SAFETY DATA SHEET

Revision Date 03-May-2016 **Version** 4380

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

Product identifier
Product Name Flurbiprofen Sodium 0.03% 2.5 mL

Other means of identification
Product Code FP-55
Synonyms Occufen

Recommended use of the chemical and restrictions on use
Recommended Use Non Steroidal Anti-Inflammatory

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
ALLERGAN
400 Interpace Parkway, Morris Corporate Center III
Parsippany, NJ 07054, USA
+1-800-272-5525
E-mail address SDS@Actavis.com

Emergency telephone number
Emergency Telephone Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is not considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.122)

Effects on or via lactation	Yes

Label elements

Emergency Overview

Hazard statements
H362 - May cause harm to breast-fed children

Appearance Liquid **Physical state** Liquid **Odor** No information available

Chemical Name	Symptoms
Potassium Chloride	The most common adverse reactions to potassium chloride are nausea, vomiting, flatulence, abdominal pain/discomfort, and diarhhea. One the the most severe adverse side effects is hyperkalemia, There have also been reports of upper and lower gastrointestinal conditions including obstruction, bleeding, ulceration, and perforation.
Flurbiprofen Sodium	Transient burning and stinging upon instillation and other minor symptoms of ocular

	irritation have been reported with the use of this ophthalmic solution. Other adverse reactions reported with the use of this ophthalmic solution include: fibrosis, hyphema, miosis, mydriasis, and ocular hyperemia. Increased bleeding tendency of ocular tissues in conjunction with ocular surgery has also been reported.
Chemical Name	**Medical Conditions Aggravated by Exposure**
Potassium Chloride	Contraindications occur in patients with hyperkalemia since a further increase in serum potassium concentration in such patients can produce cardiac arrest. Hyperkalemia may complicate the following conditions: chronic renal failure, systemic acidosis, acute dehydration, extensive tissue beakdownand adrenal insufficiency. Other contraindications occur in any patient in whom there is structural, pathological or pharmacologic cause for arrest or delay in tablet passage through the gastrointestinal tract.
Flurbiprofen Sodium	Known hypersensitivity to this medication Flurbiprofen should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin or other non-steroidal anti-inflammatory drugs. Flurbiprofen is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery (see WARNINGS)

Precautionary statements
P201 - Obtain special instructions before use
P260 - Do not breathe dust/fume/gas/mist/vapors/spray
P263 - Avoid contact during pregnancy/while nursing
P264 - Wash face, hands and any exposed skin thoroughly after handling
P270 - Do not eat, drink or smoke when using this product
P308 + P313 - IF exposed or concerned: Get medical advice/attention

Other Information
Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
Water	7732-18-5	231-791-2	60 - 100*
POLYVINYL ALCOHOL USP PVA18-88	9002-89-5	N/A	1 - 5*
SODIUM CHLORIDE USP	7647-14-5	231-598-3	0.1 - 1*
Potassium Chloride	7447-40-7	231-211-8	0.1 - 1*
Flurbiprofen Sodium	56767-76-1	260-373-2	<0.1*

*The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST AID MEASURES

First aid measures

Eye contact Rinse immediately with plenty of water and seek medical advice.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air.

Ingestion Consult a physician if necessary.

Chemical Name
Potassium Chloride
Flurbiprofen Sodium

Note to physicians
No information available.
With some non-steroidal anti-inflammatory drugs, there exists the potential for increased bleeding time due to interference with

thrombocyte aggregation. There have been reports that this ophthalmic solution may cause increased bleeding of ocular tissues (including hyphemas) in conjunction with ocular surgery. There is the potential for cross-sensitivity to acetylsalicylic acid and other non-steroidal anti-inflammatory drugs. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media
None known.

Specific hazards arising from the chemical
Fire may produce irritating, corrosive and/or toxic gases.

Explosion data
Sensitivity to Mechanical Impact Not impact sensitive.
Sensitivity to Static Discharge Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters
As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Avoid creating dust.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

Incompatible materials None known based on information supplied.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Exposure Guidelines This product, as supplied, does not contain any hazardous materials with occupational exposure limits established by the region specific regulatory bodies.

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL
Potassium Chloride 7447-40-7	N/A	N/A	N/A	5000
Flurbiprofen Sodium 56767-76-1	N/A	N/A	N/A	2000

Appropriate engineering controls

Engineering Controls The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. Good general ventilation 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 as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state	Liquid	**Appearance**	Liquid
Color	No information available	**Odor**	No information available
Odor threshold	No information available		

Property	**Values**
pH	No information available
Melting point/freezing point	No information available
Boiling point / boiling range	No information available
Flash point	No information available
Evaporation rate	No information available
Flammability (solid, gas)	No information available
Flammability Limit in Air	
Upper flammability limit:	No information available
Lower flammability limit:	No information available
Vapor pressure	No information available
Vapor density	No information available
Specific Gravity	No information available
Water solubility	No information available
Solubility in other solvents	No information available
Partition coefficient	No information available
Autoignition temperature	No information available
Decomposition temperature	No information available
Explosive properties	No information available
Oxidizing properties	No information available

Other Information

Molecular weight	No information available
VOC Content (%)	No information available
Density	No information available
Bulk density	No information available

