

Pack DropStand Immersion 300

SIS (Safety Information Sheet) del Kit

Revision date: 08/07/2021Version: 1.0

SECTION 1: Kit identification

1.1 Kit identifier

Product name : Pack DropStand Immersion 300

Product code : 340300

1.2 Details of the supplier of the Kit safety information sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC - FRANCE T 33 05 57 96 04 04 - F 33 05 57 96 04 05

1 33 03 37 30 04 04 - 1 33 03 37 30 04 03

 $\underline{commercial@ral\text{-}diagnostics.fr} - \underline{www.ral\text{-}diagnostics.com}$

SECTION 2: General information

Restrictions on use : For professional use only

In vitro diagnostic medical device.

General description : Oil for the examination of microscopic preparations under immersion objectives.

SECTION 3: Kit contents

| Name | General description | Weight or Volume | Quantity | Unit | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------|---------------------|---------------------|----------|--------------|---|
| Oil synthesis | | | 6 | pcs (pieces) | Not classified |

SECTION 4: General advice

No data available

SECTION 5: Safe handling advice

General measures : Do not handle until all safety precautions have been read and understood.

Environmental precautions : Avoid release to the environment

This material and its container must be disposed of in a safe way, and as per local

legislation

Storage conditions : Store in original container

Keep container tightly closed Store in dry, well-ventilated area

SECTION 6: First aid measures

First-aid measures after eye contact : Rinse eyes with water as a precaution

First-aid measures after ingestion : If swallowed, seek medical advice immediately and show this container or label

Rinse mouth out with water : Rinse with plenty of water

First-aid measures after skin contact : Rinse with plenty of water
First-aid measures general : If you feel unwell, seek medical advice (show the label where possible)

28/10/2021 EN (English) 1/10

Pack DropStand Immersion 300

SIS (Safety Information Sheet) del Kit

SECTION 7: Fire fighting measures

Protection during firefighting

: Do not enter fire area without proper protective equipment, including respiratory protection Exercise caution when fighting any chemical fire

SECTION 8: Transport information

Refer to section 14 of kit products' SDS

SECTION 9: Other information

No data available



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830 Revision date: 11/25/2020 Supersedes version of: 4/25/2016 Version: 10.0

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

1.1. Product identifier

Product form : Substance

Trade name : Immersion oil RAL

Product code : 339200

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

1.2.1. Relevant identified uses

Main use category : For professional use only

Use of the substance/mixture : In vitro diagnostic medical device.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

RAL DIAGNOSTICS Site Montesquieu 33650 MARTILLAC FRANCE

T 33 05 57 96 04 04 - F 33 05 57 96 04 05

<u>commercial@ral-diagnostics.fr</u> - <u>www.ral-diagnostics.com</u>

1.4. Emergency telephone number

| Country | Organisation/Company | Address | Emergency number | Comment |
|----------------|--|--|--|---------|
| Ireland | National Poisons Information Centre Beaumont Hospital | PO Box 1297 Beaumont Road 9 Dublin | +353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7) | |
| Malta | Medicines & Poisons Info Office | Mater Dei Hospital MSD Msida | +356 2545 6504 | |
| United Kingdom | National Poisons Information Service (Birmingham Centre) City Hospital | Dudley Road B18 7QH Birmingham | 0344 892 0111 | |

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Not classified

Adverse physicochemical, human health and environmental effects

To our knowledge, this product does not present any particular risk, provided it is handled in accordance with good occupational hygiene and safety practice.

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP]

No labelling applicable

2.3. Other hazards

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 3: Composition/information on ingredients

3.1. Substances

| Name | Product identifier | | Classification according to Regulation (EC) No. 1272/2008 [CLP] |
|---------------|--------------------|-----|---|
| Oil synthesis | - | 100 | Not classified |

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Wash skin with plenty of water.

First-aid measures after eye contact : Rinse eyes with water as a precaution.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

4.2. Most important symptoms and effects, both acute and delayed

No additional information available

4.3. Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam. Carbon dioxide.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case

of fire

: Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-

contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

: Ventilate spillage area. **Emergency procedures**

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further

information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

: Take up liquid spill into absorbent material. Methods for cleaning up

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

11/25/2020 (Revision date) EN (English) 4/10

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after

handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in a well-ventilated place.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

8.2.2.3. Respiratory protection

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid Appearance : clear. Colour : Colourless. : odourless. Odour

Odour threshold : No data available : No data available pΗ Relative evaporation rate (butylacetate=1) : No data available

Melting point : < -35 °C

Freezing point : No data available Boiling point : No data available

Flash point : ≈ 280 °C Auto-ignition temperature : > 400 : > 350 °C Decomposition temperature : Not applicable Flammability (solid, gas) Vapour pressure : < 1 hPa at 20 °C Relative vapour density at 20 °C : No data available : 1.091 - 1.096 Relative density

Solubility : Material nearly insoluble in water.

