according to Regulation (EC) No. 1907/2006

CRODA

PHARMALAN™ PH EUR-SO-(RB)

Version 1.1 Revision Date 20.02.2012 Print Date 26.03.2012

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

1.1 Product identifier

Trade name : PHARMALAN™ PH EUR-SO-(RB)

Product code : LA08280

Registration number : NOT AVAILABLE

INCI : Lanolin

Substance name : Lanolin

Substance No. : 232-348-6

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

Use of the : Pharmaceutical, Cosmetic additive

Substance/Mixture

1.3 Details of the supplier of the safety data sheet

Company : Croda Europe Limited

Cowick Hall, Snaith, DN14 9AA Goole +441405860551

Telephone : +441405860551 Telefax : +441405860205

E-mail address : SDSCompiler@croda.com

Responsible/issuing person

1.4 Emergency telephone number

EUROPE: 00 32 3575 5555 . USA: Transportation Emergency Involving Chemical Spills, Leaks, Fires, or Accidents (24 hr.): (800) 424-9300 . ASIA PACIFIC: 24 hr Toll Free Number: +800 ALERTSGS (+800-2537-8747) // 24 hr

Singapore Exchange Number: +65 6542-9595

2. Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture according to EC-directives 67/548/EEC or 1999/45/EC.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture according to Regulation (EC) No. 1272/2008.

2.3 Other hazards

May irritate skin.

May irritate eyes.

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May cause irritation of respiratory tract.

May cause irritation of the mucous membranes.

3. Composition/information on ingredients

3.1 Substances

Remarks : No dangerous ingredients according to Regulation (EC) No.

1907/2006

4. First aid measures

4.1 Description of first aid measures

If inhaled : If symptoms persist, call a physician.

In case of skin contact : Take off contaminated clothing and shoes immediately.

Wash off immediately with soap and plenty of water.

In case of eye contact : Rinse with plenty of water.

If swallowed : If symptoms persist, call a physician.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment : None known.

5. Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media : Use water spray, alcohol-resistant foam, dry chemical or

carbon dioxide.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

: Do NOT use water jet.

5.2 Special hazards arising from the substance or mixture

Specific hazards during

firefighting

: In case of fire hazardous decomposition products may be

produced such as: Carbon oxides

5.3 Advice for firefighters

Special protective equipment

for firefighters

: Wear self contained breathing apparatus for fire fighting if

necessary.

Further information : Use water spray to cool unopened containers.

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6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

6.3 Methods and materials for containment and cleaning up

: Sweep up and shovel into suitable containers for disposal. Methods for cleaning up

Clean contaminated surface thoroughly.

Contaminated surfaces will be extremely slippery.

6.4 Reference to other sections

None.

7. Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : Handle in accordance with good industrial hygiene and safety

practice.

Advice on protection against

fire and explosion

: Normal measures for preventive fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage

areas and containers

: Keep tightly closed in a dry, cool and well-ventilated place.

Advice on common storage : No special restrictions on storage with other products.

7.3 Specific end uses

Specific use(s) : Pharmaceutical, Cosmetic additive

8. Exposure controls/personal protection

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally

required.

Hand protection : For prolonged or repeated contact use protective gloves.

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Eye protection : Safety glasses

Skin and body protection : Impervious clothing

Hygiene measures : Handle in accordance with good industrial hygiene and safety

practice

Environmental exposure controls

General advice : Prevent product from entering drains.

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance : solid
Colour : yellow

Odour : characteristic

Flash point : > 100 °C

Lower explosion limit : Note: no data available

Upper explosion limit : Note: no data available

Oxidizing properties : Note: no data available

Autoignition temperature : Note: no data available

pH : Note: no data available

Melting point/range : 38 - 44 °C

: Note: no data available

Vapour pressure : Note: no data available

Density : Note: no data available

Water solubility : Note: emulsifiable

Partition coefficient: n-

octanol/water

: Note: no data available

Solubility in other solvents : Note: not determined

Viscosity, dynamic : Note: no data available

Viscosity, kinematic : Note: no data available

9.2 Other information

Oxidising potential : Note: no data available

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10. Stability and reactivity

10.1 Reactivity

no data available

10.2 Chemical stability

no data available

10.3 Possibility of hazardous reactions

Hazardous reactions : No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : None known.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

Thermal decomposition : Note: no data available

11. Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Acute oral toxicity : LD50: > 16,000 mg/kg

Species: rat

: LD50: > 20,000 mg/kg

Species: rat

Test substance: 25%

Skin corrosion/irritation

Skin irritation : Species: rabbit

Result: No skin irritation Classification: No skin irritation

Method: Draize Test

Remarks: No skin irritation

: Remarks: Patch test on human volunteers did not

demonstrate irritating properties.

Serious eye damage/eye irritation

Eye irritation : Species: rabbit

Result: slight irritation

Classification: No eye irritation

Method: Draize Test

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Respiratory or skin sensitization

Sensitisation : Remarks: Patch test on human volunteers did not

demonstrate sensitization properties.

Germ cell mutagenicity

Genotoxicity in vitro : Remarks: no data available

Target Organ Systemic Toxicant - Single exposure

: Remarks: no data available

Target Organ Systemic Toxicant - Repeated exposure

: Remarks: no data available

Aspiration hazard

: no data available Aspiration toxicity

12. Ecological information

12.1 Toxicity

Toxicity to fish

Remarks:

no data available

Toxicity to daphnia and other : Remarks:

aquatic invertebrates.

no data available

12.2 Persistence and degradability

Biodegradability : Remarks:

Inherently biodegradable.

12.3 Bioaccumulative potential

Bioaccumulation : Remarks:

Does not bioaccumulate.

12.4 Mobility in soil

Distribution among : Remarks:

environmental compartments no data available

12.5 Results of PBT and vPvB assessment

no data available

12.6 Other adverse effects

according to Regulation (EC) No. 1907/2006



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Additional ecological

information

: no data available

13. Disposal considerations

13.1 Waste treatment methods

Product : Dispose of in accordance with local regulations.

Contaminated packaging : Empty remaining contents.

Empty containers should be taken to an approved waste

handling site for recycling or disposal.

14. Transport information

Special precautions for

user

Not classified as dangerous in the meaning of transport regulations.

15. Regulatory information

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

Water contaminating class : WGK 1 slightly water endangering

(Germany) 3,432

ZDE_WGK Update: 2005-08-31

Notification status

REACH : Not in compliance with the inventory

CH INV : On the inventory, or in compliance with the inventory

DSL : All components of this product are on the Canadian DSL list.

AICS : On the inventory, or in compliance with the inventory

NZIoC : Not in compliance with the inventory

ENCS : On the inventory, or in compliance with the inventory ISHL : On the inventory, or in compliance with the inventory KECI : On the inventory, or in compliance with the inventory PICCS : On the inventory, or in compliance with the inventory IECSC : On the inventory, or in compliance with the inventory

15.2 Chemical Safety Assessment

not hazardous

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16. Other information

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.