

**1. Product and Company Identification**

|                     |   |                       |
|---------------------|---|-----------------------|
| Product name        | KYTRIL(R) Tablets (1 mg)  |                       |
| Product code        | 03 4388 9   |                       |
| Use                 | - KYTRIL(R) is a pharmacological product used as an anti-emetic and an anti-nauseant.                                   |                       |
| Company information | Enquiries:<br>Hoffmann-La Roche Inc.<br>340 Kingsland Street<br>USA-Nutley, N.J. 07110-1199<br>United States of America | Local representation: |
|                     | Phone 001-973/235 50 00<br>E-Mail info.sds@roche.com  |                       |
|                     | US Emergency phone: (800)-827-6243<br>US Chemtrec phone: (800)-424-9300   |                       |

**2. Hazards identification****Emergency Overview**

|                          |   |
|--------------------------|---|
| Form                     | tablets   |
| Color                    | white   |
| Potential Health Effects | <ul style="list-style-type: none"><li>- Exposure: Inhalation, Ingestion, Skin contact, Eye contact</li><li>- Target Organs: skin, eyes, mucous membranes, Cardiovascular system, gastrointestinal system, Central nervous system, Hematopoietic/blood system</li><li>- Acute Effects: May cause eye irritation., May cause skin irritation., May cause mucous membrane irritation (inflammation)., May cause central nervous system effects., Signs and symptoms may include headache, dizziness, drowsiness, fatigue and lack of muscular coordination., May cause gastrointestinal effects., Signs and symptoms may include nausea, vomiting, diarrhea, constipation, cramps, and loss of appetite., May cause cardiovascular effects., Signs and symptoms may include increase or decrease in blood pressure, irregular heartbeat, chest pains and cardiac arrest.</li><li>- Chronic Effects: May cause blood system changes.</li><li>- Carcinogenicity: formulation not listed by NTP, IARC or OSHA</li></ul> |

## KYTRIL(R) Tablets (1 mg)

### 3. Composition/Information on ingredients

|  |                      |
|--|----------------------|
| Characterization   | final product        |
| <b>Ingredients</b>   | <b>Concentration</b> |
| AVICEL PH-102 (Cellulose Microcrystalline)<br>CAS: 9004-34-6 | ~ 20 %               |
| Sodium starch glycolate<br>CAS: 9063-38-1                    | ~ 5 %                |
| Granisetron hydrochloride<br>CAS: 107007-99-8                | ~ 1 %                |

### 4. First-aid measures

|              |   |
|--------------|---|
| Eye contact  | - in case of contact with eyes rinse thoroughly with plenty of water and get medical advice |
| Skin contact | - remove immediately contaminated clothes, wash affected skin with plenty of water          |
| Inhalation   | - in case of inhalation remove to fresh air and seek medical aid                            |
| Ingestion    | - consult physician   |

### 5. Fire-fighting measures

|                                 |   |
|---------------------------------|---|
| Suitable extinguishing media    | - water spray jet, dry powder, foam, carbon dioxide |
| Flash point (liquid)            | not applicable                                      |
| Specific hazards                | - Toxic emissions may be given off in a fire        |
| Protection of fire-fighters     | - use self-contained breathing apparatus            |
| Special method of fire-fighting | - cool endangered containers with water spray       |

### 6. Accidental release measures

|                          |  |
|--------------------------|--|
| Personal precautions     | - ensure adequate ventilation  |
| Environmental protection | - avoid release to the environment   |
| Methods for cleaning up  | <ul style="list-style-type: none"><li>- Scoop or shovel spilled material into a suitable labeled open head drum</li><li>- Secure the drum cover and move the container to a safe holding area</li><li>- Clean spill area thoroughly</li><li>- Collect wash with a noncombustible absorbent material and transfer to labeled container for treatment and disposal.</li><li>- Check area for residual material and repeat clean up if detected</li></ul> |

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### 7. Handling and storage

#### Handling

Technical measures - local exhaust ventilation necessary

#### Storage

Storage conditions - keep containers tightly closed  
- room temperature  
- store in a dry place

### 8. Exposure controls/Personal protection

Engineering Measures - see 7.

Threshold value (USA) air - ACGIH-TLV: 10 mg/m<sup>3</sup> \*1  
- OSHA-PEL: 15 mg/m<sup>3</sup> (total dust) \*1  
- OSHA-PEL: 5 mg/m<sup>3</sup> (respirable fraction) \*1  
- NIOSH-REL: 10 mg/m<sup>3</sup> (total dust) \*1  
- NIOSH-REL: 5 mg/m<sup>3</sup> (respirable fraction) \*1

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.02 mg/m<sup>3</sup> \*2

#### Personal protective equipment

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.  
- respiratory protection not necessary

Hand protection - protective gloves

Eye protection - safety glasses

Body protection - protective clothing

\*1 referring to: AVICEL PH-102

\*2 referring to: Granisetron-Hydrochlorid

### 9. Physical and chemical properties

Color white

Form tablets

Solubility soluble, water

## KYTRIL(R) Tablets (1 mg)

### 10. Stability and reactivity

|                     |  |
|---------------------|--|
| Stability           | - stable under the conditions mentioned in chapter 7 |
| Conditions to avoid | - high temperatures<br>- light                       |
| Materials to avoid  | - strong acids, oxidizing agents                     |
| Note                | - Hazardous Polymerization: Will not occur.          |

