

Safety Data Sheet

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: EXTRA I, EXTRA II, EXTRA III, EXTRA H, EXTRA S

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

Relevant identified uses: Sterile Absorbable Hyaluronic Acid Dermal Filler for Tissue Repair is used as injection using syringe into deep dermis for the treatment of facial contour deformities (such as asymmetry treatment) in case of tissue loss by accident or disease. The device (Model) is intended to add volume into facial dermis for treatment of facial lipoatrophy.

Uses advised against: Not available

Reason why uses advised against: Not available

1.3. Details of the supplier of the safety data sheet

Supplier: BioPlus Co.,Ltd.

Address: #211, Migun Techno World II, 187, Techno 2-ro, Yuseong-gu, Daejeon, 34025,
Korea

Telephone number: +82-42-671-0228, Fax: +82-41-672-0292

1.4. Emergency telephone number

+82-42-671-0228

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008 (CLP) : Not applicable

2.1.2 Additional information:

For full text of Hazard- and EU Hazard-statements: see SECTION 16

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]: Not applicable

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Hazard pictograms: Not applicable

Signal word: Not applicable

Hazard statements: Not applicable

Precautionary statements: Not applicable

Supplemental Hazard information (EU): Not applicable

2.3. Other hazards: Not applicable

SECTION 3: Composition/information on ingredients

3.1. Mixtures

CAS No.	EC No.	Index No.	REACH Registration No.	% [weight]	Name	Classification according to Regulation (EC) No 1278/2008 (CLP).
9067-32-7	618-620-0	-	-	2	Sodium hyaluronate	Not Classified
7647-14-5	231-598-3	-	-	< 1	Sodium chloride	Not Classified
10028-24-7	600-053-5	-	-	< 1	Disodium hydrogen phosphate dihydrate	Not Classified
13472-35-0	603-853-2	-	-	< 1	Sodium phosphate monobasic dihydrate	Not Classified
7732-18-5	231-791-2	-	-	97	Water	Not Classified

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3.2. Additional information:

For full text of H-statements: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following inhalation:

- Move to fresh air.
- Administer oxygen if breathing is difficult.

Following skin contact:

- In case of contact with substance, immediately flush skin with running water for at least 20 minutes.
- Be aware that it can irritate damaged skin.

Following eye contact:

- In case of contact with substance, immediately flush eyes with running water for at least 20 minutes.
- If irritation persists, Arrange for medical treatment.

Following ingestion:

- If large quantities have been ingested, provide water and seek medical advice.
- Rinse the mouth and spit the fluids out.

Self-protection of the first aider:

- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Keep warm and stable.

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

Over-exposure signs/symptoms: No known significant effects or critical hazards.

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Potential acute health effects: No known significant effects or critical hazards.

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

Notes for the doctor: Treat symptomatically.

Special treatment: No specific treatment.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Dry chemical, regular foam, water spray, CO₂

Unsuitable extinguishing media: High-pressure water

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products:

- Containers may explode when heated.
- Fire may cause toxic and irritating gases.
- Do not breathe vapors from combustion may cause toxic effects.

5.3. Advice for firefighters

- Wear respiratory protection such as gas masks.
- Move containers from fire area if you can do it without risk.
- Dike fire-control water for later disposal; do not scatter the material.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Protective equipment:

- Fully encapsulating, vapor protective clothing should be worn for spills and leaks with no fire.
- Do not touch damaged containers or spilled material unless wearing appropriate

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protective clothing.

Emergency procedures:

- Prevent dust cloud.
- Eliminate all ignition sources (no smoking, flares, sparks or flames in immediate area).

6.1.2 For emergency responders: Do not touch or walk through spilled material.

6.2. Environmental precautions

- Prevent entry into waterways, sewers, basements or confined areas.
- Wet down with water and dike for later disposal.

6.3. Methods and material for containment and cleaning up

6.3.1 For containment: With clean shovel, place material into clean, dry container;
move containers from spill area.

6.3.2 For cleaning up: Absorb or cover with dry earth, sand or other non-combustible
material and transfer to containers.

6.3.3 Other information: Wash contaminated areas with water after collecting material.

6.4. Reference to other sections

- See Section 1 for emergency contact information.
- See Section 8 for information on appropriate personal protective equipment.
- See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Protective measures:

Measures to prevent fire:

- Avoid dust formation.
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- Dust formation that cannot be avoided must be collected regularly.

Measures to prevent aerosol and dust generation:

- Handling refer to engineering control/personal protection section.
- Ventilate closed spaces before entering.

Measures to protect the environment:

- Prevent entry into waterways, sewers, basements or confined areas.

Advice on general occupational hygiene:

- Remove and isolate contaminated clothing and shoes.
- See also Section 8 for additional information on hygiene measures.

7.2. Conditions for safe storage, including any incompatibilities

- Keep container tightly closed. Store in a dry place.
- Storage temperature: 1-25 °C

7.3. Specific end use(s)

Recommendations: Not available

Industrial sector specific solutions: Not available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Occupational exposure limits:

Country	Substances CAS No.	Limit value - Eight hours		Limit value - Short term		Legal basis
		ppm	mg/m ³	ppm	mg/m ³	
European Union	9067-32-7	-	-	-	-	Not applicable
	7647-14-5	-	-	-	-	Not applicable
	10028-24-7	-	-	-	-	Not applicable
	13472-35-0	-	-	-	-	Not applicable
	7732-18-5	-	-	-	-	Not applicable

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Biological limit values:

Country	Substances CAS No.	Limit value	Legal basis
European Union	9067-32-7	-	Not applicable
	7647-14-5	-	Not applicable
	10028-24-7	-	Not applicable
	13472-35-0	-	Not applicable
	7732-18-5	-	Not applicable

Exposure limits at intended use:

DNEL/PNEC-values

- Substance name : Sodium chloride

Route of exposure	Workers				Consumers			
	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic	Acute effect local	Acute effects systemic	Chronic effects local	Chronic effects systemic
Oral (mg/kg)	Not required					126.65	-	126.65
Inhalation (mg/m ³)	-	2068.62	-	2068.62	-	443.28	-	443.28
Dermal (mg/kg)	-	295.52	-	295.52	-	126.65	-	126.65

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Environmental protection target	PNEC
Fresh water	5 mg/L
Freshwater sediments	-
Marine water	-
Marine sediments	-
Food chain	-
Microorganisms in sewage treatment	500 mg/L
Soil (agricultural)	4.86 mg/kg
Air	-

8.2. Exposure controls

8.2.1 Appropriate engineering controls:

Substance/mixture related measures to prevent exposure during identified uses:

- Ensure adequate air levels using process substitution, isolation and appropriate ventilation measures such as local exhaust ventilation.

8.2.2 Personal protection equipment:

8.2.2.1 Eye and face protection: Safety goggles complying with an approved standard

8.2.2.2 Skin protection:

- **Hand protection:** Chemical-resistant, impervious gloves complying with an approved standard
- **Other skin protection:** Appropriate footwear and any additional skin protection measures

8.2.2.3 Respiratory protection:

- Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification.

8.2.3 Environmental exposure controls:

Substance/mixture related measures to prevent exposure:

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- Dike fire-control water for later disposal; do not scatter the material.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

