Australian Government
Department of Health
Therapeutic Goods Administration

TGA laboratories testing report

Survey of microwavable heat packs

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TGA Health Safety Regulation

Contents

Introduction

Microwavable grain filled heat packs (heat packs, MHPs) are widely used to provide relief for general muscular aches and pains. They consist of a fabric outer cover with a grain filling which is usually wheat, barley or lupin. The user heats the pack in a microwave and then applies the pack to the area of the body requiring relief.

The TGA has received at least twelve adverse event reports associated with MHPs where patient injuries have occurred, or have had the potential to occur. Injuries ranged from minor to severe, including patient burns, ignition of the pack due to overheating and fires from placing a heated pack in a confined space (i.e. amongst bedding fabrics). Previously, in November 2012 after a request from NSW Fire and Rescue, the TGA provided a web statement on the correct use and purchase of heat packs. A 2013 NSW coronial enquiry was undertaken after a death from smoke inhalation in which a heat pack started a house fire. In response to the coronial request, another web statement was published via the TGA website on 16 May 2013. This statement was released in conjunction with an ACCC statement via the Product Safety Australia website in May 2013.

Further reviews performed by the TGA identified that the existing design standards did not fully address the issues of the dangers arising from overheating MHPs, or from their use in place of hot water bottles and electric blankets to warm beds. Therefore, in September 2014 the TGA began testing a variety of heat packs listed on the Australian Register of Therapeutic Goods (ARTG), and non-listed heat packs available on the Australian market, to inform the development of an Australian New Zealand Standard for MHPs. The Australian–New Zealand Standard AS/NZS 5116:2016, *Microwaveable heat packs–Wheat and other organic filling materials*, was published in June 2016.

This testing project was designed to assess compliance with the new Standard.

Testing

Table 1 summarises the heat pack models tested by the TGA Laboratories. Only samples that were in the Australian Register of Therapeutic Goods were tested. Three test methods described in AS/NZS 5116:2016 were applied to each sample:

1. Filling temperature
2. Surface temperature
3. Overheating

In addition to the three tests listed above, the information provided with the heat pack was also reviewed to ensure appropriate warning labels and suitable instructions for use were present.

Table 1: Samples tested

ARTG Number	Sponsor/Supplier	Model Name	Filling Type
155962	Heat Bags Plus	Heat Bags Plus - Regular Comforter	Lupin
		Heat Bags Plus - Junior Square	Lupin
		Heat Bags Plus - 3 Panel Neck	Lupin
		Heat Bags Plus - 6 Panel Neck/Shoulder Heatbag	Lupin
		Heat Bags Plus - Caress Eyepack	Lupin
92379	Heat Wheat International Pty Ltd	Handy Pack - Wheat Filled Hot and Cold Pack	Wheat
152325	JLTK Pty Ltd	The Wheat Bag - Small	Wheat
		The Wheat Bag - Neck section	Wheat
		The Wheat Bag - Large	Wheat
155961	Kelbor Pty Ltd T/a Medi-Ice Pak Australia	Medi-Pak - Hot Wheat - Size: Square	Wheat
		Medi-Pak - Hot Wheat - Size: Medium Long	Wheat
223204[1]	MyOki Pty Ltd	MyOki - Wheat Heat Scarf	Wheat
209278	PBA Wholesale Pty Ltd	Medissentials - Wheat Pack Small	Wheat
		Medissentials - Wheat Pack Large	Wheat
107133	Physi Pak	Physi Pak - Back 3	Wheat
206688	Tollot Pty Ltd T/a Aaxis Pacific	Bodichek - Hot or Cold Wheat Pack - 2 Section Rectangle	Wheat
		Bodichek - Hot or Cold Wheat Pack - Square	Wheat
		Bodichek - Hot or Cold Wheat Pack - Long Narrow	Wheat
		Bodichek - Hot or Cold Wheat Pack - Small Rectangle	Wheat
110418	Wheat Bags Australia Pty Ltd T/a Wheat Bags	Wheat Bag - Small Joint Wrap	Wheat
		Wheat Bag - Large Rectangular Sectioned	Wheat
261932	TheraBags	TheraBags Lupin Hot/Cold Pack	Lupin
161840	Boian Surgical Pty Ltd	Vitalic Wheat Pack - Small Size	Wheat

[1] Sponsor cancelled ARTG entry before testing was complete.

