

Safety data sheet

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BASF Safety data sheet according to UN GHS 4th rev.

Date / Revised: 18.04.2016 Version: 1.0

Product: Kolliphor® RH 40

(ID no. 30555082/SDS_GEN_00/EN)

Date of print 17.02.2017

1. Identification

Product identifier

Kolliphor® RH 40

Chemical name: castor oil, hydrogenated, ethoxylated

CAS Number: 61788-85-0

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

Relevant identified uses: pharmaceutical excipient

Details of the supplier of the safety data sheet

Company:
BASF SE
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GERMANY
Operating Division Nutrition and Health

Telephone: +49 621 60-48434

E-mail address: EN-global-safety-data@basf.com

Emergency telephone number

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2. Hazards Identification

Classification of the substance or mixture

According to UN GHS criteria

No need for classification according to GHS criteria for this product.

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Label elements

Globally Harmonized System (GHS)

The product does not require a hazard warning label in accordance with GHS criteria.

Other hazards

According to UN GHS criteria

No specific dangers known, if the regulations/notes for storage and handling are considered.

3. Composition/Information on Ingredients

Substances

Chemical nature

castor oil, hydrogenated, ethoxylated CAS Number: 61788-85-0

Mixtures

Not applicable

4. First-Aid Measures

Description of first aid measures

If adverse health effects develop seek medical attention.

If inhaled:

After inhalation of vapor: fresh air.

On skin contact:

Wash thoroughly with soap and water.

On contact with eyes:

Wash affected eyes for at least 15 minutes under running water with eyelids held open. Seek medical attention if necessary.

On ingestion:

Rinse mouth and then drink plenty of water.

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Most important symptoms and effects, both acute and delayed

Symptoms: No significant symptoms are expected due to the non-classification of the product.

Hazards: No hazard is expected under intended use and appropriate handling.

Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically.

5. Fire-Fighting Measures

Extinguishing media

Suitable extinguishing media: water spray, foam, carbon dioxide, dry powder

Special hazards arising from the substance or mixture

harmful vapours

Evolution of fumes/fog. The substances/groups of substances mentioned can be released in case of fire.

Advice for fire-fighters

Special protective equipment:

Wear a self-contained breathing apparatus.

Further information:

Dispose of fire debris and contaminated extinguishing water in accordance with official regulations.

6. Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Use personal protective clothing.

Environmental precautions

Do not discharge into drains/surface waters/groundwater.

Methods and material for containment and cleaning up

For small amounts: Pick up with suitable appliance and dispose of. For large amounts: Pick up with suitable appliance and dispose of. Dispose of absorbed material in accordance with regulations.

Reference to other sections

Information regarding exposure controls/personal protection and disposal considerations can be found in section 8 and 13.

7. Handling and Storage

Precautions for safe handling

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Handle in accordance with good industrial hygiene and safety practice.

Protection against fire and explosion:

Take precautionary measures against static discharges. Avoid all sources of ignition: heat, sparks, open flame.

Conditions for safe storage, including any incompatibilities

Suitable materials for containers: glass, High density polyethylene (HDPE), Low density polyethylene (LDPE), Stove-lacquer RDL 50, tinned carbon steel (Tinplate)

Further information on storage conditions: Keep container tightly closed in a cool, well-ventilated place.

Storage stability:

Storage temperature: <= 25 °C

Protect from temperatures above: 25 °C

Properties of the product change reversibly on exceeding the limit temperature.

Specific end use(s)

For the relevant identified use(s) listed in Section 1 the advice mentioned in this section 7 is to be observed.

8. Exposure Controls/Personal Protection

Control parameters

Components with occupational exposure limits

No occupational exposure limits known.

Exposure controls

Personal protective equipment

Respiratory protection:

Breathing protection if breathable aerosols/dust are formed. Particle filter with low efficiency for solid particles (e.g. EN 143 or 149, Type P1or FFP1)

Hand protection:

Suitable chemical resistant safety gloves (EN 374) also with prolonged, direct contact (Recommended: Protective index 6, corresponding > 480 minutes of permeation time according to EN 374): E.g. nitrile rubber (0.4 mm), chloroprene rubber (0.5 mm), butyl rubber (0.7 mm) etc. Supplementary note: The specifications are based on tests, literature data and information of glove manufacturers or are derived from similar substances by analogy. Due to many conditions (e.g. temperature) it must be considered, that the practical usage of a chemical-protective glove in practice may be much shorter than the permeation time determined through testing.

Eye protection:

Safety glasses with side-shields (frame goggles) (e.g. EN 166)

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Body protection:

Body protection must be chosen depending on activity and possible exposure, e.g. apron, protecting boots, chemical-protection suit (according to EN 14605 in case of splashes or EN ISO 13982 in case of dust).