- (a) Appearance; Viscous colorless liquid
 - (b) Odour; Odorless
 - (c) Odour threshold; Not available
 - (d) pH: 5.5-8.5
 - (e) Melting point/freezing point; Not available
 - (f) Initial boiling point and boiling range; Not available
 - (g) Flash point; Not flammable
 - (h) Evaporation rate; Not available
 - (i) Flammability (solid, gas); Not applicable
 - (j) Upper/lower flammability or explosive limits; Not available
 - (k) Vapour pressure; Not available
 - (l) Vapour density; Not available
 - (m) Relative density; Not available
 - (n) Solubility(ies); Not available
 - (o) Partition coefficient: n-octanol/water; Not available
 - (p) Auto-ignition temperature; Not available
 - (q) Decomposition temperature; Not available
 - (r) Viscosity; 1.0
 - (s) Explosive properties; Not available
 - (t) Oxidising properties; Not available
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9.2. Other information: Not available

SECTION 10: Stability and reactivity

10.1. Reactivity

- No specific reactivity available at normal temperature and pressure .

10.2. Chemical stability

- Stable at normal temperature and pressure .

10.3. Possibility of hazardous reactions

- Under normal conditions of storage and use, hazardous reactions will not occur .
- Material to avoid : Combustible material

10.4. Conditions to avoid

- Ignition source(heat, spark, flame, etc.).

10.5. Incompatible materials: Not available

10.6. Hazardous decomposition products

- Toxic gases and vapors

SECTION 11: Toxicological information

11.1. Information on toxicological effects

11.1.1 Acute toxicity:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	Oral:Non- toxic	Mouse	-	-	-
9067-32-7	LD50 Oral LD50 Dermal	Rat Rabbit	>800 mg/kg >2,000 mg/kg	-	-
7647-14-5	LD50 Oral LD50 Dermal	Rat Rabbit	3,550 mg/kg 10,000 mg/kg	-	-
10028-24-7	-	-	-	-	-

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13472-35-0	-	-	-	-	-
7732-18-5	LD50 Oral	Rat	90,000 mg/kg	-	-

11.1.2 Skin corrosion/irritation:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	Not irritating	Rabbit	-	-	-
9067-32-7	-	-	-	-	-
7647-14-5	Not irritating	Rabbit	-	-	-
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

11.1.3 Serious eye damage/irritation:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	-	-	-	-	-
9067-32-7	-	-	-	-	-
7647-14-5	Congestion, temporary rise in intraocular pressure	Rabbit	-	-	-
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

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11.1.4 Respiratory or skin sensitization:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	Skin: Not sensitive	Guinea pig	-	-	-
9067-32-7	-	-	-	-	-
7647-14-5	-	-	-	-	-
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

11.1.5 Germ cell mutagenicity:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	Negative	S. typhimurium	-	-	In vitro
9067-32-7	-	-	-	-	-
7647-14-5	Negative	S. typhimurium	-	-	In vitro - Bacterial reverse mutation assay
	Positive	Rat			In vivo - Chromosome aberration assay
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

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11.1.6 Carcinogenicity:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	-	-	-	-	-
9067-32-7	-	-	-	-	-
7647-14-5	-	-	-	-	-
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

11.1.7 Reproductive toxicity:

Product/ Ingredients	Result	Species	Effective Dose	Exposure time	Method
Product	-	-	-	-	-
9067-32-7	-	-	-	-	-
7647-14-5	18% fracture defect was observed but not potentially toxic	Mouse	1,900 or 2,500 mg/kg	10, 11 days	
10028-24-7	-	-	-	-	-
13472-35-0	-	-	-	-	-
7732-18-5	-	-	-	-	-

11.1.8 STOT-single exposure: Not available

11.1.9 STOT-repeated exposure: Not available

11.1.10 Aspiration hazard: Not available

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SECTION 12: Ecological information

12.1. Toxicity

Acute (short-term), Chronic (long-term) toxicity:

Product/ Ingredients	Result	Species	Exposure time
Product	-	-	-
9067-32-7	-	-	-
7647-14-5	LC50 5,840 mg/L LC50 874 mg/L EC50 621.391 mg/L	Fish Daphnia magna Green Algae	96 hr 48 hr 96 hr
10028-24-7	-	-	-
13472-35-0	-	-	-
7732-18-5	-	-	-

