

## Section 1: IDENTIFICATION OF SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

### 1.1 Product Identifier

**Tradename:** eplex RP Control M306, eplex RP Negative  
**Article number:** M306, M31118-6

**1.2** Relevant identified uses of the substance or mixture and uses advised against:  
Sector of use SU20 Health services

Application of the substance/the mixture

**1.3** The eplex RP Control M306 and eplex RP Negative are intended for *in vitro* use as a qualitative external quality control to monitor the amplification, detection and identification steps of the cobas® eplex respiratory pathogen (RP) panel on the cobas eplex system (Roche Diagnostics).

### DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET, MANUFACTURER/SUPPLIER:

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**Manufacturer Phone Number**  
207-885-1072

**Manufacturer Fax Number**  
207-885-1079

**1.4** **Emergency telephone number:** 207-885-1072 (EST 8:30-17:00)

## Section 2: HAZARD(S) IDENTIFICATION

**2.1** **Classification of the substance or mixture:** Not applicable  
**Classification according to Regulation (EC) No 1272/2008:** Not applicable

**2.2** **Label elements:**  
**Labelling according to Regulation (EC) No 1272/2008:** Not applicable  
**Hazard pictograms:** Not applicable  
**Signal word:** Not applicable  
**Hazard statements:** Not applicable

**2.3** **Other hazards:**  
**Results of PBT and vPvB assessment:**  
**PBT:** Not applicable  
**vPvB:** Not applicable

This product is not considered to be flammable under ordinary laboratory conditions based on studies performed by MMQCI.

## Section 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Chemical Characterization: Mixtures

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
					Symbol	R-Phrases
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	10	None	None

## Section 4: FIRST AID MEASURES

### 4.1 Description of first aid measures:

**General information:** No special measures required.  
**After inhalation:** Supply fresh air; consult doctor in case of complaints.  
**After skin contact:** Generally the product does not irritate the skin.  
**After eye contact:** Rinse opened eye for several minutes under running water.  
**After swallowing:** Rinse mouth with water. Seek medical attention and appropriate follow-up.

**4.2** **Most important symptoms and effects, both acute and delayed:** Eye irritation

**4.3** **Indication of any immediate medical attention and special treatment needed:** No further relevant information available.

## Section 5: FIRE FIGHTING MEASURES

### 5.1 Extinguishing media:

**Suitable extinguishing media:** Dry powder, Dry sand  
**Unsuitable extinguishing media:** Do NOT use water jet.

**5.2** **Special hazards arising from the substance or mixture:** Carbon oxides

**5.3** **Advice for firefighters:** Wear self-contained breathing apparatus for firefighting if necessary.

**5.4** **Further information:** Use water spray to cool unopened containers.

## Section 6: ACCIDENTAL RELEASE MEASURES

- 6.1 **Personal Precautions:** Wear appropriate protective clothing.  
 6.2 **Environmental Precautions:** Wipe up with appropriate absorbent material.  
 6.3 **Methods and Material for Containment and Cleaning Up:** Normal disposal container  
 6.4 **Reference to Other sections:** Section 13 Disposal

## Section 7: HANDLING AND STORAGE

- 7.1 **Precaution for Safe Handling:** Handle per package insert instructions (IFU).  
 7.2 **Conditions for Safe Storage:** Store at -25°C to -15°C.  
 7.3 **Specific End Use(s):** No further relevant information available

## Section 8: EXPOSURE CONTROLS / PERSONAL PROTECTION

- 8.1 **Exposure Limit Values:** None  
 8.2 **Exposure Controls:** This product is not expected to require special ventilation controls. Facilities storing or using this product should be equipped with an eyewash station.

### PERSONAL PROTECTIVE EQUIPMENT:

**Respiratory Protection:** None required  
**Skin Protection:** Lab coat, gloves  
**Ventilation:** Normal

**Eye Protection:** Safety glasses  
**Work / Hygiene Practices:** Standard laboratory precautions  
**Other Protective Equipment:** None required

## Section 9 – PHYSICAL AND CHEMICAL PROPERTIES

- 9.1 **Information on basic physical and chemical properties:**  
**Appearance:** Aqueous solution. No data available  
**Odour:** Fruity  
**Odour Threshold:** No data available  
**pH:** No data available  
**Melting point/freezing point:** No data available  
**Initial boiling point and boiling range:** 86°C (186.8°F) (10% ethanol)  
**Flash point:** 44 °C (111 °F) - closed cup (10% ethanol)  
**Evaporation rate:** No data available  
**Flammability (solid, gas):** No data available  
**Upper/lower flammability or explosive limits:** No data available  
**Vapour pressure:** No data available  
**Vapour density:** No data available  
**Relative density:** No data available  
**Water solubility:** No data available  
**Partition coefficient: n-octanol/water:** No data available  
**Auto-ignition temperature:** No data available  
**Decomposition temperature:** No data available  
**Viscosity:** No data available  
**Explosive properties:** No data available  
**Oxidizing properties:** No data available  
 9.2 **Other information:** No data available

## Section 10 – STABILITY AND REACTIVITY

- 10.1 **Reactivity:** No further relevant information available.  
 10.2 **Chemical stability Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.  
 10.3 **Possibility of hazardous reactions:** No dangerous reactions known.  
 10.4 **Conditions to avoid:** No further relevant information available.  
 10.5 **Incompatible materials:** No further relevant information available.  
 10.6 **Hazardous decomposition products:** No dangerous decomposition products known.

