Innophos Quality Requirements

All vendors supplying products to Innophos and/or providing other services with respect to Innophos products (each such vendor referred to herein as a "Vendor") must comply with the quality requirements set forth herein, as applicable. These Innophos Quality Requirements are incorporated into and supplement the terms of any contract between Innophos and Vendor and any purchase order issued by Innophos to Vendor. The products supplied by Vendor to Innophos and the Innophos products that Vendor handles in connection with services Vendor provides to Innophos are referred to herein as "Products."

Vendor type	Comply with the following sections
Raw Material Supplier	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15
Contract Manufacturer / Toller	1,2,3,4,5,6,7,8,9,10,11,12,13,14,15
Warehouse	1,2,3,4,6,7,8,9,10,12,13,14,15
Transportation Carrier	1,2,3,4,6,7,8,9,10,12,13,14,15
Freight Forwarder	1,4,6,12,15

Innophos Quality Requirements Document Revision History

Brief Description of Revisions	Effective Date	Approved By
New Document	4/2/2021	Octavio Lopez, Senior Director, Quality Assurance & Regulatory Affairs

	Responsibility	Innophos	Vendor
Section 1	**Quality Management & Compliance Requirements**		
1	Implement procedures and/or documented training to meet Innophos' requirements herein and in each contract/purchase order, including the overarching requirement that Vendor provide all goods and services in a safe manner and in compliance with all applicable laws, rules and regulations.		**X**

2	Must meet federal, state, provincial, local and international standards applicable to Products supplied, stored or handled by Vendor and/or to Vendor's facility, including, to the extent applicable based on the specification requirements, good manufacturing practice (GMP) requirements, and other quality requirements communicated by Innophos to Vendor, (i) the FDA Food Safety Modernization Act (FSMA), the Foreign Supplier Verification Program (FSVP) and all other FDA rules and regulations (in the U.S.), (ii) the rules and regulations of Health Canada (in Canada), (iii) the rules and regulations of the Federal Commission for Protection against Health Risks (COFEPRIS) and the Intersecretarial Commission for the Control of the Process and Use of Pesticides and Toxic Substances (CICOPLAFEST) (in Mexico), and (iv) all applicable current GMPs.		**X**
3	Where applicable (for Products Innophos has identified as intended for human ingestion), (i) in the US and Canada, maintain GFSI certification and provide annual audit report (if not currently certified to a GFSI standard, implement a timeline for certification) and (ii) in Mexico, maintain ISO-certification (or other certification acceptable to Innophos).		**X**
4	Manufacture, package, handle, ship, store and test the Product and materials in an environment which is designed, constructed, and maintained in a manner that: a) permits the operation therein to be performed under clean, sanitary, and orderly conditions; b) permits the effective cleaning of equipment and facilities; and c) prevents the contamination of the Product and the addition of extraneous material to the Product.		**X**
5	Assure procedures are in place for release of all Product batches by a Quality representative.		**X**

6	Manufacture Product (or, if the Product is sourced from a third party, ensure that such third party manufactures the Product) in adherence to the Innophos-approved specifications (and free from extraneous material). Test Product (or, if the Product is sourced from a third party, ensure that such third party tests the Product) and provide an accurate certificate of analysis (COA) demonstrating compliance with Innophos-approved specifications.		**X**
7	Where applicable (for Products Innophos has identified as intended for human ingestion), maintain an internal GMP Quality System audit program that includes verification of Data Integrity practices for paper and electronic records.		**X**
8	Where applicable (for Products Innophos has identified as intended for human ingestion), maintain a documented Qualification program for vendors of raw materials and components, including on-site audits of critical starting materials and critical components. The program shall contain pre-set requirements for vendor qualification, documented rationale for acceptance of each vendor used to source material/component used in Product and procedures for oversight and removal, where necessary, of poorly performing vendors.		**X**
9	Maintain a Quality Dept that (i) is independent of production and (ii) fulfills both quality assurance and quality control. responsibilities.		**X**

	Responsibility	Innophos	Vendor
Section 2	**Right to Audit**		
1	Have the right to audit Vendor's facilities, Quality Systems, and documentation, including Vendor batch documentation, at no charge to Innophos, as they relate to the manufacture of Product with mutually agreed upon notification. Additionally, Innophos retains the right to conduct "for cause" audits, as necessary.	**X**	
2	Issue Vendor a confidential audit report summarizing audit observations after the audit.	**X**	

