

# Pharmaceutical packaging and medical devices

REPJOL

Polypropylene, polyethylene and EVA copolymers



## Healthcare

## Differentiated solutions for the healthcare industry

#### Repsol offer

- High quality products
- Ready to be part of new projects
- Capable of developing tailor-made grades
- Excellent logistics service
- Technical service and development

#### Our drive

To fulfill our customers' needs:

- Product reliability and traceability
- Compliance
- Long term commitment



## Commitment

Dedicated storage facilities and quality management protocols to ensure the highest quality standards.

#### Guarantee

Certifying our products to meet European & US Pharmacopoeias (USP/EP).

### Service

Aligning our Quality System with the Good Manufacturing Practices required by the Industry.

## Repsol

## Edecades of experience in the world of energy

One of the largest energy companies worldwide and one of the biggest private oil & gas companies Repsol is committed to our customers' global strategy putting our entire organization at their disposal to achieve a common goal: to create long-term relationships which enable us to rise to the common challenges our business presents.



#### Repsol Campus, Corporate Headquarters in Madrid

LEED<sup>®</sup> Platinum certificate, awarded by the prestigious US Green Building Council (USGBC), for new buildings construction

## Chemicals



#### Added value

Repsol's Chemicals Division, with a high degree of integration, focuses its strategy in the constant **generation of value** through **differentiated products and services**.



Repsol manufactures a wide variety of products, ranging from base petrochemicals to derivatives.

Base petrochemicals: ethylene, propylene, butadiene and benzene.

**Intermediate products:** styrene, propylene oxide, polyether polyols, and propylene glycols.

**Polyolefins:** polypropylene (PP) and PP compounds, both high and low-density polyethylene (HDPE and LDPE), metallocene linear low density polyethylene (mLLDPE), ethylene vinyl acetate (EVA) and ethylene butyl acrylate (EBA) copolymers.



Including qualified **personnel specialised** on Product Stewardship.

Repsol's commitment to R&D is an evidence of the company's aim to attain business excellence to meet future horizons.

## Chemicals



#### Our goal

To manufacture and sell polyolefins or **pharmaceutical packaging and medical devices**, offering he maximum quality, service, commitment and compliance worldwide, keeping the patients' safety as our number one priority.



#### Growing from our strengths

**Over 40 years of experience** producing and selling polyolefins wi h a well-built prestige in Europe.

**Three integrated production facilities in the Iberian Peninsula.** We have experience launching products with the maximum cleanliness and stringent manipulation procedures.

Food packaging: we supply regularly to the food packaging industry.

**Qualified in pharmaceutical applications.** Repsol's propylene glycol USP/EP is qualified and app oved for use as an excipient in pharmaceutical applications.





## over 34-grades for healthcare Polyolefins for pharmaceutical packaging and medical devices

Repsol takes another step in differentiating its solutions and offers

• A suitable range of polyolefins: high and low density polyethylene (HDPE, LDPE), ethylene vinyl acetate copolymers (EVA) and polypropylene (PP).

• An outstanding and differentiated level of service.

• Willingness to seek continuous improvement.

• We put your needs first, always. Our tailor-made solutions are proof of our commitment to your singular cause.

• Our industry is full of challenges awaiting inspired solutions. That's where we come in.

Results Orientation

Results Orientation Intrapreneurship Inspiring Leadership Accountability Collaboration



