with plenty of clean, lukewarm water for several minutes. Protect non-irritated eye, remove contact lenses. Consult an ophthalmologist if disturbing symptoms occur.

Ingestion: do not induce vomiting. Never give anything by mouth to an unconscious person. Consult a doctor if disturbing symptoms occur.

Inhalation: move the victim to fresh air. Keep warm and calm. Consult a doctor if disturbing symptoms occur.

4.2 Most important symptoms and effects, both acute and delayed

There are no known significant effects other than resulting from classification.

4.3 Indication of any immediate medical attention and special treatment needed

Physician makes a decision regarding further medical treatment after thoroughly examination of the injured. Treat symptomatically.

Section 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: extinguishing powder, foam resistant to alcohols, water spray.

Unsuitable extinguishing media: water jet – risk of the propagation of the flame.

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5.2 Special hazards arising from the substance or mixture

During the fire, the product may produce harmful gases of carbon oxides, nitrogen oxides and other unidentified products of thermal decomposition. Do not inhale combustion products, they can be dangerous for human health.

5.3 Advice for firefighters

Highly flammable liquid and vapour. In case of fire, cool endangered containers with water spray from the safe distance. Vapours are heavier than air and are collect at the ground and in the pits. Vapours may form explosive mixtures with air. Personal protection typical in case of fire. Do not stay in the fire zone without self-contained breathing apparatus and protective clothing resistant to chemicals. Collect used extinguishing media. Do not let extinguishing water reach surface water, ground water and soil.

Section 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Limit the access for the outsiders into the breakdown area, until the suitable cleaning operations are completed. Ensure that effects of the breakdown are removed only by qualified personnel. Use personal protective measures. Ensure adequate ventilation. Do not inhale vapours. Avoid contamination of eyes. Prohibit smoking and using of naked flames. Do not use sparking tools.

6.2 Environmental precautions

In case of release of large amounts of the product, it is necessary to take appropriate steps to prevent it from spreading into the environment. Notify relevant emergency services.

6.3 Methods and material for containment and cleaning up

Collect leakage using incombustible liquid binding materials (eg. sand, earth, diatomaceous earth, universal binding agents etc.) and place it in correctly labelled containers. Treat collected material as waste. Clean and ventilate the contaminated area. Do not use sparking tools.

6.4 Reference to other sections

Appropriate conduct with waste product – see section 13. Personal protective equipment – see section 8.

Section 7: Handling and storage

7.1 Precautions for safe handling

Handle in accordance with good occupational hygiene and safety practices. Do not eat, drink or smoke when using the product. Wash hands before breaks and after work. Avoid eye contamination. Ensure adequate ventilation. Do not allow vapours to concentrate in the air. Eliminate sources of ignition - do not use an open flame.

7.2 Conditions for safe storage, including any incompatibilities

Store only in properly labeled, tightly closed containers in dry, cool and well ventilated place. Keep away from food, animal feed. Keep away from incompatible materials (see subsection 10.5). Avoid direct sunlight, sources of fire. Reseal opened packages and store them upright to avoid leakage.

7.3 Specific end use(s)

Applications submitted in accordance with section 1.2.

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Section 8: Exposure controls/personal protection

8.1 Control parameters

Specification	TWA 8 hour	STEL 15 min	Notation
isopentyl acetate [CAS 123-92-2]	270 mg/m ³	540 mg/m ³	-

Legal Basis: Commission Directive 2006/15/EC, 2000/39/EC, 2009/161/EU, 2017/164/EU, 2019/1831/EU.

Recommended control procedures

Procedures concerning the control over the dangerous components concentrations in the air and control over the air quality in the workplace – if they are available and justified for the position – in accordance with the European Standards, with the conditions within the exposure place and a proper test methodology adapted to the working conditions.