ARTG Number	Sponsor/Supplier	Model Name	Filling Type
195283	IMA Pty Ltd	IMA Heat Pack - Small	Lupin
		IMA Heat Pack - Large	Lupin
232627	KB Medical Sales Pty Ltd	Live Well Health Essentials - Multi-Purpose Hot & Cold Bag	Lupin
123682	Nicholson Frances Therese T/A Bonny Scents	Therapeutic Hot & Cold Wheat Packs	Wheat
149235	St Francis Pharmaceuticals	The Original Hotty Pack – Shape: Rectangle	Wheat
		The Original Hotty Pack – Shape: V-Neck	Wheat

Filling temperature

Figure 2 provides the results from measuring the maximum filling temperature of the packs after heating according to the manufacturer's instructions for use. The result presented in the graph for each model type is the average of three testing heat packs. Error bars indicate the standard deviation, i.e. a measure of the variation in filling temperatures recorded between the three packs. This variation in filling temperature is generally related to how accurately manufacturers control their fill volumes, the natural variation in the fill's properties, and how accurately the temperature probe is placed into the centre of the filling mass to record the temperature. A 'fail' result— indicated in red—occurred when ***all three packs tested*** recorded a maximum filling temperature exceeding 70 °C.

Using the recorded temperature data, a model was developed to predict the maximum filling temperature of a heat pack based on its fill weight and microwave time (at 1000 W). The model is provided in Figure 1. The non-linear trend line is consistent with the specific heat capacity of wheat which varies based on a quadratic relationship with temperature. Additionally, the trend line has been fixed to intercept the y axis at 23 °C representing the maximum filling temperature at 0 seconds microwave time. The model is only based on the wheat filled packs (blue data points); lupin (green data points) has a different heat capacity than wheat that results in a longer microwave time to reach a temperature compared with the same mass of wheat. Using the model, a pack with a fill weight of **1200 grams** and microwave time **of 120 seconds** (1000 W), a filling temperature of **72.6 °C** is predicted.

$$x = \frac{microwave\ time\ (s)}{Wheat\ Bag\ Weight\ (g)} = \frac{120}{1200} = 0.10$$

$$Filling\ Temp = -900(0.091^2) + 586(0.091) + 23 = \mathbf{72.6\ °C}$$

Results indicated that the use of two or more pockets in the design of the MHP resulted in higher than predicted filling temperatures.

Figure 1: Model used to predict the maximum filling temperature of an MHP.