#### Polypropylene homopolymer

	Grade	Properties			Additives	Compliance			Applications	
-		<b>MFI</b> ISO 1133 g/10' 230°C 2.16 kg	Charpy impact strength notched ISO 179 kJ/m²	Melting point °C	Flexural modulus ISO 178 Mpa		EurPh	USP	Biocompatibility	
	HPP08G	8	4	164	1500	-	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Pharmaceutical packaging, closures and pouches.
	HPP08N	8	3	164	1800	Nucleating agent	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Pharmaceutical packaging, caps and closures, labware, dispensers, holders, gaskets
	НРРОЭМ	9	3	164	1500	Slip agent / Antiblock	In composition	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Pharmaceutical packaging, caps and closures.
	HPP12G	12	4	164	1550	-	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Injection molding, caps and closures and pharmaceutical packaging.
	HPP25G	25	3	164	1600	-	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Syringe parts, caps and closures, pharmaceutical packaging, injection molding items.
	HPP25G1	25	4	157	1250	-	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Improved impact resistance. Syringe parts, pharmaceutical packaging, caps and closures, injection molding items
	HPP40N	40	2.5	164	1700	Nucleating agent	3.1.3 / 3.1.6	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Thin wall injection molding, labware, dispensers.
IEW	HPP55RMD	55	2.5	164	1800	Clarifying agent/ Radiation Resistant	_	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Gamma ray and E-beam resistant high fluidity PP resin. Offers stiffness and excellent transparency.
NEW	HPP55CMD	55	2.5	164	1800	Clarifying agent/ Antistatic	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Injection molding medical applications and labware. Offers stiffness and high transparency.

Repsol Healthcare grades are DMF listed. For more detailed information on DMF listing, European Pharmacopoeia (Ph Eur.) and United States Pharmacopoeia (USP) Please contact Repsol's Technical Service & Development Department atd\_poliolefinas@repsol.com

All our Polypropylene grades are phthalate free

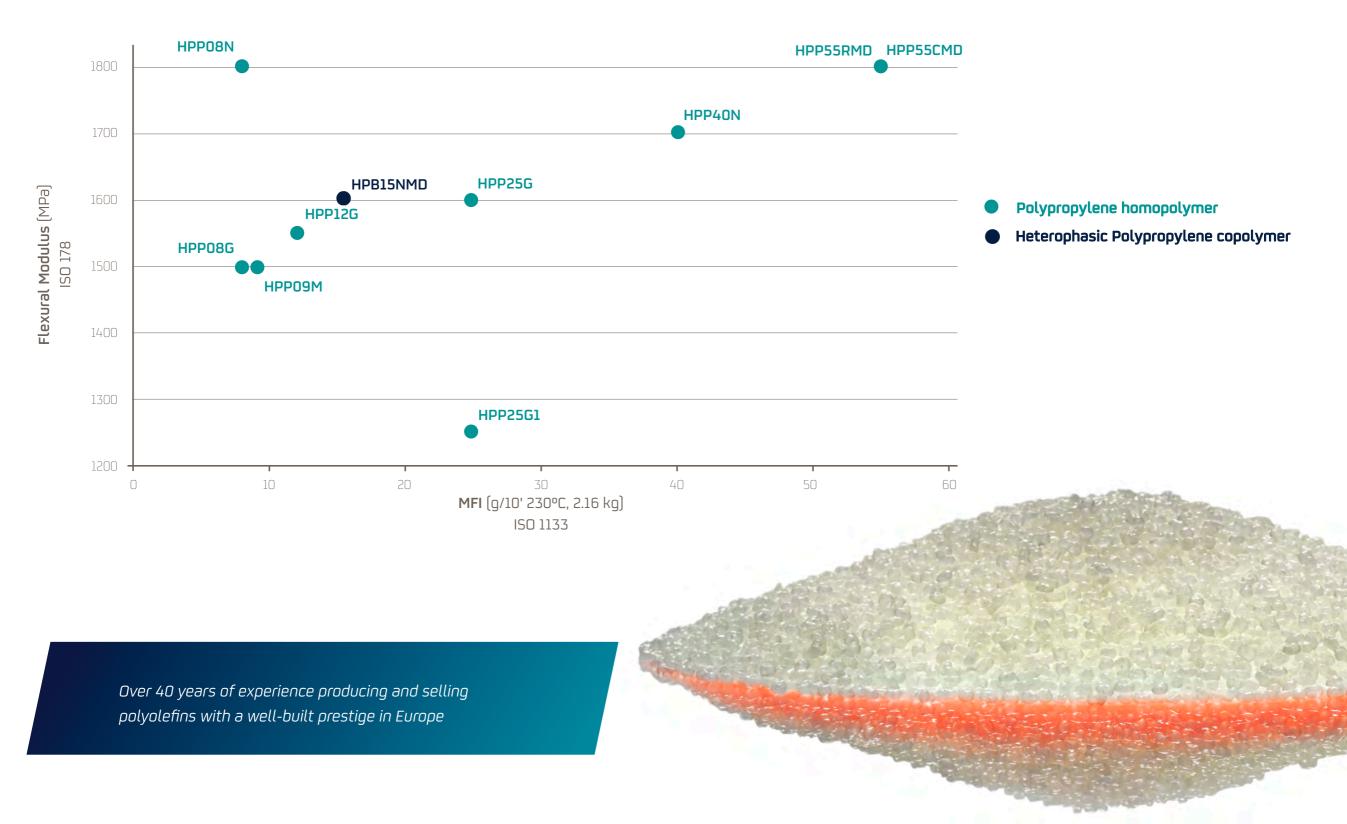
#### Heterophasic polypropylene copolymer