Partition coefficient n-octanol/water (Log

Pow)

: No data available

: ≈ 1000 mm²/s at 25 °C Viscosity, kinematic Viscosity, dynamic : 900 - 1300 mPa·s at 25 °C

Explosive properties : No data available Oxidising properties : No data available : No data available Explosive limits

9.2. Other information

Bulk density : ≈ 1.09 g/cm³ at 25 °C

SECTION 10: Stability and reactivity

10.1. ReactivityThe product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

Safety Data Sheet

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10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

| Immersion oil RAL | |
|---|---|
| LD50 oral rat | > 2000 mg/kg |
| LD50 dermal rabbit | Not irritating |
| Claire and an air and investment in the | . Details test an increase (24h), not be modul to the alice |

Skin corrosion/irritation : Patch test on humans (24h): not harmful to the skin.

Serious eye damage/irritation : Not irritating to rabbits on ocular application

Additional information : Given the available data, a clinically significant eye irritation is unlikely.

Respiratory or skin sensitisation : Test on guinea pigs (Magnusson-Kligman): not sensitizing by skin contact.

Additional information : Given the available data, a sensitization reaction due to this product is unlikely.

Germ cell mutagenicity : Test (in vitro) mutation assay on bacterial cells: negative.

Carcinogenicity : Not classified
Reproductive toxicity : Not classified
STOT-single exposure : Not classified
STOT-repeated exposure : Not classified

| Immersion oil RAL | | |
|----------------------------|---------------------------|--|
| NOAEL (oral, rat, 90 days) | 1000 mg/kg bodyweight/day | |
| Asniration hazard | · Not classified | |

Aspiration nazard : Not classified

Immersion oil RAL

Viscosity, kinematic ≈ 1000 mm²/s at 25 °C

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-

term adverse effects in the environment.

Hazardous to the aquatic environment, short-

term (acute)

: Not classified

Hazardous to the aquatic environment, long-

term (chronic)

: Not classified

12.2. Persistence and degradability

| Immersion oil RAL | |
|-------------------------------|--------------------|
| Persistence and degradability | Non-biodegradable. |
| Biodegradation | Non-biodegradable. |

12.3. Bioaccumulative potential

| Immersion oil RAL | |
|---------------------------|---------------------|
| Bioaccumulative potential | No bioaccumulation. |

12.4. Mobility in soil

No additional information available

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods

: Dispose of contents/container in accordance with licensed collector's sorting instructions. Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

| ADR | IMDG | IATA | ADN | RID |
|--------------------------|---------------|---------------|----------------------------|---------------|
| 14.1. UN number | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.2. UN proper shipping | g name | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.3. Transport hazard o | lass(es) | | | |
| Not regulated | Not regulated | Not regulated | Not regulated Not regulate | |
| 14.4. Packing group | | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |
| 14.5. Environmental haz | ards | | | |
| Not regulated | Not regulated | Not regulated | Not regulated | Not regulated |

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code Not applicable

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

SECTION 15: Regulatory information

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

15.1.1. EU-Regulations

No REACH Annex XVII restrictions

Immersion oil RAL is not on the REACH Candidate List

Immersion oil RAL is not on the REACH Annex XIV List

Immersion oil RAL is not subject to Regulation (EU) No 649/2012 of the European Parliament and of the Council of 4 july 2012 concerning the export and import of hazardous chemicals.

Immersion oil RAL is not subject to Regulation (EU) No 2019/1021 of the European Parliament and of the Council of 20 June 2019 on persistent organic pollutants

Contains no substance subject to Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors.

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

| Indication of changes | | | |
|-----------------------|----------------------------|--------|----------|
| Section | Changed item | Change | Comments |
| | Revision date | Added | |
| 16 | Abbreviations and acronyms | Added | |

| Abbreviations and | acronyms: |
|-------------------|---|
| ADN | European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways |
| ADR | European Agreement concerning the International Carriage of Dangerous Goods by Road |
| ATE | Acute Toxicity Estimate |
| BLV | Biological limit value |
| CAS-No. | Chemical Abstract Service number |
| CLP | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008 |
| DMEL | Derived Minimal Effect level |
| DNEL | Derived-No Effect Level |
| EC50 | Median effective concentration |
| EC-No. | European Community number |
| EN | European Standard |
| IATA | International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| LC50 | Median lethal concentration |
| LD50 | Median lethal dose |
| LOAEL | Lowest Observed Adverse Effect Level |
| NOAEC | No-Observed Adverse Effect Concentration |
| NOAEL | No-Observed Adverse Effect Level |
| NOEC | No-Observed Effect Concentration |
| OEL | Occupational Exposure Limit |
| PBT | Persistent Bioaccumulative Toxic |

Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

| Abbreviations and acronyms: | | |
|-----------------------------|---|--|
| PNEC | Predicted No-Effect Concentration | |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006 | |
| RID | Regulations concerning the International Carriage of Dangerous Goods by Rail | |
| SDS | Safety Data Sheet | |
| vPvB | Very Persistent and Very Bioaccumulative | |
| WGK | Water Hazard Class | |

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.