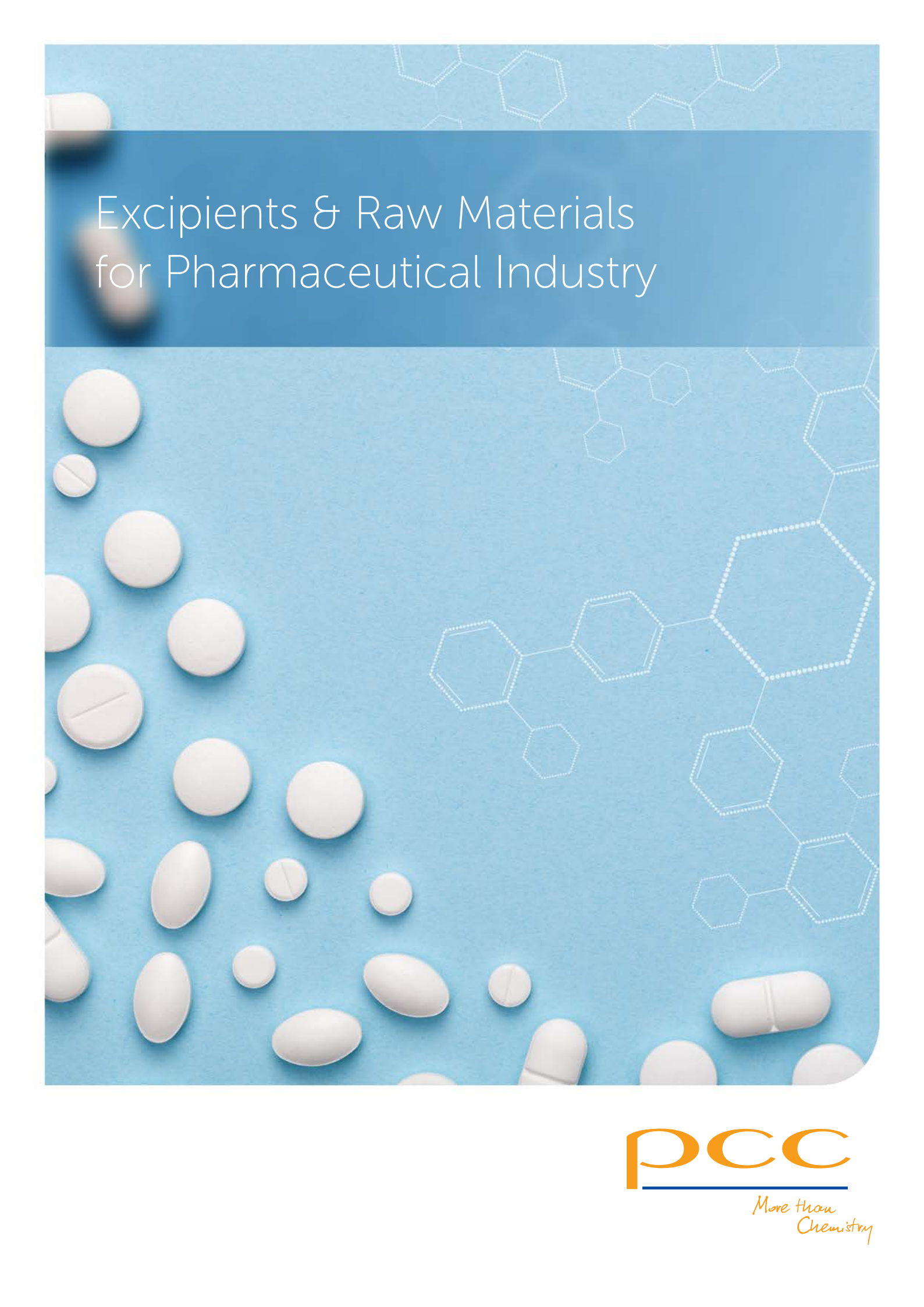




Excipients & Raw Materials for Pharmaceutical Industry

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