DNEL

ethanol [CAS 64-17-5]

Worker				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	—	1900 mg/m ³	950 mg/m ³	—
Skin	—	—	343 mg/kg b.w./day	—
Consumer				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	—	950 mg/m ³	114 mg/m ³	—
Skin	—	—	206 mg/kg b.w./day	—
Oral	—	—	87 mg/kg b.w./day	—

2-methylpropan-2-ol [CAS 75-65-0]

Worker				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	214 mg/m ³	—	2,7 mg/m ³	—
Skin	—	—	5,5 mg/kg b.w./day	—
Consumer				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	159,8 mg/m ³	—	0,5 mg/m ³	—
Skin	—	—	2,7 mg/kg b.w./day	—
Oral	—	—	0,3 mg/kg b.w./day	—

propan-2-ol [CAS 67-63-0]

Worker				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	—	—	500 mg/m ³	—
Skin	—	—	888 mg/kg b.w./day	—

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Consumer				
Route of exposure	Short-term exposure, systematic	Short-term exposure, local	Long-term exposure, systematic	Long-term exposure, local
Inhalation	—	—	89 mg/m ³	—
Skin	—	—	319 mg/kg b.w./day	—
Oral	—	—	26 mg/kg b.w./day	—

PNEC

ethanol [CAS 64-17-5]

PNEC	Value
fresh water	0.96 mg/l
marine water	0.79 mg/l
fresh water sediment	3.6 mg/kg
marine water sediment	2.9 mg/kg
soil	0.63 mg/kg
sewage treatment plant	580 mg/l

2-methylpropan-2-ol [CAS 75-65-0]

PNEC	Value
fresh water	2 mg/l
marine water	0.2 mg/l
fresh water sediment	8.04 mg/kg
marine water sediment	0.84 mg/kg
soil	1 mg/kg
sewage treatment plant	690 mg/l

propan-2-ol [CAS 67-63-0]

PNEC	Value
fresh water	140.9 mg/l
marine water	140.9 mg/l
fresh water sediment	552 mg/kg
marine water sediment	552 mg/kg
soil	28 mg/kg
sewage treatment plant	2251 mg/l
secondary poisoning	160 mg/kg

8.2 Exposure controls

Observe good occupational hygiene and safety practices. Do not eat, drink or smoke when using the product. Wash hands before breaks and after work. Avoid eye contamination. Take off contaminated clothes and wash it before reuse. Adequate ventilation should be provided in the workplace. If during work processes there is a risk of clothing fire on the employee - no more than 20 m in a horizontal line from the stations where these processes are performed, emergency showers (safety showers) for washing the whole body and separate showers (showers) for eye washing should be installed.

Hand and body protection

Not required. The product is intended for skin.

Eye protection

Use safety glasses if there is a risk of eye contamination.

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Respiratory protection

Not required for proper ventilation. In case of failure use suitable respiratory protection with a suitable organic vapor absorber.

Applied personal protective equipment must comply with the requirements of the Regulation 2016/425/EU. The employer is obliged to provide protective equipment relevant to performed activities and in accordance with all quality requirements, including its maintenance and cleaning.

Environmental exposure controls

Do not allow to enter large amounts of product to reach ground water or sewage. Possible emissions from the ventilation systems and processing equipment should be controlled in order to determinate their compatibility with environmental protection regulations.

Section 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

physical state:	liquid/ gel
colour:	acc. to assortment
odour:	characteristic
odour threshold:	not determined
pH:	not determined
melting point/freezing point:	not determined
initial boiling point and boiling range:	> 35 °C
flash point:	18 °C
evaporation rate:	not determined
flammability (solid, gas):	not applicable
upper/lower flammability or explosive limits:	not determined
vapour pressure:	not determined
vapour density:	not determined
density:	not determined
solubility(ies):	soluble in water
partition coefficient: n-octanol/water:	not determined
auto-ignition temperature:	not determined
decomposition temperature:	not determined
explosive properties:	not display
oxidising properties:	not display
viscosity:	not determined

9.2 Other information

No additional test results.

Section 10: Stability and reactivity

10.1 Reactivity

Product is reactive. Vapours may form explosive mixtures with air. See also subsections 10.4-10.5.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

Not known.

10.4 Conditions to avoid

Avoid overheating, sources of heat and fire, direct sunlight.

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10.5 Incompatible materials

Strong oxidizing agents, acids, bases.

10.6 Hazardous decomposition products

Hazardous decomposition products are not expected under normal use and storage.

Section 11: Toxicological information

11.1 Information on toxicological effects

Information regarding acute and/or delayed results of the exposure was defined on the basis of the information on product's classification and/or toxicological studies and knowledge and experience of the manufacturer.

Toxicity of components

ethanol [CAS 64-17-5]

LD ₅₀ (oral, rat)	1187 - 15010 mg/kg
LD ₅₀ (skin, rabbit)	> 20000 mg/kg
LC ₅₀ (inhalation, rat)	115,9 – 133,8 mg/l/ 4h

propan-2-ol [CAS 67-63-0]

LD ₅₀ (oral, rat)	> 5000 mg/kg
LD ₅₀ (skin, rabbit)	> 5000 mg/kg

2-methylpropan-2-ol [CAS 75-65-0]

LD ₅₀ (oral, rat)	2743 - 3384 mg/kg
LD ₅₀ (skin, rabbit)	> 2000 mg/kg
LC ₅₀ (inhalation, rat)	> 10000 ppm/l/ 4h

Toxicity of the mixture

Acute toxicity

The acute toxicity estimate (ATE_{mix}) was determined using the appropriate conversion value from Table 3.1.2 in Annex I to CLP as amended.

ATE _{mix} (inhalation)	> 20 mg/l
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Based on available data, the classification criteria are not met.

Skin corrosion/irritation

Based on available data, the classification criteria are not met.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitisation

Based on available data, the classification criteria are not met.

Germ cell mutagenicity

Based on available data, the classification criteria are not met.

Carcinogenicity

Based on available data, the classification criteria are not met.

Reproductive toxicity

Based on available data, the classification criteria are not met.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT-repeated exposure

Based on available data, the classification criteria are not met.

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Aspiration hazard

Based on available data, the classification criteria are not met.

Symptoms related to the physical, chemical and toxicological characteristics

Skin contact: there are not known negative effects of exposure.

Eye contact: possible redness, tearing, irritation.

Ingestion: possible abdominal pain, diarrhea, nausea, vomiting.

Inhalation: possible headache, dizziness, slight respiratory tract irritation.

Section 12: Ecological information

12.1 Toxicity

Toxicity of components

ethanol [CAS 64-17-5]

Toxicity of fish LC₅₀ > 100 mg/l/ 96h/ *Pimephales promelas*

Toxicity of invertebrate EC₅₀ 11,5 mg/l/ 24h/ *Daphnia pulex*

Toxicity of algae NOEC > 1,58 mg/l/ 96h/ *Scendesmus sp.*

Toxicity of water plant EC₅₀ 10789 mg/l/ 7d/ *Lemna minor*

propan-2-ol [CAS 67-63-0]

Toxicity of fish LC₅₀ > 1,4 mg/l/ 96h/ *Pimephales promelas/Lepomis macrochirus*

Toxicity of invertebrate EC₅₀ > 9000 mg/l/ 24h/ *Daphnia magna*

Toxicity of algae ErC₅₀ > 1000 mg/l/ 72h/ *Scendesmus subspicatus*

2-methylpropan-2-ol [CAS 75-65-0]

Toxicity of fish LC₅₀ > 856 mg/l/ 96h/ *Danio rerio*

Toxicity of fish NOEC 332 mg/l/ 120h/ *Clarias Gariepinus*

Toxicity of invertebrate EC₅₀ 5504 mg/l/ 48h/ *Daphnia magna*

Toxicity of invertebrate NOEC 100 mg/l/ 21d/ *Daphnia magna*

Toxicity of algae EC₅₀ > 1000 mg/l/ 72h/ *Desmodesmus subspicatus*

Toxicity of microorganism EC₅₀ > 10000 mg/l/ 16h/ *Pseudomonas putida*

Toxicity of the mixture

Product is not classified as hazardous for the aquatic environment.

12.2 Persistence and degradability

Data of components:

ethanol [CAS 64-17-5]

Substance is easily biodegradable.

propan-2-ol [CAS 67-63-0]

Substance is easily biodegradable.

12.3 Bioaccumulative potential

Data of components:

ethanol [CAS 64-17-5]

Bioaccumulation is not expected.

propan-2-ol [CAS 67-63-0]

Bioaccumulation is not expected.

