

#01 P.1

**From:**  
**Sent:** Wednesday, November 07, 2007 9:51 AM  
**To:**  
**Subject:** FW: MSDS Response

MSDS info from AgaMatrix. Let me know if this meets the cut.

Product & Supplier Management  
McKesson Medical Surgical  
8741 Landmark Road  
Richmond, VA 23228

804.264.7601 Fax

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**From:** Mike Vidmar [mailto:MVidmar@agamatrix.com]  
**Sent:** Wednesday, November 07, 2007 9:37 AM  
**To:**  
**Subject:** RE: MSDS Response

Hi,

This is what was sent as an explanation to me.

An MSDS is a Material Safety Data Sheet. The MSDS is designed to provide both **workers** and **emergency personnel** with the proper procedures for handling or working with a **particular substance**. MSDS's include information such as physical data (melting point, boiling point, flash point etc.), toxicity, health effects, first aid, reactivity, storage, disposal, protective equipment and what to do in the event of a leak or chemical. MSDS's are **not meant for consumers**. MSDS's are meant for: 1) employees who may be occupationally exposed to a hazard at work, b) employers who need to know the proper methods for handling, storage, disposal, etc. and 3) emergency responders such as fire fighters, hazardous material crews, emergency medical technicians, and emergency room personnel. An MSDS reflects the hazards of working with the "material" (acids, reagents, epoxies, RTV, and a million other substances) in an **occupational fashion**. MSDS's are not required to be submitted for anything we buy or make (meters, strips, control solution, lancing devices, lancets, etc).

Mike Vidmar  
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*\* see attached for item  
information \**

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**From:****Sent:** Wednesday, November 07, 2007 9:27 AM**To:** Mike Vidmar**Subject:** RE: MSDS Response

Mike, Thanks for your response. While it seemed your email did not get to Kristy, it did. She copied me and the 510(k) situation is resolved.

I will send a copy of the MSDS response to her this morning, but am not entirely sure it will be accepted. Our corporate view is that OSHA requires MSDS sheets to be available for customers.

From a commercial view, this will not stop products from being added to the system. However, it will confuse the team.

What would be ideal would be a formal statement from your regulatory/QA person explaining why MSDS sheets are not necessary.

I am in the office today if you want to discuss. Thanks.

Product & Supplier Management  
McKesson Medical Surgical  
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Richmond, VA 23228

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**From:** Mike Vidmar [mailto:[MVidmar@agamatrix.com](mailto:MVidmar@agamatrix.com)]**Sent:** Wednesday, November 07, 2007 8:58 AM**To:****Subject:** MSDS Response

Hi

This was the MSDS response from our QA – “MSDS’s are not required to be submitted for anything we buy or make (meters, strips, control solution, lancing devices, lancets, etc).”

I copied Christy on the 510K email but it bounced back to me.

Please let me know if you need any additional information.

Sincerely,

Mike Vidmar

11/7/2007

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	A	B	C	D	E
1	Item #	Mfg Abbv	Catalog #	MSDS Code	Description
2	638782	AGAMAT	8000-01317	01	MONITOR, BLD GLUC WAVESENSE KE
3	638783	AGAMAT	8000-01328	01	TEST STRIP, BLD GLUC WAVESENSE
4	638784	AGAMAT	8000-01333	01	CONTROL, NORMAL WAVESENSE KEYN
5	638785	AGAMAT	8000-01971	01	LANCET, WAVESENSE KEYNOTE 33G
6	638786	AGAMAT	8000-02011	01	CONTROL, HIGH WAVESENSE KEYNOT
7	638787	AGAMAT	8000-02265	01	TEST STRIP, BLD GLUC WAVESENSE
8	693965	AGAMAT	8000-02649	01	MONITOR KIT, BLD GLUC STRT WAV
9	693966	AGAMAT	8000-03329	01	TEST STRIP, BLD GLUC WAVESENSE
10	693967	AGAMAT	8000-03337	01	TEST STRIP, BLD GLUC WAVESENSE
11	693968	AGAMAT	8000-03383	01	METER, BLD GLUC WAVESENSE PRES
12	703006	AGAMAT	8000-03384	01	METER, ONLY BLD GLUC KEYNOTE P