3	Issue responses to all observations in writing to Innophos in accordance with the timeframe specified in the audit report. Where Vendor commits to a corrective action which cannot be immediately implemented, a description of the corrective action and timeframe shall be included in the response.		**X**
4	Innophos and Vendor shall mutually agree to the requirements for auditing third parties, as applicable, used in association with Product. Audits of third parties performed by Vendor shall be made available to Innophos during on-site audits (audit reports of third parties shall be provided to Innophos, upon request).	**X**	**X**

	Responsibility	Innophos	Vendor
Section 3	**Regulatory Inspections and Exchanges**		
1	Notify Innophos within a reasonable amount of time not to exceed five (5) business days of the receipt of a Regulatory Authority (which herein means a Board of Health, U.S. FDA, Health Canada, Mexico MX COFEPRIS and CICOPLAFEST, or any other international, federal, state, provincial or local authority having jurisdiction over Vendor) inspection report, deficiency letter or regulatory compliance observation, which contains any adverse findings that relate to the Product or the facilities used to produce, test, package, store and/or distribute the Product. *A significant adverse finding is herein defined as the following: Conditions, practices, or processes that adversely affect or may potentially adversely affect Product quality and/or safety, and/or the quality and integrity of data, documentation, or other materials or information addressed in the inspection.*		**X**

2	Maintain a process for review of GMP/Quality Systems deficiencies or any other operational deficiencies noted by a Regulatory Authority or notifications of deficiencies received from a certifying body, within a reasonable amount of time not to exceed three (3) business days of receipt to determine impact on quality/safety of Products already shipped to customers or other third parties. Provide a summary of any specific deficiencies affecting quality and/or safety of Product shipped to customers or other third parties, as well as the intended corrective action, to Innophos within ten (10) business days after the inspection.		**X**
3	Maintain a requirement for any third party used to produce, test, package, store and/or distribute Product to notify Vendor of any Regulatory Authority inspections which result in a significant adverse finding that relate to the Product or the facilities used to produce, test, package, store and/or distribute the Product within a reasonable amount of time not to exceed 3 (three) business days.		**X**
4	Provide copies of the inspection report, deficiency letter or regulatory compliance observation related to the process for manufacturing, testing, packaging, distributing and/or storing Product electronically within three (3) business days of the receipt of such document.		**X**

	Responsibility	Innophos	Vendor
Section 4	**Complaints**		
1	Have written procedures in place to document and investigate all quality-related Product complaints. All complaint evaluations shall include the potential impact to Product which has already been shipped to customers or other third parties.		**X**

2	Notify Innophos within three (3) business days after identifying impact to Product shipped to Innophos or third parties, which may have been identified while investigating a complaint of another customer if Product safety, quality, identity, potency or purity is suspect.		**X**
3	As a result of a Product quality complaint, a root cause analysis, actions taken for correction of the problem, actions taken for prevention of future occurrences and the conclusion will be provided to Innophos within twenty-five (25) business days of Innophos' submission of the complaint.		**X**
4	Product Quality complaints shall include Product name, Vendor batch number (or equivalent), a brief description of the issue and how it was discovered (as applicable).	**X**	
5	Both parties agree to cooperate in exchange of information required to effectively conduct the Product quality investigation. This includes Vendor coordination with any associated third party for investigation information, as applicable. Execution of confidentiality agreements may be required prior to providing information to third parties.	**X**	**X**

	Responsibility	Innophos	Vendor
Section 5	**Material Safety Questionnaires**		
1	Complete Innophos questionnaires as they relate to the potential safety risks posed by the Product. An endorsed compliance statement may take the place of completion of the questionnaires, if agreed to by Innophos. These questionnaires include at a minimum a review of: • BSE/TSE risk • Genetically Modified Organisms use • Allergens content and/or exposure of the material • Residual solvents controls/limits (consistent with ICH guidance where applicable for pharmaceutical excipients) • Elemental Impurities (consistent with ICH guidance where applicable for pharmaceutical excipients) • Melamine Risk		**X**

