

*Questionnaire - Development, Contract Manufacturing*

# Questionnaire

## Development, Contract Manufacturing

Please mail or fax this questionnaire to BRACE GmbH, Am Mittelberg 5, D-63791 Karlstein, Germany, Tel: +49 6188 991757, Fax: +49 6188 991759, email: info@brace.de

You have decided that your products could make use of the patented BRACE Microsphere Processes to obtain your materials as Microspheres or Microcapsules. We congratulate you to such a good decision.

Since we have a wide variety of processing parameters which can be changed to obtain the best results with your material(s). But this needs some knowledge about your processes, the hazards and the chemical properties.

**Company Name**

**Contact Person**

**Position**

**Direct contact**

Phone

Email

Fax

**Department**

**Invoice Address**

Address

ZIP

City

State

Country

Phone

Fax

Web

Email

**Delivery Address**

Address

ZIP

City

State

Country

Phone

Fax

**VAT No (EC) or Tax No**

**Company Registration**

Place

Number



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# 1 Application Specification

## Application

- Chemicals
- Ceramics
- Catalyst
- Agricultural
  - Fertilizer/Mineral
  - Pesticide
  - Bio-Pesticide
- Electronics
- Nutrition (Human)
  - Nutrient
  - Flavor
- Nutrition (Animal)
  - Companion
  - Large animal
  - Fish
- Pharma (Human)
- Pharma (Veterinarian)
- Cosmetics
  - Liquid detergent
  - Make-Up
- Plastic
- Biochemical/Biological
  - Bacteria
  - Fungii
  - Other cells/microbes
- Energy

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### Type of particles

- Microspheres (= Matrix encapsulation, granulation)
- Microcapsules (= Core-Shell Encapsulation)
- Coating (additional coating to either Microspheres or Microcapsules)
- Other: \_\_\_\_\_

### Secondary treatment

- Drying
  - Air drying
    - Max. temperature: \_\_\_\_\_
    - Residual humidity: \_\_\_\_\_
  - Freeze Drying
- Heat treatment
  - Temperature 1: \_\_\_\_\_
  - Holding Time: \_\_\_\_\_
  - Temperature 2: \_\_\_\_\_
  - Holding Time: \_\_\_\_\_
  - Temperature 3: \_\_\_\_\_
  - Holding Time: \_\_\_\_\_
  - If more, please describe curve: \_\_\_\_\_
- Coating
  - Dip coating
    - Material: \_\_\_\_\_
    - Coating time: \_\_\_\_\_

### Packing

- Dry
- In Liquid
  - Liquid: \_\_\_\_\_
  - Sphere content in water: \_\_\_\_\_

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### Properties

- Size
  - Target: \_\_\_\_\_
- Dissolution test
  - Test medium, cycle: \_\_\_\_\_
- Crush force
  - Target: \_\_\_\_\_
- Temperature stability
  - Stable up to: \_\_\_\_\_
- Dissolution/decomposition
  - In Water
    - Time: \_\_\_\_\_
  - In Oil
    - Time: \_\_\_\_\_
  - Shear force
    - Force: \_\_\_\_\_
  - pH
    - pH: \_\_\_\_\_
- Active load
  - Target: \_\_\_\_\_
- Sample quantity
  - Target: \_\_\_\_\_

### Misc

- Other requirements/describe application

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## 2 Processing

Please select all materials that should be used. If no requirement, please leave blank to receive a proposal from BRACE based on the Application requirement. Please complete all process constraints (based on the actives to be used). Leave blank if no requirements.

- Encapsulation materials
  - Non-Animal, Algae based such as Alginate, Agar, Carrageenan
  - Non-Animal, Non-Algae based such as Pectin
  - Animal based as Gelatine, Shellack
  - Microbiological derived, such as Pullulan, synthetic Alginate
  - Starches, Dextrin, etc.
  - Gums
  - Synthetic waxes
  - Natural waxes
  - Hydrogenated vegetable oils
  - Synthetic oils
  - Vegetable oils
  - Pharma (USP) meltable polymers
  - Polymers as epoxides, acrylates, styrene etc.
  - Other: \_\_\_\_\_

- Processing
  - Max temperature: \_\_\_\_\_
  - Min temperature: \_\_\_\_\_
  - Process temperature: \_\_\_\_\_
  - Max pressure: \_\_\_\_\_

- Solidification
  - Chemical reaction
    - Specify: \_\_\_\_\_
  - Cooling
    - Temperature: \_\_\_\_\_
  - Other: \_\_\_\_\_

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### 3 Actives

*Please list all materials, concentrations of actives to be used etc. Please attach a Material Safety Data Sheet and a technical data sheet for each material to this document. Include a SOP if available.*

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*Please specify on the technical data for each active chemical name, formular, density, viscosity, melting point (if applicable), information about waste treatment, toxicology and all other available pyhsical properties.*



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## 4 Comments and Notes

*Please add here any requirement or comment that is not covered by the questions above in respect to the final material. Please also add special instructions for handling etc.*

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## 5 Shipping Instructions

### 5.1 Shipping Documents and Marks

All shipping documents must reach BRACE GmbH **PRIOR** to arrival of goods.

Email: info@brace.de

At last those documents have to be part of the shipment and be submitted prior to shipment:

Within EU	Outside EU
<ul style="list-style-type: none"> <li>Detailed packing list</li> <li>MSDS in English or German</li> <li>Completed Questionnaire for trials</li> </ul>	<ul style="list-style-type: none"> <li>Customs Invoice</li> <li>Detailed packing list</li> <li>MSDS in English or German</li> <li>Completed Questionnaire for trials</li> <li>Certificate of analysis (BSE declaration or similar)</li> </ul>

#### 5.1.1 Customs invoice must contain:

- Exact description of material
- Customs classification No. (HS-No.)
- Gross and net weights
- Package dimensions
- Customs value
- Forwarding method, name of forwarding agent
- Classification (in case of dangerous goods)
- For all trials and developments:* Declaration that materials are for scientific purposes and not for resale or human/animal consumption

**EEC suppliers also need to indicate:**

- Supplier's VAT No.