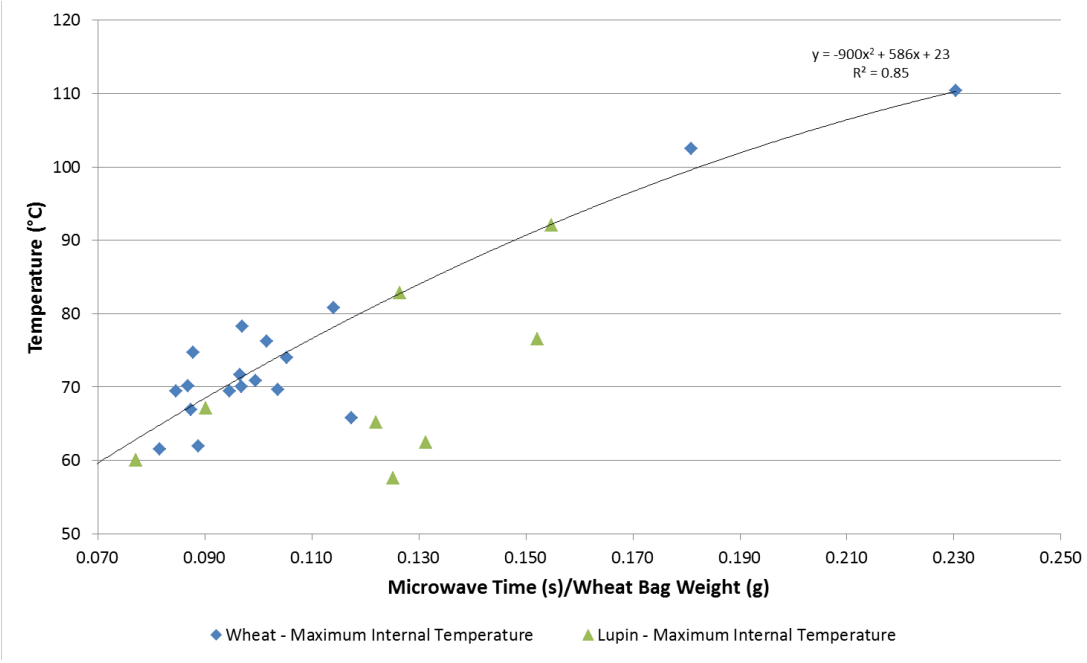
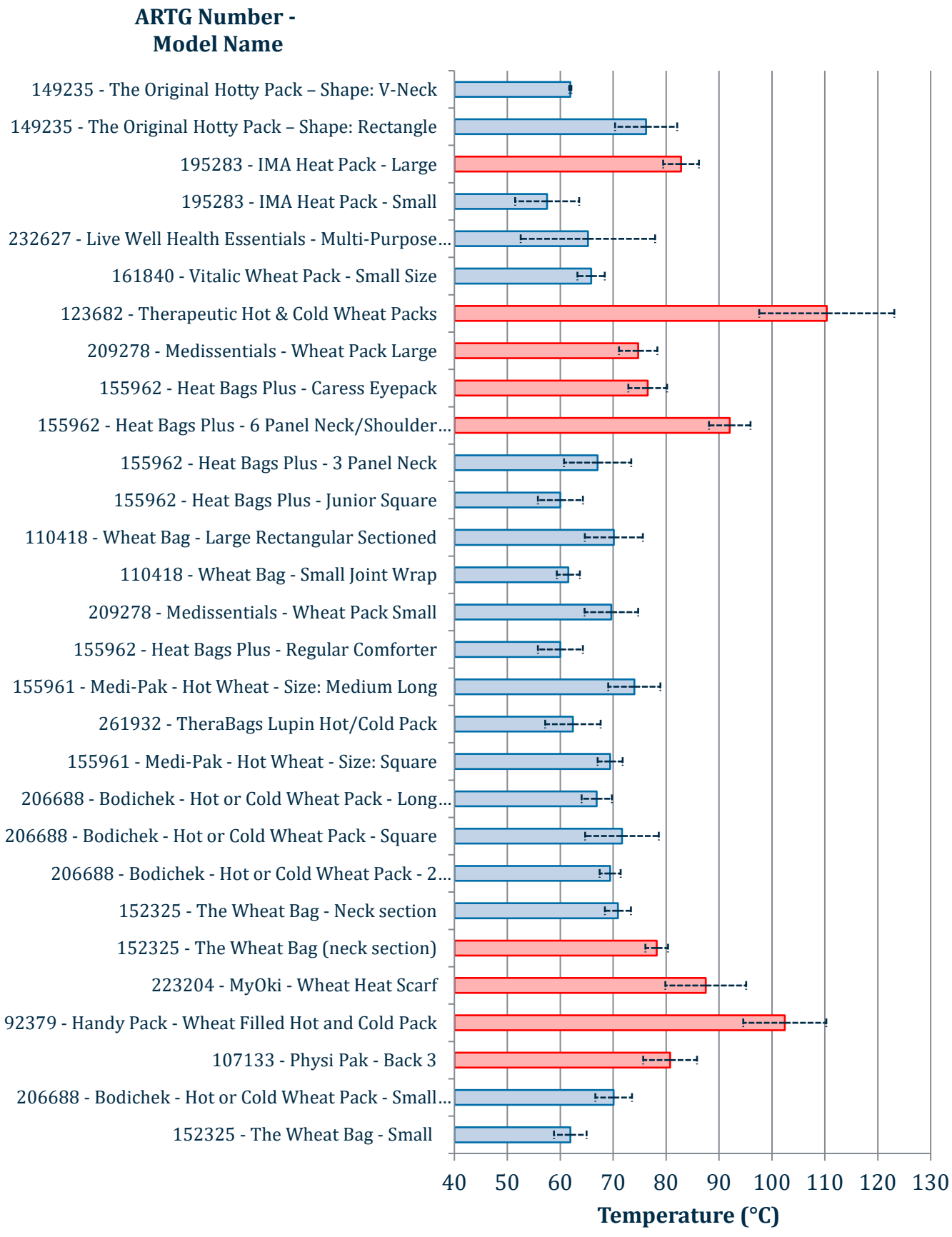