2	If animal derived materials are utilized in association with manufacturing the Product, maintain appropriate records for each lot of animal derived material to ensure traceability. Where required by local regulations, the Vendor will assure that the country of origin or slaughtering information (either or both, whichever can be obtained from the manufacturer of Product) will be documented and provided to Innophos.		**X**
3	Where there is a change in the status of handling of sensitizing materials such as those associated with animal derived materials, allergens, or highly potent materials within the facility used to manufacture, process, handle or store Product, Innophos must be notified of such change prior to implementation.		**X**
4	Product supplied to Innophos shall be guaranteed as GM free, where applicable. Any changes in the status of genetically modified source materials used to supply Product to Innophos requires notification to Innophos of this change prior to implementation.		**X**
5	Provide Safety Data Sheet or equivalent for Product, upon request, to Innophos.		**X**
6	Agree to complete Innophos surveys or provide certified statements for each Product concerning any other applicable factors which are considered to be the most current potential safety risk, in accordance with Regulatory Authority postings or inquiries and/or current scientific literature.		**X**

	Responsibility	Innophos	Vendor
Section 6	**Documents and Records**		
1	Have a controlled system to initiate, review, revise, approve, obsolete, and archive all GMP and/or Quality Systems documentation. System should address documentation changes, which may be requested by Innophos (such as test methods or specifications).		**X**

2	Have procedures in place to assure the integrity, archival, retrieval and destruction of GMP data (paper and electronic) that comply with applicable regulations.		**X**
3	All GMP records (paper and electronic) shall be completed in a manner such that the data is: • Clearly attributable to the person making the entry and executing the physical activity being recorded • Fully legible • Contemporaneously and permanently entered into the record at the time the activity is executed • An original entry and not copied from an intermediate data recording process such as a post-it notes or electronic notes • Completely accurate GMP documents (paper and electronic) that require physical entries to be completed shall be constructed in such a way that they direct the user of the document to comply with the GMP regulations.		**X**
4	Data shall be created and processed in an objective manner, free from bias that assures its integrity, using approved processes and, where required by regulations, be independently verified to ensure that data is accounted for and data is not deleted or removed. Where data is transferred between systems, the transfer process shall be validated for intended use.		**X**
5	Documentation associated with manufacturing, testing, packaging, warehousing, storage, and distribution of the Product must be signed by authorized personnel and should not be changed without documented authorization.		**X**
6	Manufacturing, testing, packaging, warehousing, and/or storing and distribution documentation for Product intended for Innophos shall be made available for Innophos review during on-site audits.		**X**

7	Where Vendor is responsible for supplying a COA, provide a CoA for each lot/shipment of the Product, containing at minimum the following information: • Manufacturing Site (name and address) • Manufacturing Date • Vendor Product number • Vendor Lot number • Name of Product • Name of the Tests • Specification Limit • Grade of Product (if applicable) • Expiration or retest date • Actual test result (as a numerical value, unless designated • Pass/Fail in the specification limit), unless parameter is guaranteed based on reduced testing plan per mutually agreed specification and so indicated on CoA. Where applicable, indicate if results are taken from third party testing, or previous lot testing, or tested on reduced frequency. • Quality approval and date (may be electronic approval)		**X**
8	Provide a document certifying Product was manufactured, tested, packaged, warehoused, stored and/or distributed (as applicable, depending on the services provided by Vendor) in accordance with applicable GMP and Quality Systems requirements.		**X**
9	Where applicable, where skip lot testing may be utilized, there should be an indication on the CoA as to which results are represented by reduced testing and/or skip lot testing. Alternately, a Vendor memo may accompany the lot to indicate which results are represented by reduced testing or skip lot testing data.		**X**

10	All records, including paper and electronic records, shall be securely retained in a manner that prevents their destruction, alteration or damage for the appropriate retention time period as complete records, including all supporting metadata and audit trails, so that the data is readily retrievable and ensures the full series of activities of the testing can be reconstructed. The records shall be readily retrievable throughout their retention period.		**X**