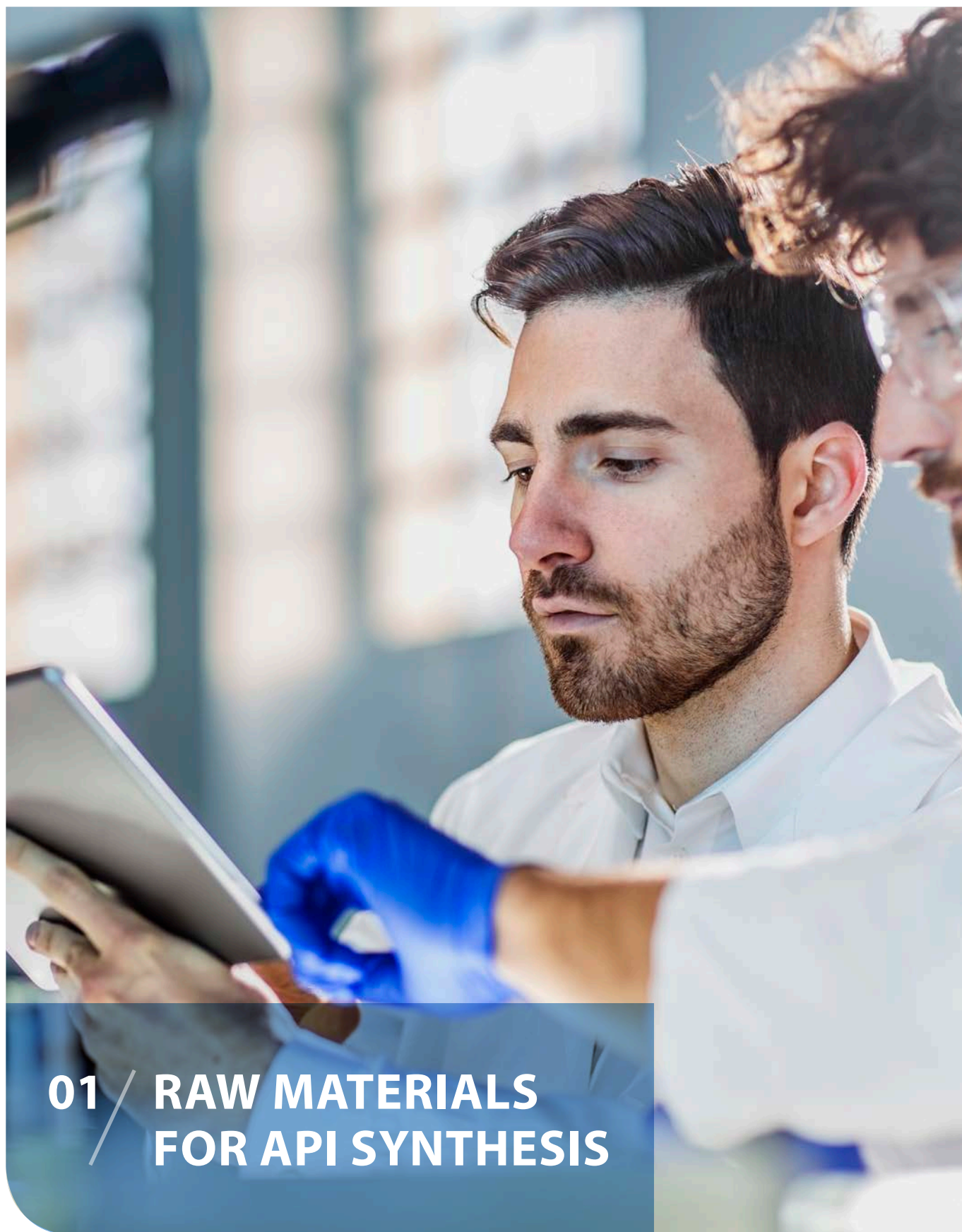
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01 / RAW MATERIALS FOR API SYNTHESIS

RAW MATERIALS FOR API SYNTHESIS

Chlorine derivatives

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
Monochlorobenzene PF	Non-applicable	108-90-7	Semi-product for API production	Liquid	Non-applicable
Orthodichlorobenzene PF	Non-applicable	95-50-1	Semi-product for API production	Liquid	Non-applicable

Monochlorobezene and Orthodichlorobenzene

Monochlorobezene (MCB) also known as chlorobenzene is a colourless, volatile, water-insoluble liquid with a light, pleasant almond fragrance. It belongs to the family of organic halogen compounds, formed by the direct chlorination reaction of benzene. In the pharmaceuticals industry it is used, among others, in:

- paracetamol synthesis (paraaminoacetylphenol)
- production of vitamin B6
- production of zoledronic acid (a drug in the treatment of osteoporosis in postmenopausal women and in men who have an increased risk of bone fractures)
- chlorfenoksamine (a drug used as an antiallergic and anti-aging agent, works analogously to diphenhydramine)
- among others it is also known as high-boiling-point solvent in industrial scale synthesis

Orthodichlorobenzene (ODCB) also referred to 1,2-Dichlorobenzene belonging to the same group of chlorine derived products formed by addition of two chlorine atoms to benzene. ODCB is a colourless liquid that is poorly soluble in water but can mix with most organic solvents. In pharmaceutical industry mostly well known as high – boiling – point solvent.

Phosphorous derivatives

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
Phosphorus Trichloride PF	Non-applicable	7719-12-2	Semi-product for API production	Liquid	Non-applicable
Phosphorus Oxychloride PF	Non-applicable	10025-87-3	Semi-product for API production	Liquid	Non-applicable

Phosphorus trichloride

Phosphorus trichloride is a colourless, fuming liquid with a sharp characteristic odour that may resemble hydrogen chloride. PCl_3 is a high-quality intermediate/raw material. Thanks to the high reactivity of phosphorus-chlorine bonds, it has become an excellent substrate for phosphoric and chlorinated chemicals, widely-used in the chemical and pharmaceutical industries. Its reactivity allows the use of PCl_3 for the synthesis of, inter alia, active substances (API – Active Pharmaceutical Ingredient).

Main use of Phosphorus trichlorine

A phosphorus introducing agent to the substrate molecule through the formation of phosphites as well as their subsequent reaction – to form e.g., phosphonates (including hydroxyphosphonates and aminophosphonates), which are inhibitors of many enzymes, acting as transition-state mimetics;

Chlorination reagent, used in substitution reactions of hydroxyl groups with a chlorine atom; activator in coupling reactions, converting carboxylic or sulphonic / sulphinic acids into their chlorides (more reactive derivatives), conjugated to various nucleophiles (e.g., alcohols to form esters or amines to form amides);

A substrate for the synthesis of catalysts, where it acts as a building block for ligands.

The above-described processes are used, inter alia, for the synthesis of drugs based on sulphonamide derivatives (phosphorus trichloride converts sulphonic acids into amides, e.g., chlorthalidone – a diuretic, sulfadiazine – bacteriostatic).

Phosphorus trichloride is also a key substrate in the synthesis of bisphosphonates using the method of von Bayer and Hoffmann. Bisphosphonates are used as bone diseases therapeutic agents (e.g., osteoporosis), inhibiting bone resorption and increasing its mass, e.g., alendronate, risedronate, and etidronate.



Phosphorus oxychloride

Phosphorus oxychloride is a colourless liquid with a sharp, very characteristic odour. POCl_3 is a high purity intermediate/raw material which, thanks to its high reactivity, is an excellent substrate for the synthesis of phosphorus and chlorine compounds, widely-used in the chemical and pharmaceutical industries. Its reactivity allows the use of POCl_3 for the synthesis of, inter alia, active substances (API – Active Pharmaceutical Ingredient).

Main use of Phosphorus oxychloride

Phosphorus introducing agent to the substrate molecule through the formation of phosphates (phosphorylation);

Chlorination reagent, used in substitution reactions of hydroxyl groups with a chlorine atom;

Activator in coupling reactions, converting carboxylic or sulphonic / sulphinic acids into their chlorides (more reactive derivatives), conjugated to various nucleophiles (e.g., alcohols to form esters or amines to form amides);

A substrate for the synthesis of catalysts, where it acts as a building block for ligands;

Reagent in cyclisation processes, e.g., in the process of isoquinoline synthesis using the Bischler-Napieralski procedure.



The above-described processes are used, inter alia, for the synthesis of drugs based on isoquinoline derivatives (phosphorus oxychloride allows the occurrence of intramolecular aromatic electrophilic substitution, e.g., spasmolytic drugs – drotaverine). The phosphorylation process, for example, leads to the synthesis of B vitamins, and nucleotides are formed in the reaction with nucleosides (e.g., fludarabine phosphate used to treat leukaemia).

Important notice:

Dangerous goods – transport and storage in original packaging protected from moisture.

Products are double use items according to the UE Directive 428/2009 dated 5 May 2009.



02 / EXCIPIENTS FOR PHARMACEUTICAL FORMULATIONS

EXCIPIENTS FOR PHARMACEUTICAL FORMULATIONS

Macrogols – Polyethylene Glycols

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	MOLECULAR MASS [g/mol]	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
POLIkol 300PF	Macrogol 300	25322-68-3	Polyethylene glycol	300	Liquid	conforms
POLIkol 400PF	Macrogol 400	25322-68-3	Polyethylene glycol	400	Liquid	conforms
POLIkol 600PF	Macrogol 600	25322-68-3	Polyethylene glycol	600	Liquid	conforms
POLIkol 1500PF	Macrogol 1500	25322-68-3	Polyethylene glycol	1500	Solid in form of wax or flakes	conforms
POLIkol 3350PF	Macrogol 3350	25322-68-3	Polyethylene glycol	3350	Solid in form of wax or flakes	conforms
POLIkol 6000PF	Macrogol 6000	25322-68-3	Polyethylene glycol	6000	Solid in form of wax or flakes	conforms

PEG's

PEG's (polyethyleneglycols) belong to the group of non-ionic, tasteless substances, which are characterised by a non-toxic profile. PEG's are supplied in a wide variety of molecular weight grades.

PEG's with a low molecular weight up to 1000 are colourless or almost colourless liquids at room temperature. Polyethylene glycols with a molecular weight higher than 1000 g/mol are solid white waxes also available in flakes form. The melting point of solid PEG's form is in the range between 50 - 60°C.

Main advantages for using Macrogols in final dosage forms are:

Solubilisation

PEG's are perfect solvents for multiple substances which are insoluble in water, for instance: anilina, benzene, chloroform, pyridine, and methanol, therefore PEG's are widely-used as solvents and solubilisers for many active ingredients in pharmaceutical liquid or semi-liquid formulations.

Improvement in bioavailability for active ingredients

Polyethylene glycols are making complexes with multiple active substances which significantly improves their bioavailability. On the other hand, for some substances PEG's may contribute to the deactivation process. Taking that into account the usage of PEG's as a solvent has to be proven by research every single time.

Rheology modifiers

These substances have become a powerful tool for adjusting the viscosity level of the final formulation.

Good thickeners

Makes them an efficient additive for eye and/or ear drops.

Lubricating and binding properties

They are used in tablets formulation, production of capsules, and tablet coatings.

Formulation of stable ointments basis

Blending pasty or solid PEG's with liquid PEG's will lead to a white pasty ointment with good solubility in water and good dissolving properties which are suitable for plenty of API (Active Pharmaceutical Ingredient).

High stability

Easy mould release, good storage conditions are improved by using solid PEG's with high molecular mass for the production of suppositories and globules, additionally good solubilising properties improves solubilisation property.



ROKAnols TPF – Macrogols Cetostearyl Ethers

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
ROKAnol® T6PF	Macrogol 6 Cetostearyl Ether	68439-49-6	Polyoxyethylene (6) Cetostearyl Ether	Solid in a form of wax	conforms
ROKAnol® T12PF	Macrogol 12 Cetostearyl Ether	68439-49-6	Polyoxyethylene (12) Cetostearyl Ether	Solid in a form of wax	conforms
ROKAnol® T20PF	Macrogol 20 Cetostearyl Ether	68439-49-6	Polyoxyethylene (20) Cetostearyl Ether	Solid in form of wax or flakes	conforms
ROKAnol® T25PF	Macrogol 25 Cetostearyl Ether	68439-49-6	Polyoxyethylene (25) Cetostearyl Ether	Solid in form of wax or flakes	conforms

ROKAnols OPF – Macrogol Oleyl Ethers

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
ROKAnol® O10PF	Macrogol 10 Oleyl Ether	9004-98-2	Polyoxyethylene (10) Oleyl Ether	Solid in a form of wax	conforms
ROKAnol® O20PF	Macrogol 20 Oleyl Ether	9004-98-2	Polyoxyethylene (20) Oleyl Ether	Solid in a form of wax	conforms

These group of products are ethoxylated derivatives of oleyl and cethostearyl alcohols with a strong hydrophilic character, making it an ideal additive for preparing stable oil-in-water (O / W) emulsions. Possessing very good emulsifying properties, it can be used in the process of preparing emulsions at room temperature. This is important while using high temperature sensitive ingredients.

ROKAnols TPF and **ROKAnols OPF** are have significant dispersing and stabilising properties which are important for introducing API's in a solid form in to stable formulations. Good dispersion of active ingredients improves distribution of final formulation on the skin.

Common applications for ROKAnol OPF & ROKAnol TPF



Antiseptic ointments



Ointments



Creams



Oils



Spray dressings



ROKAcet R36PF – Macrogol Glycerol Ricinoleate

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
ROKAcet R36PF	Macrogol Glycerol Ricinoleate	61791-12-6	Castor Oil Ethoxylated	Clear, yellow viscous liquid or semi-solid	conforms

ROKAcet R36PF belongs to the group of nonionic surfactants and is characterised by good solubilising and emulsifying properties for pharmaceutical formulation. The product is in line with the current European Pharmacopeia Monograph for Macrogol Glycerol Ricinoleate which corresponds to the UPS monograph for Polyoxyl 35 Castor Oil.

- ✓ ROKAcet R36PF is recommended to use as a solubiliser for preparing stable emulsion for oral, topical, parental application
- ✓ Verry good emulsifier for active substances like: Miconazole, Hexedatine, Clotrimazole
- ✓ Widely used emulsifier for functional ingredient like in vitamins A, D, E, K

This type of substance in a highly purified version is also used as a solubility enhancer for injection and infusion preparations.

ROKacet HR40PF – Macrogolglycerol Hydroxystearate

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
ROKAcet HR40PF	Macrogolglycerol Hydroxystearate	61788-85-0	Castor Oil, Hydrogenated, Ethoxylated	White to yellowish paste	conforms

ROKAcet HR40PF is produced during ethoxylation of Hydrogenated Castor Oil. It is characterised by very good solubilising properties used for the production of aqueous solutions of vitamins A, D, E, K. The product improves production of clear and stable aqueous formations once added to other hydrophobic substances like some API's or essential oils. It improves the stability of formulation and bioavailability for API's. It is widely-used for oral and topical application because of its odourless and tasteless characteristics.

ROKAfenol N9PF – Nonoxynol-9

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
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ROKAfenol N9PF

Nonoxynol-9

127087-87-0

Nonylphenol, Ethoxylated

Clear or opalescent oily liquid

conforms

ROKAfenol N9 belongs to the group of non-ionic surfactants, this product varies in a number of repeating ethoxy (oxy-1,2-ethanediyl) groups. Rokafenol N9 is widely-used as an active ingredient in most spermicidal creams, jellies, foams, gels, and films. It is sold in most over-the-counter spermicidal products. Many models of condoms are lubricated with Nonoxynol-9 solutions. In this role, it has been promoted as a backup method for avoiding pregnancy and a microbicide for sexually-transmitted diseases in the event of condom failure. Nonoxynol-9 appears in almost all brands of diaphragm jellies and contraceptive sponges as the active ingredient.

It is sometimes used as an ingredient in shaving creams because it helps to break down skin oils that normally protect hair from moisture. It also appear in pain killers used for temporarily relieve muscle and joint pain associated with arthritis, bruises, simple back aches, sprains and strains.



ROKwinol 20PF – Sorbitan Monolaureate Ethoxylated

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
ROKwinol 20PF	Polysorbate 20	9005-64-5	Sorbitan Monolaureate, Ethoxylated	Clear liquid	conforms

ROKwinol 20PF is an ethoxylated sorbitan ester containing approximately 20 moles of EO. These product is in line with the current monograph of European Pharmacopeia for Polysorbate 20. The product is a nonionic emulsifier and O/W type co-emulsifier, applied to emulsification of oils, waxes and solvents of cosmetic and pharmaceutical formulations. These is an excipient added to final drug dosage forms in order to provide suitable consistency. Mainly used as a binder, diluent or base for pills, tablets, creams. These product also finds application in the pharmaceutical and cosmetic industry in lotions, medical preparations (vitamin oils, vaccines, intravenous preparations).

Polysorbate 20 is frequently used for the treatment of kidneys, metabolic acidosis (positive effect in normalising excess acid in blood and urine), eyes (bacterial inflammation of the eye surface, eyesight allergies, symptoms associated with dry eye syndrome, contact lenses intolerance).





03 / FUNCTIONAL ADDITIVES

FUNCTIONAL ADDITIVES

Caustic soda – Sodium Hydroxide Flakes PF

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
Sodium hydroxide flakes PF	Sodium hydroxide	1310-73-2	Intermediates in pharma production, pH control	Solid (Flakes)	conforms

Sodium hydroxide in solid form, also called caustic soda, is an inorganic chemical compound belonging to the strongest alkali. In solid form, it is a white substance with crystalline appearance (flakes). It has hygroscopic properties.

This product is characterized by high quality and purity, which confirms compliance with the latest edition of European Pharmacopoeia.

Caustic soda is mainly applicable:

- in the production of salicylic acid and sulfonamides
- in the production of sodium ascorbate – an alternative to vitamin C as the sodium salt of ascorbic acid
- in the production of iodoform used as a raw material (sodium carrier) in various kinds of syntheses in the pharmaceutical industry (including in the production of polopyrine, salicylic acid, sulfanilamides).
- as an auxiliary in the production of ointments and medicated creams for external use. Aqueous solution of sodium hydroxide is used to neutralize the carboxylic groups, and thus to the cross-linking of gelling agents, e.g. polyacrylic acids in therapeutic gels. This increases the pharmaceutical availability of active ingredients in hydrogel preparations.

Hydrochloric acid min. 37% PF

PRODUCT NAME	MONOGRAPH NAME	CAS	CHEMICAL DESCRIPTION	APPEARANCE	COMPLIANCE WITH Eur.Ph MONOGRAPH
Hydrochloric acid min 37% grade PF	Hydrochloric acid concentrated	7647-01-0	synthesis catalyst, pH controller semi product for API's	Liquid	conforms

Hydrochloric acid min. 37% PF (HCl) is a chemical compound that is an aqueous solution of hydrogen chloride gas. It has strong corrosive properties, a strong, irritating odour, and colourless to pale yellow. Hydrochloric acid pure grade is produced by direct synthesis by burning chlorine in hydrogen and then absorbing hydrogen chloride into water.

Offered ultra pure grade of hydrochloric acid with pharmaceutical quality in line with Eur.Ph monograph.

Pharmaceutical industry uses hydrochloric acid as:

- a catalyst for synthesis
- pH control
- deionisation of water and as a reducing agent (for example in the production of ascorbic acid and para-aminobenzoic acid).

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PCC Group

We build value through sustainable innovation



Operating in 18 countries,
in 41 different locations,
PCC SE currently employs
3400 people.

Each project or venture with a long-term success story shares one common thing – it's based on in-depth market research and on the knowledge acquired through years of experience. It is knowledge and experience that enables us to constantly aim higher and deliver greater value through dynamic and sustainable world-wide development of the PCC Group.

The companies, operating as a part of the PCC Group, act with responsibility and care.

We only embark on new business challenges when we are certain that we have the skills and knowledge to achieve success. We operate in three major markets: chemicals, energy and logistics. Several dozen business units, managed by PCC SE, work in synergy to generate the greatest possible competitive advantage in both local and international markets. Each day nearly three thousand professionals contribute their energy, and effort, to secure the sustainable

development of the PCC Group. The key element of our strategy is to ensure the development of each individual business unit through taking advantage of innovative technology and new market applications. We achieve our goals in a sustainable and responsible way – we care about the environment and the society within which we operate.

We are always ready to reach our strategic goals. Efficient and dynamic management helps our employees to fully develop their potential and therefore enhances the overall PCC Group value. Joint enterprises and individual initiatives of our companies are the results of the entrepreneurship culture promoted within

the PCC Group. Our philosophy is built on simple values - integrity, trust and reliability. We believe that following those principles is the only way to build a long-term competitive advantage.

The PCC Group currently employs nearly 3400 people. We operate in 18 countries, in 41 different locations around the world. Our portfolio includes eight basic segments. Individual operational responsibility is assigned to seven of them - Polyols, Surfactants, Chlorine, Specialty Chemicals, Consumer Products, Energy and Logistics. Each of these segments is supported by 19 business units, all under the management of the PCC Group.

The divisions, segments and business units of the PCC Group

Divisions	Segments	Business units	Divisions	Segments	Business units
Chemicals	 Polyols	• Polyols • Polyurethane Systems	Energy	 Energy	• Renewable Energies • Conventional Energies
	 Surfactants	• Anionic Surfactants • Non-ionic Surfactants • Amphoteric Surfactants (Betaines)		 Logistics	• Intermodal Transport • Road Haulage • Rail Transport
	 Chlorine	• Chlorine • MCAA • Other Chlorine Downstream Products	Holding	 Holding	• Portfolio Management • Projects • Services
	 Specialty Chemicals	• Phosphorus and Naphthalene Derivatives • Alkylphenols • Chemicals and Commodities Trading • Quartzite			
	 Consumer Products	• Household and Industrial Cleaners, Detergents and Personal Care Products • Matches and Firelighters			

PCC Group - Industrial Park in Brzeg Dolny, Poland

PCC Rokita SA

PCC Rokita Capital Group, 22 companies, including:

PCC Rokita SA

PCC Prodex Sp. z o.o.

PCC Prodex GmbH (Germany)

PCC PU Sp. z o.o.

IRPC PCC Co. Ltd. (Thailand)

PCC Therm Sp. z o.o.

PCC EXOL SA

PCC EXOL Capital Group, 5 companies, including:

PCC EXOL SA

PCC Chemax Inc. (the USA)

PCC EXOL Kimya Sanayi Ve Ticaret Limited Şirketi (Turkey)

PCC CP Kosmet Sp. z o.o.

