

Doc nº:	QQISO-004
Replaces to:	QQISO-003
Title:	<b>STANDARD PRE-AUDIT QUESTIONNAIRE QEMICAL PRODUCTS</b>

<b>1. COMPANY NAME</b>	<b>QUALITY CHEMICALS S.L.</b>
<b>2. ADDRESS</b>	<i>C/ Fornal 35, 08292 Esparreguera (Barcelona, Spain)</i>
<b>3. YEAR OF FOUNDATION</b>	1997
<b>4. MANUFACTURING SITE</b>	<b>QUALITY CHEMICALS S.L. / PURITY CHEMICALS S.L.</b>
<b>5. MANUFACTURING SITE ADDRESS</b>	<b>QUALITY CHEMICALS S.L.</b> <i>C/ Fornal 35 08292 Esparreguera (Barcelona, Spain)</i> <b>PURITY CHEMICALS S.L.</b> <i>Av. Tren Expreso, 82-84 34200 Venta de Baños (Palencia, Spain)</i>
a. Date of construction of production facility	QUALITY CHEMICALS: 2000 / PURITY CHEMICALS: 2009
b. Contact person	Lluís Aragonès
c. Position	General Manager
d. Telephone	+34 979 76 10 97
e. e-mail	qemical@qualitychemicals.com
<b>6. COMPANY DATA</b>	
f. web	<a href="http://www.qualitychemicals.com">www.qualitychemicals.com</a> <a href="http://www.purity-chemicals.com">www.purity-chemicals.com</a>
g. Certifications (please attach a copy of the certificates):	
i. Quality	ISO 9001:2015
ii. Environmental	ISO 14001:2015
iii. Risk and safety	OSHAS 18001
iv. Other	ISO 22000
v. In process of implementing:	
<b>7. HUMAN RESOURCES</b>	
h. Number of employees	78 (Quality Chemicals: 54. Purity Chemicals: 24)
i. Production	42 (Quality Chemicals: 26. Purity Chemicals: 16)
1. Production plant	35
2. Warehouse	7
ii. Engineering and maintenance	6
iii. Quality Unit	15
1. Quality control	12
2. Quality management	3
iv. HSE	1
v. R&D	2
vi. Sales	5
vii. Human resources	1
viii. Rest of departments	7
i. Is Quality Unit independent from production?	Yes
j. Who Quality Assurance reports to?	Technical Manager
k. Does a training plan for employees exist?	Yes
l. Are there records of training for employees?	Yes
m. How many hours are spent on training per employee / year?	30 h

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<b>8. MANAGEMENT OF MATERIALS</b>	
a. Is a lot number assigned to the raw materials?	Yes
b. Is a lot number assigned to the finished products?	Yes
c. Is there a procedure for the releasing of materials?	Yes
d. Is the releasing of materials recorded?	Yes
e. Are all the materials/batches tested prior to use/shipping?	Yes.
f. Is there a record of the operations of analysis?	Yes
g. Are CoA of the shipped batches issued?	Yes
h. How many years is documentation of production and analysis kept?	3 years
<b>9. PRODUCTION</b>	
a. Productive capacity (kg/year)	<i>Aprox. 5,000 Tn/year</i>
b. Are production methods written and approved?	Yes
c. Is the production documented in manufacturing sheets with information of raw materials, batches, operations, workers and supervision?	Yes
d. Is there a preventive maintenance plan for equipment?	Yes
e. Is there a calibration plan for equipment/measuring instruments in production plant?	Yes
f. Does production equipment have an unambiguous reference that relates to the production documentation?	Yes
g. Are deviations in production registered and/or investigated?	Yes
h. Are critical parameters in the production process defined?	Yes
i. Are there measures to prevent cross-contamination in production plant?	Yes
j. Is there a plan for cleaning the production plant equipment?	Yes
k. Are cleaning operations registered?	Yes
l. Are products manufactured in dedicated or multipurpose equipments?	<i>Multipurpose equipments</i>
m. In case of multipurpose plant, are products manufactured in the same equipment/facilities which manufacture pesticides, herbicides, penicillanic derivatives, hormones, cephalosporines, sensitizing and anti-cancer products?	No
n. Please describe the quality of water used in production	<i>Deionized water</i>

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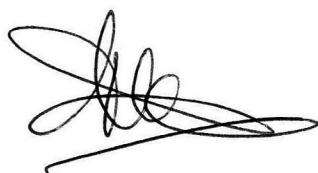
10. QUALITY		
a.	Does the company have a Quality Manual?	Yes
b.	Who performs the sampling of finished products?	<i>Quality Control personnel</i>
c.	Is there a formally approved quality specification for the product? If yes, does a change control procedure exist?	Yes
d.	Are all the batches analyzed and formally approved or refused?	Yes
e.	Does Quality Chemicals / Purity Chemicals retain a sample of every batch? How long?	<i>Yes. 12 months</i>
f.	Is there a calibration procedure for analytical equipment?	Yes
g.	Does Quality Chemicals / Purity Chemicals carry out stability studies?	No
h.	What's the expiry date / retest date of the product?	<i>Determined experience, bibliographic data.</i>
i.	Are products affected by BEE/TSE, GMO, dioxins? Can you issue a certificate?	<i>No. We can issue a certificate.</i>
j.	Does Quality Chemicals / Purity Chemicals perform a qualification of suppliers?	Yes
k.	Does Quality Chemicals / Purity Chemicals have a procedure for management of non conformities?	Yes
l.	Does Quality Chemicals / Purity Chemicals have a change control procedure?	Yes
m.	Does Quality Chemicals / Purity Chemicals carry out product quality review?	No
n.	Does Quality Chemicals / Purity Chemicals have a procedure for management of customer complaints?	Yes
o.	Does Quality Chemicals / Purity Chemicals carry out internal audits?	Yes
p.	Is there a CAPA program in place?	Yes
q.	Would Quality Chemicals / Purity Chemicals allow to:	
	i. Visit our facilities	Yes
	ii. Perform a quality audit of production and quality control processes	Yes
r.	In case of a change in the process o specifications affecting the quality of the product, would Quality Chemicals / Purity Chemicals inform their customers?	<i>Yes, if there is a change control agreement.</i>
s.	Do Quality Chemicals / Purity Chemicals have customer quality audits? How many and how often?	<i>Yes. About 20-25 audits per year</i>

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<b>11. ENVIRONMENT AND SAFETY</b>		
a.	Is there a system in place in order to prevent job risks?	Yes
b.	Are accidents at work recorded and investigated? Is there a CAPA system for accidents at work?	Yes
c.	Does the staff in Quality Chemicals / Purity Chemicals have appropriate security measures to the operations carried out?	Yes
d.	Does Quality Chemicals / Purity Chemicals perform environmental analysis concerning risk and safety at work?	Yes
e.	Does Quality Chemicals / Purity Chemicals have an internal emergency plan?	Yes
f.	Does Quality Chemicals / Purity Chemicals have a fire fighting system?	Yes
g.	Is there an environmental management system?	Yes
h.	Does Quality Chemicals / Purity Chemicals aim to reduce its potential environmental impact?	Yes
i.	Is Quality Chemicals / Purity Chemicals aware of REACH regulation?	Yes

**QUESTIONNAIRE COMPLETED BY:**

Name: **David Carreras**  
Position: **Quality Assurance**  
Date and signature:

**02/01/2019**