	Responsibility	Innophos	Vendor
Section 7	**Change Control**		
1	Have established written procedures for control of changes impacting or potentially impacting the Product including, but not limited to, manufacturing components or process, computer hardware/software, Product and/or starting material specifications, test methods, vendors, and subcontractors. Procedures shall include a process for assessing changes for the impact on the identity, strength, safety, potency, quality, stability, composition, purity, regulatory status or validation status of the Product and include notification to customers of such changes.		**X**
2	Notify Innophos of intent to make changes that may impact the identity, strength, safety, potency, quality, stability, composition, purity, regulatory status or validation status of the Product prior to implementation of the change. Allow mutually agreed time for Innophos to comment on notified changes.		**X**
3	Innophos agrees to provide a written response to the Vendor within the mutually agreed upon time, indicating any impact to Innophos finished product or regulatory application requirements.	**X**	
4	Where Vendor process change(s) has a potential impact to Product, Vendor agrees to work with Innophos on a timeline for implementation of the applicable change.		**X**

5	Changes to previously Innophos approved specifications must be agreed to in writing prior to implementation.	**X**	**X**
6	Notify Innophos of name/facility change, corporate reorganization, consolidation, merger or acquisition of Vendor or any third party which supports Vendor in connection with the Product.		**X**

	Responsibility	Innophos	Vendor
Section 8	**Recalls (Product Retrieval)**		
1	In the case of a Product recall/retrieval by Vendor, Vendor shall inform Innophos, within one (1) business day of the planned recall/retrieval.		**X**
2	Vendor shall have a written Product recall/retrieval procedure, which includes the process for notification to all affected customers.		**X**
3	Innophos shall notify Vendor of any Product recall by Innophos which has been investigated or is under investigation and has potential to be related to the quality of the Product Vendor supplied to Innophos (or otherwise handled for Innophos) as soon as possible.	**X**	
4	The parties shall cooperate in exchange of information required to effectively conduct a Product recall or recall investigation which may be associated with Product supplied or handled by Vendor.	**X**	**X**
5	Innophos shall be responsible for all agency communications related to the status of Innophos products as impacted by any Vendor Product recall/retrieval.	**X**	

	Responsibility	Innophos	Vendor
Section 9	**Deviations**		
1	There shall be procedures in place for notification to Innophos of any Product quality issue which could affect the Product already shipped or to be shipped to Innophos or third parties. Notification shall include Product and batch numbers affected by any quality issues.		**X**
2	Have procedures for the identification, investigation, and reporting of deviations and out-of-specification (OOS) results that occur during the manufacture, packaging, testing, storage or any other processing of the Product.		**X**
3	Investigations into non-conformances shall include identification of root cause, risk analysis (including risk to other lots, including those already distributed), corrective and/or preventative actions taken, and a conclusion approved by the Vendor Quality department.		**X**
4	Notify Innophos of any deviations that have the potential to adversely affect the identity, strength, safety, potency, quality, stability, composition, purity of the Product as it relates to its safety or effectiveness.		**X**

	Responsibility	Innophos	Vendor
Section 10	**Production and In Process Controls, Packaging and Labeling**		
1	Procures from approved vendors, tests as required, and releases raw materials, packaging and labeling components used in the manufacture and distribution of Product. Stores materials and components in accordance with manufacturer's recommended storage conditions.		X
2	Maintain a documented manufacturing and packaging process, including records for critical process parameters, batch adjustments, re-processing (if applicable), associated with the production of each lot of Product which can be reviewed upon on-site audit.		X

3	Review and approval of applicable records (such as batch record, deviations, reports) by Quality department prior to batch release. Release Product by Quality department. The independent review and verification of all GMP records shall include the original source data and where appropriate electronic meta data and audit trails that support the GMP record.		**X**
4	Each container of Product supplied to Innophos or third parties shall contain a permanently affixed label with at least the following information: • Vendor name and location • Product name, including grade (if applicable) • Amount (weight or volume, including unit of measure) • Batch number • Retest date, or expiry date (where applicable) • Any special storage conditions or handling precautions • Known Allergen products identified on the label or with a burst sticker • Vendor name and location		**X**
5	Control, use, dispose, and destroy production materials in a secure and legal manner that prevents unauthorized use or diversion in compliance with environmental regulations. Maintain destruction records.		**X**
6	Will not provide reprocessed and/or reworked Product manufactured outside of the approved process to Innophos.		**X**
7	Vendor will not ship to Innophos material that was previously returned by another customer due to non-quality issues, without prior written consent of Innophos. This consent will be given on a case-by-case basis and will require Vendor to provide documented assurance of supply chain integrity throughout the custody of the specific lot/batch of Product.		**X**