10. STABILITY AND REACTIVITY

Reactivity

Not defined As Reactive substance

Chemical stability
Stable under normal conditions.
Possibility of Hazardous Reactions
None under normal processing.
Conditions to avoid
Dust formation.
Incompatible materials
None known based on information supplied.
Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
Potassium Chloride	Inhalation of airborne dusts generated by this product may slightly irritate the nose, throat, and lungs. Symptoms are generally alleviated upon breathing fresh air.	Contact with the eyes of airborne dusts generated by this product may cause mild to moderate irritation, redness, and tearing.	Prolonged contact may cause redness and irritation.	Ingestion is not a significant route of occupational exposure. Acute ingestion of large quantities of this product or chronic ingestion caused by poor hygiene practices may cause adverse symptoms, including nausea, vomiting, diarrhea, and abdominal cramps and gastrointestinal ulceration. Ingestion of large quantity or chronic ingestion may cause hemorrhage and perforation or formation of digestive system strictures.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
Water	> 90 mL/kg (Rat)	N/A	N/A
POLYVINYL ALCOHOL USP PVA18-88	> 20 g/kg (Rat)	N/A	N/A
SODIUM CHLORIDE USP	= 3000 mg/kg (Rat)	> 10 g/kg (Rabbit)	> 42 g/m^3 (Rat) 1 h
Potassium Chloride	= 2600 mg/kg (oral Rat)	-	-
Flurbiprofen Sodium	117 mg/kg (rat)	N/A	N/A

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Chemical Name	Germ cell mutagenicity	Carcinogenicity	Reproductive toxicity	Effects on or via lactation
Potassium Chloride	Not mutagenic in the standard battery of tests.	Not suspected of being a human carcinogen.	This product does not contain any known or suspected reproductive hazards.	The normal potassium ion content of human milk is about 13 mEq per liter. Since oral potassium becomes part of the body potassium pool, so long as body potassium pool is not excessive, the contribution of potassium chloride supplementation should have little or no effect on the level in human milk.
Flurbiprofen Sodium	No information available.	Not suspected of being a human carcinogen. Studies in mice and rats have not shown evidence of carcinogenicity.	Pregnancy Category C: This medication has been shown to be embryocidal, delay parturition, prolong gestation, reduce weight,	It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential

			and/or slightly retard growth of fetuses when given to rats in daily oral doses of 0.4 mg/kg (approximately 300 times the human daily topical dose) and above.	for serious adverse reactions in nursing infants, nursing mothers should be advised of these effects and the appropriate action should be taken to prevent exposure.

Chemical Name	STOT - single exposure	STOT - repeated exposure
Potassium Chloride	No information available.	No information available.

Target Organ Effects Gastrointestinal tract (GI).

Numerical measures of toxicity - Product Information

The following values are calculated based on chapter 3.1 of the GHS document .

ATEmix (oral) 1430000 mg/kg

12. ECOLOGICAL INFORMATION

Ecotoxicity

1.9% of the mixture consists of components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
SODIUM CHLORIDE USP 7647-14-5	N/A	5560 - 6080: 96 h Lepomis macrochirus mg/L LC50 flow-through 12946: 96 h Lepomis macrochirus mg/L LC50 static 6020 - 7070: 96 h Pimephales promelas mg/L LC50 static 6420 - 6700: 96 h Pimephales promelas mg/L LC50 static 4747 - 7824: 96 h Oncorhynchus mykiss mg/L LC50 flow-through 7050: 96 h Pimephales promelas mg/L LC50 semi-static	1000: 48 h Daphnia magna mg/L EC50 340.7 - 469.2: 48 h Daphnia magna mg/L EC50 Static
Potassium Chloride 7447-40-7	2500: 72 h Desmodesmus subspicatus mg/L EC50	1060: 96 h Lepomis macrochirus mg/L LC50 static 750 - 1020: 96 h Pimephales promelas mg/L LC50 static	825: 48 h Daphnia magna mg/L EC50 83: 48 h Daphnia magna mg/L EC50 Static

Chemical Name	Persistence and degradability	Bioaccumulation	Mobility	Partition coefficient
Potassium Chloride 7447-40-7	This product has not been tested for persistence or biodegradability. It is expected that the components will slowly degrade in the environment and form a variety of organic and inorganic materials; however, no specific information is known.	No information available	This product has not been tested for mobility in soil	-

Other adverse effects No information available

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Disposal of wastes Disposal should be in accordance with applicable regional, national and local laws and regulations.

Contaminated packaging Do not reuse container. Dispose of contents/containers in accordance with local regulations.

14. TRANSPORT INFORMATION

DOT Not regulated

TDG Not regulated

ICAO (air) Not regulated

IATA Not regulated

IMDG Not regulated

ADR Not regulated

ADN Not regulated

15. REGULATORY INFORMATION

International Inventories

TSCA	Not Listed
DSL/NDSL	Not Listed
EINECS/ELINCS	Not Listed

Legend:

TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

US Federal Regulations

Carcinogenicity The table below indicates whether each agency has listed any ingredient as a carcinogen This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B)

Chemical Name	ACGIH	IARC	NTP	OSHA
POLYVINYL ALCOHOL USP PVA18-88 9002-89-5	-	Group 3	-	-

IARC (International Agency for Research on Cancer)
Not classifiable as a human carcinogen

SARA 313
Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372

SARA 311/312 Hazard Categories

Acute health hazard	Yes
Chronic Health Hazard	No
Fire hazard	No
Sudden release of pressure hazard	No
Reactive Hazard	No

CWA (Clean Water Act)
This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material

US State Regulations

California Proposition 65
This product does not contain any Proposition 65 chemicals

U.S. State Right-to-Know Regulations

16. OTHER INFORMATION

Revision Date 03-May-2016
Revision Note No information available
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet