



Data Sheet

Issued:

05-Oct-2006

Product Name

Isopropyl Alcohol-GMP*

* Meets excipient level

Product Code
S1155 Europe
Product Category
Alcohols
Alternate Name

IPA-GMP*, 2-propanol

CAS Registry Number

67-63-0

EINECS Number

200-661-7

Description


Isopropyl alcohol-GMP* (IPA-GMP*) is a special grade of Isopropyl Alcohol which is produced according to the IPEC (International Pharmaceutical Excipient Council) guidelines on Good Manufacturing Practices (GMP) for excipients.

Sales Specification

Property	Unit	Min	Max	Method
Purity	%m/m	99.9		DIN 55685
Water	%m/m		0.10	ASTM D1364
Appearance	Clear & Free From Suspended Matter			ASTM D4176
Color	Pt-Co		5	ASTM D1209 (4)
Initial diluted odor		4		SMS 547
Density @20°C	g/mL	0.785	0.786	ASTM D4052 (4)
Refractive Index @20°C		1.376	1.378	ASTM D1218 (4)
Acidity as Acetic acid	%m/m		0.001	ASTM D1613
Non Volatile Matter	g/100mL		0.001	ASTM D1353
Peroxides		Pass	1	Eu.Pharm
Distillation, IBP	°C	81.8		ASTM D1078 (4)
Distillation, DP	°C		82.8	ASTM D1078 (4)
Benzene	mg/kg		1	LPM 5230
Water Miscibility		Miscible		ASTM D1722
UV Absorbance @230nm			0.30	Eu. Ph 2.2.25
UV Absorbance @250nm			0.10	Eu. Ph 2.2.25
UV Absorbance @270nm			0.03	Eu. Ph 2.2.25
UV Absorbance @290nm			0.02	Eu. Ph 2.2.25
UV Absorbance @310nm			0.01	Eu. Ph 2.2.25

(4) Agreed Specification limits - no results: Statistical average value reported

Product as produced complies with the European Pharmacopoeia, ASTM D770 and DIN 53245.

Typical Properties

Property	Unit	Method	Value
Purity	% m/m	GC	min. 99.9
Water	% m/m	ASTM D1364	0.03
Density @20°C	kg/L	ASTM D4052	0.785
Cubic Expansion Coefficient @20°C	(10 ⁻⁴)/°C	Calculated	11
Refractive Index @20°C	-	ASTM D1218	1.378
Color	Pt-Co	ASTM D1209	< 5
Boiling Point	°C	-	82
Relative Evaporation Rate (nBuAc=1)	-	ASTM D3539	1.5
Relative Evaporation Rate (Ether=1)	-	DIN 53170	11
Antoine Constant A #	kPa, °C	-	6.86618
Antoine Constant B #	kPa, °C	-	1360.13
Antoine Constant C #	kPa, °C	-	197.592
Antoine Constants: Temperature range	°C	-	-10 to +90
Vapor Pressure @20°C	kPa	Calculated	4.1
Vapor Pressure @50°C	kPa	Calculated	24
Saturated Vapor Concentration @20°C	g/m ³	Calculated	102
Flash Point	°C	IP 170	12
Auto Ignition Temperature	°C	ASTM E659	425
Explosion Limit: Lower	%v/v	-	2.0
Explosion Limit: Upper	%v/v	-	12
Electrical Conductivity @20°C	µS/m	ASTM D4308	6
Dielectric Constant @20°C	-	-	18.6
Freezing Point	°C	-	-88
Surface Tension @20°C	mN/m	-	23
Viscosity @20°C	cSt	ASTM D445	2.4
Hildebrand Solubility Parameter	(cal/cm ³) ^{1/2}	-	11.5
Hydrogen Bonding Index	-	-	-16.7
Fractional Polarity	-	-	0.178
Heat of Vaporization @Tboil	kJ/kg	-	664
Heat of Combustion (Net) @25°C	kJ/kg	-	31000
Specific Heat @20°C	kJ/kg/°C	-	2.6
Thermal Conductivity @20°C	W/m/°C	-	0.14
Miscibility @20°C: Solvent in Water	% m/m	-	complete
Miscibility @20°C: Water in Solvent	% m/m	-	complete
Azeotrope with Water: Boiling Point	°C	-	80.3
Azeotrope with Water: Solvent Content	% m/m	-	87.4
Molecular Weight	g/mol	-	60

(#) In the Antoine temperature range, the vapor pressure P (kPa) at temperature T (°C) can be calculated by means of the Antoine equation: $\log P = A - B/(T+C)$

Test Methods	<p>Copies of copyrighted test methods can be obtained from the issuing organisations:</p> <p>American Society for Testing and Materials (ASTM) : www.astm.org Energy Institute (IP) : www.energyinst.org.uk Deutsches Institut für Normung (DIN) : www.din.de</p> <p>Shell Method Series (SMS) methods are issued by Shell International Chemicals B.V., Shell Research and Technology Centre, Amsterdam, The Netherlands. Copies of SMS can be obtained through your local Shell Chemicals company.</p> <p>For routine quality control analyses, local test methods may be applied that are different from those mentioned in this datasheet. Such methods have been validated and can be obtained through your local Shell Chemicals company.</p>
Quality	<p>Isopropyl Alcohol-GMP* can be supplied to meet the various requirements of the European Pharmacopoeia. It meets requirements of the excipient level of Good Manufacturing Practice (GMP) as described in the IPEC Guidelines on Good Manufacturing Practices for Pharmaceutical Excipients. Isopropyl Alcohol-GMP* also meets the requirements of ASTM D770, DIN 53245 and BS 1595. It does not contain detectable quantities of heavy metals, chlorinated compounds or polycyclic aromatic hydrocarbons.</p>
Storage and Handling	<p>Provided proper storage and handling precautions are taken we would expect Isopropyl Alcohol-GMP* to be technically stable for at least 12 months. For detailed advice on Storage and Handling please refer to the Material Safety Data Sheet on www.shell.com/chemicals.</p>
Hazard Information	<p>For detailed Hazard Information please refer to the Material Safety Data Sheet on www.shell.com/chemicals.</p>
Warranty	<p>All products purchased or supplied by Shell Chemicals are subject to terms and conditions set out in the relevant contract, order acknowledgment and/or bill of lading. The relevant Shell company warrants that its product will meet those specifications designated as such herein or in other publications. All other information including that herein, supplied by Shell Chemicals is considered accurate but is furnished upon the express condition that the customer shall make its own assessment to determine the product's suitability for a particular purpose. Shell Chemicals make no other warranty either expressed or implied, regarding such other information, the data upon which the same is based, or the results to be obtained from use thereof; that any products shall be merchantable or fit for any purpose; or that the use of such other information or product will not infringe any patent.</p> <p>"Shell Chemicals" collectively refers to the companies of the Shell Group engaged in the chemicals business, each of which is an independent entity and has its own separate identity</p>