



Neutron[®]Pharmachemical Co.
Manufacturer of Laboratory Chemical & Pharmaceutical Materials

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Revision Date 26.10.2019

Version 10.1

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

1.1 Product identifier

Catalogue No.	1.2790
Product name	Papanicolaou's solution 2a Orange G solution (OG 6) for cytological cancer and cycle diagnosis
REACH Registration Number	This product is a mixture. REACH Registration Number see section 3. This product is a mixture. REACH Registration Number see section 3.

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

Identified uses	In vitro diagnostic reagent, Reagent for analysis For additional information on uses please refer to the Neutron Chemicals portal (www.neutronpharmachemical.com).
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1.3 Details of the supplier of the safety data sheet

Company	98, 9th Floor, Borjsaz Building, Azadi Ave, Tehran, Iran. T 021-66906732-3 - F 021-66581408
Responsible Department	LS-QHC * e-mail: Info@neutronpharmachemical.com

1.4 Emergency telephone number 125

SECTION 2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquid, Category 2, H225

Eye irritation, Category 2, H319

For the full text of the H-Statements mentioned in this Section, see Section 16.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms



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Catalogue No.	1.2790
Product name	Papanicolaou's solution 2a Orange G solution (OG 6) for cytological cancer and cycle diagnosis

Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements

Prevention

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources.

No smoking.

P240 Ground/bond container and receiving equipment.

Response

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

Storage

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

Reduced labelling (≤ 125 ml)

Hazard pictograms



Signal word

Danger

Precautionary statements

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

2.3 Other hazards

None known.

SECTION 3. Composition/information on ingredients

Chemical nature Aqueous-ethanolic dye solution.

3.1 Substance

Not applicable

3.2 Mixture

Hazardous components (REGULATION (EC) No 1272/2008)

Chemical name (Concentration)

CAS-No.	Registration number	Classification
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ethanol ($\geq 50\%$ - $\leq 100\%$)

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

64-17-5	01-2119457610-43-XXXX	Flammable liquid, Category 2, H225 Eye irritation, Category 2, H319
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For the full text of the H-Statements mentioned in this Section, see Section 16.

SECTION 4. First aid measures

4.1 Description of first aid measures

After inhalation: fresh air.

In case of skin contact: Take off immediately all contaminated clothing. Rinse skin with water/ shower.

After eye contact: rinse out with plenty of water. Call in ophthalmologist. Remove contact lenses.

After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

irritant effects, Dermatitis, Dizziness, Nausea, Vomiting, respiratory paralysis, inebriation, euphoria, narcosis

4.3 Indication of any immediate medical attention and special treatment needed

No information available.

SECTION 5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, Carbon dioxide (CO₂), Dry powder

Unsuitable extinguishing media

For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Combustible.

Vapours are heavier than air and may spread along floors.

Forms explosive mixtures with air at ambient temperatures.

Pay attention to flashback.

Development of hazardous combustion gases or vapours possible in the event of fire.

5.3 Advice for firefighters

Special protective equipment for firefighters

In the event of fire, wear self-contained breathing apparatus.

Further information

Remove container from danger zone and cool with water. Prevent fire extinguishing water from contaminating surface water or the ground water system.

SECTION 6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

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Advice for non-emergency personnel: Do not breathe vapours, aerosols. Avoid substance contact. Ensure adequate ventilation. Keep away from heat and sources of ignition. Evacuate the danger area, observe emergency procedures, consult an expert.

Advice for emergency responders:

Protective equipment see section 8.

6.2 Environmental precautions

Do not let product enter drains. Risk of explosion.

6.3 Methods and materials for containment and cleaning up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemisorb®). Dispose of properly. Clean up affected area.

6.4 Reference to other sections

Indications about waste treatment see section 13.

SECTION 7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Observe label precautions.

Advice on protection against fire and explosion

Keep away from open flames, hot surfaces and sources of ignition. Take precautionary measures against static discharge.

Hygiene measures

Change contaminated clothing. Wash hands after working with substance.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed in a dry and well-ventilated place. Keep away from heat and sources of ignition.

Recommended storage temperature see product label.

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

SECTION 8. Exposure controls/personal protection

8.1 Control parameters

Derived No Effect Level (DNEL)

ethanol (64-17-5)

Worker DNEL, acute Local effects

inhalation

1900 mg/m³

Worker DNEL, longterm Systemic effects

dermal

343 mg/kg Body weight

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Worker DNEL, longterm	Systemic effects	inhalation	950 mg/m ³
Consumer DNEL, acute	Local effects	inhalation	950 mg/m ³
Consumer DNEL, longterm	Systemic effects	dermal	206 mg/kg Body weight
Consumer DNEL, longterm	Systemic effects	inhalation	114 mg/m ³
Consumer DNEL, longterm	Systemic effects	oral	87 mg/kg Body weight

Predicted No Effect Concentration (PNEC)

ethanol (64-17-5)

PNEC Fresh water	0,96 mg/l
PNEC Marine water	0,79 mg/l
PNEC Fresh water sediment	3,6 mg/kg
PNEC Soil	0,63 mg/kg
PNEC Aquatic intermittent release	2,75 mg/l
PNEC Sewage treatment plant	580 mg/l
PNEC oral	720 mg/kg

8.2 Exposure controls

Engineering measures

Technical measures and appropriate working operations should be given priority over the use of personal protective equipment.