General safety and hygiene measures

Handle in accordance with good industrial hygiene and safety practice. No eating, drinking, smoking or tobacco use at the place of work. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and Chemical Properties

Information on basic physical and chemical properties

Form: pasty

Colour: white to slightly yellow Odour: almost odourless

Odour threshold:

not determined

pH value: 6,0 - 7,0

(100 g/I, 20 °C)

melting range: 16 - 26 °C

Boiling point:

not determined

Flash point: 242 °C (DIN ISO 2592)

Evaporation rate:

Value can be approximated from Henry's Law Constant or vapor

pressure.

Flammability: not flammable Flammability of Aerosol Products:

not applicable, the product does not

form flammable aerosoles

Lower explosion limit:

For solids not relevant for classification and labelling.

Upper explosion limit:

For solids not relevant for classification and labelling.

Ignition temperature: 375 °C (DIN 51794)

Vapour pressure:

not determined

Density: 1,03 g/cm3 (DIN 51757)

(60 °C) 1,026 g/cm3 (20 °C)

Relative density:

No data available.

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Relative vapour density (air):

not determined

Solubility in water:

> 490 g/l

(23 °C)

Solubility (qualitative) solvent(s): organic solvents

soluble

Partitioning coefficient n-octanol/water (log Kow): -0,76

Self ignition: Based on its structural properties the

product is not classified as self-

igniting.

Thermal decomposition: approx. 300 °C Viscosity, dynamic:

approx. 176 mPa.s

(60 °C)

Viscosity, kinematic:

not determined

not explosive Explosion hazard:

not fire-propagating Fire promoting properties:

Other information

approx. 1 kg/l Bulk density:

(20 °C)

Miscibility with water:

soluble

Other Information:

If necessary, information on other physical and chemical parameters is indicated in this section.

No further information available.

10. Stability and Reactivity

Reactivity

No hazardous reactions if stored and handled as prescribed/indicated.

Chemical stability

The product is stable if stored and handled as prescribed/indicated.

Possibility of hazardous reactions

No hazardous reactions if stored and handled as prescribed/indicated.

Conditions to avoid

Avoid all sources of ignition: heat, sparks, open flame.

See MSDS section 7 - Handling and storage.

Incompatible materials

Substances to avoid:

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No substances known that should be avoided.

Hazardous decomposition products

Hazardous decomposition products:

No hazardous decomposition products if stored and handled as prescribed/indicated.

11. Toxicological Information

Information on toxicological effects

Acute toxicity

Assessment of acute toxicity:

Virtually nontoxic after a single ingestion. Virtually nontoxic by inhalation. Inhalation-risk test (IRT): No mortality within 8 hours as shown in animal studies. The inhalation of a highly saturated vapor-air mixture represents no acute hazard.

Experimental/calculated data:

LD50 rat (oral): > 20.000 mg/kg (BASF-Test)

LC50 rat (by inhalation): > 2,06 mg/l 4 h (OECD Guideline 403)

rat (by inhalation): 8 h (BASF-Test)

Inhalation-risk test (IRT): No mortality within 8 hours as shown in animal studies. The inhalation of a highly saturated vapor-air mixture represents no acute hazard.

<u>Irritation</u>

Assessment of irritating effects:

Not irritating to the skin. Not irritating to the eyes.

Experimental/calculated data:

Skin corrosion/irritation rabbit: non-irritant (OECD Guideline 404)

Serious eye damage/irritation rabbit: non-irritant (BASF-Test)

Respiratory/Skin sensitization

Assessment of sensitization:

Skin sensitizing effects were not observed in animal studies.

Experimental/calculated data:

Guinea pig maximization test guinea pig: Non-sensitizing.

Germ cell mutagenicity

Assessment of mutagenicity:

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In the majority of studies performed with microorganisms and in mammalian cell culture, a mutagenic effect was not found. A mutagenic effect was also not observed in in vivo tests.

Carcinogenicity

Assessment of carcinogenicity:

The chemical structure does not suggest a specific alert for such an effect.

Reproductive toxicity

Assessment of reproduction toxicity:

The chemical structure does not suggest a specific alert for such an effect.

Developmental toxicity

Assessment of teratogenicity:

No indications of a developmental toxic / teratogenic effect were seen in animal studies.

Specific target organ toxicity (single exposure)

Assessment of STOT single:

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

Repeated dose toxicity and Specific target organ toxicity (repeated exposure)

Assessment of repeated dose toxicity:

The information available on the product provides no indication of toxicity on target organs after repeated exposure.

Aspiration hazard

No aspiration hazard expected.

12. Ecological Information

Toxicity

Assessment of aquatic toxicity:

There is a high probability that the product is not acutely harmful to aquatic organisms. The inhibition of the degradation activity of activated sludge is not anticipated when introduced to biological treatment plants in appropriate low concentrations.

Toxicity to fish:

LC50 (48 h) > 10.000 mg/l, Oryzias latipes (YIK S 0102-1974 ITEM 55, static)

Limit concentration test only (LIMIT test). The details of the toxic effect relate to the nominal concentration.

Aquatic invertebrates:

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EC50 (48 h) > 100 mg/l, Daphnia magna (OECD Guideline 202, part 1, static)

The details of the toxic effect relate to the nominal concentration. Toxic effects occur within the range of solubility.

Aquatic plants:

EC50 (72 h) > 100 mg/l (growth rate), Desmodesmus subspicatus (OECD Guideline 201, static) The details of the toxic effect relate to the nominal concentration.

Microorganisms/Effect on activated sludge:

EC20 (0,5 h) 700 mg/l, activated sludge, domestic (OECD Guideline 209, aerobic)

Persistence and degradability

Assessment biodegradation and elimination (H2O):

Readily biodegradable (according to OECD criteria).

Elimination information:

80 - 90 % BOD of the ThOD (28 d) (OECD Guideline 301 F) (aerobic, activated sludge, domestic) Readily biodegradable (according to OECD criteria).

(Annex III, part A) The surfactant(s) contained in this preparation complies(comply) with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents. Data to support this assertion are held at the disposal of the competent authorities of the Member States and will be made available to them at their direct request or at the request of a detergent manufacturer.

Bioaccumulative potential

Bioaccumulation potential:

Accumulation in organisms is not to be expected.

Mobility in soil

Assessment transport between environmental compartments: Adsorption in soil: Adsorption to solid soil phase is not expected.

Results of PBT and vPvB assessment

According to Annex XIV of Regulation (EC) No.1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH): The product does not contain a substance fulfilling the PBT (persistent/bioaccumulative/toxic) criteria or the vPvB (very persistent/very bioaccumulative) criteria. Self classification

Other adverse effects

The substance is not listed in Regulation (EC) 1005/2009 on substances that deplete the ozone layer.

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Waste treatment methods

Must be disposed of or incinerated in accordance with local regulations.

Contaminated packaging:

Uncontaminated packaging can be re-used.

Packs that cannot be cleaned should be disposed of in the same manner as the contents.

14. Transport Information

Land transport

ADR

Not classified as a dangerous good under transport regulations

UN number: Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: Not applicable Environmental hazards: Not applicable

Special precautions for None known

user

RID

Not classified as a dangerous good under transport regulations

Not applicable UN number: UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Not applicable Packing group: Environmental hazards: Not applicable Special precautions for None known

user

Inland waterway transport

ADN

Not classified as a dangerous good under transport regulations

UN number: Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: Not applicable Environmental hazards: Not applicable Special precautions for None known

user:

Transport in inland waterway vessel

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Not evaluated

Sea transport

IMDG

Not classified as a dangerous good under transport regulations

UN number: Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: Not applicable Environmental hazards: Not applicable None known

Special precautions for

user

IATA/ICAO

Air transport

Not classified as a dangerous good under transport regulations

UN number: Not applicable Not applicable UN proper shipping name: Not applicable Transport hazard class(es): Not applicable Packing group: Environmental hazards: Not applicable Special precautions for None known

user

UN number

See corresponding entries for "UN number" for the respective regulations in the tables above.

UN proper shipping name

See corresponding entries for "UN proper shipping name" for the respective regulations in the tables above.

Transport hazard class(es)

See corresponding entries for "Transport hazard class(es)" for the respective regulations in the tables above.

Packing group

See corresponding entries for "Packing group" for the respective regulations in the tables above.

Environmental hazards

See corresponding entries for "Environmental hazards" for the respective regulations in the tables above.

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Special precautions for user

See corresponding entries for "Special precautions for user" for the respective regulations in the tables above.

Transport in bulk according to Annex II of MARPOL and the IBC Code

Regulation:
Shipment approved:
Pollution name:
Pollution category:
Ship Type:
Not evaluated
Not evaluated
Not evaluated
Not evaluated
Not evaluated

15. Regulatory Information

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

If other regulatory information applies that is not already provided elsewhere in this safety data sheet, then it is described in this subsection.

16. Other Information

Information on intended use: This product is of industrial quality and unless otherwise specified or agreed intended exclusively for industrial use. This includes the mentioned and recommended usage. Any other intended applications should be discussed with the manufacturer. In particular this concerns the application for products that are the object of special standards and regulations.

The data contained in this safety data sheet are based on our current knowledge and experience and describe the product only with regard to safety requirements. This safety data sheet is neither a Certificate of Analysis (CoA) nor technical data sheet and shall not be mistaken for a specification agreement. Identified uses in this safety data sheet do neither represent an agreement on the corresponding contractual quality of the substance/mixture nor a contractually designated use. It is the responsibility of the recipient of the product to ensure any proprietary rights and existing laws and legislation are observed.

Vertical lines in the left hand margin indicate an amendment from the previous version.