# SAFETY DATA SHEET



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

1.1. Product identifier

Trade name or designation

SPECTRO JEL FOR OILY AND COMBINATION SKIN

of the mixture

Registration number -

Synonyms SPECTRO JEL FOR OILY SKIN \* SPECTRO JEL FOR COMBINATION SKIN \* FORMULA NO:

600160 AND 600170, FORMULATED PRODUCT

Issue date 27-April-2014

Version number 02

Revision date 27-April-2014

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

Identified uses Cosmetic Product

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant

to medicinal use of the product. In this instance patients should consult prescribing

information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate

safety data sheet for each ingredient.

Uses advised against No other uses are advised.

1.3. Details of the supplier of the safety data sheet

GlaxoSmithKline UK 980 Great West Road

Brentford, Middlesex TW8 9GS UK

UK General Information (normal business hours): +44-20-8047-5000

Email Address: msds@gsk.com Website: www.gsk.com

1.4. Emergency telephone

number

TRANSPORT EMERGENCIES::

UK In-country toll call: +(44)-870-8200418
International toll call: +1 703 527 3887

available 24 hrs/7 days; multi-language response

## **SECTION 2: Hazards identification**

### 2.1. Classification of the substance or mixture

### Classification according to Directive 67/548/EEC or 1999/45/EC as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

### Classification according to Regulation (EC) No 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

#### 2.2. Label elements

### Label according to Regulation (EC) No. 1272/2008 as amended

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Supplemental label information Not applicable.

**2.3. Other hazards** Expected to be non-combustible.

See section 11 for additional information on health hazards.

# **SECTION 3: Composition/information on ingredients**

#### 3.2. Mixtures

**General information** 

CAS-No. / EC No. REACH Registration No. INDEX No. **Chemical name** % **Notes** 

**ETHANOL** 3 - < 5 64-17-5 603-002-00-5

200-578-6

Classification: **DSD:** F;R11, Xi;R36

> CLP: Flam. Liq. 2;H225, Eye Irrit. 2;H319

**GLYCERIN** 1 - < 3 56-81-5

200-289-5

DSD: -Classification:

CLP: -

**CETYL ALCOHOL** < 1 36653-82-4

253-149-0

Classification: DSD: Xi;R38

CLP: Skin Irrit, 2:H315

Triethanolamine < 0.1 102-71-6

203-049-8

Classification: DSD: Xi;R36

CLP: Eye Irrit. 2;H319

Other components below reportable levels 90 - 100

CLP: Regulation No. 1272/2008.

DSD: Directive 67/548/EEC.

M: M-factor

vPvB: very persistent and very bioaccumulative substance.

PBT: persistent, bioaccumulative and toxic substance.

#: This substance has been assigned Community workplace exposure limit(s).

Composition comments The full text for all R- and H-phrases is displayed in section 16.

# **SECTION 4: First aid measures**

**General information** Pre-placement and periodic health surveillance is not usually indicated. The final determination of

the need for health surveillance should be determined by local risk assessment.

4.1. Description of first aid measures

Inhalation Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Take off contaminated clothing and wash before reuse. Immediately flush skin with plenty of water.

Eye contact Immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if

irritation develops and persists.

If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large Ingestion

amount does occur, call a poison control centre immediately.

4.2. Most important symptoms and effects, both acute and

delayed

Direct contact with eyes may cause temporary irritation.

4.3. Indication of any immediate medical attention and special treatment needed No specific antidotes are recommended. Treat according to locally accepted protocols. For

additional guidance, refer to the local poison control information centre.

### **SECTION 5: Firefighting measures**

General fire hazards Expected to be non-combustible.

5.1. Extinguishing media

None known.

media

Suitable extinguishing Water fog. Foam. Dry chemical powder. Carbon dioxide (CO2).

Unsuitable extinguishing

media

5.2. Special hazards arising from the substance or mixture During fire, gases hazardous to health may be formed.

5.3. Advice for firefighters

equipment for firefighters

Special protective Self-contained breathing apparatus and full protective clothing must be worn in case of fire.

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Move containers from fire area if you can do so without risk.