Figure 2: Filling material temperature measured after heating to manufacturer's instructions for use (Error bars = standard deviation)

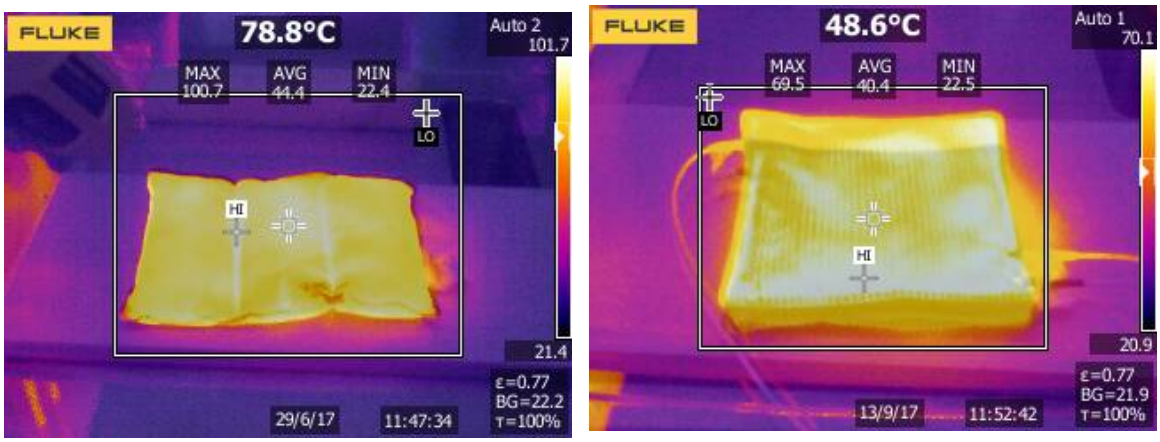


Surface temperature

The surface temperature of the heat pack was measured using a thermal imaging camera after heating according to the manufacturer's instructions for use. The results showed that typically the maximum temperature would be localized at a seam of the heat pack, either between pockets (Figure 3 – Left) or on the edge (Figure 3 – Right). The non-uniform temperature gradient of the heat pack surface makes it difficult to represent the surface temperature with a single value as required by AS/NZS 5116:2016 (the requirement of the Standard is that the surface temperature cannot exceed 50 °C). Additionally, the surface temperature profile of the heat pack is dependent on its position within the microwave. None of the models tested in this study recorded a maximum surface temperature less than 50 °C; for 24 of the 29 samples, the maximum surface temperature was greater than the maximum filling temperature.

Due to the difficulties in reporting a single temperature value that would appropriately describe the heat pack's surface temperature, the AS/NZS 5116:2016 criterion for surface temperature (50 °C) was not used as a pass/fail condition. The results do indicate that users must take care when removing heat packs from microwaves and be aware that localized hot spots exist.

Figure 3: Location of maximum temperature measured using the thermal imaging camera. The reading at the top of the image is the temperature measured at the centre of the heat pack (camera crosshairs); the MAX, MIN, and AVG temperature values are recorded within the camera target area (white outlined box).



Dangers of over-heating heat packs

To assess the potential dangers of over-heating heat packs, each model was heated for four times longer than the manufacturer's instruction for use (as required by AS/NZS 5116:2016). Figure 4 shows the results from four heat pack models that recorded internal temperatures greater than 150 C. Significant charring of the organic filling was observed with grains adhering together to form clumps. The devices would often produce smoke while still in the microwave and in some instances the microwave time was prematurely terminated due to the risk of fire. For one heat pack model that used a synthetic material to contain the filling material (bottom row of images), the covering melted.

