Safety Data Sheet

1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Code:	**000894**
Product name	**IODINE FU-BP-USP**
Empirical formula	
CAS number	**7553-56-2**
INDEX number	**053-001-00-3**
EC number	**231-442-4**

1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use	**Pharmaceutical intermediate**

1.3. Details of the supplier of the safety data sheet

Name	**ACEF S.p.A.**
Full address	**Via Umbria, 8/14**
District and Country	**29017 Fiorenzuola d'Arda PC** **Italia** **Tel. 0523/241911** **Fax 0523/241968**
e-mail address of the competent person responsible for the Safety Data Sheet	**sicurezza@acef.it**

1.4. Emergency telephone number

For urgent inquiries refer to

Centro Antiveleni di Milano - Tel. +39 02-66101029 - (Ospedale Niguarda)
Centro Antiveleni di Pavia - Tel. +39 0382-24444 - (IRCCS Fondazione Maugeri)
Centro Antiveleni di Bergamo - Tel. 800-883300 - (Ospedali Riuniti)
Centro Antiveleni di Firenze - Tel. +39 055-7947819 - (Ospedale Careggi)
Centro Antiveleni di Roma - Tel. +39 06-3054343 - (Policlinico Gemelli)
Centro Antiveleni di Roma - Tel. +39 06-49978000 - (Policlinico Umberto I)
Centro Antiveleni di Napoli - Tel. +39 081-7472870 - (Ospedale Cardarelli)

2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulationn 1907/2006 and subsequent amendments.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments

Hazard classification and indication:

Acute Tox. 4	H302
STOT RE 1	H372
Eye Irrit. 2	H319
Acute Tox. 4	H332
Acute Tox. 4	H312
Skin Irrit. 2	H315
STOT SE 3	H335
Aquatic Acute 1	H400

2.1.2. Directive 67/548/EEC and following amendments and adjustments

Danger Symbols:	Xn-N
R phrases:	20/21-50

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms:

Warning: Danger

Hazard indication:

H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.
H372	Causes damage to organs.
H400	Very toxic to aquatic life.

Caution recommendations:

P280	Wear protective gloves/protective clothing/eye protection/face protection.
P273	Avoid release to the environment.
P260	Do not breathe dust/fume/gas/mist/vapours/spray.
P309+P311	IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.
P304+P340	IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
P405	Store locked up.

Contains: IODINE

INDEX 053-001-00-3

2.3. Other hazards

Information not available

3. Composition/information on ingredients

3.1. Substances

Contains:

Identification	Conc.%	Classification 67/548/EEC	Classification 1272/2008 (CLP)
IODINE *CAS 7553-56-2* *EC 231-442-4* *INDEX 053-001-00-3*	100	Xn R20/21, N R50	Acute Tox. 4 H302, STOT RE 1 H372, Eye Irrit. 2 H319, Acute Tox. 4 H332, Acute Tox. 4 H312, Skin Irrit. 2 H315, STOT SE 3 H335, Aquatic Acute 1 H400

Xn= HARMFUL,N= DANGEROUS FOR THE ENVIRONMENT

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet

3.2. Mixtures

Information not relevant

4. First aid measures

4.1. Description of first aid measures

EYES: Irrigate copiously with clean, fresh water for at least 15 minutes. Seek medical advice.
SKIN: Wash immediately with plenty of water. Remove contaminated clothing. If irritation persists, seek medical attention. Wash contaminated clothing before using them again.
INHALATION: Remove to open air. If breathing is irregular, seek medical advice.

INGESTION: Obtain immediate medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms and effects, both acute and delayed

For symptoms and effects caused by the contained substances see chap. 11

4.3. Indication of any immediate medical attention and special treatment needed

Follow doctor's orders

5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA

The extinction equipment used should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with ties around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator’s face or a self-respirator (self-protector) in the event of large quantities of fume.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

If there are no contraindications, spray powder with water to prevent the formation of dust. Use breathing equipment if powders are released into the air.

6.2. Environmental precautions

The product must not penetrate the sewer system, surface water, ground water and neighbouring areas.

6.3. Methods and material for containment and cleaning up

Use mechanical tools to collect leaked product and eliminate the remainder using jets of water. Make sure the leakage site is well aired.
Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage

7.1. Precautions for safe handling

Do not smoke while handling and use.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well ventilated place, keep far away from sources of heat, bright flames and sparks and other sources of ignition.