# **SECTION 6: Accidental release measures**

#### 6.1. Personal precautions, protective equipment and emergency procedures

For non-emergency

personnel

Keep unnecessary personnel away. For personal protection, see section 8.

Keep unnecessary personnel away. Use personal protection recommended in Section 8 of the For emergency responders

SDS.

Avoid discharge into drains, water courses or onto the ground. 6.2. Environmental precautions

6.3. Methods and material for containment and cleaning up Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth

and place into containers. Following product recovery, flush area with water.

Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to

remove residual contamination.

Never return spills to original containers for re-use.

6.4. Reference to other

sections

For personal protection, see section 8. For waste disposal, see section 13.

# SECTION 7: Handling and storage

7.1. Precautions for safe

handling

Avoid prolonged exposure. Observe good industrial hygiene practices.

7.2. Conditions for safe storage, including any incompatibilities

Store in original tightly closed container. Store away from incompatible materials (see Section 10 of the SDS).

Cosmetic Product 7.3. Specific end use(s)

# **SECTION 8: Exposure controls/personal protection**

## 8.1. Control parameters

# Occupational exposure limits

G	S	K
u	J	r

Components	Туре	Value		
Triethanolamine (CAS 102-71-6)	8 HR TWA	4000 mcg/m3	4000 mcg/m3	
,	OHC	1		
UK. EH40 Workplace Exposure Li	mits (WELs)			
Components	Туре	Value	Form	
ETHANOL (CAS 64-17-5)	TWA	1920 mg/m3		

GLYCERIN (CAS 56-81-5) Recommended monitoring

Follow standard monitoring procedures.

**TWA** 

**Derived No Effect Level (DNEL)** 

Not available.

Predicted no effect concentrations (PNECs) Not available.

8.2. Exposure controls

Appropriate engineering controls

procedures

Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level. An Exposure Control Approach (ECA) is established for operations involving this material based upon the OEL/Occupational Hazard Category and the outcome of a site- or operation-specific risk

1000 ppm

10 mg/m3

Mist.

assessment.

### Individual protection measures, such as personal protective equipment

**General information** 

Personal protection equipment should be chosen according to the CEN standards and in discussion with the supplier of the personal protective equipment. Follow all local regulations if

personal protective equipment (PPE) is used in the workplace.

Eye/face protection

Skin protection

If contact is likely, safety glasses with side shields are recommended. (eg. EN 166)

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The choice of an appropriate glove does not only depend on its material but also on other quality - Hand protection

features and is different from one producer to the other. Glove selection must take into account any solvents and other hazards present. With respect to the above precautions select suitable chemical resistant protective gloves (EN 374) with a protective index 6 (>480min permeation time).

Wear suitable protective clothing. (EN 14605 for splashes, EN ISO 13982 for dust) - Other

No personal respiratory protective equipment normally required. Respiratory protection Wear appropriate thermal protective clothing, when necessary. Thermal hazards

For advice on suitable monitoring methods, seek guidance from a qualified environment, health Hygiene measures

and safety professional.

**Environmental exposure controls** 

Hazard guidance and control recommendations Environmental manager must be informed of all major releases.

# **SECTION 9: Physical and chemical properties**

### 9.1. Information on basic physical and chemical properties

**Appearance** 

**Physical state** Liquid. **Form** Gel.

Not available. Colour Not available. Odour **Odour threshold** Not available. Not available. pН Not available. Melting point/freezing point Not available. Initial boiling point and boiling

range

Not available. Flash point **Evaporation rate** Not available. Flammability (solid, gas) Not available. Upper/lower flammability or explosive limits

Flammability limit - lower

Not available.

Flammability limit - upper

Not available.

(%)

Not available. Vapour pressure Vapour density Not available. Not available. Relative density

Solubility(ies)

Not available. Solubility (water) Not available. Solubility (other) Partition coefficient Not available.