See section 7.1.

Individual protection measures

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of the hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.

Eye/face protection

Safety glasses

Hand protection

full contact:

Glove material:	butyl-rubber
Glove thickness:	0,7 mm
Break through time:	> 480 min

splash contact:

Glove material:	Nitrile rubber
Glove thickness:	0,40 mm
Break through time:	> 120 min

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The protective gloves to be used must comply with the specifications of EC Directive 89/686/EEC and the related standard EN374, for example KCL 898 Butoject® (full contact), KCL 730 Camatril® -Velours (splash contact).

The breakthrough times stated above were determined by KCL in laboratory tests acc. to EN374 with samples of the recommended glove types.

This recommendation applies only to the product stated in the safety data sheet, supplied by us and for the designated use. When dissolving in or mixing with other substances and under conditions deviating from those stated in EN374 please contact the supplier of CE-approved gloves (e.g. KCL GmbH, D-36124 Eichenzell, Internet: www.kcl.de).

Other protective equipment

Flame retardant antistatic protective clothing.

Respiratory protection

required when vapours/aerosols are generated.

Recommended Filter type: Filter A (acc. to DIN 3181) for vapours of organic compounds

The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer.

These measures have to be properly documented.

Environmental exposure controls

Do not let product enter drains.

Risk of explosion.

SECTION 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Form	liquid
Colour	orange
Odour	of ethanol
Odour Threshold	No information available.
pH	No information available.
Melting point	No information available.
Boiling point	No information available.
Flash point	14 °C
Evaporation rate	No information available.
Flammability (solid, gas)	No information available.
Lower explosion limit	No information available.

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Upper explosion limit	No information available.
Vapour pressure	No information available.
Relative vapour density	No information available.
Density	0,83 g/cm ³ at 20 °C
Relative density	No information available.
Water solubility	at 20 °C soluble
Partition coefficient: n-octanol/water	No information available.
Auto-ignition temperature	No information available.
Decomposition temperature	No information available.
Viscosity, dynamic	No information available.
Explosive properties	Not classified as explosive.
Oxidizing properties	none

9.2 Other data

none

SECTION 10. Stability and reactivity

10.1 Reactivity

Vapours may form explosive mixture with air.

Vapours may form explosive mixture with air.

10.2 Chemical stability

The product is chemically stable under standard ambient conditions (room temperature) .

10.3 Possibility of hazardous reactions

Risk of explosion/exothermic reaction with:

hydrogen peroxide, perchlorates, perchloric acid, Nitric acid, mercury(II) nitrate, permanganic acid, Nitriles, peroxy compounds, Strong oxidizing agents, nitrosyl compounds, Peroxides, sodium, Potassium, halogen oxides, calcium hypochlorite, nitrogen dioxide, metallic oxides, uranium hexafluoride, iodides, Chlorine, Alkali metals, Alkaline earth metals, alkali oxides, Ethylene oxide

silver, with, Nitric acid

silver compounds, with, Ammonia

potassium permanganate, with, conc. sulfuric acid

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Risk of ignition or formation of inflammable gases or vapours with:
halogen-halogen compounds, chromium(VI) oxide, chromyl chloride, Fluorine,
hydrides, Oxides of phosphorus, platinum
Nitric acid, with, potassium permanganate

10.4 Conditions to avoid

Warming.

10.5 Incompatible materials

rubber, various plastics

10.6 Hazardous decomposition products

no information available

SECTION 11. Toxicological information

11.1 Information on toxicological effects

Mixture

Acute oral toxicity

Symptoms: Nausea, Vomiting

Acute inhalation toxicity

Symptoms: slight mucosal irritations

Symptoms: Possible symptoms:

Acute dermal toxicity

This information is not available.

Skin irritation

Repeated or prolonged exposure may cause skin irritation and dermatitis, due to degreasing properties of the product.

Eye irritation

Mixture causes serious eye irritation.

Sensitisation

This information is not available.

Germ cell mutagenicity

This information is not available.

Carcinogenicity

This information is not available.

Reproductive toxicity

This information is not available.

Teratogenicity

This information is not available.

Specific target organ toxicity - single exposure

This information is not available.

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Specific target organ toxicity - repeated exposure

This information is not available.

Aspiration hazard

This information is not available.

11.2 Further information

Systemic effects:

euphoria

After absorption of large quantities:

Dizziness, inebriation, narcosis, respiratory paralysis, Dermatitis

Other dangerous properties can not be excluded.

Handle in accordance with good industrial hygiene and safety practice.