8	Manufacture, test, package, handle, store and ship Product in a manner that prevents contamination by other materials including carryovers.		**X**

	Responsibility	Innophos	Vendor
Section 11	**Laboratory Controls**		
1	Maintain written procedures for sample management, testing, approval, disposition and the recording, storage, retention, and disposal of laboratory data.		**X**
2	Retain samples (raw materials and Product) as applicable, at least as long as the expiry or re-evaluation period of the Product.		**X**
3	Maintain compliance with Innophos-approved specifications, including microbiological testing as applicable and mutually agreed upon, and test procedures for the Product, which are consistent with compendia monographs, where applicable.		**X**
4	Maintain written procedures and appropriately document the preparation, use and management of reagents, solutions, and standards including qualification of use periods.		**X**
5	Test Product in accordance with approved validated or qualified methods and Innophos agreed specifications using calibrated equipment. Parameters performed on a reduced testing /skip lot testing regiment will be indicated on COA and written notice will be provided to Innophos before testing frequency of a parameter is changed from per lot basis to less frequent basis.		**X**
6	Document all required testing steps at the time of execution. Perform an independent review and verification of all testing records, including the original source data and where appropriate electronic meta data and audit trails that support the analytical testing.		**X**

7	Maintain a program for qualification, calibration, and preventative maintenance of all analytical equipment used for Product.		**X**
8	Implement additional surveillance testing for Product where deemed necessary by Innophos due to economic adulteration risk, utilizing test methods provided by or agreed to by Innophos. Maintain records of surveillance testing, as GMP records.		**X**
9	If using an internal laboratory, it must be on a Lab Proficiency Program.		**X**

	Responsibility	Innophos	Vendor
Section 12	**Facility, Storage and Distribution**		
1	Maintain Product in facilities appropriate for conditions specified on the Product label (and any instructions provided by Innophos) prior to shipment to Innophos or other third parties. Maintain monitoring records of critical parameters associated with the storage facility.		**X**
2	Maintain facilities in a manner to prevent cross-contamination.		**X**
3	Have procedures and maintain the facility in such a manner as to segregate products of differing status, such as receipt, quarantine, released, returned, and rejected products. Product may be segregated by electronic system(s), except for returned product. Assure recalled or rejected materials are not distributed to Innophos.		**X**
4	Maintain a documented pest control program for the facility.		**X**
5	Maintain and supply upon request documentation that supports the recommended storage and transportation conditions.		**X**

6	Store Product(s) in a limited access, secure storage area and in a manner to protect the Product quality as well as packaging and labeling integrity prior to shipment to Innophos or third parties. Maintain adequate security systems for all storage locations. Product should be stored in a manner to facilitate location of the correct Products for dispatch.		**X**
7	Any wood pallets/skids used to hold Product or Product components during processing, storage and distribution of Product shall be in compliance with ISPM- 15, "International Standards for Phytosanitary Measures: Guidelines for Regulating Wood Packaging Materials in International Trade". Supplier should have specs for all pallets and ensure durability of pallets to handle the appropriate product weight.		**X**
8	Maintain procedures for acceptability of receiving trucks, appropriate documentation verification for receipts and transport equipment acceptance. Document all instances of non-compliance by transportation vendors transporting Product.		**X**
9	Vendor shall maintain distribution records for each manufacturer lot to assure traceability and completeness of retrieval.		**X**
10	Product shall be transported in such a manner as to prevent contamination and to protect the integrity of the Product containers and storage conditions as identified on the Product label (and consistent with any instructions provided by Innophos).		**X**
11	Temperature or other deviations from shipping instructions, during transport to Innophos or third parties, shall be documented and investigated to assess the impact to the Product, as applicable. Vendor shall inform Innophos of such deviations affecting Product.		**X**
12	Agree upon requirements for re-usable shipping containers, as applicable.	**X**	**X**

	Responsibility	Innophos	Vendor
Section 13	**Supply Chain Integrity**		
1	Vendor shall utilize tamper evidence packaging. Vendor shall provide identifying information on tamper evidence device(s) to Innophos as requested.		**X**
2	Notify Vendor of tampering events of Product identified upon receipt at Innophos.	**X**	
3	Vendor shall maintain documentation of the original manufacturers of each critical material used in the production and packaging of Product.		**X**
4	Vendor shall qualify transportation services/carriers contracted by Vendor to distribute Product, as it relates to maintaining the quality and integrity of the Product en-route to Innophos or third parties.		**X**

