


1. Identification

Product identifier	OFIRMEV® (acetaminophen) Injection		
CAS #	Mixture		
Other means of identification			
SDS number	OFRMV		
Synonyms	Acetaminophen Injection		
Recommended use	Pharmaceuticals		
Recommended restrictions	None known.		
Manufacturer/Importer/Supplier/Distributor information			
Manufacturer			
Company name	Mallinckrodt		
Address	675 McDonnell Blvd. Hazelwood, MO 63042		
E-mail	Not available.		
Emergency phone number	Customer Service	888-744-1414	
	24 Hour Emergency	314-654-1600	
	Chemtrec	800-424-9300	
Item code	43825-102-01		

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Specific target organ toxicity, single exposure	Category 2 (Kidney, Liver)	
	Specific target organ toxicity, repeated exposure	Category 2 (Liver)	
Environmental hazards	Not classified.		
OSHA defined hazards	Not classified.		
Labeling			
Contains	ACETAMINOPHEN		
Label elements			
Signal word	Warning		
Hazard statement	May cause damage to organs (Kidney, Liver). May cause damage to organs (Liver) through prolonged or repeated exposure.		
Precautionary statement			
Prevention	Do not breathe mist or vapor. Do not eat, drink or smoke when using this product. Wash thoroughly after handling.		
Response	If exposed or concerned: Call a poison center/doctor.		
Storage	Store locked up.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	None known.		
Supplemental information	None.		

3. Composition/information on ingredients**Mixtures**

Material name: OFIRMEV® (acetaminophen) Injection
 SDS ID: OFRMV Version #: 03 Revision date: 07-18-2017

Chemical name	Common name and synonyms	CAS number	%
WATER		7732-18-5	> 95
MANNITOL		69-65-8	< 4
ACETAMINOPHEN		103-90-2	1

Composition comments All concentrations are in percent by weight unless ingredient is a gas. Gas concentrations are in percent by volume.

4. First-aid measures

Inhalation	No specific treatment is necessary since this material is not likely to be hazardous by inhalation.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Not relevant, due to the form of the product.
Ingestion	Rinse mouth. Never give anything by mouth to a victim who is unconscious or is having convulsions. Do not induce vomiting. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs. Get medical advice/attention if you feel unwell.
Most important symptoms/effects, acute and delayed	Edema. Jaundice. Prolonged exposure may cause chronic effects.
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and treat symptomatically. Keep victim under observation. Symptoms may be delayed.
General information	If you feel unwell, seek medical advice (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Flammable properties	Not flammable by OSHA criteria.
Suitable extinguishing media	Water fog. Foam. Dry chemical powder. Carbon dioxide (CO ₂). Use any media suitable for the surrounding fires.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire-fighting equipment/instructions	As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep out of low areas. Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Wear appropriate protective equipment and clothing during clean-up. Wear appropriate personal protective equipment. Do not breathe mist or vapor. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. No special precautions are necessary beyond normal good hygiene practices. See Section 8 of the SDS for additional personal protection advice when handling this product. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	This product is miscible in water. Large Spills: Stop the flow of material, if this is without risk. Dike the spilled material, where this is possible. Cover with plastic sheet to prevent spreading. Absorb in vermiculite, dry sand or earth and place into containers. Following product recovery, flush area with water. Small Spills: Wipe up with absorbent material (e.g. cloth, fleece). Clean surface thoroughly to remove residual contamination. Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS. Prevent entry into waterways, sewer, basements or confined areas.
Environmental precautions	Avoid release to the environment. Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Do not handle until all safety precautions have been read and understood. Do not breathe mist or vapor. Avoid prolonged exposure. Provide adequate ventilation. Use personal protective equipment as required. Wear appropriate personal protective equipment. When using, do not eat, drink or smoke. Wash hands thoroughly after handling. Observe good industrial hygiene practices. Handle and open container with care. Avoid release to the environment. Avoid any exposure.
Conditions for safe storage, including any incompatibilities	Store locked up. Store in original tightly closed container. Do not allow material to freeze. Store away from incompatible materials (see Section 10 of the SDS). Keep away from food, drink and animal feedings. Store in closed original container at temperatures between 15°C and 30°C.

8. Exposure controls/personal protection

Occupational exposure limits

Mallinckrodt Components

	Type	Value
ACETAMINOPHEN (CAS 103-90-2)	TWA	5 mg/m ³

Biological limit values No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls Good general ventilation (typically 10 air changes per hour) should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Individual protection measures, such as personal protective equipment

Eye/face protection Not relevant, due to the form of the product. Chemical respirator with organic vapor cartridge and full facepiece.

Skin protection

Hand protection Chemical resistant gloves.

Other Wear protective gloves. Use of an impervious apron is recommended.

Respiratory protection When workers are facing concentrations above the exposure limit they must use appropriate certified respirators. Chemical respirator with organic vapor cartridge and full facepiece. Not relevant, due to the form of the product.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations When using, do not eat, drink or smoke. Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	Liquid.
Physical state	Liquid.
Form	Liquid.
Color	Clear. Colorless.
Odor	Odorless.
Odor threshold	Not available.
pH	5 - 6.2
Melting point/freezing point	28 °F (-2.22 °C)
Initial boiling point and boiling range	212 °F (100 °C) estimated
Flash point	Not available.
Evaporation rate	Approx. to water
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.