Grade		Prope	erties		Additives		Compliance		Applications
	<b>MFI</b> ISO 1133 g/10' 230°C 2.16 kg	Charpy impact strength notched ISO 179 kJ/m²	Melting point °C	Flexural modulus ISO 178 Mpa		EurPh	USP	Biocompatibility	
HPB15NMD	15	6	164	1600	Nucleating Agent	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Injection molding medical applications. Offers excellent impact/stiffness balance.

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#### Polypropylene homopolymer & Heterophasic polypropylene copolymer



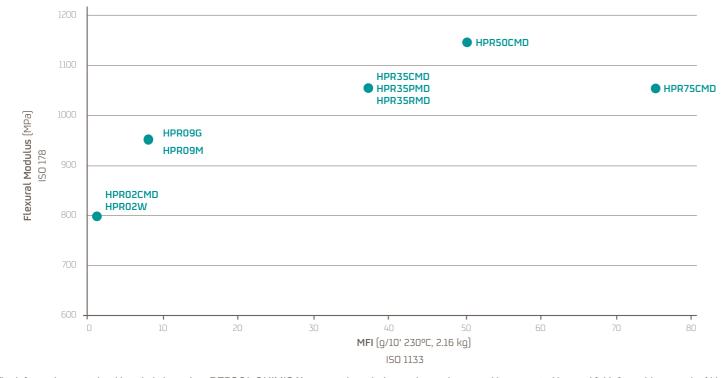


#### Polypropylene random copolymer



Grade		Prop	erties		Additives	Compliance			Applications	
	<b>MFI</b> ISO 1133 g/10' 230°C 2.16 kg	Charpy impact strength notched ISO 179 kJ/m²	Melting point °C	Flexural modulus ISO 178 Mpa		EurPh	USP	Biocompatibility		
HPR02CMD	1.6	>9	143	800	Clarifying agent	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	dical packaging, film and pouches, vials.	
HPR02W	1.6	>9	143	800	-	3.1.3. / 3.1.6.	661.1.		e volume parenteral blow fill seal bottles apt for autoclave lization at 121°C. Medical packaging, film and pouches.	
HPR09G	9	8	145	950	-	3.1.3 / 3.1.6	661.1.	USP 87 USP Cytotoxicity (Elution Test) Bare USP 88 class VI ISO 10993-4, -5, -10, -11 Injec	efoot grade. Medical packaging, films and pouches. ction moulding items.	
HPR09M	9	8	145	950	Slip agent / Antiblock	In composition	In composition	· · · · · · · · · · · · · · · · · · ·	tains slip and antiblock. Medical packaging, labware, caps closures and ISBM.	
HPR35CMD	38	6	149	1050	Clarifying agent / Antistatic	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	s and closures, syringe parts, medical device components.	
HPR35RMD	38	6	149	1050	Clarifying agent / Radiation resistance	-	In composition		as and closures, syringe parts, tubes, labware. Gamma and eam rad.	
HPR50CMD	50	5	149	1150	Clarifying agent / Antistatic	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11 Cap	and closures, syringe parts, medical device components.	
HPR75CMD	75	6	149	1050	Clarifying agent / Antistatic	-	In composition	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11 Sma	all syringes, thin wall parts.	