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12.4 Mobility in soil

Mobility of components of the mixture in soil depends on the hydrophilic and hydrophobic properties and biotic and abiotic conditions of soil, including its structure, climatic conditions, seasons and soil organisms.

12.5 Results of PBT and vPvB assessment

Product does not contain ingredients, which meet criteria for PBT or vPvB.

12.6 Other adverse effects

The mixture is not classified as hazardous to the ozone layer and global warming.

Section 13: Disposal considerations

13.1 Waste treatment methods

Disposal methods for the product: do not empty into drains. Dispose in accordance with the local legislation. Waste code should be assigned in place of its formation.

Disposal methods for used packing: reuse/recycle/eliminate empty containers in accordance with the local legislation. Only completely emptied packaging can be recycled.

Legal basis: Directive 2008/98/EC as amended, 94/62/EC as amended.

Section 14: Transport information

14.1 UN number

UN 1993

14.2 UN proper shipping name

FLAMMABLE LIQUID, N.O.S. [ETHANOL]

14.3 Transport hazard class(es)

3

14.4 Packing group

II

14.5 Environmental hazards

Product is not classified as dangerous for the environment according to transport regulations.

14.6 Special precautions for user

Keep away sources of ignition. Use with extreme caution.

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

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC as amended.

Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 as amended.

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Commission Regulation (EU) No 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).

Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives as amended.

Commission Directive 2019/1831/EU of 24 October 2019 establishing a fifth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

ADR European Agreement concerning the international carriage of dangerous goods by road.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste as amended.

Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work.

Commission Directive 2006/15/EC of 7 February 2006 establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC.

Commission Directive 2009/161/EU of 17 December 2009 establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC.

Commission Directive 2017/164/EU of 31 January 2017 establishing a fourth list of indicative occupational exposure limit values pursuant to Council Directive 98/24/EC, and amending Commission Directives 91/322/EEC, 2000/39/EC and 2009/161/EU.

Regulation (EU) No 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC.

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products.

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for mixtures in accordance with REACH Regulation.

Section 16: Other information

Full text of indicated H phrases mentioned in section 3

H225	Highly flammable liquid and vapour.
H226	Flammable liquid and vapour.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H336	May cause drowsiness or dizziness.
EUH066	Repeated exposure may cause skin dryness or cracking.

Clarification of aberrations and acronyms

Flam. Liq. 2, 3	Flammable liquid category 2, 3
Skin Irrit. 2	Skin irritation category 2
Eye Irrit. 2	Eye irritation category 2
STOT SE 3	Specific target organ toxicity — single exposure category 3
PBT	Persistent, Bioaccumulative and Toxic substance
vPvB	very Persistent, very Bioaccumulative substance
DNEL	Derived No-Effect Level
PNEC	Predicted No Effect Concentration
STEL	Short Term Exposure Limit
TWA	Total Weighted Average (permissible exposure limit; Occupational Safety and Health Administration)

Trainings

Before commencing working with the product, the user should learn the Health & Safety regulations, regarding handling chemicals, and in particular, undergo a proper workplace training. Persons related to the transportation of the dangerous goods in compliance with the ADR Agreement should be properly trained within the scope of performed tasks (general training, on-the-job training and training related to the safety issues).

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Key literature references and data sources

This SDS was prepared on the basis of sheets of the individual components, literature data, online databases (eg. ECHA, TOXNET, COSING) as well as our knowledge and experience, taking into account current legislation.

Procedures used to classify the mixture

Classification was based on physicochemical data of the mixture and on the content of hazardous substances by calculation method under the guidance of Regulation 1272/2008/EC (CLP) as amended.

Other data

Data of issue: 30.09.2020

Version: 1.0/EN

Safety Data Sheet made by: „**THETA**” Doradztwo Techniczne

The information above is based on a current available data concerning the product, but also on the experience and knowledge in this field of the producer. They are neither a quality description of the product nor a guarantee of particular features. They are to be treated as aid to safety in transport, storage and usage of the product. That does not free the user from the responsibility of improper usage of the information above and also of improper compliance with the law norms in the field.