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

1.1 Product identifiers

Product Name: STAT-Intra Operative-Intact PTH kit
Item number: 4K-IPT-00

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

Identified uses: For *In Vitro* Diagnostics use only.

1.3 Details of the supplier of the safety data sheet

Legal Manufacturer: Future Diagnostics Solutions B.V.
Nieuweweg 279
6603 BN Wijchen
The Netherlands
Tel: +31 (0) 24 6452900
Monday to Friday, during office hours (UTC+1:00)
info@future-diagnostics.nl

Emergency Phone No.: EU: 112
US: 911

Section 2 Hazards Identification

2.1 Classification of the substance or mixture

Classification according to EU regulation 1272/2008

Standards (S0, S1, S2, S3, S4 and S5): Considered non-hazardous
Controls (C1 and C2): Considered non-hazardous
Wash solution: Considered non-hazardous
RTU (Ready to use) plate: Considered non-hazardous
NC (Non coated) plate: Considered non-hazardous
Activator 1: Skin corrosive category 1B, H314
Activator2: Considered non-hazardous

For the full text of the H-Statements mentioned in this Section, see section 16.

2.2 Labeling elements

Labeling according EU regulation 1272/2008

Activator 1

Pictogram:

GHS05



Signal Word:

Danger

Hazard statement:

H314:

Causes severe skin burns and eye damage

Precautionary statement(s)

P280:

Wear protective gloves/protective clothing/eye protection/face protection

P303+P361+P353:

IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water/shower.

P305+P351+P338:

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P310:

Immediately call a POISON CENTER or doctor/physician.

2.3 Other hazards

Standards (S0, S1, S2, S3, S4 and S5): Contains Sodium Azide (NaN_3 , <0.1%) and material from human origin. Though each donor was tested and found negative for HBV, HCV and HIV, complete absence of these of other infectious reagents can never be assured. Therefore these materials should be regarded as potentially infectious.

Controls (C1 and C2):

Contains Sodium Azide (NaN_3 , <0.1%) and material from human origin. Though each donor was tested and found negative for HBV, HCV and HIV, complete absence of these of other infectious reagents can never be assured. Therefore these materials should be regarded as potentially infectious.

Wash solution:

Contains Sodium Azide (NaN_3 , <0.1%).

RTU-plate:

Contains material of animal origin and should be considered potentially infectious.

Section 3 Composition/Information of ingredients

3.1. Substance

Not applicable

3.2. Mixture

Synonyms: Activator 1

Chemical name: Sodium hydroxide solution

Hazardous ingredients

Sodium hydroxide					
Cas No.	EG No.	Art. No.	Reach. No.	%(w/w)	Classification according to Regulation (EC) 1272/2008
1310-73-2	215-185-5	3C-UVL-01	01-2119457892-27-XXXX	4	Skin Corr. 1A H314

For the full text of the H-statements mentioned in this Section, see Section 16.

Section 4 First Aid Measures

4.1 Description of first aid measures

Skin Contact:

In case of skin contact, wash thoroughly with soap and water of at least 15 minutes. Remove contaminated clothing and shoes. If pain or irritation occurs, obtain medical attention.

Eye Contact:

If product enters eyes, wash gently under running water for 15 minutes or longer, making sure that the eyelids are held open. If pain or irritation occurs, obtain medical attention.

Ingestion:

Never give anything by mouth to an unconscious person. If ingested, wash mouth out with water and seek medical attention.

Inhalation:

If product is inhaled, move exposed individual to fresh air. If individual is not breathing, begin artificial respiration immediately and obtain medical attention.

4.2 Most important symptoms and effects, both acute and delayed

Activator 1 causes severe skin burns and eye damage

4.3 Indication of any immediate medical attention and special treatment needed

For any immediate medical attention see section 4.1.

Section 5 Fire Fighting Measures

5.1 Extinguishing media

Suitable extinguishing media:

Use extinguishing media suitable for surrounding fire. Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Sodium oxides

5.3 Advice for firefighters

Self-contained breathing apparatus is recommended in all chemical fire situations.

Section 6 Accidental Release Measures

6.1 Personal precautions, protective equipment and emergency procedures

All components:

Use personal protective equipment. Avoid breathing vapors, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. For personal protection see section 8.

Standards (S0, S1, S2, S3, S4 and S5):

Product contains material of human and animal origin and should be considered potentially infectious.

Controls (C1 and C2):

Product contains material of human and animal origin and should be considered potentially infectious.

RTU plate:

Product contains material of human and animal origin and should be considered potentially infectious.

6.2 Environmental precautions

Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Standards (S0, S1, S2, S3, S4 and S5):

As a precautionary measure, treat spilled material with a 1:10 bleach water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Controls (C1 and C2):

As a precautionary measure, treat spilled material with a 1:10 bleach water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

RTU plate:

As a precautionary measure, treat spilled material with a 1:10 bleach water solution. Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Activator 1:

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Activator 2:

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

Wash solution:

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed containers for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations.

6.4 Reference to other sections

For disposal see section 13.