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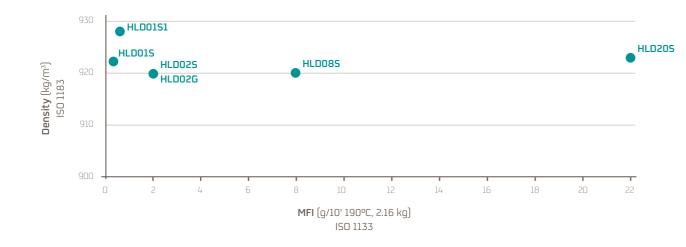
Stringent production procedures to ensure product consistency and the highest quality standards. All our Polypropylene grades are phthalate free

#### Low density polyethylene



	Grade	de Properties		Properties Additives Compliance					Applications		
		<b>MFI</b> ISO 1133 g/10' 190°C 2.16 kg	<b>Density</b> ISO 1183 kg/m <sup>3</sup>	Melting point °C		EurPh	USP	Biocompatibility			
NEW	HLD01S	0.3	922	110	No additives	*	*	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Excellent flexibility for small volume parenteral bottles and ampoules.		
NEW	HLD01S1	0.55	928	117	No additives	3.1.3. / 3.1.4.	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Small volume parenteral bottles and ampoules for steam autoclave treatment up to 110°C.		
	HLD02S	2	920	110	No additives	3.1.3 / 3.1.4	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Very flexible grade for ampoules. LDPE for pharmaceutical bags, pouches and medical devices.		
	HLD02G	2	920	110	Antioxidants / Antiblock / Slip agent	3.1.3 / 3.1.4	661	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Soft LDPE containing slip and antiblock. For pharmaceutical packaging, caps and closures and other medical devices.		
NEW	HLD08S	8	920	109	No additives	3.1.3. / 3.1.4.	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Extrusion coating and medical films.		
NEW	HLD20S	22	923	104	No additives	3.1.3. / 3.1.4.	661.1.	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Caps and lids. Injection molded parts that require flexibility.		

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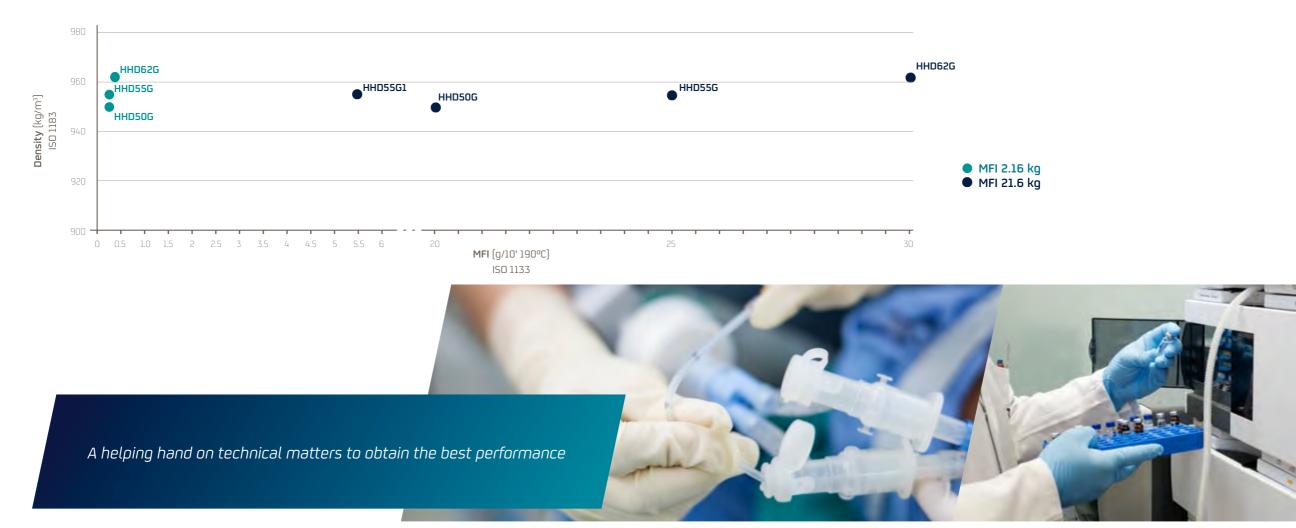
A comprehensive range of products designed according to the standards of pharmaceutical packaging and medical devices

