MATERIAL SAFETY DATA SHEET

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

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ChemSafe (24 hours): +44 (0)208 762 8322

Material Name: Loperamide Hydrochloride 2mg Coated Tablets

Trade Name: Travello Coated Tablets
Chemical Family: Mixture
Intended Use: Pharmaceutical product for the treatment of diarrhea

2. COMPOSITION/INFORMATION ON INGREDIENTS

Hazardous

Ingredient	CAS Number	EU EINECS List	%
Loperamide Hydrochloride	34552-83-5	252-082-4	<2
Titanium dioxide	13463-67-7	236-675-5	*
Magnesium stearate	557-04-0	209-150-3	*
Maize starch	9005-25-8	232-679-6	*
Talc (non-asbestiform)	14807-96-6	238-877-9	*
Microcrystalline cellulose	9004-34-6	232-674-9	*

Ingredient	CAS Number	EU EINECS List	%
Lactose	63-42-3	200-559-2	*
Hypromellose	9004-65-3	Not listed	*
Macrogol 6000	Not assigned	Not listed	*
Carnauba wax	8015-86-9	232-399-4	*
Polysorbate 80	9005-65-6	Not listed	*
White wax	8006-40-4	Not listed	*
Polysorbate 60	9005-67-8	Not listed	*
Propylene glycol	57-55-6	200-338-0	*

Additional Information: * Proprietary
Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

3. HAZARDS IDENTIFICATION

Appearance: White tablets

Statement of Hazard: Non-hazardous in accordance with international standards for workplace safety.

Additional Hazard Information:
Short Term: Accidental ingestion may cause effects similar to those seen in clinical use.

Long Term:	Repeat-dose studies in animals have shown a potential to cause adverse effects on reproductive system.
Known Clinical Effects:	Based on human experience, possible adverse effects following exposure to this compound may include nausea, abdominal discomfort, headache, dizziness, constipation.
EU Indication of danger:	Not classified

Note:	This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

4. FIRST AID MEASURES

Eye Contact:	If irritation occurs or persists, get medical attention. Flush eyes with water as a precaution
Skin Contact:	Wash skin with soap and water. If irritation occurs or persists, get medical attention.
Ingestion:	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
Inhalation:	Remove to fresh air and keep patient at rest. Seek medical attention immediately.

5. FIRE FIGHTING MEASURES

Extinguishing Media:	Use carbon dioxide, dry chemical, or water spray.
Hazardous Combustion Products:	May emit toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride, and other chlorine-containing compounds.
Fire Fighting Procedures:	During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
Fire / Explosion Hazards:	Not applicable

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Additional Consideration for Large Spills:	Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE

General Handling: If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes.

Storage Conditions: Store at room temperature in properly labeled containers. Keep away from heat, sparks and flames.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Titanium dioxide

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Magnesium stearate

ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	except stearates of toxic metals
Australia TWA	= 10 mg/m^3 TWA	

Maize starch

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Talc (non-asbestiform)

OSHA - Final PELs - Table Z-3 Mineral D:	= 20 mppcf TWA	
ACGIH Threshold Limit Value (TWA)	= 2 mg/m^3 TWA	
Australia TWA	= 2.5 mg/m^3 TWA	containing no asbestos fibers

Microcrystalline cellulose

OSHA - Final PELS - TWAs:	= 15 mg/m^3 TWA = 5 mg/m^3 TWA	total
ACGIH Threshold Limit Value (TWA)	= 10 mg/m^3 TWA	
Australia TWA	= 10 mg/m^3 TWA	

Propylene glycol

Australia TWA	= 10 mg/m^3 TWA = 150 ppm TWA = 474 mg/m^3 TWA	

The exposure limit(s) listed for solid components are only relevant if dust may be generated.

Engineering Controls: Engineering controls should be used as the primary means to control exposures.

Personal Protective Equipment:

Hands: Not required for the normal use of this product. Wear protective gloves when working with large quantities.

Eyes: Not required under normal conditions of use. Wear safety glasses or goggles if eye contact is possible.

Skin: Not required for the normal use of this product. Wear protective clothing when working with large quantities.

Respiratory protection: Not required for the normal use of this product. If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES:

Physical State:	Tablets	**Color:**	White
Molecular Formula:	Mixture	**Molecular Weight:**	Mixture

10. STABILITY AND REACTIVITY

Stability: Stable under normal conditions of use.
Conditions to Avoid: None known
Incompatible Materials: As a precautionary measure, keep away from strong oxidizers.

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Loperamide Hydrochloride
Rat Oral LD 50 185 mg/kg
Mouse Oral LD 50 105 mg/kg

Magnesium stearate
Rat Oral LD50 > 2000 mg/kg
Rat Inhalation LC50 > 2000 mg/m^3

Lactose
Rat Oral LD50 > 10 g/kg

Microcrystalline cellulose
Rat Oral LD50 > 5000 mg/kg
Rabbit Dermal LD50 > 2000 mg/kg

Titanium dioxide
Rat Oral LD50 > 7500 mg/kg
Rat Subcutaneous LD 50 50 mg/kg

Talc (non-asbestiform)
Rat Oral LD50 > 1600 mg/kg

Propylene glycol
Mouse Oral LD50 22,000 mg/kg
Rat Oral LD50 20,000 mg/kg
Rabbit Dermal LD50 20,800 mg/kg

Polysorbate 80
Rat Oral LD50 25 g/kg

Polysorbate 60

Rat Oral LD50 64,000 mg/kg

Hypromellose
Rat Oral LD50 > 10,000 mg/kg
Acute Toxicity Comments: A greater than symbol (>) indicates that the toxicity endpoint being tested was not achievable at the highest dose used in the test.

Irritation / Sensitization: (Study Type, Species, Severity)

Microcrystalline cellulose
Skin Irritation Rabbit Non-irritating
Eye Irritation Rabbit Non-irritating

Propylene glycol
Skin Irritation Rabbit Mild
Eye Irritation Rabbit Mild

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Loperamide Hydrochloride
Reproductive & Fertility Rat Oral 12 mg/kg LOEL Fertility
Fertility and Embryonic Development Rat Oral 2.4 mg/kg NOEL Not Teratogenic
Fertility and Embryonic Development Rabbit Oral 2.4 mg/kg NOEL Not Teratogenic

Carcinogenicity: (Duration, Species, Route, Dose, End Point, Effect(s))

Loperamide Hydrochloride
18 Month(s) Rat Oral 32 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: See below

Titanium dioxide
IARC: Group 2B
OSHA: Present

Talc (non-asbestiform)
IARC: Group 3

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Disposal Procedures: Dispose of waste in accordance with all applicable laws and regulations.

14. TRANSPORT INFORMATION

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

15. REGULATORY INFORMATION

EU Indication of danger: Not classified

OSHA Label:
Non-hazardous in accordance with international standards for workplace safety.

Canada - WHMIS: Classifications

WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Loperamide Hydrochloride

Australia (AICS):	Present
EU EINECS List	252-082-4

Titanium dioxide

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	236-675-5

Magnesium stearate

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	209-150-3

Maize starch

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-679-6

Lactose

Inventory - United States TSCA - Sect. 8(b)	Present

Australia (AICS):	Present
EU EINECS List	200-559-2

Hypromellose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
Standard for the Uniform Scheduling for Drugs and Poisons:	Schedule 4

Talc (non-asbestiform)

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	238-877-9

Carnauba wax

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	232-399-4

Microcrystalline cellulose

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present
EU EINECS List	232-674-9

Polysorbate 80

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Polysorbate 60

Inventory - United States TSCA - Sect. 8(b)	XU
Australia (AICS):	Present

Propylene glycol

Inventory - United States TSCA - Sect. 8(b)	Present
Australia (AICS):	Present
EU EINECS List	200-338-0

16. OTHER INFORMATION

Reasons for Revision: Updated Section 2 - Composition / Information on Ingredients. Updated Section 3 - Hazard Identification. Updated Section 5 - Fire Fighting Measures. Updated Section 10 - Stability and Reactivity. Updated Section 11 - Toxicology Information. Updated Section 13 - Disposal Considerations.

Prepared by: Toxicology and Hazard Communication
Pfizer Global Environment, Health, and Safety

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End of Safety Data Sheet