Section 7 Handling and Storage

7.1 Precautions for safe handling

Avoid contact with eyes or skin. Avoid inhalation of vapor or mist. Do not eat, drink or smoke during handling this product. Wash hands after handling. This product should be handled as though capable of transmitting infectious diseases. For further precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

For storage temperatures see product label. Containers which are opened must be carefully resealed and kept upright to prevent leakage. The activators should be stored unopened in the original vials in a dry and well-ventilated place. Keep away from incompatible materials see section 10.5

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are defined.

Section 8 Exposure controls and personal protection

8.1 Control parameters

Not applicable

8.2 Exposure controls

Engineering Controls

Handle in accordance with good industrial hygiene and safety practice.

Personal protecting equipment

Respiratory Protection:

Under normal conditions of use, as mentioned in section 1.2, the use of this product should not require respiratory protection.

Eye Protection:

Tightly fitting safety goggles. Face shield (8-inch minimum). Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin Protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Full contact and splash contact:

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

8.3 Environmental exposure controls

See section 6.

Section 9 Physical and Chemical Properties

Appearance:

Standards (S0, S1, S2, S3, S4 and S5):

Freeze dried

Controls (C1 and C2):

Freeze dried

Wash solution:

Clear liquid, colorless

Activator 1:

Clear liquid, colorless

Activator 2:

Clear liquid, colorless

RTU plate:

Coated plate containing accuspheeres

NC plate:

Non coated empty plate

Odor:

No data available

Odor Threshold:

No data available

pH:

No data available

Melting point/Freezing Point:

No data available

Boiling Point/Boiling range:

No data available

Flash Point:

No data available

Evaporation rate:

No data available

Flammability (Solid, Gas):

Not applicable

Upper/lower flammability or explosion limits:

No data available

Vapor Pressure:

No data available

Vapor Density:

No data available

Relative density:

No data available

Solubility:

Standards (S0, S1, S2, S3, S4 and S5) and controls (C1 and C2) are soluble in water.

Partition coefficient of Water/Oil:

No data available

Auto-ignition Temp.:

No data available

Decomposition Temp.:

No data available

Viscosity:

No data available

Explosive properties:

No data available

Oxidizing properties:

No data available

Section 10 Stability and reactivity

10.1 Reactivity

See subsection 10.3

10.2 Stability

Stable under normal temperatures and pressures.

10.3 Possibility of hazardous reactions

Wash solution:

Sodium azide forms explosive compounds with heavy metals. This product contains <1% (w/w) which with repeated contact with lead and copper commonly found in plumbing drains may result in the buildup of shock sensitive compounds.



Safety Data Sheet

MSDS 4K-IPT-00

Version 9

Publication date: 01 July 2019

Activator 1:

Strong acids; Strong bases; Strong oxidizers

10.4 Conditions to avoid

Avoid contact with incompatible materials, see subsection 10.5.

10.5 Incompatible materials

Wash solution:

Heavy metals such as lead and copper see subsection 10.3.

Activator 1:

Water, acids, Organic materials, Chlorinated solvents, Aluminum, Phosphorus, Tin/tin oxides, Zinc.

10.6. Hazardous Decomposition Products

No decomposition products posing significant hazards would be expected from this product.

Section 11 Toxicological Information

11.1. Information on toxicological effects

Acute Toxicity :

No data available

Skin corrosion and irritation:

No data available

Serious eye damage/irritation:

No data available

Respiratory or skin sensitization:

No data available

Germ cell mutagenicity:

No data available

Carcinogenicity:

No component in this product is listed as carcinogen.

Reproductive toxicity:

No data available

Specific target organ toxicity - single exposure:

No data available

Specific target organ toxicity - repeated exposure:

No data available

Aspiration hazard:

No data available

Primary routes of exposure:

Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

Additional Information:

This product contains materials of human and animal origin and should be considered potentially infectious

Section 12 Ecological Information

12.1 Toxicity

No information available.

12.2 Persistence and degradability

No information available.



Safety Data Sheet

MSDS 4K-IPT-00

Version 9

Publication date: 01 July 2019

12.3 Bio accumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

No information available.

12.6 Other Adverse Effects

No information available.

Section 13 Disposable Considerations

13.1. Waste treatment methods

Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

Section 14 Transport regulations

Sodium hydroxide					
	UN number	Transport hazard class	PG	UN Proper shipping name	Environmental hazard
IATA	1824	8	II	Sodium hydroxide solution	No
ADR/RID	1824	8	II	Sodium hydroxide solution	Marine pollutant: No
IMDG	1824	8	II	Sodium hydroxide solution	No

Section 15 Regulatory Information

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

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

Directive 98/79/EC of the European Parliament and of the Council of 27th October 1998 on in vitro diagnostic medical devices.

No component in this product is listed as carcinogen, mutagenic or reproductive toxic.



Safety Data Sheet

MSDS 4K-IPT-00

Version 9

Publication date: 01 July 2019

15.2 Chemical safety assessment

No chemical safety assessment has been carried out for this mixture by the supplier.

Section 16 Other Information

Complete text of the H-phrases as mentioned in section 2 and 3

H314: Causes severe skin burns and eye damage

Indications of changes

Removed print date from the MSDS.

Further information

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to the appropriate safety precautions. It does not represent any guarantee of the properties of this product. Future Diagnostics Solutions B.V. shall not be held liable for any damage resulting from handling or contact with the above product. The burden of safe use of these materials rests solely with the user.

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