#### High density polyethylene



Grade			Properties			Additives	Compli	ance		Applications
	<b>MFI</b> ISO 1133 g/10' 190°C 2.16 kg	<b>MFI</b> ISO 1133 g/10' 190°C 5 kg	<b>MFI</b> ISO 1133 g/10' 190°C 21.6 kg	<b>Density</b> ISO 1183 kg/m³	Melting point °C		EurPh	USP	Biocompatibility	
HHD50G	0.25	-	20	950	135	Antioxidants	3.1.3 / 3.1.5	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Typical extrusion blow moulding grade for pill jars, offering increased density and barrier properties. Typically also converted in IBM process.
HHD55G	0.25	-	25	955	135	Antioxidants	3.1.3 / 3.1.5	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Blow molding HDPE grade presenting stiffness and excellent stress cracking resistance. Grade used for pill jars and containers for pharmaceutical packaging.
HHD62G	0.3	-	30	962	137	Antioxidants	3.1.3 / 3.1.5	661.1	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Packaging, diagnostic and tubes, blow moulding bottles.
HHD55G1	-	24	5.5	955	136	Antioxidants	3.1.3. / 3.1.5.	661.1.	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Extrusion blow molding HDPE grade for pharmaceutical packaging including BFS processes. Good process stability.

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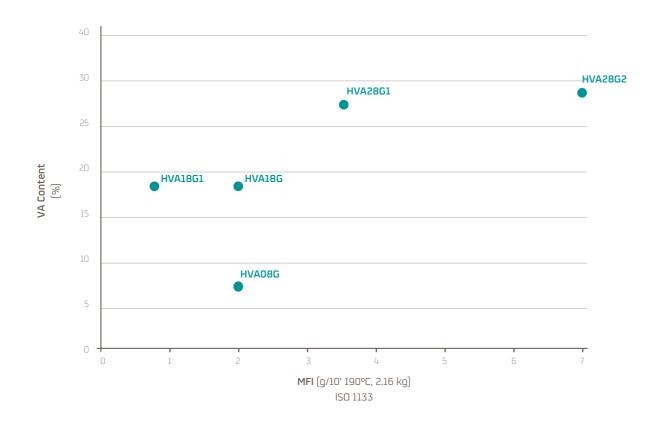


#### EVA copolymer



Grade	Pro	operties	Additives Compliance		Applications		
	<b>MFI</b> ISO 1133 g/10' 190°C 2.16 kg	VA content %		Biocompatibility			
HVA08G	2	7.5	Antioxidants	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	It is used for transdermal patches but can also be used for small blow molding, injection molding or tubing.		
HVA18G1	0.7	18	Antioxidants	Testing in progress	Extrusion of medical film and production of medical bags, seals.		
HVA18G	2	18	Antioxidants	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Medical film and bags, tubing, seals and closures.		
HVA28G1	3.5	27.5	Antioxidants	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Medicəl film.		
HVA28G2	7	28	Antioxidants	USP 87 USP Cytotoxicity (Elution Test) USP 88 class VI ISO 10993-4, -5, -10, -11	Injection moulding medical devices.		