Explosive limit - upper (%)	Not available.
Vapor pressure	Approx. to water.
Vapor density	Not available.
Relative density	1.015
Solubility(ies)	
Solubility (water)	Miscible with water in any proportion.
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Density	1.015 g/l

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	Hazardous polymerization does not occur.
Conditions to avoid	Contact with incompatible materials. Freezing.
Incompatible materials	Not available.
Hazardous decomposition products	Carbon monoxide. Carbon dioxide. Nitrogen oxides (NOx). Sulfur oxides.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Prolonged inhalation may be harmful. May cause damage to organs by inhalation.
Skin contact	No adverse effects due to skin contact are expected.
Eye contact	Direct contact with eyes may cause temporary irritation.
Ingestion	Expected to be a low ingestion hazard.

Symptoms related to the physical, chemical and toxicological characteristics Edema. Jaundice.

Information on toxicological effects

Acute toxicity May be harmful if swallowed.

Components	Species	Test Results
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ACETAMINOPHEN (CAS 103-90-2)

Acute

Oral

LD50	Mouse	338 mg/kg
	Rat	2400 mg/kg

MANNITOL (CAS 69-65-8)

Acute

Oral

LD50	Mouse	22 g/kg
	Rat	13500 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Due to partial or complete lack of data the classification is not possible.

Serious eye damage/eye irritation Due to partial or complete lack of data the classification is not possible.

Respiratory or skin sensitization

Respiratory sensitization Due to partial or complete lack of data the classification is not possible.

Skin sensitization	Due to partial or complete lack of data the classification is not possible.
Germ cell mutagenicity	Acetaminophen was not mutagenic in the bacterial reverse mutation assay. In contrast, acetaminophen tested positive in the in vitro mouse lymphoma assay and the in vitro chromosomal aberration assay using human lymphocytes.
Carcinogenicity	Not classifiable as to carcinogenicity to humans. Acetaminophen is not classifiable as to its carcinogenicity to humans (IARC Group 3). It is not listed by NTP, ACGIH, or OSHA. Long-term studies in mice and rats have been completed by the National Toxicology Program to evaluate the carcinogenic potential of acetaminophen. In 2-year feeding studies, F344/N rats and B6C3F1 mice were fed a diet containing acetaminophen up to 6000 ppm. Female rats demonstrated equivocal evidence of carcinogenic activity based on increased incidences of mononuclear cell leukemia at 0.8 times the maximum human daily dose (MHDD) of 4 grams/day, based on a body surface area comparison. In contrast, there was no evidence of carcinogenic activity in male rats or mice.

IARC Monographs. Overall Evaluation of Carcinogenicity

ACETAMINOPHEN (CAS 103-90-2) 3 Not classifiable as to carcinogenicity to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

US. OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not available.

Reproductive toxicity	Pregnancy Category C. There are no studies of OFIRMEV in pregnant women; however, epidemiological data on oral acetaminophen use in pregnant women show no increased risk of major congenital malformations. The results from a large population-based prospective cohort, including data from 26,424 women with live born singletons who were exposed to oral acetaminophen during the first trimester, indicate no increased risk for congenital malformations, compared to a control group of unexposed children. The rate of congenital malformations (4.3%) was similar to the rate in the general population. A population-based, case-control study from the National Birth Defects Prevention Study showed that 11,610 children with prenatal exposure to acetaminophen during the first trimester had no increased risk of major birth defects compared to 4,500 children in the control group.
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In studies conducted by the National Toxicology Program, fertility assessments have been completed in Swiss mice via a continuous breeding study. There were no effects on fertility parameters in mice consuming up to 1.7 times the MHDD of acetaminophen, based on a body surface area comparison. Although there was no effect on sperm motility or sperm density in the epididymis, there was a significant increase in the percentage of abnormal sperm in mice consuming 1.7 times the MHDD (based on a body surface area comparison) and there was a reduction in the number of mating pairs producing a fifth litter at this dose, suggesting the potential for cumulative toxicity with chronic administration of acetaminophen near the upper limit of daily dosing.

Specific target organ toxicity - single exposure	May cause damage to organs (Kidney, Liver).
Specific target organ toxicity - repeated exposure	May cause damage to organs (Liver) through prolonged or repeated exposure.
Aspiration hazard	Due to partial or complete lack of data the classification is not possible.
Chronic effects	Prolonged inhalation may be harmful. May cause damage to organs through prolonged or repeated exposure. May cause damage to the liver and kidneys.

12. Ecological information

Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Partition coefficient n-octanol / water (log Kow)	
MANNITOL	-3.1
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Dispose of contents/container in accordance with local/regional/national/international regulations.
Local disposal regulations	Dispose in accordance with all applicable regulations.

Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

IMDG

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not available.

15. Regulatory information

US federal regulations This material is not subject to the Federal OSHA Hazard Communication Standard 29 CFR 1910.1200 (b)(5)(iii).
TSCA exempt status. This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.
One or more components are not listed on TSCA.
This product is not known to be a "Hazardous Chemical" as defined by the OSHA Hazard Communication Standard, 29 CFR 1910.1200.

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not regulated.

CERCLA (Superfund) reportable quantity

None

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - Yes
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical Yes

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)

Not listed.

US. Massachusetts RTK - Substance List

Not regulated.

US. New Jersey Worker and Community Right-to-Know Act

Not listed.

US. Pennsylvania Worker and Community Right-to-Know Law

Not listed.

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	Yes
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date	04-01-2015
Revision date	07-18-2017
Version #	03
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