	Responsibility	Innophos	Vendor
Section 14	**Validation/Qualification**		
1	Have a written master validation/qualification plan for the facilities, equipment/instruments, manufacturing process, cleaning procedures, analytical procedures, in process control tests and computerized systems approved by the quality department.		**X**
2	Qualify all critical systems (e.g., water, HVAC, gases, etc.), utilities, and equipment used for the manufacture, testing, packaging, handling and control of Product (Installation Qualification (IQ), Operational Qualification (OQ), and/or Performance Qualification (PQ)). Maintain documentation.		**X**
3	Prepare and maintain validation documentation approved by the quality department, including protocols, reports and associated documentation.		**X**
4	Have a written master validation/qualification plan for the facilities, equipment/instruments, manufacturing process, cleaning procedures, analytical procedures, in process control tests and computerized systems approved by the quality department.		**X**

	Responsibility	Innophos	Vendor
Section 15	**Transportation**		
1	Transport Products (or, in the case of a freight forwarder, arrange for a third party to transport Products) in a manner to ensure the Products are not damaged, contaminated or adulterated (including complying with all transportation, handling and storage instructions provided by Innophos).		**X**
2	Transport Products (or, in the case of a freight forwarder, arrange for a third party to transport Products) in compliance with all applicable laws, rules and regulations, including maintaining all required licenses and registrations.		**X**
3	Utilize transport personnel who are appropriately licensed and properly trained.		**X**
4	When transporting (or, in the case of a freight forwarder, arranging for a third party to transport) Products Innophos has identified as intended for human ingestion, comply with the following requirements (unless otherwise noted below all requirements refer to Sanitary Transport of Human and Animal Food (81 FR 20091), as well as comparable requirements in Canada, Mexico and other jurisdictions (as applicable). Vehicles and transportation equipment used in transportation operations must: 1) Be designed of material and be of workmanship as to be suitable for adequate cleaning for their intended use to prevent food from becoming potentially unsafe during transportation per §1.908(a). 2) Be maintained in sanitary condition for their intended use to prevent food from becoming potentially unsafe during transportation. Bulk vehicles require a food grade cleanout ticket when changing product or at agreed upon intervals where applicable. All bulk vehicles shall be dedicated to food only per §1.908(b).		**X**

4 (Continued)	3) Be stored in a manner that prevents the harboring of pests or becoming contaminated in any other manner that could result in food becoming potentially unsafe during transportation per §1.908(c). 4) Be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming potentially unsafe during transportation. This includes verification the transport has been pre-cooled as specified prior to loading per §1.908(d) and assuring the transport maintains the required temperature through the transportation operation per §1.908(b)(2).		**X**
5	Effective measures must be taken to prevent contamination of Products Innophos has identified as intended for human ingestion: 1) Responsibility for ensuring that transportation operations are carried out in compliance with all requirements must be assigned to competent supervisory personnel per §1.908(a)(2). 2) Before loading, verify the transportation equipment is in appropriate sanitary condition. Drivers must visually inspect non-bulk freight prior to loading. Damaged, contaminated or otherwise leaking freight shall not be accepted. This includes loads other than Innophos on a less than load shipment (LTL) to prevent contamination in transit per §1s.908(e)(1) and 21 CFR 121.135. 3) Segregation, isolation, or other protective measures to protect food from contamination by raw foods or non-food items in the same load per §1.908(a)(3)(i).		**X**

5 (Continued)	4) Segregation, isolation, or other protective measures, such as handwashing or gloves, to protect food transported in bulk vehicles or food not completely enclosed from contamination or cross contact per §1.908(a)(3)(ii). 5) Food that requires temperature control is transported under adequate temperature control per §1.908(a)(3)(iii). 6) Seal numbers or padlock serial number will be confirmed with the BOL before accepting a load for transport. LTL shipments will be locked with a high security core padlock in which the driver has the only access as a mitigation strategy per 21 CFR 121.135.		**X**

Notes/Comments from Vendor:

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