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Qualified in more pharmaceutical applications: Repsol's propylene glycol USP/EP is qualified and approved for use as an excipient in pharmaceutical applications



#### Sterilization

Repsol Healthcare	Autoclave	EtO	Gamma and E-beam radiation
Polypropylene Homopolymer HPP			Only for HPP55RMD
Polypropylene Random Copolymer HPR	D	D	Only for HPR35RMD
Low Density Polyethylene HLD			1
High Density Polyethylene HHD			
EVA Copolymer HVA			1





#### MEDICAL POLICY DISCLAIMERS

/ The use of this product in any Medical Device must comply with the following criteria:

- Class I Medical Devices (European Union and/or U.S. FDA): the product may only be used for this purpose with prior notification to REPSOL QUIMICA, S.A. of each specific final application.
- Class II Medical Devices (European Union and/or U.S. FDA): the product may only be used for this purpose with REPSOL QUIMICA, S.A.'s prior written approval.

This product may not be used for implantable devices and for Class III Medical Devices (European Union and/or U.S. FDA).

/ REPSOL QUÍMICA, S.A. makes no warranties, express or implied, which extend beyond the description contained herein. Nothing herein shall constitute any warranty of merchantability or fitness for a particular purpose.

/ Before using a product sold by REPSOL QUÍMICA, S.A. users should make their own independent determination that the product is safe, lawful and technically suitable for the intended use.

/ REPSOL QUÍMICA, S.A. accepts no liability from the use of its materials in conjunction with other materials.

A global company that seeks the welfare of people and is a step ahead in building a better future through the development of smart energy

## Building trust through safety and transparency

Excellence is intrinsic to Repsol's values. It infuses our daily work and helps guide our decisions and actions, contributing to achieve the commitment made to our customers, stakeholders, employees, suppliers / partners and society to build a better future.



Petrochemical complexes, packaging facilities and logistics centres all have OHSAS 18001.2007 (Occupational Health and Safety Assessment Series) certifi ation for their rigorous safety measures.

Petrochemical complexes, packaging facilities and logistics centres

**OHSAS 18001.2007** 

Technical Data Sheets and MSDS are available on: www.repsol.com

#### Quality

All petrochemical plants are compliant with the current ISO 9001:2015 standards, for the quality of processes from manufacture to distribution, transport management and end product warehousing.

All petrochemical plants

#### ISO 9001:2015 FSSC 22000





#### Environment

We set up and deploy ambitious energy efficie y programmes to reduce energy consumption and GHG emissions as one of the key elements of our strategy. These programmes pursue long term targets which have been made public in order to facilitate their progress by the stakeholders. In this sense, Repsol Química has attained a final eduction of 0.56 million tonnes of GHG emissions at the end of the 2006-2013 period. Repsol is currently working on a new target covering the period 2014-2020, that involves an additional reduction of 0.42 million tonnes of CO<sub>2</sub>.

All petrochemical complexes, have ISO 14001 certifi ation for their environmental management and the reduction of the impact of their facilities; and ISO 14064 for the annual verifi ation of greenhouse gas (GHG) emissions.

The Chemical area of our complexes in Tarragona (2015), Puertollano (2013) and Sines (2016), has implemented an Energy Management system according to the requirements indicated in the International Standard ISO 50001. This system is dedicated to developing and implementing our organization's energy policy, as well as manage the energy aspects of our activities, products or services. The objective is to increase and improve our energy efficie y, based on systems' implementation aimed at continuous energy performances improvement and thus contribute to a more efficien and sustainable use of energy.

Repsol reinforced its commitment with sustainability by signing the "Paris Pledge for Action" document. An historical agreement in which both developed countries and less developed countries and companies engaged to contribute towards a low CO<sub>2</sub> emission economy.

Puertollano, Tarragona and Sines

#### ISO 50001 / ISO 14001 / ISO 14064

December 2020

#### **Customer** Care

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Intrapreneurship

Results Orientation Inspiring Leadership Collaboration Accountability