

SECTION 1: Identification of the substance/mixture and of the company/undertaking
1.1. Product identifier

Product form : Mixture
 Product name : MicroVue Bone Human Intact PTH
 Product code : 60-3100

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

Use of the substance/mixture : Research use only.

1.2.2. Uses advised against

Restrictions on use : Restricted to professional users.

1.3. Details of the supplier of the safety data sheet
Manufacturer

Quidel Corporation
 2005 East State Street, Suite 100
 45701 Athens - USA
 T 1.800.874.1517 - F 1.740.592.9820
gehs@quidel.com - quidel.com

1.4. Emergency telephone number

Emergency number : 1.866.519.4752

SECTION 2: Hazards identification
2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]

Components	CLP classification
ELISA Stop Solution (11 mL)	Skin Corr. 1, H314 Eye Dam. 1, H318


Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

Causes severe skin burns and eye damage. Causes serious eye damage.

2.2. Label elements

Labeling according to Regulation (EC) No. 1272/2008 [CLP]

Components	Pictograms	Signal word	Hazard statements	Precautionary statements
ELISA Stop Solution (11 mL)		Danger	H314 - Causes severe skin burns and eye damage	P264 - Wash hands thoroughly after handling P280 - Wear protective gloves/protective clothing/eye protection/face protection. P301+P330+P331 - IF SWALLOWED: Rinse mouth. Do NOT induce vomiting P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water . P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing. P305+P351+P338 - If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing P321 - Specific treatment: Seek medical attention if ill effect develops P501 - Dispose of contents/container to hazardous or special waste collection point, in accordance with local, regional, national and/or international regulation.

2.3. Other hazards

Other hazards not contributing to the classification : Ciprofloxacin (<0.1%) is used as a preservative in various components within this kit. Refer to kit specific package insert.

SECTION 3: Composition/Information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Name	Chemical name	CAS-No. EC-No.	%	CLP classification
ELISA Stop Solution (11 mL)	Sulfuric Acid	7664-93-9 --	<= 5.56	Skin Corr. 1A, H314

Full text of H-phrases: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a physician immediately.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact : Rinse skin with water/shower. Remove/Take off immediately all contaminated clothing. Call a physician immediately.

First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a physician immediately.

First-aid measures after ingestion : Rinse mouth. Do not induce vomiting. Call a physician immediately.

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

Symptoms/effects after skin contact : Burns.

Symptoms/effects after eye contact : Serious damage to eyes.

Symptoms/effects after ingestion : Burns.

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

Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water spray. Dry powder. Foam.

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapors/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up	: Mechanically recover the product.
Other information	: Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling	: Ensure good ventilation of the work station. Avoid contact with skin and eyes. Do not breathe dust/fume/gas/mist/vapors/spray. Wear personal protective equipment.
Hygiene measures	: Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions	: Store locked up. Store in a well-ventilated place. Keep cool.
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7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

Personal protective equipment:

Gloves. Safety glasses.

Materials for protective clothing:

Lab coat

Hand protection:

Protective gloves

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

In case of insufficient ventilation, wear suitable respiratory equipment

Personal protective equipment symbol(s):



Environmental exposure controls:

Avoid release to the environment.

Other information:

Do not eat, drink or smoke when using this product.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: EIA Kit.
Color	: No data available
Odor	: No data available
Odor threshold	: No data available
pH	: ELISA Stop Solution (11 mL): pH 2.0
Relative evaporation rate (butyl acetate=1)	: No data available
Melting point	: No data available
Freezing point	: Not applicable
Boiling point	: No data available
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: No data available
Flammability (solid, gas)	: Non flammable.
Vapor pressure	: No data available
Relative vapor density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidizing properties	: No data available
Explosion limits	: Not applicable

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity
10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information
11.1. Information on toxicological effects

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation)	: Not classified
Skin corrosion/irritation	: Causes severe skin burns and eye damage.
Serious eye damage/irritation	: Causes serious eye damage.
Respiratory or skin sensitization	: Not classified

Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
Specific target organ toxicity – single exposure	: Not classified
Specific target organ toxicity – repeated exposure	: Not classified
Aspiration hazard	: Not classified

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general	: Before neutralisation, the product may represent a danger to aquatic organisms.
Aquatic acute	: Not classified
Aquatic chronic	: Not classified

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste)	: Disposal must be done according to official regulations.
Waste treatment methods	: Dispose of contents/container in accordance with licensed collector's sorting instructions.
Sewage disposal recommendations	: Disposal must be done according to official regulations.
Ecology - waste materials	: Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG / RID

14.1. UN number

UN-No. (ADR)	: Not regulated
UN-No. (IMDG)	: Not regulated
UN-No. (IATA)	: Not regulated
UN-No. (RID)	: Not regulated

14.2. UN proper shipping name

Proper Shipping Name (ADR)	: Not regulated
Proper Shipping Name (IMDG)	: Not regulated
Proper Shipping Name (IATA)	: Not regulated
Proper Shipping Name (RID)	: Not regulated

14.3. Transport hazard class(es)

ADR

Transport hazard class(es) (ADR)	: Not regulated
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IMDG

Transport hazard class(es) (IMDG)	: Not regulated
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IATA

Transport hazard class(es) (IATA)	: Not regulated
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RID

Transport hazard class(es) (RID) : Not regulated

14.4. Packing group

 Packing group (ADR) : Not regulated
 Packing group (IMDG) : Not regulated
 Packing group (IATA) : Not regulated
 Packing group (RID) : Not regulated

14.5. Environmental hazards

 Dangerous for the environment : No
 Marine pollutant : No
 Other information : No supplementary information available

14.6. Special precautions for user
Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Rail transport

Not regulated

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information
15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
15.1.1. EU-Regulations

 Contains no REACH substances with Annex XVII restrictions
 Contains no REACH candidate substance
 Contains no REACH Annex XIV substances.

15.1.2. National regulations
Germany

Reference to AwSV : Water hazard class (WGK) 1, slightly hazardous to water (Classification according to AwSV, Annex 1)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : None of the components are listed

SZW-lijst van mutagene stoffen : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : None of the components are listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : None of the components are listed

Denmark

Danish National Regulations : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Other information : Please review product insert prior to using this product.

Full text of H- and EUH-phrases:

Eye Dam. 1	Serious eye damage/eye irritation Category 1
Skin Corr. 1	Skin corrosion/irritation Category 1
H314	Causes severe skin burns and eye damage
H318	Causes serious eye damage

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.