The results indicate the dangers that exist when either the manufacturer does not provide clear, usable instructions for a consumer to follow based on microwave time and power, or the potential consequences when a user does not follow the instructions for use provided with the heat pack.

Figure 4: Charring of heat pack filling material.

Labels and packaging

The labels and packaging provided with the heat packs were assessed for compliance to the medical device regulations regarding information to be supplied with a medical device. While the omission of administrative details, i.e. suppliers name and address, were communicated to suppliers for correction, it was the safety related non-compliances regarding insufficient instructions regarding the use of the devices and insufficient warnings, restrictions, or precautions that posed the greatest risk to safety.

Each model assessed was required to have two items of information provided to the end user: heating time with microwave power, and warning and precautions for the customer to be aware. Because a heat pack is reusable, and the likelihood of consumers maintaining packaging or instruction cards for the life of the item (several years) is low, it is important that the information was attached to heat pack itself to be available at each use.

AS/NZS 5116:2016 provides the minimum warning and precaution information to be attached to the device (Figure 5). The requirement for displaying heating time is also communicated in AS/NZS 5116:2016. Additionally, microwave heating times should be accompanied by microwave power (in Watts). At a minimum, the time for an 800 to 1000 W microwave should be provided.

Figure 5: Typical warning label attached to the device ***(Copied from AS/NZS 5011:2016, Page 9)***

Testing and outcomes

Table 2 summarises the testing results and outcomes from the investigation.

Table 2: Results from testing and regulatory outcomes.

Sponsor/Supplier	Model Name	Filling Temperature	Labelling	Outcome
Heat Bags Plus	Heat Bags Plus - Regular Comforter	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
	Heat Bags Plus - Junior Square	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
	Heat Bags Plus - 3 Panel Neck	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
	Heat Bags Plus - 6 Panel Neck/Shoulder Heatbag	**FAIL**	**FAIL**	Testing of the heat pack model indicated labelling non-compliances and a filling temperature in excess of AS/NZS 5116:2016 specifications. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements. The supplier also updated heating instructions and provided testing results for filling temperature.
	Heat Bags Plus - Caress Eyepack	**FAIL**	**FAIL**	Supplier has discontinued this model.

Sponsor/Supplier	Model Name	Filling Temperature	Labelling	Outcome
Heat Wheat International Pty Ltd	Handy Pack - Wheat Filled Hot and Cold Pack	**FAIL**	**FAIL**	Testing of the heat pack model indicated labelling non-compliances and a filling temperature in excess of AS/NZS 5116:2016 specifications. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements. The Sponsor also updated heating instructions and provided testing results for filling temperature.
JLTK Pty Ltd	The Wheat Bag - Small	PASS	PASS	N/A
	The Wheat Bag – Neck Section	**FAIL**	PASS	Testing of the heat pack model indicated a filling temperature in excess of AS/NZS 5116:2016 specifications. The supplier provided testing results for filling temperature prepared by an independent testing facility.
	The Wheat Bag - Large	PASS	PASS	N/A
Kelbor Pty Ltd T/a Medi-Ice Pak Australia	Medi-Pak - Hot Wheat - Size: Square	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels and operating instructions to be consistent with the AS/NZS 5116:2016 requirements.
	Medi-Pak - Hot Wheat - Size: Medium Long	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels and operating instructions to be consistent with the AS/NZS 5116:2016 requirements.
MyOki Pty Ltd	MyOki - Wheat Heat Scarf	**FAIL**	**FAIL**	Supplier has discontinued this model.
PBA Wholesale Pty	Medissentials - Wheat Pack Small	PASS	PASS	N/A