12.2. Persistence and degradability

Abiotic Degradation: Not available

Physical- and photo-chemical elimination: Not available

Biodegradation: Not available

12.3. Bioaccumulative potential

Product/Ingredients	log Kow	BCF
Product	-	-
9067-32-7	-	-
7647-14-5	-0.46 (estimated)	3.162 (estimated)
10028-24-7	-	-
13472-35-0	-	-
7732-18-5	-1.38 (estimated)	3.162 (estimated)

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12.4. Mobility in soil

Product/Ingredients	Kow	Mobility
Product	-	-
9067-32-7	-	-
7647-14-5	0.3984 (estimated)	-
10028-24-7	-	-
13472-35-0	-	-
7732-18-5	0.06337 (estimated)	-

12.5. Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6. Other adverse effects: Not available

12.7. Additional information: Not available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

13.1.1 Product / Packaging disposal:

Waste codes / waste designations according to LoW:

- Not classified as hazardous waste according to European Union regulations.
- Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.

13.1.2 Waste treatment-relevant information:

- Dispose of empty containers and wastes safely.
- Dispose according to legislation.

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SECTION 14: Transport information

- 14.1. **UN number:** Not available
- 14.2. **UN proper shipping name:** Not available
- 14.3. **Transport hazard class(es):** Not available
- 14.4. **Packing group:** Not available
- 14.5. **Environmental hazards(IMDG/ADR/ADN/IATA):** Not available
- 14.6. **Special precautions for user:** Not available
- 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**

EU Regulation (EC) No. 1907/2006(REACH) / Authorisations and/or restrictions on use:

Authorisations: Not applicable (Annex XIV)

Substances of very high concern: Not applicable

Restrictions on use: Not applicable (Annex XVII)

- 15.2. **Chemical safety assessment**

No Chemical Safety Assessment has been carried out for this substance/mixture by the Supplier.

SECTION 16: Other information

- 16.1. **Indication of changes / Date of issue:** 0 time / 11 Nov 2019
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16.2. Abbreviations and acronyms:

ADN= European Agreement Concerning the International Carriage of Dangerous Goods by
Inland Waterways

ADR= European Agreement Concerning the International Carriage of Dangerous Goods by
Road

ATE= Acute Toxicity Estimate

BCF= Bio-concentration factor

CAS No.= Chemical Abstracts Service number

CLP= Classification Labelling Packaging Regulation

DNEL= Derived No Effect Level

EC= European Community

EC-Number= EINECS and ELINCS Number

EC50= Effective Concentration 50%

EU= European Union

IATA= International Air Transport Association

IBC= International Code for the Construction and Equipment of Ships Carrying
Dangerous Chemicals in Bulk

IMDG= International Maritime Dangerous Goods Code

Kow= Octanol-water partition coefficient

LC50= Lethal Concentration 50%

LD50= Lethal Dose 50%

LoW= List of Wastes

PBT= Persistent, Bioaccumulative and Toxic substance

PNEC(s)= Predicted No Effect Concentration(s)

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REACH= Registration, Evaluation, Authorisation and Restriction of Chemicals

Regulation (EC) No 1907/2006

STOT= Specific Target Organ Toxicity

VOC= Volatile Organic Compounds

VPvB= Very Persistent and Very Bioaccumulative

16.3. Key literature references and sources for data

- ATSDR
 - CAMEO Chemicals NOAA
 - ChemIDplus
 - ECHA CHEM
 - ECOSAR
 - Emergency response guide book
 - EU RAR
 - HSDB
 - HPVIS
 - IARC
 - ICSC
 - IRIS
 - IUCLID
 - NIOSH Pocket guide
 - NITE
 - OECD SIDS
 - QSAR
 - Recommendations on the transport of dangerous goods
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16.4. Classification and procedure used to derive the classification for mixtures

according to Regulation (EC) 1272/2008 [CLP]: Not classified