Capital Group PCC CP Kosmet, 3 companies, including:

PCC CP Kosmet Sp. z o.o.

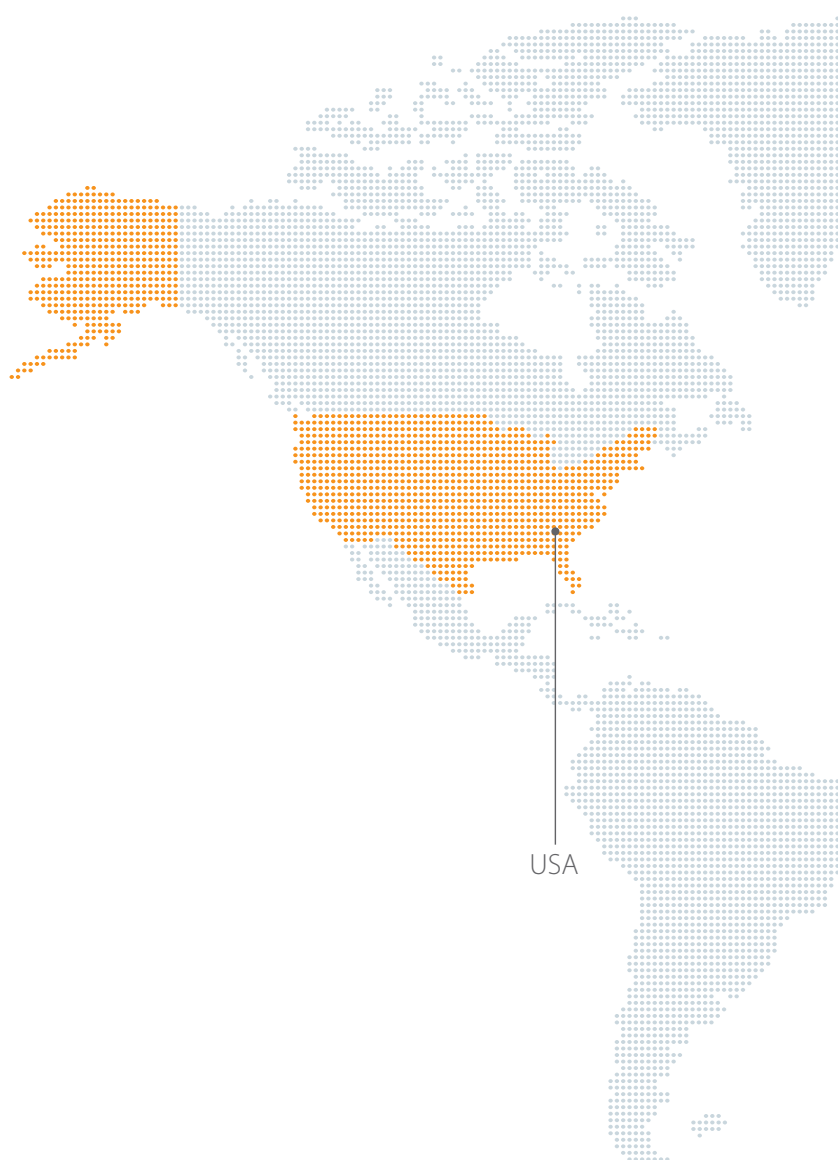
OOO PCC Consumer Products Navigator (Belarus)

OOO PCC Consumer Products (Russia)

PCC MCAA Sp. z o.o.

PCC Autochem Sp. z o.o.

PCC Intermodal SA





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Number of pages	24

COVER PAGES

Brand	Cocoon Silk
Grammage	250
Number of pages	4

PUBLICATION

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19		kg of landfill
2		kg CO ₂ and greenhouse gases
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772		litres of water
42		kWh of energy
32		kg of wood

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Please visit our capital group business platform:

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