Sponsor/Supplier	Model Name	Filling Temperature	Labelling	Outcome
Ltd	Medissentials - Wheat Pack Large	**FAIL**	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels and operating instructions to be consistent with the AS/NZS 5116:2016 requirements. The supplier informs the TGA that the out of specification result for internal temperature (on average 5°C greater than the 70°C limit) was the result of the WA drought producing wheat smaller than typical. Adjustments to filling have been made by the manufacture to reduce filling temperature.
Physi Pak	Physi Pak – Back 3	**FAIL**	PASS	Testing of the heat pack model indicated a filling temperature in excess of AS/NZS 5116:2016 specifications. The supplier updated heating instructions and provided testing results for filling temperature.
Tollot Pty Ltd T/a Aaxis Pacific	Bodichek - Hot or Cold Wheat Pack - 2 Section Rectangle	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated labels to include the necessary information (heating instructions).
	Bodichek - Hot or Cold Wheat Pack - Square	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated labels to include the necessary information (heating instructions).
	Bodichek - Hot or Cold Wheat Pack - Long Narrow	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated labels to include the necessary information (heating instructions).
	Bodichek - Hot or Cold Wheat Pack - Small Rectangle	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated labels to include the necessary information (heating instructions).
Wheat Bags Australia Pty Ltd T/a Wheat Bags	Wheat Bag - Small Joint Wrap	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.

Sponsor/Supplier	Model Name	Filling Temperature	Labelling	Outcome
	Wheat Bag - Large Rectangular Sectioned	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
TheraBags	TheraBags Lupin Hot/Cold Pack	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
Boian Surgical Pty Ltd	Vitalic Wheat Pack - Small Size	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels and instructions for use to be consistent with the AS/NZS 5116:2016 requirements.
IMA Pty Ltd	IMA Heat Pack - Small	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
	IMA Heat Pack - Large	**FAIL**	**FAIL**	Testing of the heat pack model indicated labelling non-compliances and a filling temperature in excess of AS/NZS 5116:2016 specifications. The supplier has since updated labelling. The Sponsor also updated heating instructions and provided testing results for filling temperature.
KB Medical Sales Pty Ltd	Live Well Health Essentials - Multi-Purpose Hot & Cold Bag	PASS	**FAIL**	Testing of the heat pack model indicated labelling non-compliances. The supplier has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
Nicholson Frances Therese T/A Bonny Scents	Therapeutic Hot & Cold Wheat Packs	**FAIL**	**FAIL**	Testing of the heat pack model indicated labelling non-compliances and a filling temperature in excess of AS/NZS 5116:2016 specifications. The Sponsor has since updated labelling. The Sponsor also updated heating instructions.

Sponsor/Supplier	Model Name	Filling Temperature	Labelling	Outcome
St Francis Pharmaceuticals	The Original Hotty Pack – Shape: Rectangle	PASS	**FAIL**	Testing of the device indicated labelling non-compliances. The Sponsor has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.
	The Original Hotty Pack – Shape: V-Neck	PASS	**FAIL**	Testing of the device indicated labelling non-compliances. The Sponsor has since updated user warning and caution labels to be consistent with the AS/NZS 5116:2016 requirements.

Observations

The results from this study provide numerous insights to improve the safety and performance of heat pack designs. They include:

1. The heating instructions for each heat pack design must be verified by ensuring the filling temperature does not exceed 70 °C. While the temperature model produced in this study can be used as a starting point to identify a suitable heating time, the ultimate responsibility of ensuring heating instructions are appropriate remains with the Sponsor.

2. Appropriate warnings and user instructions must be attached to the device itself so that they are available to the end user even if the main packaging has been discarded. Heating instructions should always include a heating time and microwave power. Preferably the heating instructions should have heating times corresponding to different microwave power levels. The minimum warning and precaution information to be supplied to the end user is presented in AS/NZS 5116:2016 (reproduced below).

Guidance to users

1. When selecting a microwavable heat pack, consumers are advised to ensure fire and burn hazard warning labels are present instructing the user not to overheat, and not to use under bedding. Heating instructions should always have a microwave power (i.e. 1000 W) associated with the microwave time.

2. The warning labels and heating instructions should be attached to the device itself, so that they are available to the end user even if the main packaging has been discarded. Consumers are strongly encouraged to always follow the product heating instructions.

3. Consumers should be aware that localised heating may produce hotspots on the heat pack surface.

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	TGA Laboratories	September 2019

Therapeutic Goods Administration

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