#### 5.1.2 Material Safety Data Sheet (MSDS)

The customer must forward a completed safety data sheet (SDS) **in English or German** complying with REACH and international standards (e.g. „(EC) No 1907/2006 (REACH)“, or „DIN safety data sheet“)

#### 5.1.3 Shipping Marks and Way Bill

Shipping marks and way bill must include:

- Name of shipper
- Consignee
- Storage requirements (cold storage, etc.)



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- **In case of dangerous goods, additional labels must be used according to the regulations listed in section 5.2.**

At the outside of the box at last the following marks have to be visible:

- Consignee
- Name of Shipper
- If available: BRACE Project Number

### 5.1.4 Forwarding Address

**Consignee:** BRACE GmbH  
Am Mittelberg 5  
ATT: *BRACE Contact Person* or *Dr. Thorsten Brandau*  
D-63791 Karlstein am Main  
Germany

**Airport:** Frankfurt am Main (FRA)

**Contact:** BRACE GmbH  
Tel: +49 6188 991757  
Fax: +49 6188 991759  
email: info@brace.de

## 5.2 Material Specific Handling Instructions

### 5.2.1 Nano Particles

In the case of Nano particles (0.01 - 0.1 µm particles) please refer to your BRACE GmbH contact person for specific instructions.

### 5.2.2 Dangerous/Hazardous Goods

In order to avoid violation of international law and to protect the persons involved in handling of goods, the following points must be strictly followed.

**If NOT, additional costs for handling and re-packing WILL be charged to the client.**

**Dispatch of material according to:**

**By ship:** IMDG Code  
**By road:** ADR and IMDG Code  
**By air:** IATA Dangerous Goods Regulations

**Dangerous goods must never be sent by courier service or mail.**

Copies of SDS for dangerous goods are to follow the consignment and to be emailed to BRACE GmbH, contact person or Dr. Thorsten Brandau.

All packaging material **must be UN approved and marked with:**



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Labels **must be** in accordance with the regulations listed above under „Dispatch of material“.

Please refer to Client Shipment Department for further advice. If a shipment department is not available or if any doubts arise, please refer to a shipment agent with experience in handling dangerous goods.

### 5.3 **Product Declarations / Confidentiality Agreement**

It is an invariable demand that a specific product analysis must be available to BRACE GmbH prior to each test if the product is unknown to BRACE GmbH.

If the product represents customer's special know-how, a mutual confidentiality agreement can be signed.

***Without knowing the chemical, physical or technical properties of the materials, BRACE declines any work on the material and will return them on senders costs as dangerous goods.***

### 5.4 **Packaging**

It is crucial that the client follows the instructions below when transporting test materials to the Test Centre. Non-compliance with the present instructions can delay planned test work or, in the worst case, cause cancellation.

- The packaging must be approved by existing legislation and be in accordance with the materials which are to be dispatched.
- Information on the current rules can be obtained through the client's Shipping department or a shipping agent.
- Materials categorized as hazardous goods **must be transported in UN approved packaging. If NOT, delays and/or additional costs may occur.**
- An updated MSDS (Material Safety Data Sheet) must be attached to the material.
- Further the packaging material must be chosen to ease handling in the Test Centre as much as possible.
- General directions for packaging of the various types of test materials along with UN approved packaging examples are listed in the following table.

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## Questionnaire – Development, Contract Manufacturing

### Dry material / Filter cakes / Paste

*Materials that cannot be pumped fall under this category*

Supplied in small packaging of max. 25 kg/each

- sacks
- small drums
- open top casks with a large lid covering the whole diameter of the drum.



**If dangerous goods use only UN certified packaging**

### Solutions

*The material is NOT to precipitate.*

*Small quantities (up to 25 kg) :*

- Suitable containers from which pouring or transfer by pump is possible.

*Large quantities:*

- Suitable drums up to 200 L or intermediate bulk container (IBC) with a bung-hole of min. 60 mm for introduction of pump and a ventilating aperture.



**If dangerous goods use only UN certified packaging**

### Organic solvents and flammable liquids



**Only use UN certified packaging**

**Must be shipped in accordance with international legislation regarding shipment of dangerous goods**



### Suspensions

- Supplied in packaging allowing efficient stirring of content before transfer
- Must be equipped with a detachable, tight-fitting lid with a min. diameter of 15 cm.
- Should only be filled to a maximum of 75%. Large quantities:
- Should be packed in 200 l plastic or steel casks



**If dangerous goods use only UN certified packaging**

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## Questionnaire – Development, Contract Manufacturing

### Small samples

- Must be supplied in well-chosen, tight-fitting packaging. An updated MSDS must be attached to the material
- The small sample must be representative of the product that the client wants BRACE GmbH to test; if it is not, a correct evaluation will not be possible.



**If dangerous goods use only UN certified packaging**

### 5.5 Storage, Return, Destruction of Material

The customer is obliged to take back all processed and unprocessed test material immediately upon termination of tests.

#### Storage

In special cases it is possible, against payment, to arrange for storage of the test material for a short period.

#### Return of Material

The test material will be returned without any notice other than ordinary shipping documents. Special instructions for the return of material must be given together with delivery of goods.

#### Destruction or Other Disposal

At customer's request BRACE GmbH is prepared to investigate whether destruction or other disposal can be arranged for in Germany. **The expenses are to be paid by the customer.**

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