# SAFETY DATA SHEET

according to 1907/2006/EC, Article 31  
English

## Section 11 – TOXICOLOGICAL INFORMATION

- 11.1 Information on toxicological effects:**  
Acute toxicity: Based on available data, the classification criteria are not met.
- 11.2 Primary irritant effect:**  
Skin corrosion/irritation: Based on available data, the classification criteria are not met.  
Serious eye damage/irritation: Based on available data, the classification criteria are not met.  
Respiratory or skin sensitization: Based on available data, the classification criteria are not met.
- 11.3 CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):**  
Germ cell mutagenicity: Based on available data, the classification criteria are not met.  
Carcinogenicity: Based on available data, the classification criteria are not met.  
Reproductive toxicity: Based on available data, the classification criteria are not met.  
STOT-single exposure: Based on available data, the classification criteria are not met.  
STOT-repeated exposure: Based on available data, the classification criteria are not met.  
Aspiration hazard: Based on available data, the classification criteria are not met.

## Section 12 – ECOLOGICAL INFORMATION

- 12.1 Toxicity:**  
Aquatic toxicity: Regarded as having low toxicity to aquatic organisms.
- 12.2 Persistence and degradability:** Readily biodegradable.
- 12.3 Bioaccumulative potential:** Low bioaccumulation potential.
- 12.4 Mobility in soil:** Water soluble, will partition to aqueous phase. Lost within short period through evaporation and dissolution. Poorly absorbed into soils and sediments
- 12.5 Results of PBT and vPvB assessment:**  
PBT: Not applicable.  
vPvB: Not applicable.
- 12.6 Other adverse effects:** No further relevant information available.

## Section 13: DISPOSAL CONSIDERATIONS

- 13.1 Waste Treatment Methods:** Dispose of unused product, spilled substance and waste in normal disposal container.
- 13.2 Uncleaned packaging:**  
Recommendation: Disposal must be made according to official regulations.  
Recommended cleansing agent: Water, if necessary with cleansing agents.

## Section 14: TRANSPORT INFORMATION

- |   |                                    |               |
|---|------------------------------------|---------------|
| <b>14.1 UN-Number:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated |
| <b>14.2 UN proper shipping name:</b>  | <b>ADR, ADN, IMDG, IATA:</b>       | Not Regulated |
| <b>14.3 Transport hazard class(es):</b>   | <b>ADR, ADN, IMDG, IATA Class:</b> | Not Regulated |
| <b>14.4 Packing group:</b>  | <b>ADR, IMDG, IATA:</b>            | Not Regulated |
| <b>14.5 Environmental hazards:</b>  | <b>Marine pollutant:</b>           | No            |
| <b>14.6 Special precautions for user:</b>                                       | Not applicable                     |               |
| <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:</b> | Not applicable                     |               |

## Section 15: REGULATORY INFORMATION

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture:**  
Directive 2012/18/EU:  
Named dangerous substances - ANNEX I: None of the ingredients are listed.  
National regulations:  
Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water.
- 15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

Chemical Name	EC-No.	Index-No	CAS-No.	%	Classification	Labeling
Ethyl Alcohol	200-578-6	603-002-00-5	64-17-5	10	Symbol None	R-Phrases None

**California Proposition 65:** This product does not contain any substances listed on California's listing of known or potential carcinogens.  
**Chemical Safety Assessment:** Observe general laboratory safety regulations when handling chemicals.

## SAFETY DATA SHEET

according to 1907/2006/EC, Article 31  
English

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### Section 16: OTHER INFORMATION

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SDS Prepared by: MMQCI  
Preparation Date: Month 2025

Disclaimer: The information contained in this SDS is provided only for use as a guide. The SDS was carefully prepared based on references and tests believed to be reliable; however, MMQCI makes no guarantee of the accuracy and completeness of the data. Any use of the data must be in accordance with applicable federal, state and local regulations.

#### **Abbreviations and acronyms:**

ADR: *Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)*  
IMDG: *International Maritime Code for Dangerous Goods*  
IATA: *International Air Transport Association*  
GHS: *Globally Harmonised System of Classification and Labelling of Chemicals*  
EINECS: *European Inventory of Existing Commercial Chemical Substances*  
ELINCS: *European List of Notified Chemical Substances*  
CAS: *Chemical Abstracts Service (division of the American Chemical Society)*  
PBT: *Persistent, Bioaccumulative and Toxic*  
vPvB: *very Persistent and very Bioaccumulative*