7.3. Specific end use(s)

Information not available

8. Exposure controls/personal protection

8.1. Control parameters

Information not relevant

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration or bad air vent. If such operations do not make it possible to keep the concentration of the product below the permitted workplace exposure thresholds a suitable respiratory tract protection must be used. See product label for hazard details during use. Ask your chemical substance suppliers for advice when choosing personal protection equipment. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category II (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVC, neoprene, nitryl or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

EYE PROTECTION

Wear protective airtight goggles (ref. standard EN 166).

SKIN PROTECTION

Wear category II professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear an FFP3 (ref. standard EN 141) type half mask.

The use of breathing protection equipment, such as masks with organic vapour and dust/mist cartridges, is necessary in the absence of technical measures limiting worker exposure. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

An emergency eye washing and shower system must be provided.

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	solid
Colour	grey/black
Odour	pungent
Odour threshold	Not available
pH	Not available
Melting or freezing point	113 °C
Boiling point	184 °C
Distillation range	Not available
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	0,3 mmHg 20 °C
Vapour density	Not available
Specific gravity	4,930 Kg/l
Solubility	Water solubility (20 °C) 0,30 g/l
Partition coefficient: n-octanol/water	Not available
Ignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Reactive Properties	Not available

9.2. Other information

Molecular weight	253,80
VOC (Directive 1999/13/EC) :	0%

10. Stability and reactivity

10.1. Reactivity
There are no particular risks of reaction with other substances in normal conditions of use

10.2. Chemical stability
The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions
No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid
None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials
Information not available

10.6. Hazardous decomposition products
In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.

11. Toxicological information

11.1. Information on toxicological effects
Acute effects: inhalation and cutaneous absorption of this product are harmful. This product may irritate mucosas, the upper respiratory tract, and eyes. Exposure symptoms may include: stinging and irritated eyes, mouth, nose, throat; cough, respiratory disorders, dizziness, headache, nausea and sickness.
In the most serious cases, inhalation of this product may cause larynx and bronchial tube edema and irritation, chemical pneumonia and pulmonary edema. Upon contact with skin, this product may irritate it, causing an increase in skin temperature, swelling and itchiness.
Ingestion of even small amounts of this product may cause health problems (stomach pain, nausea, sickness, diarrhoea).

IODINE
LD50 (Oral): 14,000 g/Kg rat

12. Ecological information

12.1. Toxicity
This product is dangerous for the environment and highly toxic for aquatic organisms.

12.2. Persistence and degradability
Information not available

12.3. Bioaccumulative potential
Information not available

12.4. Mobility in soil
Information not available

12.5. Results of PBT and vPvB assessment
Information not available

12.6. Other adverse effects
Information not available

13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.
Waste transportation may be subject to ADR restrictions.

14. Transport information

These goods must be transported by vehicles authorized to the carriage of dangerous goods according to the provisions set out in the current edition of the Code of International Carriage of Dangerous Goods by Road (ADR) and in all the applicable national regulations.
These goods must be packed in their original packagings or in packagings made of materials resistant to their content and not reacting dangerously with it. People loading and unloading dangerous goods must be trained on all the risks deriving from these substances and on all actions that must be taken in case of emergency situations.

Road and rail transport:

ADR/RID Class:	8	UN:	3495
Packing Group:	III		
Label:	8, 6.1		
Nr. Kemler:	86		
Limited Quantity	5 kg		
Proper Shipping Name:	Iodio		

Carriage by sea (shipping):

IMO Class:	8	UN:	3495
Packing Group:	III		
Label:	8, 6.1		
EMS:			
Marine Pollutant	YES		
Proper Shipping Name:	Iodio		

Transport by air:

IATA:	8	UN:	3495
Packing Group:	III		
Label:	8, 6.1		
Cargo:			
Packaging instructions:		Maximum quantity:	
Pass.:			
Packaging instructions:		Maximum quantity:	
Proper Shipping Name:	Iodio		

15. Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso category 9i

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
None

Substances subject to authorisarion (Annex XIV REACH)
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains

16. Other information

Key for the CLP classifications mentioned in sections 2 and 3 of the sheet:

Acute Tox. 4	Acute toxicity, category 4
STOT RE 1	Specific target organ toxicity - repeated exposure, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity category 1

H332	Harmful if inhaled.
H312	Harmful in contact with skin.
H302	Harmful if swallowed.
H372	Causes damage to organs.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R20/21	HARMFUL BY INHALATION AND IN CONTACT WITH SKIN.
R50	VERY TOXIC TO AQUATIC ORGANISMS.

GENERAL BIBLIOGRAPHY

1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Changes to previous review:
The following sections were modified:
02/03/14