(n-octanol/water)

Not available. **Auto-ignition temperature** Not available. **Decomposition temperature** Not available. **Viscosity** Not available. **Explosive properties** Not available. Oxidizing properties

9.2. Other information No relevant additional information available.

# **SECTION 10: Stability and reactivity**

Not available. 10.1. Reactivity

10.2. Chemical stability Material is stable under normal conditions.

10.3. Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

10.4. Conditions to avoid Contact with incompatible materials.

10.5. Incompatible materials Strong oxidising agents.

10.6. Hazardous decomposition products Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

# **SECTION 11: Toxicological information**

**General information** Occupational exposure to the substance or mixture may cause adverse effects.

Information on likely routes of exposure

**Ingestion** Expected to be a low ingestion hazard.

**Inhalation** Under normal conditions of intended use, this material is not expected to be an inhalation hazard.

Skin contact Health injuries are not known or expected under normal use.

Eye contact Direct contact with eyes may cause temporary irritation.

Symptoms Direct contact with eyes may cause temporary irritation.

11.1. Information on toxicological effects

Acute toxicity Health injuries are not known or expected under normal use.

Components Species Test results

CETYL ALCOHOL (CAS 36653-82-4)

Acute

Oral LD50

Rat 5 g/kg

ETHANOL (CAS 64-17-5)

Acute

Oral

LD50 Rat > 2000 mg/kg

Chronic

Oral

LOAEL Monkey 40 %, 48 months % ingested calories

**Subacute** 

Oral

LOEL Rat 16.9 g/kg, 4 weeks Dietary - Dose given as

g/kg/day

6 %, 4 weeks percent in diet - continuous

**Subchronic** 

Inhalation

LOEL Rat 2 ml, 36 weeks haematological parameters

NOAEL Guinea pig 3000 ppm No adverse effects

Rat 86 mg/m3, 90 Day Daily dosing

Oral

LOAEL Rat 5000 mg/kg/day, 10 weeks Liver toxicity

80 ml/kg, 85 Day Daily dose - Liver toxicity

10.2 g/kg, 12 weeks Dosed in drinking

water - Continuous

7.7 g/kg, 12 weeks Dosed in drinking water

- continuous

**GLYCERIN (CAS 56-81-5)** 

Acute

Oral

LD50 Rat > 2000 mg/kg

\* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Health injuries are not known or expected under normal use.

Corrosivity

ETHANOL OECD 404

Result: Negative; not considered a significant irritant

Species: Rabbit

Serious eye damage/eye

irritation

Direct contact with eyes may cause temporary irritation.

Eye

ETHANOL OECD 405

Result: Severe Species: Rabbit

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Respiratory sensitisation

Skin sensitisation

Sensitisation **ETHANOL**  Due to partial or complete lack of data the classification is not possible.

This product is not expected to cause skin sensitisation.

mutagenic or genotoxic.

**OECD 406** Result: negative Species: Guinea pig

Germ cell mutagenicity

Mutagenicity **ETHANOL**  No data available to indicate product or any components present at greater than 0.1% are

Ames

Result: negative

Chromosomal Aberration Assay In Vitro, CHO cells

Result: negative Dominant lethal assay Result: positive Species: Mouse Dominant lethal assay Result: positive Species: Rat

Gene mutation and repair

Result: negative Species: Bacteria Gene mutation and repair

Result: positive Species: Bacteria

In vitro cytogenetics assay

Result: positive

In vitro cytogenetics assay

Result: positive

Species: Aspergillus niger

L5178Y mouse lymphoma thymidine kinase locus assay

Result: Weakly positive

Yeast mutation Result: negative Yeast mutation Result: positive

in vitro micronucleus assay

Result: negative

in vivo cytogenetics assay

Result: negative Species: Hamster

in vivo cytogenetics assay

Result: negative Species: Rat

in vivo cytogenetics assay

Result: positive Species: Mouse

sister chromatid exchange

Result: positive

Carcinogenicity

Health injuries are not known or expected under normal use. Contains a material (ethanol) classified as a carcinogen by external agencies.

**ETHANOL** 

Epidemiology, causation linked to excessive consumption.

Species: Human

Organ: oral cavity, larynx, pharynx, oesophagus, liver

Neonatal, inadequate study

Result: negative Species: Rat inadequate study

Result: Increase in liver sarcomas

Species: Mouse inadequate study

Result: Time to tumour reduced

Species: Mouse Test Duration: 80 weeks inadequate study Result: negative Species: Hamster Test Duration: 807 Day

Material name: SPECTRO JEL FOR OILY AND COMBINATION SKIN

Carcinogenicity

**ETHANOL** 

inadequate study Result: negative Species: Mouse

Test Duration: 1020 Day inadequate study Result: negative

Species: Rat inadequate study Result: negative Species: Rat

Test Duration: 78 weeks

IARC Monographs. Overall Evaluation of Carcinogenicity

Triethanolamine (CAS 102-71-6)

3 Not classifiable as to carcinogenicity to humans.

Reproductive toxicity

Components in this product have been shown to cause birth defects and reproductive disorders in

laboratory animals.

Reproductivity **ETHANOL** 

0.3 - 4.1 g/kg Embryo-foetal development - Oral, daily dose

Species: Monkey

Organ: facial anomolies, nervous system dysfunction 1 - 2 g/kg Embryo-foetal development - Oral, daily dose

Result: embryolethality

Species: Rat

1.8 g/kg Embryo-foetal development - Oral, daily dose

Result: Increased abortion

Species: Monkey

5 g/kg Embryo-foetal development - Oral, daily dose -

intravenous

Result: reduced foetal body weight; no malformations or

other variations Species: Monkey

7 - 17 g/kg Embryo-foetal development - Oral, daily dose -

gavage Species: Rat

Organ: skeletal malformations, dilated renal pelves Embryo-foetal development - Oral, 15-30% in diet Result: resorptions, neural defects, cardiac malformations

Species: Mouse

Embryo-foetal development - Oral, Causation is linked to

excessive consumption.

Species: Human

Organ: growth deficiency, CNS dysfunction, facial defects,

major organ malformation

Embryofetal Development, in utero - 36% total calories

Species: Rat

Organ: gonadal growth and development Fertility, Female, 10% in drinking water

Result: negative Species: Rat

Fertility, Female, 20-25% total calories

Result: negative Species: Rat

Fertility, Male, 5-6% v/v liquid diet

Species: Mouse

Organ: significant effects on testes and seminal vesicles

Test Duration: 70 Day

Specific target organ toxicity -

single exposure

Not applicable.

Specific target organ toxicity -

repeated exposure

None known.

**Aspiration hazard** 

Mixture versus substance

Not established.

information

12.1. Toxicity

No information available.

Other information None known.

**SECTION 12: Ecological information** 

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Material name: SPECTRO JEL FOR OILY AND COMBINATION SKIN

Components Species Test results

CETYL ALCOHOL (CAS 36653-82-4)

**Aquatic** 

Acute

Algae EC50 Green algae (Scenedesmus 676 mg/l, 96 hours

subspicatus)

Fish EC50 Bluegill sunfish (Adult Lepomis > 1000 mg/l, 96 hours

macrochirus)

Fathead minnow (Adult Pimephales > 500 mg/l, 5 days

promelas)

ETHANOL (CAS 64-17-5)

Aquatic

Acute

Algae EC50 Blue-green algae (Microcystis 1450 mg/l, 72 hours

aeruginosa)

Crustacea EC50 Water flea (Daphnia magna) 9190 mg/l, 48 hours Static test

Fish EC50 Fathead minnow (Adult Pimephales

14200 mg/l, 96 hours Flow-through test

promelas)

Rainbow trout (Adult Salmo gairdneri) 13000 mg/l, 96 hours Static test

**12.2. Persistence and** No data is available on the degradability of this product.

degradability

**Photolysis** 

Half-life (Photolysis-aqueous)

ETHANOL 1 - 36.6 years Measured

Half-life (Photolysis-atmospheric)

CETYL ALCOHOL 16.7 Hours Estimated ETHANOL 4 - 5.9 Days Estimated

Biodegradability

Percent degradation (Aerobic biodegradation-inherent)

CETYL ALCOHOL 0.4 %, < 1 day Other degradation test system, Activated

sludge

30 - 60 %, 5 days BOD5

ETHANOL 37 - 86 %, 5 days BOD5, Activated sludge

12.3. Bioaccumulative potential No data available.

Partition coefficient n-octanol/water (log Kow)

ETHANOL -0.31
GLYCERIN -1.76
Triethanolamine -1

**Bioconcentration factor (BCF)** 

CETYL ALCOHOL > 9999 Measured

**12.4. Mobility in soil** No data available.

Adsorption

Soil/sediment sorption - log Koc

CETYL ALCOHOL 3.58 - 4.67 Estimated ETHANOL 1.2 Calculated

Mobility in general Not available.