### 11. Toxicological information

|                       |   |    |
|-----------------------|---|----|
| Acute toxicity        | - LD <sub>50</sub> > 5'000 mg/kg (oral, rat)                            | *1 |
|                       | - LD <sub>50</sub> > 2'000 mg/kg (dermal, rabbit)                       | *1 |
|                       | - LD <sub>50</sub> 350 mg/kg (oral, rat)                                | *2 |
| Local effects         | - skin: non-irritant (several species)                                  | *2 |
|                       | - eye: may cause irritations (several species)                          | *2 |
| Sensitization         | - non-sensitizing (guinea pig)  | *2 |
| Subchronic toxicity   | - NOAEL 25 mg/kg (oral, rat; 28 d)                                      | *2 |
|                       | - NOAEL 3 mg/kg (i.v., rat; 28 d)                                       | *2 |
| Chronic toxicity      | - NOEL 5 mg/kg/d (oral, rat; 1 year)                                    | *2 |
| Mutagenicity          | - no indication for mutagenicity (various in vitro test systems)        | *2 |
| Carcinogenicity       | - animal carcinogen, liver  | *2 |
|                       | - no indication for carcinogenicity (man); by therapeutic dose          | *2 |
| Reproduction toxicity | - not teratogenic, not embryotoxic                                      | *2 |
| Note                  | - prolonged exposition or overdosing may cause: disturbances of the CNS | *2 |
|                       | - metabolism and elimination via liver and faeces                       | *2 |
|                       | - therapeutic dose: 2 mg/d  | *2 |
|                       | - elimination half-life: 9 h  | *2 |
| *1 referring to:      | AVICEL PH-102   |    |
| *2 referring to:      | Granisetron-Hydrochlorid  |    |

### 12. Ecological information

|                           |   |    |
|---------------------------|---|----|
| Ready biodegradability    | - not readily biodegradable<br>0 %, 28 d  | *2 |
| Inherent biodegradability | - not inherently biodegradable<br>0 %, 28 d   | *2 |
| Abiotic degradation       | - unstable in water, probably photodegradation  | *2 |
|                           | - rapid degradation, probably photodegradation (river water)<br>t <sub>1/2</sub> 5 d                    | *2 |
|                           | - unstable in water, hydrolysis (206 mg/l, water; HPLC)<br>22 %, 120 h, ~ 20 °C, both in dark and light | *2 |

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|                                    |   |
|------------------------------------|---|
| Ecotoxicity                        | <ul style="list-style-type: none"> <li>- moderately toxic for fish (bluegill sunfish)<br/>LC<sub>50</sub> (96 h) 16 mg/l<br/>NOEC (96 h) 3.9 mg/l<br/>(OECD No. 203) *2</li> <li>- moderately toxic for planktonic crustaceans (Daphnia magna)<br/>EC<sub>50</sub> (48 h) 20.8 mg/l<br/>NOEC (48 h) 5.4 mg/l<br/>(OECD No. 202) *2</li> <li>- moderately toxic for microorganisms<br/>EC<sub>50</sub> (15 min) 70 mg/l<br/>(Microtox test) *2</li> <li>- barely inhibitory on aerobic bacterial respiration<br/>EC<sub>50</sub> (3 h) &gt; 717.6 mg/l<br/>(OECD No. 209) *2</li> <li>- moderately toxic for algae (Scenedesmus (=Desmodesmus) subspicatus)<br/>ErC<sub>50</sub> (72 h) 22.6 mg/l<br/>NOEC (72 h) 3.13 mg/l<br/>(OECD No. 201) *2</li> </ul> |
| Mobility                           | <ul style="list-style-type: none"> <li>- low mobility, barely volatile<br/>logK<sub>d</sub> = 1.8 (activated sludge)<br/>logK<sub>OC</sub> = 3.8 (soil, sediment)<br/>K<sub>H</sub> = 0.000000013 atm*m<sup>3</sup>/mol (water-air) *2</li> <li>- low mobility (water-activated sludge, 24 h)<br/>K<sub>d</sub> = 2813 l/kg (activated sludge, 24 h)<br/>(Adsorption to activated sludge in biodegradability test) *2</li> </ul>  |
| *2                                 | referring to: Granisetron-Hydrochlorid  |
| <b>13. Disposal considerations</b> |   |
| Waste from residues                | <ul style="list-style-type: none"> <li>- incinerate in qualified installation with flue gas scrubbing</li> <li>- observe local/national regulations regarding waste disposal</li> <li>- DO NOT FLUSH unused medications or POUR them down a sink or drain. If available in your area, use takeback programs run by household hazardous waste collection programs or community pharmacies to dispose of unused and expired medicines. If you don't have access to a takeback program, dispose of these medicines in the household trash by removing them from their original containers and mixing them with an undesirable substance, such as used coffee grounds or kitty litter.</li> </ul>   |
| Contaminated packaging             | <ul style="list-style-type: none"> <li>- Empty containers must be triple rinsed prior to disposal, recycling or reuse.</li> </ul>   |
| RCRA waste                         | <ul style="list-style-type: none"> <li>- not regulated under RCRA</li> </ul>  |
| <b>14. Transport information</b>   |   |
| Note                               | <ul style="list-style-type: none"> <li>- not classified by transport regulations, proper shipping name non-regulated</li> </ul>   |

## KYTRIL(R) Tablets (1 mg)

### 15. Regulatory information

|                        |  |
|------------------------|--|
| TSCA Status            | - FDA Exemption - not on inventory   |
| Reporting Requirements | <ul style="list-style-type: none"><li>- The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.</li><li>- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.</li><li>- State and local regulations vary and may impose additional reporting requirements.</li></ul> |

### 16. Other information

|                       |                 |
|-----------------------|-----------------|
| Edition documentation | - first edition |
|-----------------------|-----------------|

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.