SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**DILAUDID®(Hydromorphone Hydrochloride) Injection, USP Simplist®**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive Lake Zurich, Illinois 60047
General Phone Number:	(847) 550-2300
Customer Service Phone Number:	(888) 386-1300
Health Issues Information:	(800) 551-7176
SDS Creation Date:	February 13, 2019
SDS Revision Date:	May 01, 2020

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word:	WARNING!
GHS Class:	Acute Toxicity Oral, Category 4.
Hazard Statements:	Harmful if swallowed.
Precautionary Statements:	Wash hands thoroughly after handling. Do not eat, drink or smoke when using this product. IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth. Dispose of contents/container in accordance with Local, State, Federal and Provincial regulations.
Potential Health Effects:	This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Citric acid monohydrate	5949-29-1	2 mg/mL by weight	
Hydromorphone	71-68-1	0.2, 1.0, 2.0 mg/mL by weight	
Sodium citrate dihydrate	6132-04-3	2 mg/mL by weight	200-675-3
Water for Injection	7732-18-5	Quantity Sufficient	

Notes : Dilaudid (Hydromorphone hydrochloride) Injection, USP,

0.2mg Hydromorphone / 1mL
0.5mg Hydromorphone / 0.5mL
1.0mg Hydromorphone / 1mL
2.0mg Hydromorphone / 1mL

SECTION 4 : FIRST AID MEASURES

Eye Contact:	Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.
Skin Contact:	Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.
Inhalation:	If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.
Ingestion:	If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.
Other First Aid:	For Adverse Event Information, please call (800) 551-7176.

SECTION 5 : FIRE FIGHTING MEASURES

Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
Lower Flammable/Explosive Limit:	Not established.
Upper Flammable/Explosive Limit:	Not established.
Fire Fighting Instructions:	Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water.
Extinguishing Media:	Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Protective Equipment:	As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.
Hazardous Combustion Byproducts:	Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

SECTION 6 : ACCIDENTAL RELEASE MEASURES

Personal Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8.
Environmental Precautions:	Avoid runoff into storm sewers, ditches, and waterways.
Methods for containment:	Contain spills with an inert absorbent material such as soil, sand or oil dry.
Methods for cleanup:	Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue.

SECTION 7 : HANDLING and STORAGE

Handling:	When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions.
Storage:	Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Protect from light. Do not freeze.
Work Practices:	Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower.
Hygiene Practices:	Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist.

SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

Engineering Controls:	General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.
Eye/Face Protection:	Chemical splash goggles. Wear a face shield also when splash hazard exist.
Skin Protection Description:	Protective laboratory coat, apron, or disposable garment recommended.
Hand Protection Description:	Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended.
Respiratory Protection:	No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers.
Other Protective:	Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment.

EXPOSURE GUIDELINES

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	Odorless.
Odor Threshold:	No information.

Boiling Point:	Approximately that of water, 100°C (212°F)
Melting Point:	Approximately that of water, 0°C (32°F)
Specific Gravity:	Approximately 1.0
Solubility:	Not established.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.5 - 5.5
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Hydromorphone :

Acute Toxicity:	The lethal human dose has been identified as 0.3 to 0.4 g (4.3 to 5.7 mg/kg in a 70 kg adult).

Hydromorphone :

RTECS Number:	QD26250000
Ingestion:	Oral - Rat LD50: 199 mg/kg Oral - Mouse LD50: 215 - 261 mg/kg
Mutagenicity:	Hydromorphone was not mutagenic is an in vitro Ames reverse mutation assay or a human lymphocyte chromosome aberration assay. Hydromorphone was not clastogenic in the in vivo mouse micronunucleus assay.
Reproductive Toxicity:	No effects on fertility, reproductive performance or reproductive organ morphology were observed in male or female rates receiving oral dosages up to 7.0 mg/kg/day. Neither embryo-fetal toxicity nor teratogenic effects were observed following administration of hydromorphone at oral doses up to 7 mg/kg/day in rats from day 6 to day 17 of gestation and up to 25 mg/kg/day in rabbits from day 6 to day 20 of gestation. Hydromorphone hydrochloride administration to pregnant Syrian hamsters showed that hydromorphone hydrochloride is teratogenic at a dose of 20 mg/kg which is 600 times the human dose. A maximal teratogenic effect (50% of fetuses affected) in the Syrian hamster was observed at a dose of 125 mg/kg.
Teratogenicity:	Pregnancy Category C: Morphine sulfate is not teratogenic in rats at 35 mg/kg/day (thirty-five times the usual human dose) but does result in increased pup mortality and growth retardation at doses that narcotize the animal (> 10 mg/kg/day, ten times the usual human dose). Astramorph/PF should only be given to pregnant women when no other method of controlling pain is available and means are at hand to manage the delivery and perinatal care of the opiate-dependent infant.
Other Toxicological Information:	Intravenous - Mouse LD50 - Lethal dose, 50 percent kill: 55 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50 - Lethal dose, 50 percent kill: 51 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50 - Lethal dose, 50 percent kill: 120 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Sodium citrate dihydrate :

Eye:	Eye - Rabbit Standard Draize test.: 10 mg [Moderate]
Skin:	Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value] Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild] Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild]
Inhalation:	Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value]
Ingestion:	Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value] Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

Waste Disposal:	Dispose of in accordance with Local, State, Federal and Provincial regulations.

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name:	Not Regulated.
DOT UN Number:	Not Regulated.

SECTION 15 : REGULATORY INFORMATION

Hydromorphone :

Canada DSL:	Listed

Sodium citrate dihydrate :

TSCA Inventory Status:	Listed
Canada DSL:	Listed
EC Number:	200-675-3

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

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SDS Revision Notes:	Added new format of product (0.2 mg/mL).
Disclaimer:	The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product.