Components

ethanol

Acute oral toxicity

LD50 Rat: 10.470 mg/kg

OECD Test Guideline 401

Acute inhalation toxicity

LC50 Rat: 124,7 mg/l; 4 h ; vapour

OECD Test Guideline 403

Skin irritation

Rabbit

Result: No skin irritation

OECD Test Guideline 404

Eye irritation

Rabbit

Result: Eye irritation

OECD Test Guideline 405

Sensitisation

Local lymph node assay (LLNA) Mouse

Result: negative

Method: OECD Test Guideline 429

Germ cell mutagenicity

Genotoxicity in vitro

Ames test

Salmonella typhimurium

Result: negative

Method: OECD Test Guideline 471

In vitro mammalian cell gene mutation test

Mouse lymphoma test

Result: negative

Method: OECD Test Guideline 476

Reproductive toxicity

Application Route: Oral

Mouse

Method: OECD Test Guideline 416

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SECTION 12. Ecological information

Mixture

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

Substance(s) in the mixture do(es) not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII, or a PBT/vPvB assessment was not conducted.

12.6 Other adverse effects

Discharge into the environment must be avoided.

Components

ethanol

Toxicity to fish

flow-through test EC50 Pimephales promelas (fathead minnow): 15.300 mg/l; 96 h

Analytical monitoring: yes

US-EPA

Toxicity to daphnia and other aquatic invertebrates

EC50 Daphnia magna (Water flea): 9.268 - 14.221 mg/l; 48 h
(IUCLID)

Toxicity to algae

IC5 Scenedesmus quadricauda (Green algae): 5.000 mg/l; 7 d
(Lit.)

Toxicity to bacteria

EC5 Pseudomonas putida: 6.500 mg/l; 16 h
(IUCLID)

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity)

semi-static test NOEC Daphnia magna (Water flea): 9,6 mg/l; 9 d

(ECHA)

Biodegradability

94 %

OECD Test Guideline 301E

Readily biodegradable

Biochemical Oxygen Demand (BOD)

930 - 1.670 mg/g (5 d)

(Lit.)

Theoretical oxygen demand (ThOD)

2.100 mg/g

(Lit.)

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Ratio COD/ThBOD

90 %

(Lit.)

Partition coefficient: n-octanol/water

log Pow: -0,31

(experimental)

(Lit.) Bioaccumulation is not expected.

Substance does not meet the criteria for PBT or vPvB according to Regulation (EC) No 1907/2006, Annex XIII.

SECTION 13. Disposal considerations

Waste treatment methods

See www.retrologistik.com for processes regarding the return of chemicals and containers, or contact us there if you have further questions.

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SECTION 14. Transport information

Land transport (ADR/RID)

14.1 UN number	UN 1170
14.2 Proper shipping name	ETHANOL SOLUTION
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
Tunnel restriction code	D/E

Inland waterway transport (ADN)

Not relevant

Air transport (IATA)

14.1 UN number	UN 1170
14.2 Proper shipping name	ETHANOL SOLUTION
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--

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14.6 Special precautions for user no

Sea transport (IMDG)

14.1 UN number	UN 1170
14.2 Proper shipping name	ETHANOL SOLUTION
14.3 Class	3
14.4 Packing group	II
14.5 Environmentally hazardous	--
14.6 Special precautions for user	yes
EmS	F-E S-D

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not relevant

SECTION 15. Regulatory information

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

EU regulations

Major Accident Hazard Legislation	SEVESO III FLAMMABLE LIQUIDS P5c Quantity 1: 5.000 t Quantity 2: 50.000 t
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Occupational restrictions	Take note of Dir 94/33/EC on the protection of young people at work. Take note of Dir 94/33/EC on the protection of young people at work.
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Regulation (EC) No 1005/2009 on substances that deplete the ozone layer not regulated

Regulation (EC) No 850/2004 of the European Parliament and of the Council of 29 April 2004 on persistent organic pollutants and amending Directive 79/117/EEC	not regulated
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Substances of very high concern (SVHC)

This product does not contain substances of very high concern according to Regulation (EC) No 1907/2006 (REACH), Article 57 above the respective regulatory concentration limit of $\geq 0.1\%$ (w/w).

National legislation

Storage class 3

15.2 Chemical safety assessment

For this product a chemical safety assessment was not carried out.

SECTION 16. Other information

Full text of H-Statements referred to under sections 2 and 3.

H225	Highly flammable liquid and vapour.
H319	Causes serious eye irritation.

Training advice

Provide adequate information, instruction and training for operators.

Labelling

Hazard pictograms



Signal word

Danger

Hazard statements

H225 Highly flammable liquid and vapour.

H319 Causes serious eye irritation.

Precautionary statements

Prevention

P210 Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P240 Ground/bond container and receiving equipment.

Response

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes.

Remove contact lenses, if present and easy to do. Continue rinsing.

Storage

P403 + P233 Store in a well-ventilated place. Keep container tightly closed.

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Key or legend to abbreviations and acronyms used in the safety data sheet

Used abbreviations and acronyms can be looked up at www.wikipedia.org.

Regional representation

This information is given on the authorised Safety Data Sheet for your country.

The information contained herein is based on the present state of our knowledge. It characterises the product with regard to the appropriate safety precautions. It does not represent a guarantee of any properties of the product.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.