Volatility

Henry's law

CETYL ALCOHOL 0.000073 atm m^3/mol Estimated ETHANOL 0.000005 atm m3/mol Measured

12.5. Results of PBT Not available.

and vPvB assessment

12.6. Other adverse effects Not available.

# **SECTION 13: Disposal considerations**

# 13.1. Waste treatment methods

<sup>\*</sup> Estimates for product may be based on additional component data not shown.

**Residual waste** Dispose of in accordance with local regulations. Empty containers or liners may retain some

product residues. This material and its container must be disposed of in a safe manner (see:

Disposal instructions).

**Contaminated packaging** Empty containers should be taken to an approved waste handling site for recycling or disposal.

Since emptied containers may retain product residue, follow label warnings even after container is

emptied.

**EU waste code**The Waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

**Disposal methods/information** Collect and reclaim or dispose in sealed containers at licensed waste disposal site.

**Special precautions**Dispose in accordance with all applicable regulations.

# **SECTION 14: Transport information**

#### **ADR**

Not regulated as dangerous goods.

#### IATA

Not regulated as dangerous goods.

#### **IMDG**

Not regulated as dangerous goods.

14.7. Transport in bulk according to Annex II of

MARPOL Annex II applies to liquids used in a ship's operation that pose a threat to the marine

environment. These materials may not be transported in bulk.

MARPOL73/78 and the IBC Code

# **SECTION 15: Regulatory information**

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

### **EU** regulations

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex I

Not listed.

Regulation (EC) No. 1005/2009 on substances that deplete the ozone layer, Annex II

Not listed.

Regulation (EC) No. 850/2004 On persistent organic pollutants, Annex I as amended

Not listed

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 1 as amended Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 2 as amended Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex I, part 3 as amended Not listed.

Regulation (EC) No. 689/2008 concerning the export and import of dangerous chemicals, Annex V as amended Not listed.

Regulation (EC) No. 166/2006 Annex II Pollutant Release and Transfer Registry

Not listed

Regulation (EC) No. 1907/2006, REACH Article 59(1) Candidate List as currently published by ECHA

Not listed.

### **Authorisations**

Regulation (EC) No. 1907/2006, REACH Annex XIV Substances subject to authorization, as amended

Not listed.

# Restrictions on use

Regulation (EC) No. 1907/2006, REACH Annex XVII Substances subject to restriction on marketing and use as amended ETHANOL (CAS 64-17-5)

Directive 2004/37/EC: on the protection of workers from the risks related to exposure to carcinogens and mutagens at work

Not listed.

Directive 92/85/EEC: on the safety and health of pregnant workers and workers who have recently given birth or are breastfeeding

Not listed.

### Other EU regulations

Directive 96/82/EC (Seveso II) on the control of major-accident hazards involving dangerous substances

Not listed.

Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work ETHANOL (CAS 64-17-5)

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# Directive 94/33/EC on the protection of young people at work

Not listed.

Other regulations The product is classified and labelled in accordance with EC directives or respective national laws.

This Safety Data Sheet complies with the requirements of Regulation (EC) No 1907/2006.

National regulations 15.2. Chemical safety

assessment

Follow national regulation for work with chemical agents. No Chemical Safety Assessment has been carried out.

# **SECTION 16: Other information**

List of abbreviations Not available.

References GSK Hazard Determination

Information on evaluation method leading to the classification of mixture

The classification for health and environmental hazards is derived by a combination of calculation

methods and test data, if available.

Full text of any statements or R-phrases and H-statements

under Sections 2 to 15 R11 Highly flammable.

R36 Irritating to eyes. R38 Irritating to skin.

H225 Highly flammable liquid and vapour.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

Revision information Product and Company Identification: Product and Company Identification

Composition / Information on Ingredients: Ingredients

Regulatory Information: United States

**Training information** Follow training instructions when handling this material.

**Disclaimer** The information and recommendations in this safety data sheet are, to the best of our knowledge,

accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and

the suitability of the material or product for any particular purpose.

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